

ACORDA THERAPEUTICS INC  
Form 10-Q  
November 07, 2013

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

FORM 10-Q

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended September 30, 2013  
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 or other jurisdiction of incorporation  
or organization)

13-3831168  
(I.R.S. Employer  
Identification No.)

420 Saw Mill River Road, Ardsley, New York  
(Address of principal executive offices)

10502  
(Zip Code)

(914) 347-4300  
(Registrant's telephone number,  
including area code)

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.

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

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

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

| Class  | Outstanding at October 31, 2013 |
|--|---------------------------------|
| Common Stock, \$0.001 par value<br>per share | 41,274,587 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 or our other products 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 Diazepam Nasal Spray or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray or other products under development; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our intellectual property, to defend against the intellectual property claims of others, or to obtain third party intellectual property licenses needed for the commercialization of our products; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "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 in this report and in our Annual Report on Form 10-K for the year ended December 31, 2012 (particularly in the "Risk Factors" section of our 2012 Form 10-K as updated by the disclosures in Part II, Item 1A of 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," "Zanaflex Capsules," and Qutenza. 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 and for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.

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## PART I

## Item 1. Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

| (In thousands, except share data)   | September<br>30,<br>2013<br>(unaudited) | December 31,<br>2012 |
|---|---|----------------------|
| <b>Assets</b>   |   |                      |
| <b>Current assets:</b>  |   |                      |
| Cash and cash equivalents   | \$46,266                                | \$ 41,876            |
| Restricted cash   | 136                                     | 380                  |
| Short-term investments  | 246,043                                 | 191,949              |
| Trade accounts receivable, net of allowances of \$639 and \$555, as of September 30, 2013 and December 31, 2012, respectively                                       | 24,998                                  | 26,327               |
| Prepaid expenses  | 8,617                                   | 6,936                |
| Finished goods inventory held by the Company  | 25,574                                  | 20,176               |
| Finished goods inventory held by others   | 671                                     | 781                  |
| Deferred tax asset  | 28,940                                  | 35,091               |
| Other current assets  | 6,558                                   | 9,547                |
| <b>Total current assets</b>   | <b>387,803</b>                          | <b>333,063</b>       |
| Long-term investments   | 57,069                                  | 99,363               |
| Property and equipment, net of accumulated depreciation   | 17,752                                  | 16,706               |
| Deferred tax asset  | 101,725                                 | 101,636              |
| Intangible assets, net of accumulated amortization  | 17,590                                  | 9,319                |
| Non-current portion of deferred cost of license revenue   | 4,332                                   | 4,808                |
| Other assets  | 376                                     | 437                  |
| <b>Total assets</b>   | <b>\$586,647</b>                        | <b>\$ 565,332</b>    |
| <b>Liabilities and Stockholders' Equity</b>   |   |                      |
| <b>Current liabilities:</b>   |   |                      |
| Accounts payable  | \$15,907                                | \$ 22,503            |
| Accrued expenses and other current liabilities  | 29,920                                  | 35,758               |
| Deferred product revenue—Zanaflex   | 31,221                                  | 29,275               |
| Current portion of deferred license revenue   | 9,057                                   | 9,057                |
| Current portion of revenue interest liability   | 1,009                                   | 1,134                |
| Current portion of convertible notes payable  | 1,144                                   | 1,144                |
| <b>Total current liabilities</b>  | <b>88,258</b>                           | <b>98,871</b>        |
| Non-current portion of deferred license revenue   | 61,892                                  | 68,685               |
| Put/call liability  | —                                       | 329                  |
| Non-current portion of revenue interest liability   | 659                                     | 1,111                |
| Non-current portion of convertible notes payable  | 3,196                                   | 4,244                |
| Other non-current liabilities   | 6,251                                   | 6,171                |
| <b>Commitments and contingencies</b>  |   |                      |
| <b>Stockholders' equity:</b>  |   |                      |
| Common stock, \$0.001 par value. Authorized 80,000,000 shares at September 30, 2013 and December 31, 2012; issued and outstanding 40,623,609 and 39,804,493 shares, | 41                                      | 40                   |

including those held in treasury, as of September 30, 2013 and December 31, 2012, respectively

|  |            |            |
|--|------------|------------|
| Treasury stock at cost (12,420 shares at September 30, 2013 and December 31, 2012) | (329 )     | (329 )     |
| Additional paid-in capital   | 670,855    | 640,671    |
| Accumulated deficit  | (244,274 ) | (254,523 ) |
| Accumulated other comprehensive income   | 98         | 62         |
| Total stockholders' equity   | 426,391    | 385,921    |
| Total liabilities and stockholders' equity   | \$586,647  | \$ 565,332 |

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(unaudited)

| (In thousands, except per share data)  | Three-month<br>period ended<br>September<br>30, 2013 | Three-month<br>period ended<br>September<br>30, 2012 | Nine-month<br>period<br>ended<br>September<br>30, 2013 | Nine-month<br>period<br>ended<br>September<br>30, 2012 |
|--|--|--|--|--|
| <b>Revenues:</b>   |  |  |  |  |
| Net product revenues   | \$ 79,760  | \$ 72,206  | \$ 223,969   | \$ 206,992   |
| Royalty revenues   | 2,895  | 2,967  | 13,076   | 10,557   |
| License revenue  | 2,264  | 2,264  | 6,793  | 6,793  |
| <b>Total net revenues</b>  | <b>84,919</b>  | <b>77,437</b>  | <b>243,838</b>   | <b>224,342</b>   |
| <b>Costs and expenses:</b>   |  |  |  |  |
| Cost of sales  | 17,213   | 14,761   | 47,631   | 40,802   |
| Cost of license revenue  | 159  | 159  | 476  | 476  |
| Research and development   | 13,839   | 12,031   | 39,575   | 35,690   |
| Selling, general and administrative  | 42,336   | 40,121   | 138,538  | 123,096  |
| <b>Total operating expenses</b>  | <b>73,547</b>  | <b>67,072</b>  | <b>226,220</b>   | <b>200,064</b>   |
| Operating income   | 11,372   | 10,365   | 17,618   | 24,278   |
| <b>Other expense (net):</b>  |  |  |  |  |
| Interest and amortization of debt discount expense   | (544 )   | (373 )   | (1,884 )   | (1,501 )   |
| Interest income  | 162  | 135  | 501  | 393  |
| <b>Total other expense (net)</b>   | <b>(382 )</b>  | <b>(238 )</b>  | <b>(1,383 )</b>  | <b>(1,108 )</b>  |
| Income before taxes  | 10,990   | 10,127   | 16,235   | 23,170   |
| Provision for income taxes   | (3,513 )   | (533 )   | (5,985 )   | (1,185 )   |
| <b>Net income</b>  | <b>\$ 7,477</b>                                      | <b>\$ 9,594</b>                                      | <b>\$ 10,250</b>                                       | <b>\$ 21,985</b>                                       |
| <b>Net income per share—basic</b>  |  |  |  |  |
| Net income per share—basic   | \$ 0.19  | \$ 0.24  | \$ 0.26  | \$ 0.56  |
| <b>Net income per share—diluted</b>  |  |  |  |  |
| Net income per share—diluted   | \$ 0.18  | \$ 0.24  | \$ 0.25  | \$ 0.55  |
| <b>Weighted average common shares outstanding used in computing net income per share—basic</b>   |  |  |  |  |
| Weighted average common shares outstanding used in computing net income per share—basic          | 40,315   | 39,463   | 40,037   | 39,412   |
| <b>Weighted average common shares outstanding used in computing net income per share—diluted</b> |  |  |  |  |
| Weighted average common shares outstanding used in computing net income per share—diluted        | 41,996   | 40,159   | 41,541   | 40,222   |

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Comprehensive Income

(unaudited)

| (In thousands)   | Three-month<br>period<br>ended<br>September<br>30, 2013 | Three-month<br>period<br>ended<br>September<br>30, 2012 | Nine-month<br>period<br>ended<br>September<br>30, 2013 | Nine-month<br>period<br>ended<br>September<br>30, 2012 |
|--|---|---|--|--|
| Net income   | \$ 7,477  | \$ 9,594  | \$ 10,250  | \$ 21,985  |
| Other comprehensive income (loss):                             |   |   |  |  |
| Unrealized losses on available for sale securities, net of tax | 44  | 108   | 36   | 3  |
| Other comprehensive income (loss), net of tax                  | 44  | 108   | 36   | 3  |
| Comprehensive income   | \$ 7,521  | \$ 9,702  | \$ 10,286  | \$ 21,988  |

See accompanying Unaudited Notes to Consolidated Financial Statements



## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(unaudited)

| (In thousands)  | Nine-month<br>period<br>ended<br>September<br>30, 2013 | Nine-month<br>period<br>ended<br>September<br>30, 2012 |
|---|--|--|
| Cash flows from operating activities:   |  |  |
| Net income  | \$ 10,250  | \$ 21,985  |
| Adjustments to reconcile net income to net cash provided by operating activities: |  |  |
| Share-based compensation expense  | 18,001   | 15,349   |
| Amortization of net premiums and discounts on investments                         | 1,774  | 3,700  |
| Amortization of revenue interest issuance cost                                    | 37   | 58   |
| Depreciation and amortization expense   | 4,623  | 3,050  |
| Gain on put/call liability  | (329 )   | (476 )   |
| Deferred tax provision  | 6,063  | —  |
| Changes in assets and liabilities:  |  |  |
| Decrease (increase) in accounts receivable  | 1,328  | (399 )   |
| Decrease (increase) in prepaid expenses and other current assets                  | 1,308  | (4,140 )   |
| (Increase) decrease in inventory held by the Company                              | (5,308 )   | 8,850  |
| Decrease in inventory held by others  | 111  | 292  |
| Decrease in non-current portion of deferred cost of license revenue               | 476  | 476  |
| Decrease (increase) in other assets   | 25   | (88 )  |
| Decrease in accounts payable, accrued expenses, other current liabilities         | (13,481 )  | (4,854 )   |
| Increase in revenue interest liability interest payable                           | 92   | 495  |
| Decrease in non-current portion of deferred license revenue                       | (6,793 )   | (6,793 )   |
| Decrease in other non-current liabilities   | (272 )   | (160 )   |
| Increase (decrease) in deferred product revenue—Zanaflex                          | 1,946  | (1,800 )   |
| Decrease (increase) in restricted cash  | 244  | (167 )   |
| Net cash provided by operating activities   | 20,095   | 35,378   |
| Cash flows from investing activities:   |  |  |
| Purchases of property and equipment   | (3,663 )   | (9,167 )   |
| Purchases of intangible assets  | (2,518 )   | (1,865 )   |
| Acquisition   | (7,499 )   | —  |
| Purchases of investments  | (128,038 )   | (232,633 )   |
| Proceeds from maturities of investments   | 114,500  | 188,250  |
| Net cash used in investing activities   | (27,218 )  | (55,415 )  |
| Cash flows from financing activities:   |  |  |
| Proceeds from issuance of common stock and option exercises                       | 12,183   | 2,921  |
| Repayments of revenue interest liability  | (670 )   | (812 )   |
| Net cash provided by financing activities   | 11,513   | 2,109  |
| Net increase (decrease) in cash and cash equivalents                              | 4,390  | (17,928 )  |
| Cash and cash equivalents at beginning of period                                  | 41,876   | 57,954   |
| Cash and cash equivalents at end of period  | \$ 46,266  | \$ 40,026  |
| Supplemental disclosure:  |  |  |
| Cash paid for interest  | 1,695  | 881  |

|                     |       |       |
|---------------------|-------|-------|
| Cash paid for taxes | 1,742 | 1,097 |
|---------------------|-------|-------|

See accompanying Unaudited Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(unaudited)

(1) Organization and Business Activities

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

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, 2012 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 the Company has the ability and intent to hold them and such holding period is longer than one year. The Company classifies its short-term and long-term 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.

## Accumulated Other Comprehensive Income

The Company's accumulated other comprehensive income is comprised of gains and losses on available for sale securities and is recorded and presented net of income tax.

## Revenue Recognition

### Ampyra

Ampyra is available only through a network of specialty pharmacy providers that provide 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. Bureau of Prisons and 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, and 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 Permanente, and the specialty distributor to the VA. The specialty pharmacy providers, Kaiser Permanente, and the specialty distributor to the VA are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 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 Permanente 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, historical trends, 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. Effective December 1, 2012, the Company no longer accepts returns of Ampyra with the exception of product damages that occur during shipping.

### Zanaflex

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

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

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

Adjustments are recorded for estimated chargebacks, rebates, and discounts. These allowances are established by management as its best estimate based

on available information and are adjusted to reflect known changes in the factors that impact such allowances. Allowances for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebates, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. In addition, the Company records a charge to cost of goods sold for the cost basis of the estimated product returns the Company believes may ultimately be realized at the time of product shipment to wholesalers. The Company has recognized this charge at the date of shipment since it is probable that it will receive a level of returned products; upon the return of such product it will be unable to resell the product considering its expiration dating; and it can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns. Product shipping and handling costs are included in cost of sales.

#### Qutenza

Qutenza is sold through a specialty distributor, who sells Qutenza to physician offices, hospitals, clinics, and specialty 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, and the amount of returns can be reasonably estimated and collectability is reasonably assured. This means that, for Qutenza, the Company recognizes product sales following shipment of product to its specialty distributor.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated rebates 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, an adjustment is recorded for estimated rebates and returns. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for rebates and returns are established based on the contractual terms with customers, historical trends, 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.

#### 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 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.

#### In-Process Research and Development

The cost of in-process research and development (IPR&D) acquired directly in a transaction other than a business combination is capitalized if the projects will be further developed or have an alternative future use; otherwise they are

expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. The Company utilizes the "income method," and uses estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. IPR&D intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense recognized on the statement of operations. These are tested at least annually or sooner when a triggering event occurs that could indicate a potential impairment.



## 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 Credit Risk

The Company's principal direct customers as of September 30, 2013 were a network of specialty pharmacies, Kaiser Permanente, and the specialty distributor to the VA for Ampyra, wholesale pharmaceutical distributors for Zanaflex Capsules and Zanaflex tablets, and a specialty distributor for Qutenza. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary. Four customers individually accounted for more than 10% of the Company's revenue in 2013 and 2012, and three customers in 2011. Four customers individually accounted for more than 10% of the Company's accounts receivable as of September 30, 2013 and December 31, 2012. The Company's net product revenues are generated in the United States.

## Segment and Geographic Information

The Company is managed and operated as one business which is focused on the identification, development and commercialization of novel therapies that improve neurological function in people with MS, SCI and other disorders of the central nervous system. 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 and the Company does not prepare discrete financial information with respect to separate products or product candidates or by location. Accordingly, the Company views its business as one reportable operating segment. Net product revenues reported to date are derived from the sales of Ampyra, Zanaflex and Qutenza in the United States.

## Subsequent Events

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined there were no subsequent events requiring disclosure in or requiring adjustment to these financial statements.

## Recent Accounting Pronouncements

In February 2013, the FASB amended its guidance to require an entity to present the effect of certain significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. The new accounting guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The guidance is effective prospectively for fiscal years beginning after December 15, 2012. The Company adopted these new provisions for the quarter beginning January 1, 2013. As the guidance requires additional presentation only, there was no impact to the Company's consolidated results of operations or financial position.

In July 2013, the FASB issued ASU 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists, (ASU 2013-11), an amendment to ASC

740, Income Taxes. ASU 2013-11 clarifies that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax benefit is disallowed. In situations where a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction or the tax law of the jurisdiction does not require, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be netted with the deferred tax asset. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. Early adoption is permitted. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date.

Retrospective application is permitted. The Company is currently evaluating the impact that adoption will have on the determination or reporting of its financial results.

### (3) Acquisition

#### NeurogesX Acquisition

On July 8, 2013, Acorda acquired certain assets from NeurogesX, Inc. (“NeurogesX”), including two neuropathic pain management assets: Qutenza and NP-1998. Qutenza is approved by the FDA for the management of neuropathic pain associated with postherpetic neuralgia. NP-1998 is a Phase 3 ready prescription strength capsaicin topical solution being assessed for the treatment of neuropathic pain. NP-1998 was previously referred to as NGX-1998. Prior to the acquisition, NeurogesX was a specialty pharmaceutical company focused on developing and commercializing a portfolio of novel non-opioid pain management therapies headquartered in San Mateo, CA. Acquisition-related costs during the nine-month period ended September 30, 2013 of approximately \$1.0 million for advisory, legal, regulatory and valuation costs incurred in connection with the NeurogesX acquisition have been expensed in selling, general and administrative expenses.

Astellas Pharma Europe Ltd. (“Astellas”) has exclusive commercialization rights for Qutenza in the European Economic Area including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland, certain countries in Eastern Europe, the Middle East and Africa. Astellas also has an option to develop NP-1998 in those same territories. Astellas is currently conducting clinical trials of Qutenza including a Phase 3 trial to assess its use in the treatment of pain associated with painful diabetic neuropathy (“PDN”). Under the terms of the agreement, Acorda will have rights to review data from that trial, and the companies may also collaborate and/or share costs of future clinical trials.

In consideration for the acquisition of assets pursuant to the Asset Purchase Agreement, Acorda paid NeurogesX \$7.5 million in cash and will pay up to an additional \$5.0 million of post-closing milestone payments (“Milestone Payments”), as follows:

- \$2.0 million upon the approval for sale of an NP-1998 liquid formulation product in the United States for the cutaneous treatment of PDN in humans, if FDA approval is obtained prior to December 31, 2016; and
- \$3.0 million if net sales of an NP-1998 approved product in Acorda’s territory reach \$100,000,000 during the first 12 months that such product is sold in Acorda’s territory, commencing with the first date that such product is commercially available for purchase anywhere in Acorda’s territory. Acorda’s territory consists of all territories worldwide other than those jurisdictions covered by the Astellas Agreement, which generally comprise countries in Europe, Africa and the Middle East.

There is no assurance that any of the conditions for the Milestone Payments will be met. Refer to Note 7 – Fair Value Measurements for more information on the contingent consideration liability.

Total preliminary estimated purchase price is summarized as follows:

(in thousands)

|   |         |
|---|---------|
| Cash paid to NeurogesX shareholders and its creditors | \$7,499 |
| Fair value of contingent liabilities                  | 205     |
| Total preliminary estimated purchase price            | \$7,704 |

The preliminary allocation of the purchase price to the fair value of assets acquired reflects the estimated fair values of NeurogesX’s assets as of the acquisition date. In accordance with the acquisition method of accounting, the Company

allocated the acquisition cost for the NeurogesX transaction to the underlying assets acquired by the Company, based upon the estimated fair values of those assets at the date of acquisition and will classify the fair value of acquired IPR&D as an indefinite-lived asset until the successful completion or abandonment of the associated research and development efforts. The Company accounted for the transaction as a business combination and is in the process of finalizing the valuation of intangible assets and fair value of the contingent purchase price. As a result, the preliminary measurements of intangible assets and certain tangible assets described below are subject to change. The results of NeurogesX's operations have been included in the consolidated statements of operations from the date of acquisition.

The following table presents the preliminary allocation of purchase price to assets acquired:

|   |       |
|---|-------|
| (in thousands)                                |       |
| Inventory                                     | \$90  |
| Equipment                                     | 173   |
| Identifiable intangible assets:               |       |
| Developed technology - Qutenza                | 450   |
| In-process research and development – NP-1998 | 6,991 |
| Fair value of acquired assets                 | 7,704 |
| Aggregate purchase price                      | 7,704 |
| Goodwill                                      | \$—   |

#### Pro Forma Financial Information (Unaudited)

The following table summarizes certain supplemental pro forma financial information which was prepared as if the acquisition of NeurogesX had occurred as of January 1, 2012. The unaudited pro forma financial information was prepared for comparative purposes only and is not necessarily indicative of what would have occurred had the acquisition been made at that time or of results which may occur in the future.

| (In thousands) | Three-month period ended<br>September 30, 2013 |           | Three-month period ended<br>September 30, 2012 |           |
|----------------|--|-----------|--|-----------|
|                | Reported                                       | Pro Forma | Reported                                       | Pro Forma |
| Net revenues   | \$84,919                                       | \$84,919  | \$77,437                                       | \$80,285  |
| Net income     | 7,477  | 7,477     | 9,594  | 3,595     |

| (In thousands) | Nine-month period ended<br>September 30, 2013 |           | Nine-month period ended<br>September 30, 2012 |           |
|----------------|---|-----------|---|-----------|
|                | Reported                                      | Pro Forma | Reported                                      | Pro Forma |
| Net revenues   | \$243,838                                     | \$249,122 | \$224,342                                     | \$232,887 |
| Net income     | 10,250  | 6,751     | 21,985  | 3,988     |

The pro forma financial information includes a non-recurring pro forma adjustment of \$1.7 million for the nine-month period ended September 30, 2013, related to transaction costs incurred by the Company and NeurogesX as part of the acquisition. Revenue and earnings from the acquired business since the acquisition date included in our consolidated statements of operations were not material.

#### (4) Share-based Compensation

During the three-month periods ended September 30, 2013 and 2012, the Company recognized share-based compensation expense of \$6.5 million and \$5.6 million, respectively. During the nine-month periods ended September 30, 2013 and 2012, the Company recognized share-based compensation expense of \$18.0 million and \$15.3 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2013 and related balances outstanding as of that date are reflected below. The weighted average fair value per share of options granted to employees for the three-month periods ended September 30, 2013 and 2012 were approximately \$18.02 and \$13.00, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2013 and 2012 were approximately \$15.76 and \$13.74, respectively.



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

| (In millions)                       | For the three-month period ended September 30, |       | For the nine-month period ended September 30, |        |
|-------------------------------------|--|-------|---|--------|
|                                     | 2013   | 2012  | 2013  | 2012   |
| Research and development            | \$1.5  | \$1.4 | \$4.2   | \$3.7  |
| Selling, general and administrative | 5.0  | 4.2   | 13.8  | 11.6   |
| Total                               | \$6.5  | \$5.6 | \$18.0  | \$15.3 |

A summary of share-based compensation activity for the nine-month period ended September 30, 2013 is presented below:

#### Stock Option Activity

|   | Number of Shares<br>(In thousands) | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Intrinsic Value<br>(In thousands) |
|---|------------------------------------|---------------------------------|---|-----------------------------------|
| Balance at January 1, 2013                        | 5,667                              | \$22.30                         |   |                                   |
| Granted   | 1,600                              | 31.05                           |   |                                   |
| Cancelled   | (165)                              | 27.48                           |   |                                   |
| Exercised   | (797)                              | 15.29                           |   |                                   |
| Balance at September 30, 2013                     | 6,305                              | \$25.27                         | 7.0   | \$56,639                          |
| Vested and expected to vest at September 30, 2013 | 6,237                              | \$25.22                         | 7.0   | \$56,316                          |
| Vested and exercisable at September 30, 2013      | 3,675                              | \$22.97                         | 5.7   | \$41,346                          |

#### Restricted Stock Activity

| (In thousands)                  | Number of Shares |
|---------------------------------|------------------|
| Restricted Stock                |                  |
| Nonvested at January 1, 2013    | 458              |
| Granted                         | 211              |
| Vested                          | (22)             |
| Forfeited                       | (30)             |
| Nonvested at September 30, 2013 | 617              |

Unrecognized compensation cost for unvested stock options and restricted stock awards as of September 30, 2013 totaled \$46.6 million and is expected to be recognized over a weighted average period of approximately 2.6 years.

## (5) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the three and nine-month periods ended September 30, 2013 and 2012:

| (In thousands, except per share data)   | Three-month<br>period ended<br>September<br>30, 2013 | Three-month<br>period ended<br>September<br>30, 2012 | Nine-month<br>period<br>ended<br>September<br>30, 2013 | Nine-month<br>period<br>ended<br>September<br>30, 2012 |
|---|--|--|--|--|
| <b>Basic and diluted</b>  |  |  |  |  |
| Net income  | \$ 7,477   | \$ 9,594   | \$ 10,250  | \$ 21,985  |
| Weighted average common shares outstanding used in computing net income per share—basic   | 40,315   | 39,463   | 40,037   | 39,412   |
| Plus: net effect of dilutive stock options and restricted common shares                   | 1,681  | 696  | 1,504  | 810  |
| Weighted average common shares outstanding used in computing net income per share—diluted | 41,996   | 40,159   | 41,541   | 40,222   |
| Net income per share—basic  | \$ 0.19  | \$ 0.24  | \$ 0.26  | \$ 0.56  |
| Net income per share—diluted  | \$ 0.18  | \$ 0.24  | \$ 0.25  | \$ 0.55  |

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

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

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<br>period ended<br>September<br>30, 2013 | Three-month<br>period ended<br>September<br>30, 2012 | Nine-month<br>period ended<br>September<br>30, 2013 | Nine-month<br>period ended<br>September<br>30, 2012 |
|--|--|--|---|---|
| <b>Denominator</b>                         |  |  |   |   |
| Stock options and restricted common shares | 1,558  | 3,910  | 2,786   | 3,831   |
| Convertible note                           | 39   | 48   | 39  | 48  |

## (6) Income Taxes

For the three-month periods ended September 30, 2013 and 2012, the Company recorded a \$3.5 million and \$533,000 provision for income taxes, respectively, based upon its estimated tax liability for the year. The provision for income taxes is based on federal, state and Puerto Rico income taxes. The effective income tax rates for the Company for the three-month periods ended September 30, 2013 and 2012 were 32.0% and 5.2%, respectively. For the nine-month periods ended September 30, 2013 and 2012, the Company recorded a \$5.9 million and \$1.2 million provision for income taxes, respectively, based upon its estimated tax liability for the year. The provision for income taxes is based



on federal, state and Puerto Rico income taxes. The effective income tax rates for the Company for the nine-month periods ended September 30, 2013 and 2012 were 36.8% and 5.1%, respectively. As a result of the January 2013 extension of the Federal research and development tax credit retroactive to January 2012 the Company recorded a benefit of \$1.2 million for the estimated 2012 credit. During the nine-month period ended September 30, 2013 the Company also settled an IRS examination of their corporate income tax returns for years ending December 31, 2009 through December 31, 2011. The impact of the settlement partially offset the benefit recorded for the research and development tax credit.

The Company continues to evaluate the realizability of its deferred tax assets and liabilities on a periodic basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes.

(7) Fair Value Measurements

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2013 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 liabilities represent our put/call liability related to the Paul Royalty Fund (PRF) transaction and contingent consideration related to the NeurogesX acquisition. No changes in valuation techniques or inputs occurred during the nine months ended September 30, 2013.

| (In thousands)                     | Level 1  | Level 2 | Level 3 |
|------------------------------------|----------|---------|---------|
| <b>September 30, 2013</b>          |          |         |         |
| Assets Carried at Fair Value:      |          |         |         |
| Cash equivalents                   | \$38,381 | \$—     | \$—     |
| Short-term investments             | —        | 246,043 | —       |
| Long-term investments              | —        | 57,069  | —       |
| Liabilities Carried at Fair Value: |          |         |         |
| Put/call liability                 | —        | —       | —       |
| Contingent purchase price          | —        | —       | 205     |
| <b>December 31, 2012</b>           |          |         |         |
| Assets Carried at Fair Value:      |          |         |         |
| Cash equivalents                   | \$27,932 | \$—     | \$—     |
| Short-term investments             | —        | 191,949 | —       |
| Long-term investments              | —        | 99,363  | —       |
| Liabilities Carried at Fair Value: |          |         |         |
| Put/call liability                 | —        | —       | 329     |
| Contingent purchase price          | —        | —       | —       |

The following tables present 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.

Put/call liability

| (In thousands) | Three-month<br>period<br>ended | Three-month<br>period<br>ended | Nine-month<br>period<br>ended | Nine-month<br>period<br>ended |
|----------------|--------------------------------|--------------------------------|-------------------------------|-------------------------------|
|                |                                |                                |                               |                               |

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|  | September<br>30, 2013 | September<br>30, 2012 | September<br>30, 2013 | September<br>30, 2012 |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
| <b>Put/call liability:</b>   |                       |                       |                       |                       |
| Balance, beginning of period   | \$ —                  | \$ 511                | \$ 329                | \$ 1,030              |
| Total realized and unrealized gains included in selling,<br>general and administrative expenses: | —                     | 43                    | (329 )                | (476 )                |
| Balance, end of period   | \$ —                  | \$ 554                | \$ —                  | \$ 554                |

The Company estimates the fair value of its 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 selling, general and administrative expenses.

The put/call liability has been classified as a Level 3 liability 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.

#### Contingent purchase price

| (In thousands)   | Three-month<br>period<br>ended<br>September<br>30, 2013 | Three-month<br>period<br>ended<br>September<br>30, 2012 | Nine-month<br>period<br>ended<br>September<br>30, 2013 | Nine-month<br>period<br>ended<br>September<br>30, 2012 |
|--|---|---|--|--|
| <b>Contingent purchase price:</b>  |   |   |  |  |
| Balance, beginning of period   | \$ —  | \$ —  | \$ —   | \$ —   |
| Fair value of contingent purchase price as of July 8, 2013   | 205   | —   | 205  | —  |
| Fair value adjustment to contingent purchase price included in selling, general and administrative expenses: | —   | —   | —  | —  |
| Balance, end of period   | \$ 205  | \$ —  | \$ 205   | \$ —   |

The Company measures the fair value of the contingent purchase price using a Monte Carlo simulation. Using this approach, the present value of each of the milestone payments is calculated using the probability of milestone achievement under various different scenarios. Some of the more significant assumptions used in the valuation include (i) the probability of FDA approval for NP-1998 and (ii) the variability in net sales for NP-1998 if FDA approval is achieved. The milestone achievement probabilities range from 0% to 10%, and the milestone payment outcomes range from \$0 to \$5.0 million. The valuation will be performed periodically when the significant assumptions change. Fair value adjustments will be included in selling, general and administrative expenses. There is no assurance that any of the conditions for the milestone payments will be met. Refer to Note 3 – Acquisition for more information on the milestones associated with the contingent consideration liability.

The contingent purchase price has been classified as a Level 3 liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the various inputs to the valuation approach including, but not limited to, assumptions involving the probability of FDA approval for NP-1998 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.

#### (8) 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<br>Cost | Gross<br>unrealized<br>gains | Gross<br>unrealized<br>losses | Estimated<br>fair<br>value |
|----------------|-------------------|------------------------------|-------------------------------|----------------------------|
|----------------|-------------------|------------------------------|-------------------------------|----------------------------|

|                    |            |        |      |            |
|--------------------|------------|--------|------|------------|
| September 30, 2013 |            |        |      |            |
| US Treasury bonds  | \$ 302,948 | \$ 164 | \$—  | \$ 303,112 |
| December 31, 2012  |            |        |      |            |
| US Treasury bonds  | 291,209    | 104    | (1 ) | 291,312    |

The contractual maturities of short-term available-for-sale debt securities at September 30, 2013 and December 31, 2012 are greater than 3 months but less than 1 year. The contractual and intended maturities of long-term available-for-sale debt securities at September 30, 2013 and December 31, 2012 are greater than 1 year and up to 15 months. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of September 30, 2013.

Short-term investments with maturity of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$38.4 million and \$27.9 million as of September 30, 2013 and December 31, 2012, respectively.

The Company holds available-for-sale investment securities which are reported at fair value on the Company's balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive income (AOCI) in the statements of comprehensive (loss) income. The changes in AOCI associated with the unrealized holding gain on available-for-sale investments during the nine months ended September 30, 2013, were as follows (in thousands):

| (In thousands)  | Net<br>Unrealized<br>Gains<br>(Losses) on<br>Marketable<br>Securities | Total |
|---|---|-------|
| Balance at December 31, 2012  | \$62  | \$62  |
| Other comprehensive income before reclassifications:                |   |       |
| Amounts reclassified from accumulated other<br>comprehensive income | 36  | 36    |
| Net current period other comprehensive income                       | —   | —     |
| Balance at September 30, 2013                                       | 36  | 36    |
|   | \$98  | \$98  |

#### (9) 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 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 \$25.0 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 \$10.0 million based on the successful achievement of future regulatory milestones and up to \$365.0 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 September 30, 2009, the Company recorded a license receivable and deferred revenue of \$110.0 million for the upfront payment due to the Company from Biogen Idec under the Collaboration Agreement. Also, as a result of such payment to Acorda, a payment of \$7.7 million became payable by Acorda to Alkermes and was recorded as a cost of license payable and deferred expense. The payment of \$110.0 million was received from Biogen Idec on July 1, 2009 and the payment of \$7.7 million was made to Alkermes on July 7, 2009.

The Company considered the following deliverables with respect to the revenue recognition of the \$110.0 million

upfront payment: (1) the license to use the Company's technology, (2) the Collaboration Agreement to develop and commercialize licensed product in all countries outside the U.S., and (3) the Supply Agreement. Due to the inherent uncertainty in obtaining regulatory approval, the applicability of the Supply Agreement is outside the control of the Company and Biogen Idec. Accordingly, the Company has determined the Supply Agreement is a contingent deliverable at the onset of the agreement. As a result, the Company has determined the Supply Agreement does not meet the definition of a deliverable that needs to be accounted for at the inception of the arrangement. The Company has also determined that there is no significant and incremental discount related to the supply agreement since Biogen Idec will pay the same amount for inventory that the Company would pay and the Company effectively acts as a middle man in the arrangement for which it adds no significant value due to various factors such as the Company does not have any manufacturing capabilities or other knowhow with respect to the manufacturing process.

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and reliable evidence of fair value for the deliverables. Accordingly, the non-contingent deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen Idec as revenue and the associated payment to Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company had determined this was the most probable expected benefit period. The Company recognized \$2.3 million and \$6.8 million in license revenue, a portion of the \$110.0 million received from Biogen Idec, and \$159,000 and \$476,000 in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during the three and nine-month periods ended September 30, 2013, 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 currently estimates the recognition period to be approximately 12 years from the date of the Collaboration Agreement. As part of its ex-U.S. license agreement, Biogen Idec owes Acorda royalties based on ex-U.S. net sales, and milestones based on ex-U.S. regulatory approval, new indications, and ex-U.S. net sales. These milestones included a \$25.0 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 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 Idec 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.

#### Actavis/Watson

The Company has an agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly 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-month periods ended September 30, 2013 and 2012, the Company recognized royalty revenue of \$869,000 and \$1.5 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the three-month periods ended September 30, 2013 and 2012, the Company also recognized revenue and a corresponding cost of sales of \$1.0 million and \$550,000, 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.

During the nine-month periods ended September 30, 2013 and 2012, the Company recognized royalty revenue of \$6.0 million and \$4.7 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the nine-month periods ended September 30, 2013 and 2012, the Company also recognized revenue and a corresponding cost of

sales of \$2.7 and \$2.0 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Watson, which is recorded in net product revenues and cost of sales.

#### Neuronex

In December 2012, the Company acquired Neuronex, Inc., a privately-held development stage pharmaceutical company (Neuronex). Neuronex is developing Diazepam Nasal Spray under Section 505(b)(2) of the Food, Drug and Cosmetic Act as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS.

Under the terms of the agreement, the Company made an upfront payment of \$2.0 million in February 2012. The Company also paid \$1.5 million during the twelve month period ended December 31, 2012 pursuant to a commitment under the agreement to fund research to prepare for the Diazepam Nasal Spray pre-NDA meeting with the Food and Drug Administration (FDA). In December 2012, the Company completed the acquisition by paying \$6.8 million to former Neuronex shareholders less a \$300,000 holdback provision to be settled in December 2013.

The former equity holders of Neuronex are entitled to receive from Acorda up to an additional \$18.0 million in contingent earnout payments upon the achievement of specified regulatory and manufacturing-related milestones with respect to the Diazepam Nasal Spray product, and up to \$105.0 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray 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 Diazepam Nasal Spray 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.

The patent and other intellectual property and other rights relating to the Diazepam Nasal Spray product are licensed from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which granted worldwide rights to Neuronex, except certain specified Asian countries, the Company's subsidiary Neuronex is obligated to pay SK up to \$8.0 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product and up to \$3.0 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. A \$1.0 million milestone was triggered during the three-month period ending September 30, 2013 upon the acceptance of an FDA new drug application (NDA). Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

The Company evaluated the transaction based upon the guidance of ASC 805, Business Combinations, and concluded that it only acquired inputs and did not acquire any processes. At the time of acquisition the Company had to develop its own processes in order to produce an output. Therefore the Company accounted for the transaction as an asset acquisition and accordingly the \$2.0 million upfront payment, \$1.5 million in research funding and \$6.8 million of closing consideration net of tangible net assets acquired of \$3.7 million which were primarily the taxable amount of net operating loss carryforwards, were expensed as research and development expense during the twelve-month period ended December 31, 2012.

#### (10) 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, 2012. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. While losses, if any, are possible, the Company is not able to estimate any ranges of losses as of September 30, 2013. Litigation expenses are expensed as incurred.

## 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 \$77.8 million for the three-months ended September 30, 2013 and \$69.8 million for the three-months ended September 30, 2012.

More than 80,000 patients have tried Ampyra therapy since the 2010 launch. As of September 2013, approximately 70% of all people with MS who were prescribed Ampyra received a first refill, and approximately 40% of all people with MS who were prescribed Ampyra have been dispensed at least six months of the medicine through refills, consistent with previously reported trends.

Ampyra is marketed in the United States through our own specialty sales force and commercial infrastructure. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Managed Markets Account Directors 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.

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. Bureau of Prisons and 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 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 competitive tier, which means that it is listed in either the lowest branded co-pay tier or the lowest branded specialty tier (if more than one specialty tier exists) of their commercial preferred drug list or formulary. Approximately 75% of commercially insured individuals in the U.S. continue to have no or limited prior authorization requirements, or PAs, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by commercial health plans.

## License and Collaboration Agreement with Biogen Idec

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec International GmbH, or Biogen Idec, under a license and collaboration agreement that we entered into in June 2009. Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets, and anticipates regulatory approval in other countries. We received a \$25.0 million milestone payment from Biogen Idec in 2011, which was triggered by Biogen Idec's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15.0 million, due when ex-U.S. net sales exceed \$100.0 million over four consecutive quarters.

## Ampyra Patent Update

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

- The first is U.S. Patent No. US 8,007,826 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027.
- The second is U.S. Patent No. 5,540,938 ("the '938 patent"), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In April 2013, the '938 patent received a five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the '938 patent would expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan's Drug Technologies business).
- The third, which issued in January 2013, is U.S. Patent No. 8,354,437, which includes claims relating to methods to improve walking, increase walking speed, and treat walking disability in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2026.
- The fourth, which issued in May 2013, is U.S. Patent No. 8,440,703 which includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with MS by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2025.

In 2011, the European Patent Office, or EPO, granted the counterpart European patent to U.S. Patent No. 8,354,437 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.

## 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 \$815,000 for the three-months ended

September 30, 2013 and \$1.9 million for the three-months ended September 30, 2012. In 2012, Apotex Inc. 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 (a subsidiary of Actavis). In March 2013, Mylan Pharmaceuticals commercially launched their own generic version of Zanaflex Capsules. The commercial launch of generic tizanidine hydrochloride capsules has caused a significant decline in net revenue of Zanaflex Capsules, and the launch of these generic versions and the potential launch of other generic versions is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2013 and beyond.

## NeurogesX Transaction

In July 2013, we completed the acquisition of two neuropathic pain management assets from NeurogesX, Inc., including: Qutenza®, which is approved by the FDA for the management of neuropathic pain associated with postherpetic neuralgia, also known as post-shingles pain; and NP-1998, a Phase 3 ready, prescription strength capsaicin topical solution, being assessed for the treatment of neuropathic pain. NP-1998 was previously referred to as NGX-1998. We made a \$7.5 million payment to acquire development and commercialization rights for Qutenza and NP-1998 in the United States, Canada, Latin America and certain other territories. We will also make up to \$5.0 million in payments contingent upon the achievement of certain regulatory and sales milestones related to NP-1998.

Astellas Pharma Europe Ltd. has exclusive commercialization rights for Qutenza in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland, certain countries in Eastern Europe, the Middle East and Africa. Astellas also has an option to develop NP-1998 in those same territories.

Qutenza is a dermal patch containing 8% prescription strength capsaicin that is applied once every three months for the management of neuropathic pain associated with postherpetic neuralgia. The drug was approved by the FDA in 2010 and launched in April 2010 but NeurogesX discontinued active promotion of the product in March 2012. We plan to support Qutenza in the United States using our existing commercial organization, including our specialty neurology sales force of approximately 100 sales professionals, as well as our medical and safety reporting infrastructure. Net revenue for Qutenza was \$103,000 for the three-months ended September 30, 2013.

NP-1998 is a topical solution containing 20% prescription strength capsaicin under clinical development as a treatment for pain associated with neuropathic pain conditions such as painful diabetic neuropathy (PDN). Astellas is currently conducting clinical trials of Qutenza including a Phase 3 trial to assess its use in the treatment of pain associated with PDN. This trial is expected to finish in early 2014. While Qutenza and NP-1998 are different products, they contain the same active ingredient, capsaicin, so the results of the Astellas Qutenza trial will help inform our next steps in developing NP-1998. Under the terms of the agreement, Acorda will have rights to review data from that trial, and the companies may also collaborate and/or share costs of future clinical trials.

## Research & Development Programs

We are developing what we believe is one of the industry's leading pipelines of novel neurological therapies. We are developing Diazepam Nasal Spray, which we acquired in December 2012, for the treatment of certain epileptic seizures. We are also studying dalfampridine extended release tablets to improve a range of functional impairments, in addition to walking disability, caused by MS, as well as its potential use in other neurological conditions, including post-stroke deficits. In addition, we have several research and development programs focused on distinct therapeutic approaches to restoring neurologic and/or cardiac function. We are developing the clinical stage compounds AC105 for acute treatment of SCI, GGF2 for the treatment of heart failure, and rHlgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and peripheral nerve injury. Chondroitinase, an enzyme that encourages nerve plasticity in SCI, is in preclinical development. We believe these programs for restoring neurologic and/or cardiac function have the potential to be first-in-class therapies, and may be applicable across a number of CNS disorders, including stroke and traumatic brain injury, or TBI, because many of the mechanisms of tissue damage and repair are similar. Our research and development programs also include our recently acquired NP-1998 program, described above.

## Diazepam Nasal Spray



In February 2012, we signed an agreement to acquire Neuronex, Inc., a privately-held pharmaceutical company developing a proprietary nasal spray formulation of diazepam as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity, also known as cluster or acute repetitive seizures, or ARS. We completed the acquisition of Neuronex in December 2012.

In November 2013, we announced that we submitted a New Drug Application (NDA) filing for Diazepam Nasal Spray to the FDA. We expect the filing to be reviewed under the criteria established by the Prescription Drug User Fee Act (PDUFA-4), which provides for a standard 10-month review timeframe or expedited 6-month review timeframe. We anticipate a standard review for Diazepam Nasal Spray.

Diazepam Nasal Spray was filed under section 505(b)2 of the Food Drug and Cosmetic Act, referencing data from a therapy previously approved by the FDA (DIASTAT® Rectal Gel) and providing pharmacokinetic data comparing the reference product to Diazepam Nasal Spray. The Company is initially seeking an indication for Diazepam Nasal Spray in adults with epilepsy who experience cluster seizures, also known as acute repetitive seizures. It also plans to pursue a pediatric indication.

Subject to obtaining FDA approval, there is potential for a commercial launch in 2014. We have obtained orphan drug designation, which would confer seven years of market exclusivity from the date of approval. We anticipate that our current infrastructure can support sales and marketing of this product, if it receives FDA approval, and market planning is underway.

In June 2013 at the biennial International Congress of the International League Against Epilepsy and International Bureau for Epilepsy, we announced results of the first clinical study to assess pharmacokinetics, safety, and tolerability of Diazepam Nasal Spray in people with epilepsy. The study results showed that the Diazepam Nasal Spray pharmacokinetics are comparable whether it is administered during or immediately following a seizure.

#### Ampyra Development Programs

We believe there may be potential for Ampyra to be applied to other indications within MS and also in other neurological conditions. For example, we have conducted a Phase 2 proof-of-concept trial of dalfampridine extended release tablets in post-stroke deficits. This study, which was initiated in 2012, explored the use of dalfampridine in patients who have experienced a stroke at least 6 months prior to enrollment and who have stabilized with chronic neurologic deficits, which may include impaired walking, motor and sensory function and manual dexterity. Over the first six months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. This trial targeted motor impairments that remain after such recovery. In April 2013, we announced that data from the proof-of-concept trial showed improved walking in people with post-stroke deficits. In October 2013, we provided additional information regarding the study results. The safety findings in this study were consistent with previously clinical trials and post-marketing experience of dalfampridine-ER in MS. We plan to proceed with a clinical development program for this indication. We plan to present data from the post-stroke deficits trial in appropriate medical forums following additional analysis of the data. We also are continuing to evaluate possible grants for investigator-initiated studies looking for potential benefits on a range of functional deficits in MS and other neurological disorders.

We have been working with external partners on a once-daily formulation of dalfampridine. We are planning to move forward with a Phase 2b/3 study that will assess the use of a once-daily formulation of dalfampridine as a treatment for post-stroke walking deficits. Pending discussions with FDA and results of a second pharmacokinetic study of the once-daily formulation, we plan to begin the trial in the second quarter of 2014.

Also, we previously conducted a proof-of-concept clinical study of dalfampridine in adults with cerebral palsy, or CP. The study included a single dose phase primarily intended to evaluate safety and tolerability, and a second multi-dose phase study to evaluate both safety and efficacy. In April 2013 we announced that efficacy from the second phase suggested potential treatment activity on measures of walking and hand strength, but that these data were still being analyzed to determine if they were sufficiently robust to warrant further clinical studies. After a thorough analysis of the study, we concluded that although there were some signs of biological activity the data were not strong enough to justify additional clinical development and we will not proceed with additional CP trials.

#### AC105

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 submitted a Phase 2 clinical trial protocol for AC105 for acute treatment of SCI to the FDA for review. In September 2013, we announced that the first patient was enrolled in this clinical trial. This trial will evaluate the safety and tolerability of AC105 in people with traumatic SCI, and also incorporates several exploratory efficacy measures.

## Glial Growth Factor 2

We have completed a GGF2 Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. In March 2013, we presented three-month data from this clinical trial in a platform presentation at the American College of Cardiology (ACC) annual meeting. These data showed a dose-related improvement in ejection fraction in addition to safety findings. Dose-limiting toxicities were also identified in the highest planned dose cohort including acute liver injury meeting Hy's Law for drug induced hepatotoxicity. In October 2013, we announced that the first patient was enrolled in the second clinical trial of GGF2. This Phase 1b single-infusion trial in people with heart failure will assess tolerability of three dose levels of GGF2, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product independently or to enter into a partnership, most likely with a cardiovascular-focused company.

## Remyelinating Antibodies

We have a remyelinating antibodies program that we acquired under license from the Foundation for Medical Education and Research, or Mayo Clinic. Studies have demonstrated the ability of this family of antibodies to stimulate repair of the myelin sheath in three different animal models of MS. Some antibodies within this portfolio also stimulate the growth of neurons and may have applications beyond demyelinating disorders. First identified in mice, similar remyelinating antibodies were subsequently identified in human blood samples by Mayo Clinic and we have been able to produce a recombinant human antibody (rHlgM22) that may be suitable for clinical development. We are developing this antibody as a potential therapeutic for MS. We believe a therapy, such as this antibody, that could repair myelin sheaths has the potential to restore substantial neurological function to those affected by demyelinating conditions. In April 2013, we initiated a Phase 1 clinical trial of rHlgM22 to assess the safety and tolerability of rHlgM22 in patients with MS. The study also includes several exploratory efficacy measures.

## Chondroitinase Program

We are continuing research 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.

## Corporate Update

In October 2013, we announced the appointment of Michael Rogers as our Chief Financial Officer, and the appointment of David Lawrence, who has served as our Chief Financial Officer since January 2005, to the new position of Chief of Business Operations. As Chief of Business Operations, Mr. Lawrence will have oversight of our technical operations/manufacturing, project management, information technology, facilities, and certain other functions.

## Outlook for 2013

## Financial Guidance for 2013

We are providing the following guidance with respect to our 2013 financial performance:

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We expect 2013 net revenue from the sale of Ampyra to range from \$295 million to \$305 million. We are encouraged by our sales in fourth quarter to date, and this is a narrowing of previous guidance.

- We expect Zanaflex (tizanidine hydrochloride) and ex-U.S. Fampyra 2013 revenue to be \$25 million, which includes sales of branded Zanaflex products, royalties from ex-U.S. Fampyra and authorized generic tizanidine hydrochloride capsules sales, and \$9.1 million in amortized licensing revenue from the \$110 million payment we received from Biogen Idec in 2009 for Fampyra ex-U.S. development and commercialization rights.
- Research and development expenses in 2013 are expected to range from \$45 million to \$55 million, excluding share-based compensation charges. This is a revision from previous guidance, and results from the decision to not move forward with a clinical program for dalfampridine in CP and adjustments in other research and development

programs. Research and development expenses in 2013 related to Ampyra include proof-of-concept studies in CP and post-stroke deficits, and sponsorship of investigator-initiated studies. Additional expenses include clinical trials for AC105 and rHlgM22, continued development of Diazepam Nasal Spray and GGF2, as well as ongoing preclinical studies. This guidance is not affected by the acquisition of assets from NeurogesX, Inc., but excludes costs associated with expenditures related to the potential acquisition of new products or other business development activities. Research and development expenses are expected to increase in 2014 as our clinical programs advance.

- Selling, general and administrative expenses in 2013 are expected to range from \$165 million to \$175 million, excluding share-based compensation charges. This is a revision from previous guidance, based on changes in program timing. SG&A expenses will be primarily driven by support for Ampyra and the dalfampridine franchise, the possible commercialization of Diazepam Nasal Spray, if approved, and the development of our pipeline products. This guidance is not affected by the acquisition of assets from NeurogesX, Inc., but excludes costs associated with expenditures related to the potential acquisition of new products or other business development activities. SG&A expenses are expected to increase in 2014 as we move closer to the potential launch of Diazepam Nasal Spray.
- We expect to be cash flow positive in 2013. This guidance is not affected by the acquisition of assets from NeurogesX, Inc., but excludes costs associated with expenditures related to the potential acquisition of new products or other business development activities.

The range of SG&A and R&D expenditures for 2013 are non-GAAP financial measures because they exclude share-based compensation charges and costs associated with product acquisitions. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures, when viewed in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock and expenses that do not arise from the ordinary course of our business. We believe these non-GAAP financial measures help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses these non-GAAP financial measures to establish budgets and operational goals, and to manage our business and to evaluate its performance.

#### Development Pipeline Goals

Our planned goals and key initiatives with respect to our development pipeline for the remainder of 2013 are as follows:

- Continue with activities to prepare for a potential commercial launch of Diazepam Nasal Spray in 2014, subject to receiving FDA approval, including conducting market research, holding advisory boards, and completing managed market assessments. In November 2013, we announced that we submitted an NDA filing for Diazepam Nasal Spray to the FDA. We expect the filing to be reviewed under the criteria established by the Prescription Drug User Fee Act (PDUFA-4), which provides for a standard 10-month review timeframe or expedited 6-month review timeframe. We anticipate a standard review for Diazepam Nasal Spray.
- Continue planning for a Phase 2b/3 study that will assess the use of a once-daily formulation of dalfampridine as a treatment for post-stroke walking deficits. Pending discussions with FDA and results of a second pharmacokinetic study of the once-daily formulation, we plan to begin the trial in the second quarter of 2014.
  - Continue to progress our Phase 1 clinical trial of rHlgM22, which we initiated in April 2013.

- Continue to progress our second clinical trial of GGF2, a Phase 1b single-infusion trial in people with heart failure that will assess tolerability of three dose levels of GGF2, and which also includes assessment of drug-drug interactions and several exploratory measures of efficacy. In October 2013, we announced that the first patient was enrolled in this clinical trial.
- Continue to progress our AC105 clinical trial, which is evaluating the safety and tolerability of AC105 in people with traumatic SCI, and also incorporates several exploratory efficacy measures. In September 2013, we announced that the first patient was enrolled in this clinical trial.
- Continue funding of ongoing investigator-initiated studies of Ampyra in MS, focused on a range of functional

deficits in MS and other neurological disorders.

## Results of Operations

Three-Month Period Ended September 30, 2013 Compared to September 30, 2012

### Net Product Revenues

#### Ampyra

We recognize product sales of Ampyra following shipment of product to our network of specialty pharmacy providers, Kaiser Permanente and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra to these customers of \$77.8 million as compared to \$69.8 million for the three-month periods ended September 30, 2013 and 2012, respectively, an increase of \$8.0 million, or 11.5%. The net revenue increase comprised net volume increases of \$1.0 million and price increases net of discount and allowance adjustments of \$7.0 million. Net revenue from sales of Ampyra increased for the three-month period ended September 30, 2013 compared to the same period of 2012 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our First Step and Step Together programs. Effective January 2, 2013, we increased our sale price to our customers by 10.75%.

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

#### Zanaflex

We recognize product sales of Zanaflex Capsules and Zanaflex tablets using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules during the three-month period ended September 30, 2013. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$815,000 for the three-month period ended September 30, 2013, as compared to \$1.9 million for the three-month period ended September 30, 2012. The decrease was due to the commercial launch of generic versions of tizanidine hydrochloride capsules. Net product revenues also include \$1.0 million, which represents the sale of Zanaflex Capsules authorized generic product to Actavis for the three-month period ended September 30, 2013. Generic competition has caused a significant decline in sales of Zanaflex Capsules and is expected to cause the Company’s net revenue from Zanaflex Capsules to decline further in 2013 and beyond. In March 2013, Mylan Pharmaceuticals commercially launched their own generic version of Zanaflex Capsules. The decrease in net revenues was also the result of a disproportionate decrease in discounts and allowances due to the mix of customers continuing to purchase our product. These customers receive higher levels of rebates and allowances.

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.



## Qutenza

We recognize product sales of Qutenza following shipment of product to our specialty distributor. We recognized net revenue from the sale of Qutenza to these customers of \$103,000 for the three-month period ended September 30, 2013.

## License Revenue

We recognized \$2.3 million in license revenue for the three-month periods ended September 30, 2013 and 2012, related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

## Royalty Revenues

We recognized \$2.0 million and \$1.5 million in royalty revenue for the three-month periods ended September 30, 2013 and 2012, respectively, related to ex-U.S. sales of Fampyra by Biogen Idec.

We also recognized \$869,000 and \$1.4 million in royalty revenue for the three-month periods ended September 30, 2013 and 2012, respectively, related to the authorized generic sale of Zanaflex Capsules.

## Cost of Sales

### Ampyra

We recorded cost of sales of \$15.6 million for the three-month period ended September 30, 2013 as compared to \$13.8 million for the three-month period ended September 30, 2012. Cost of sales for the three-month period ended September 30, 2013 consisted primarily of \$13.6 million in inventory costs related to recognized revenues. The cost of Ampyra inventory is based on a percentage of net product sales of the product in the quarter shipped to Acorda by Alkermes or our alternative manufacturer. Cost of sales for the three-month period ended September 30, 2013 also consisted of \$1.8 million in royalty fees based on net sales, \$147,000 in amortization of intangible assets, and \$33,000 in period costs related to freight and stability testing.

Cost of sales for the three-month period ended September 30, 2012 consisted primarily of \$12.0 million in inventory costs related to recognized revenues. Cost of sales for the three-month period ended September 30, 2012 also consisted of \$1.6 million in royalty fees based on net sales, \$147,000 in amortization of intangible assets, and \$42,000 in period costs related to freight and stability testing.

### Zanaflex

We recorded cost of sales of \$411,000 for the three-month period ended September 30, 2013 as compared to \$398,000 for the three-month period ended September 30, 2012. Cost of sales for the three-month period ended September 30, 2013 consisted of \$235,000 in inventory costs primarily related to recognized revenues, \$121,000 in royalty fees based on net product shipments, and \$55,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$1.0 million of costs for Zanaflex Capsules authorized generic product sold for the three-month period ended September 30, 2013.

Cost of sales for the three-month period ended September 30, 2012 included \$249,000 in inventory costs related to recognized revenues, \$114,000 in royalty fees based on net product shipments, and \$35,000 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.

### Qutenza

We recorded cost of sales of \$117,000 for the three-month period ended September 30, 2013. Cost of sales for the three-month period ended September 30, 2013 consisted of \$71,000 in inventory costs related to recognized revenues as well as inventory obsolescence and royalty fees based on net product shipments, \$28,000 in amortization of intangible assets and \$18,000 in period costs related to inventory destruction, freight and stability testing.

## Cost of License Revenue

We recorded cost of license revenue of \$159,000 for the three-month periods ended September 30, 2013 and 2012, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan) in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

#### Research and Development

Research and development expenses for the three-month period ended September 30, 2013 were \$13.8 million as compared to \$12.0 million for the three-month period ended September 30, 2012, an increase of approximately \$1.8 million, or 15%. The increase was primarily due to an increase of \$2.2 million for current year research and development expenses related to Diazepam Nasal Spray. A \$1.0 million milestone payable to SK was triggered during the three-month period

ending September 30, 2013 upon the acceptance of an FDA new drug application (NDA). The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$1.2 million to support the various research and development initiatives, an increase of \$926,000 in preclinical expenses for the remyelinating antibodies program (rHIgM22), and an increase of \$234,000 for pipeline research related to AC105. The increases in research and development expenses for the three-month period ended September 30, 2013 were partially offset by a decrease of \$2.8 million related to our life cycle management program for Ampyra due to timing.

#### Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2013 were \$23.9 million compared to \$23.6 million for the three-month period ended September 30, 2012, an increase of approximately \$370,000, or 2%. The increase was attributable to an increase in overall compensation, benefits, and other selling expenses of \$733,000 and an increase of \$589,000 for pre-launch activities associated with the possible commercialization of Diazepam Nasal Spray, if approved. The increase in sales and marketing expenses was partially offset by a decrease in overall marketing, selling, distribution, and market research expenses for Ampyra of \$918,000.

General and administrative expenses for the three-month period ended September 30, 2013 were \$18.4 million compared to \$16.5 million for the three-month period ended September 30, 2012, an increase of approximately \$1.8 million, or 11%. This increase was the result of an increase of \$3.1 million for staff and compensation expenses and other expenses related to supporting the growth of the organization. The increases in general and administrative expenses for the three-month period ended September 30, 2013 were partially offset by a decrease of \$814,000 in safety and surveillance expense and a decrease medical affairs expenses including educational programs of \$460,000.

#### Other Expense

Other expense was \$382,000 for the three-month period ended September 30, 2013 compared to \$239,000 for the three-month period ended September 30, 2012, an increase of approximately \$143,000, or 60%. The increase was due to an increase in interest expense of \$171,000 principally related to the PRF revenue interest agreement due to a decrease in Zanaflex sales partially offset by an increase in interest income of \$27,000.

#### Provision for Income Taxes

For the three-month periods ended September 30, 2013 and 2012, we recorded a provision for income taxes of \$3.5 million and a \$533,000, respectively, based upon our estimated tax liability for the year. The provision for income taxes is based on federal, state and Puerto Rico income taxes. The effective income tax rates for the three-month periods ended September 30, 2013 and 2012 were 32.0% and 5.2%, respectively.

We continue to evaluate the realizability of the Company's deferred tax assets and liabilities on a periodic basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes.

#### Nine-Month Period Ended September 30, 2013 Compared to September 30, 2012

##### Net Product Revenues

##### Ampyra

We recognize product sales of Ampyra following shipment of product to our network of specialty pharmacy providers, Kaiser Permanente and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra to these customers of \$217.9 million as compared to \$193.4 million for the nine-month periods ended September 30, 2013 and 2012, respectively, an increase of \$24.5 million, or 13%. The net revenue increase comprised net volume increases of \$5.7 million and price increases net of discount and allowance adjustments of \$18.9 million. Net revenue from sales of Ampyra increased for the nine-month period ended September 30, 2013 compared to the same period of 2012 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our First Step and Step Together programs. Effective January 2, 2013, we increased our sale price to our customers by 10.75%.

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

#### Zanaflex

We recognize product sales of Zanaflex Capsules and Zanaflex tablets using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules during the nine-month period ended September 30, 2013. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$3.3 million for the nine-month period ended September 30, 2013, as compared to \$11.6 million for the nine-month period ended September 30, 2012. The decrease was due to the commercial launch of generic versions of tizanidine hydrochloride capsules in February 2012. Net product revenues also include \$2.7 million, which represents the sale of Zanaflex Capsules authorized generic product to Actavis for the nine-month period ended September 30, 2013. Generic competition has caused a significant decline in sales of Zanaflex Capsules and is expected to cause the Company’s net revenue from Zanaflex Capsules to decline further in 2013 and beyond. In March 2013, Mylan Pharmaceuticals commercially launched their own generic version of Zanaflex Capsules. The decrease in net revenues was also the result of a disproportionate decrease in discounts and allowances due to the mix of customers continuing to purchase our product. These customers receive higher levels of rebates and allowances.

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.

#### Qutenza

We recognize product sales of Qutenza following shipment of product to our specialty distributor. We recognized net revenue from the sale of Qutenza to these customers of \$103,000 for the nine-month period ended September 30, 2013.

#### License Revenue

We recognized \$6.8 million in license revenue for the nine-month periods ended September 30, 2013 and 2012, related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

#### Royalty Revenues

We recognized \$7.1 million and \$5.8 million in royalty revenue for the nine-month periods ended September 30, 2013 and 2012, respectively related to ex-U.S. sales of Fampyra by Biogen Idec. In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product’s comparative efficacy. Biogen Idec launched Fampyra in Germany in August 2011. During the six-month period ended June 30, 2012, the government agency completed its comparative efficacy

assessment of Fampyra indicating a range of pricing below Biogen Idec's initial launch price, which was unregulated for the first 12 months after launch consistent with German law. The Company recognized royalty revenue during a portion of 2012 based on the lowest point of the initially indicated German pricing authority range. Biogen Idec signed the pricing agreement during the three-month period ended March 31, 2013 and the Company recognized additional royalty revenue related to 2012, contributing to the increase in royalty revenue as compared to the nine-month period ended September 30, 2013.

We also recognized \$6.0 million and \$4.7 million in royalty revenue for the nine-month periods ended September 30, 2013 and 2012, respectively, related to the authorized generic sale of Zanaflex Capsules.

## Cost of Sales

### Ampyra

We recorded cost of sales of \$43.8 million for the nine-month period ended September 30, 2013 as compared to \$37.0 million for the nine-month period ended September 30, 2012. Cost of sales for the nine-month period ended September 30, 2013 consisted primarily of \$38.1 million in inventory costs related to recognized revenues. The cost of Ampyra inventory is based on a percentage of net product sales of the product in the quarter shipped to Acorda by Alkermes or our alternative manufacturer. Cost of sales for the nine-month period ended September 30, 2013 also consisted of \$5.2 million in royalty fees based on net sales, \$441,000 in amortization of intangible assets, and \$83,000 in period costs related to freight and stability testing.

Cost of sales for the nine-month period ended September 30, 2012 consisted primarily of \$32.0 million in inventory costs related to recognized revenues. Cost of sales for the nine-month period ended September 30, 2012 also consisted of \$4.7 million in royalty fees based on net sales, \$441,000 in amortization of intangible assets, and \$127,000 in period costs related to freight and stability testing.

### Zanaflex

We recorded cost of sales of \$1.1 million for the nine-month period ended September 30, 2013 as compared to \$1.8 million for the nine-month period ended September 30, 2012. Cost of sales for the nine-month period ended September 30, 2013 consisted of \$611,000 in inventory costs primarily related to recognized revenues, \$315,000 in royalty fees based on net product shipments, and \$141,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$2.7 million of costs for Zanaflex Capsules authorized generic product sold for the nine-month period ended September 30, 2013.

Cost of sales for the nine-month period ended September 30, 2012 included \$1.1 million in inventory costs related to recognized revenues, \$629,000 in royalty fees based on net product shipments, and \$69,000 in period costs related to packaging, freight, and stability testing. 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.

### Qutenza

We recorded cost of sales of \$117,000 for the nine-month period ended September 30, 2013. Cost of sales for the nine-month period ended September 30, 2013 consisted of \$71,000 in inventory costs related to recognized revenues as well as inventory obsolescence and royalty fees based on net product shipments, \$28,000 in amortization of intangible assets and \$18,000 in period costs related to inventory destruction, freight and stability testing.

## Cost of License Revenue

We recorded cost of license revenue of \$476,000 for the nine-month periods ended September 30, 2013 and 2012, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan) in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

## Research and Development



Research and development expenses for the nine-month period ended September 30, 2013 were \$39.6 million as compared to \$35.7 million for the nine-month period ended September 30, 2012, an increase of approximately \$3.9 million, or 11%. The increase was primarily due to an increase in overall research and development staff, compensation and related expenses of \$5.5 million to support the various research and development initiatives. The increase was also due to an increase of \$1.8 million for current year research and development expenses related to Diazepam Nasal Spray, and an increase of \$1.6 million in preclinical expenses for the remyelinating antibodies program (rHIgM22), an increase of \$625,000 for technical operations and regulatory costs associated with our various pipeline initiatives (exclusive of Diazepam Nasal Spray expenses), and an increase of \$546,000 related to GGF2. A \$1.0 million milestone payable to SK was triggered during the nine-month period ending September 30, 2013 upon the acceptance of an FDA new drug application (NDA). The

increases in research and development expenses for the nine-month period ended September 30, 2013 were partially offset by a decrease of \$6.3 million related to our life cycle management program for Ampyra due to timing.

#### Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2013 were \$82.9 million compared to \$76.3 million for the nine-month period ended September 30, 2012, an increase of approximately \$6.7 million, or 9%. The increase was attributable to an increase in overall compensation, benefits, and other selling expenses of \$4.0 million. The increase was also related to an increase of \$2.2 million for pre-launch activities associated with the possible commercialization of Diazepam Nasal Spray, if approved, as well as an increase in overall marketing, selling, distribution, and market research expenses for Ampyra of \$600,000.

General and administrative expenses for the nine-month period ended September 30, 2013 were \$55.6 million compared to \$46.8 million for the nine-month period ended September 30, 2012, an increase of approximately \$8.8 million, or 19%. This increase was the result of an increase of \$8.1 million for staff and compensation expenses and other expenses related to supporting the growth of the organization, an increase in business development expenses of \$1.0 million, and an increase of \$870,000 for an FDA post approval commitment study on Zanaflex Capsules. The increases in general and administrative expenses for the nine-month period ended September 30, 2013 were partially offset by a decrease in medical affairs expenses including educational programs of \$1.2 million.

#### Other Expense

Other expense was \$1.4 million for the nine-month period ended September 30, 2013 compared to \$1.1 million for the nine-month period ended September 30, 2012, an increase of approximately \$275,000, or 25%. The increase was due to an increase in interest expense of \$383,000 principally related to the PRF revenue interest agreement due to a decrease in Zanaflex sales offset by a slight increase in interest income of \$108,000.

#### Provision for Income Taxes

For the nine-month periods ended September 30, 2013 and 2012, we recorded a provision for income taxes of \$5.9 million and a \$1.2 million, respectively, based upon our estimated tax liability for the year. The provision for income taxes is based on federal, state and Puerto Rico income taxes. The effective income tax rates for the nine-month periods ended September 30, 2013 and 2012 were 36.8% and 5.1%, respectively. As a result of the January 2013 extension of the Federal research and development tax credit retroactive to January 2012 we recorded a benefit of \$1.2 million for the estimated 2012 credit. During the nine-month period ended September 30, 2013 the Company also settled an IRS examination of their corporate income tax returns for years ending December 31, 2009 through December 31, 2011. The impact of the settlement partially offset the benefit recorded for the research and development tax credit.

We continue to evaluate the realizability of the Company's deferred tax assets and liabilities on a periodic basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits and the regulatory approval of products currently under development. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes.

#### 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 2012 and, at September 30, 2013, we had \$349.4 million of cash, cash equivalents and short-term and long-term investments, compared to \$333.2 million at December 31, 2012. We expect to be cash flow positive in 2013. Any investments classified as long-term had maturity dates of no later than December 31, 2014. 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 2013 business plan, including our currently anticipated development pipeline activities in 2013.

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Ampyra, the continued progress of our research and development activities, the amount and timing of milestone or other payments payable under collaboration, license and acquisition agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, and the extent to which we acquire or in-license new products and compounds including the development costs relating to those products or compounds. To the extent our capital resources are insufficient to meet future operating requirements we will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund our operations. If we require additional financing in the future, we cannot assure you that it will be available to us on favorable terms, or at all.

#### Financing Arrangements

In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, Elan transferred these promissory notes to funds affiliated with Saints Capital. As of September 30, 2013, \$4.3 million of these promissory notes was outstanding, which amount includes accrued interest. The third of seven annual payments on this note was due and paid on the three year anniversary of Ampyra approval on January 22, 2013 and will continue to be paid annually until paid in full.

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products including the authorized generic version of Zanaflex Capsules being sold by Watson effective in February 2012. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, including the authorized generic version of Zanaflex Capsules revenue, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006. An additional \$5.0 million was due to us if net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in our December 31, 2006 financial statements. Under the terms of the amendment, we repaid PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met.

Under the agreement and the amendment, PRF is entitled to the following portion of Zanaflex net revenues:

- with respect to Zanaflex net revenues up to and including \$30.0 million for each fiscal year during the term of the agreement, 15% of such net revenues;
- with respect to Zanaflex net revenues in excess of \$30.0 million but less than and including \$60.0 million for each fiscal year during the term of the agreement, 6% of such net revenues; and
- with respect to Zanaflex net revenues in excess of \$60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF has received and retained payments under the agreement that are at least 2.1 times the aggregate amount PRF has paid us under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we recorded a liability as of September 30, 2013, referred to as the revenue interest liability, of approximately \$1.9 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 5.8%. 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. As of September 30, 2013, the Company has no liability recorded related to the put/call option to reflect its current estimated fair value due to the timing and amount of current projections. This liability is revalued on an as needed basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings.

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

On August 3, 2012, we received a letter from PRF alleging that we breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also includes an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it does not specify or quantify those injuries. We believe that the allegations are without merit and that the put option has not been validly exercised. Although the letter from PRF does not include a purported calculation of the put option price, if it were validly exercised, we estimate that the incremental cost to the Company in excess of amounts already accrued to PRF at September 30, 2013 would be no more than approximately \$1.8 million.

#### Investment Activities

At September 30, 2013, cash, cash equivalents, short-term and long-term investments were approximately \$349.4 million, as compared to \$333.2 million at December 31, 2012. 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 US Treasury bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of September 30, 2013, our cash and cash equivalents were \$46.2 million, as compared to \$41.9 million as of December 31, 2012. 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 \$246.0 million as of September 30, 2013, as compared to \$191.9 million as of December 31, 2012. Our long-term investments consist of US Treasury bonds with original maturities greater than one year. The balance of these investments was \$57.1 million as of September 30, 2013, as compared to \$99.4 million as of December 31, 2012.

#### Net Cash Provided by Operations

Net cash provided by operations was \$20.1 million for the nine-month period ending September 30, 2013 while \$35.4 million was provided for the nine-month period ended September 30, 2012. Cash provided by operations for the nine-month period ended September 30, 2013 was primarily due to a decrease in working capital items of \$13.8 million attributable to a decrease in accounts payable, accrued expenses, prepaid items, and accounts receivable and an increase in inventory held by the company. Cash provided by operations was also attributable to a decrease in non-current portion of deferred license revenue of \$6.8 million and a gain due to the reduction of our put/call liability related to the PRF revenue interest agreement \$329,000. Cash provided by operations was partially offset by non-cash

share-based compensation expense of \$18.0 million, depreciation and amortization of \$4.6 million, net income of \$10.3 million, a deferred tax provision of \$6.1 million, an increase of deferred product revenue related to Zanaflex of \$1.9 million, and amortization of net premiums and discounts on investments of \$1.8 million.

Cash provided by operations for the nine-month period ended September 30, 2012 was primarily attributable to net income of \$21.8 million principally resulting from net product and license and royalty revenues, a non-cash share-based compensation expense of \$15.3 million, amortization of net premiums and discounts on investments of \$3.7 million and depreciation and amortization of \$3.1 million. Cash provided by operations was partially offset by a net decrease of \$1.9 million due to changes in working capital items primarily due to the payment of prepaid and accrued items totaling \$8.9

million during the nine-month period ended September 30, 2012, a decrease in deferred product revenue of \$1.8 million, and an increase in accounts receivable of \$399,000. These working capital decreases were partially offset by a decrease in inventory held by the company and others of \$9.1 million and an increase in the revenue interest liability of \$495,000. The offset to cash provided by operations was also attributable to a decrease in non-current portion of deferred license revenue of \$6.8 million due to the amortization of the upfront collaboration payment received during the nine-month period ended September 30, 2009 and a decrease in the loss on our put/call liability of \$476,000.

#### Net Cash Used in Investing

Net cash used in investing activities for the nine-month period ended September 30, 2013 was \$27.2 million, primarily due to \$128.0 million in purchases of investments, acquisitions of \$7.5 million, purchases of property and equipment of \$3.7 million, and purchases of intangible assets of \$2.5 million, partially offset by \$114.5 million in proceeds from maturities and sales of investments.

#### Net Cash Provided by Financing

Net cash provided by financing activities for the nine-month period ended September 30, 2013 was \$11.5 million, primarily due to \$12.2 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by \$670,000 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, 2012. The acquisition of certain NeurogesX assets during the nine-month period ending September 30, 2013 increased our contractual commitments. Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. Under certain supply agreements and other agreements with manufacturers and suppliers, we are required to make payments for the manufacture and supply of our clinical and approved products. During the nine-month period ended September 30, 2013, commitments related to the purchase of inventory decreased as compared to December 31, 2012. As of September 30, 2013, we have inventory-related purchase commitments totaling approximately \$17.3 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. As of September 30, 2013, we have committed to make potential future milestone payments to third parties of up to approximately \$206 million as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of September 30, 2013, such contingencies have not been recorded in our financial statements with the exception of a liability for the fair value of the contingent consideration relating to two milestones as a result of the acquisition of certain assets of NeurogesX. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.



Critical Accounting Policies and Estimates

Our critical accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2012. As of September 30, 2013, our critical accounting policies have not changed materially from December 31, 2012.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash equivalents, short-term and long-term investments, grants receivable, convertible notes payable, accounts payable, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at September 30, 2013.

We have cash equivalents, short-term and long-term investments at September 30, 2013, 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 short-term and long-term investments approximate their fair value at September 30, 2013. Our investments designated as long-term as of September 30, 2013 had maturity dates no later than December 31, 2014. At September 30, 2013, we held \$349.4 million in cash, cash equivalents, short-term and long-term investments which had an average interest rate of approximately 0.05%.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and to meet operating needs. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

#### Item 4. Controls and Procedures

##### Evaluation of disclosure controls and procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act") we carried out an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the third quarter of 2013, the period covered by this report. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of September 30, 2013, our disclosure controls and procedures were effective to achieve their stated purpose.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules, regulations, and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding disclosure.

##### Change in internal control over financial reporting

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our chief executive officer and chief financial officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended September 30, 2013, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

##### Limitations on the effectiveness of controls

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



## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc., advising that it had submitted an Abbreviated New Drug Application, or ANDA, to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex in the U.S. District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557. In September 2011, the Court ruled against us and, following our appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We did not seek any further appeal of the decision. On September 6, 2011, we filed a citizen petition with the FDA requesting that the FDA not approve Apotex's ANDA because of public-safety concerns about Apotex's proposed drug. On December 2, 2011, Apotex filed suit against us in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleged, 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 made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. Following our filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed five of the six counts in the amended complaint, including all of the antitrust claims, leaving only a claim under the Lanham Act relating to alleged product promotional activities. The case is now proceeding, and the Company intends to defend itself vigorously in the litigation.

Item 1 of Part II of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31 and June 30, 2013, include prior updates to the litigation described above.

### Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012, as updated by the information in Item 1A of Part II of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013, and as further updated by this Item 1A, all of which could materially affect our business, financial condition or future results. These risks 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 2012 Annual Report on Form 10-K and our update to the risk factors in our Quarterly Report for the quarter ended June 30, 2013.

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

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS and spinal cord injury, or SCI.

Our competitors may succeed in developing products that are more effective, safer or more convenient than our products or the ones we have under development or that render our approved or proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any

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

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

For example, we are aware that Catalyst Pharmaceuticals is developing a 3,4 diaminopyridine product, licensed from Biomarin, that may compete with Ampyra. In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis. We are aware that at present compounded dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available. Several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Ampyra or some of our product candidates.

Also, Diazepam Nasal Spray is a proprietary nasal spray formulation of diazepam, which is currently available as an FDA approved rectal gel and in other formulations, such as used for intramuscular and intravenous administration. Our current understanding is that many patients would prefer a therapeutic delivered intranasally rather than delivery options of rectal or intramuscular administration, but we cannot be certain that physicians would prescribe Diazepam Nasal Spray in preference over the other available formulations of diazepam. Also, if we obtain FDA approval for and launch Diazepam Nasal Spray, it may be more expensive than some or all of the generic or branded versions of diazepam otherwise available. Furthermore, we are aware that Meridian Medical Technologies (a Pfizer subsidiary) is developing an intramuscular auto-injector for diazepam, Neurelis, through BioTie Therapies, is developing an intranasal diazepam spray, and Upsher Smith is developing a nasal delivery form of midazolam, which could have a labeled indication similar to Diazepam Nasal Spray. Diazepam Nasal Spray could be subject to substantial competition from these potential products, depending on whether and when they receive FDA approval, their cost, their labeled indications, patient acceptance, and other factors. Additionally, in May 2013, the diazepam auto-injector from Meridian Medical Technologies received Orphan drug designation for the management of selected, refractory patients with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity. The product is still in clinical development and has not been approved yet. If this product receives FDA approval before Diazepam Nasal Spray, the FDA will not approve our NDA for Diazepam Nasal Spray unless we are able to prove to the FDA that the nasal spray is clinically superior to the intramuscular diazepam auto-injector for the same target population.

In addition to these examples, there are numerous other companies with early stage development programs for the treatment of epilepsy, cluster or breakthrough seizures, and acute repetitive seizures that could compete with Diazepam Nasal Spray in the future.

Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. A number of companies are marketing generic versions of tizanidine hydrochloride tablets. In addition, on February 6, 2012, Apotex Inc. launched generic tizanidine hydrochloride capsules and we launched an authorized generic version of Zanaflex Capsules under our agreement with Watson Pharma (a subsidiary of Actavis). 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. The FDA approved Mylan's ANDA on November 9, 2012. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. Our net revenue from Zanaflex Capsules has declined significantly due to competition from existing generic versions, and we expect it will continue to decline significantly in 2013 and beyond due to competition from existing and potentially other generic versions.

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

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent and trademark protection for the technologies, compounds and products, if any, resulting from our licenses and research and development programs. Without protection for the intellectual property we use or intend to use, other companies could offer substantially identical products for sale without incurring the sizable discovery, research, development and

licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

We have patent portfolios relating to Ampyra, Zanaflex Capsules, neuregulins, remyelinating antibodies, chondroitinase, AC105, Diazepam Nasal Spray, Qutenza and NP-1998, comprised of both our own and in-licensed patents and patent applications. Our intellectual property also includes copyrights, confidential and trade secret information and a portfolio of trademarks. The process of obtaining patents and trademarks can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent or trademark may not issue, it may not issue in a timely manner, or it may not have sufficient scope or strength to protect the technology it was intended to protect or to

provide us with any commercial advantage. We may never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because patent applications are confidential until they are published, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not allowed or issued for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or trademarks or the patents or trademarks of our licensors. For example, starting in late January 2014, generic drug manufacturers may attempt to file Abbreviated New Drug Applications, or ANDAs, for generic versions of Ampyra with the FDA. In filing these ANDAs for Ampyra, generic drug manufacturers may choose to challenge one or more of the patents that protect the Ampyra franchise. As such, Acorda may need to initiate legal proceedings by asserting one or more of its patents against the generic drug manufacturer. Patent litigation involves complex legal and factual questions. As such, we may need to devote significant resources to such legal proceedings, and if we are not successful our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of any such patent related lawsuits.

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

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

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





Item 6. Exhibits

| Exhibit No. | Description  |
|-------------|--|
| 10.1*       | Employment Offer Letter dated September 20, 2013, by and between the Registrant and Michael W. Rogers  |
| 31.1        | Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.                                     |
| 31.2        | Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.                                     |
| 32.1        | Certification by the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2        | Certification by the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS**   | XBRL Instance Document   |
| 101.SCH**   | XBRL Taxonomy Extension Schema Document  |
| 101.CAL**   | XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.DEF**   | XBRL Taxonomy Extension Definition Linkbase Document   |
| 101.LAB**   | XBRL Taxonomy Extension Label Linkbase Document  |
| 101.PRE**   | XBRL Taxonomy Extension Presentation Linkbase Document   |

\* Indicates management contract or compensatory plan or arrangement.

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

SIGNATURES

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

Acorda Therapeutics, Inc.

By:

/s/ Ron Cohen  
Ron Cohen, M.D.  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: November 7, 2013

By:

/s/ Michael Rogers  
Michael Rogers  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: November 7, 2013

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