

ACORDA THERAPEUTICS INC  
Form 10-Q  
November 09, 2015

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, 2015

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.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller Reporting Company

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(Do not check if a  
smaller reporting  
company)

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

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

| Class  | Outstanding at October 31, 2015 |
|--|---------------------------------|
| Common Stock, \$0.001 par value<br>per share | 43,155,369 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: The ability to realize the benefits anticipated from the Civitas Therapeutics, Inc. transaction and to successfully integrate Civitas's operations into our operations; 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 CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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 in connection therewith; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements in this report and in our Annual Report on Form 10-K for the year ended December 31, 2014, particularly in the "Risk Factors" section (as updated by the disclosures in our subsequent quarterly reports), that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.

We and our subsidiaries 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," "Qutenza" and "ARCUS." 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 (e.g., "Plumiaz") in the U.S. and worldwide for potential product names or for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.

## PART I

## Item 1. Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

| (In thousands, except share data)   | September 30,<br>2015 | December 31,<br>2014 |
|---|-----------------------|----------------------|
|   | (unaudited)           |                      |
| <b>Assets</b>   |                       |                      |
| <b>Current assets:</b>  |                       |                      |
| Cash and cash equivalents   | \$ 89,837             | \$ 182,170           |
| Restricted cash   | 1,139                 | 1,205                |
| Short-term investments  | 233,593               | 125,448              |
| Trade accounts receivable, net of allowances of \$911 and \$771, as of September 30, 2015 and December 31, 2014, respectively | 31,755                | 32,211               |
| Prepaid expenses  | 13,876                | 15,523               |
| Finished goods inventory held by the Company  | 46,838                | 26,256               |
| Finished goods inventory held by others   | —                     | 581                  |
| Deferred tax asset  | 4,967                 | 18,420               |
| Other current assets  | 7,563                 | 7,324                |
| <b>Total current assets</b>   | <b>429,568</b>        | <b>409,138</b>       |
| Property and equipment, net of accumulated depreciation   | 42,415                | 46,090               |
| Goodwill  | 183,636               | 182,952              |
| Intangible assets, net of accumulated amortization  | 431,279               | 432,822              |
| Non-current portion of deferred cost of license revenue   | 3,064                 | 3,540                |
| Restricted cash   | 4,809                 | —                    |
| Other assets  | 5,507                 | 6,137                |
| <b>Total assets</b>   | <b>\$ 1,100,278</b>   | <b>\$ 1,080,679</b>  |
| <b>Liabilities and Stockholders' Equity</b>   |                       |                      |
| <b>Current liabilities:</b>   |                       |                      |
| Accounts payable  | \$ 14,005             | \$ 17,751            |
| Accrued expenses and other current liabilities  | 68,472                | 56,118               |
| Deferred product revenue—Zanaflex   | —                     | 29,420               |
| Current portion of deferred license revenue   | 9,057                 | 9,057                |
| Current portion of revenue interest liability   | 561                   | 893                  |
| Current portion of convertible notes payable  | 1,144                 | 1,144                |
| <b>Total current liabilities</b>  | <b>93,239</b>         | <b>114,383</b>       |
| Convertible senior notes (due 2021)   | 293,492               | 287,699              |

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|  |              |              |
|--|--------------|--------------|
| Acquired contingent consideration  | 60,000       | 52,600       |
| Non-current portion of deferred license revenue  | 43,777       | 50,570       |
| Non-current portion of convertible notes payable   | 1,091        | 2,184        |
| Deferred tax liability   | 24,568       | 23,885       |
| Other non-current liabilities  | 9,223        | 9,103        |
| Commitments and contingencies  |              |              |
| Stockholders' equity:  |              |              |
| Common stock, \$0.001 par value. Authorized 80,000,000 shares at September 30, 2015 and December 31, 2014; issued and outstanding 42,889,088 and 41,883,843 shares, including those held in treasury, as of September 30, 2015 and December 31, 2014, respectively | 43           | 42           |
| Treasury stock at cost (12,420 shares at September 30, 2015 and December 31, 2014)   | (329 )       | (329 )       |
| Additional paid-in capital   | 793,774      | 761,026      |
| Accumulated deficit  | (218,557 )   | (220,410 )   |
| Accumulated other comprehensive loss   | (43 )        | (74 )        |
| Total stockholders' equity   | 574,888      | 540,255      |
| Total liabilities and stockholders' equity   | \$ 1,100,278 | \$ 1,080,679 |

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 period ended September 30, 2015 | Three-month period ended September 30, 2014 | Nine-month period ended September 30, 2015 | Nine-month period ended September 30, 2014 |
|--|---|---|--|--|
| <b>Revenues:</b>   |   |   |  |  |
| Net product revenues                                       | \$ 141,330                                  | \$ 98,481                                   | \$ 342,394                                 | \$ 262,662                                 |
| Royalty revenues   | 4,605                                       | 5,216                                       | 12,571                                     | 14,153                                     |
| License revenue  | 2,264                                       | 2,264                                       | 6,793                                      | 6,793                                      |
| <b>Total net revenues</b>                                  | <b>148,199</b>                              | <b>105,961</b>                              | <b>361,758</b>                             | <b>283,608</b>                             |
| <b>Costs and expenses:</b>                                 |   |   |  |  |
| Cost of sales  | 24,741                                      | 20,575                                      | 65,896                                     | 55,004                                     |
| Cost of license revenue                                    | 159   | 159   | 476  | 476  |
| Research and development                                   | 43,356                                      | 16,578                                      | 105,221                                    | 47,548                                     |
| Selling, general and administrative                        | 51,056                                      | 47,820                                      | 152,645                                    | 145,357                                    |
| Changes in fair value of acquired contingent consideration | 3,200                                       | —   | 7,400                                      | —  |
| <b>Total operating expenses</b>                            | <b>122,512</b>                              | <b>85,132</b>                               | <b>331,638</b>                             | <b>248,385</b>                             |
| <b>Operating income</b>                                    | <b>25,687</b>                               | <b>20,829</b>                               | <b>30,120</b>                              | <b>35,223</b>                              |
| <b>Other expense (net):</b>                                |   |   |  |  |
| Interest and amortization of debt discount expense         | (4,037 )                                    | (4,597 )                                    | (12,098 )                                  | (5,116 )                                   |
| Interest income  | 120   | 257   | 281  | 596  |
| Other (expense) income                                     | (59 )                                       | —   | 411  | —  |
| <b>Total other expense (net)</b>                           | <b>(3,976 )</b>                             | <b>(4,340 )</b>                             | <b>(11,406 )</b>                           | <b>(4,520 )</b>                            |
| <b>Income before taxes</b>                                 | <b>21,711</b>                               | <b>16,489</b>                               | <b>18,714</b>                              | <b>30,703</b>                              |
| <b>Provision for income taxes</b>                          | <b>(17,770 )</b>                            | <b>(4,536 )</b>                             | <b>(16,861 )</b>                           | <b>(13,361 )</b>                           |
| <b>Net income</b>  | <b>\$ 3,941</b>                             | <b>\$ 11,953</b>                            | <b>\$ 1,853</b>                            | <b>\$ 17,342</b>                           |
| <b>Net income per share—basic</b>                          |   |   |  |  |
|  | \$ 0.09                                     | \$ 0.29                                     | \$ 0.04                                    | \$ 0.42                                    |
| <b>Net income per share—diluted</b>                        |   |   |  |  |
|  | \$ 0.09                                     | \$ 0.28                                     | \$ 0.04                                    | \$ 0.41                                    |
|  | 42,174                                      | 41,094                                      | 42,097                                     | 41,022                                     |

Weighted average common  
shares outstanding used in  
computing net income per  
share—basic

Weighted average common  
shares outstanding used in  
computing net income per  
share—diluted

|        |        |        |        |
|--------|--------|--------|--------|
| 43,432 | 42,365 | 43,434 | 42,346 |
|--------|--------|--------|--------|

See accompanying Unaudited Notes to Consolidated Financial Statements



ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income

(unaudited)

| (In thousands)   | Three-month                              | Three-month                              | Nine-month                               | Nine-month                               |
|--|--|--|--|--|
|  | period<br>ended<br>September<br>30, 2015 | period<br>ended<br>September<br>30, 2014 | period<br>ended<br>September<br>30, 2015 | period<br>ended<br>September<br>30, 2014 |
| Net income   | \$ 3,941                                 | \$ 11,953                                | \$ 1,853                                 | \$ 17,342                                |
| Other comprehensive income:                                      |  |  |  |  |
| Unrealized gains on available<br>for sale securities, net of tax | 17                                       | 69                                       | 31                                       | 129                                      |
| Other comprehensive income,<br>net of tax                        | 17                                       | 69                                       | 31                                       | 129                                      |
| Comprehensive income   | \$ 3,958                                 | \$ 12,022                                | \$ 1,884                                 | \$ 17,471                                |

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, 2015 | Nine-month<br>period<br>ended<br>September<br>30, 2014 |
|--|--|--|
| <b>Cash flows from operating activities:</b>   |  |  |
| Net income   | \$ 1,853   | \$ 17,342  |
| Adjustments to reconcile net income to net cash provided by operating activities:    |  |  |
| Recognition of deferred product revenue - Zanaflex                                   | (22,186 )  | —  |
| Share-based compensation expense   | 24,748   | 20,644   |
| Amortization of net premiums and discounts on investments                            | 2,372  | 3,099  |
| Amortization of debt discount and debt issuance costs                                | 6,383  | 2,226  |
| Amortization of revenue interest issuance cost                                       | 15   | 19   |
| Depreciation and amortization expense  | 11,153   | 5,375  |
| Change in acquired contingent consideration obligation                               | 7,400  | —  |
| Gain on put/call liability   | —  | (147 )   |
| Deferred tax provision   | 16,861   | 13,441   |
| Changes in assets and liabilities:   |  |  |
| Decrease in accounts receivable  | 455  | 5,992  |
| Decrease (increase) in prepaid expenses and other current assets                     | 1,408  | (2,515 )   |
| Increase in inventory held by the Company  | (20,582 )  | (1,111 )   |
| Decrease in inventory held by others   | 581  | 67   |
| Decrease in non-current portion of deferred cost of license revenue                  | 476  | 476  |
| Decrease in other assets   | 25   | 25   |
| (Decrease) increase in accounts payable, accrued expenses, other current liabilities | (2,158 )   | 5,732  |
| (Decrease) increase in revenue interest liability interest payable                   | (124 )   | 25   |
| Decrease in non-current portion of deferred license revenue                          | (6,793 )   | (6,793 )   |
| Increase in other non-current liabilities  | —  | 27   |
| Decrease in deferred product revenue—Zanaflex  | (988 )   | (2,575 )   |
| (Increase) decrease in restricted cash   | (4,743 )   | 83   |
| Net cash provided by operating activities  | 16,156   | 61,432   |
| <b>Cash flows from investing activities:</b>   |  |  |
| Purchases of property and equipment  | (5,025 )   | (2,330 )   |
| Purchases of intangible assets   | (781 )   | (1,577 )   |

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|   |           |           |
|---|-----------|-----------|
| Purchases of investments                                    | (359,968) | (580,381) |
| Proceeds from maturities of investments                     | 249,500   | 183,500   |
| Net cash used in investing activities                       | (116,274) | (400,788) |
| Cash flows from financing activities:                       |           |           |
| Proceeds from issuance of convertible senior notes          | —         | 345,000   |
| Debt issuance costs   | —         | (7,516 )  |
| Proceeds from issuance of common stock and option exercises | 8,000     | 7,628     |
| Repayments of revenue interest liability                    | (215 )    | (452 )    |
| Net cash provided by financing activities                   | 7,785     | 344,660   |
| Net (decrease) increase in cash and cash equivalents        | (92,333 ) | 5,304     |
| Cash and cash equivalents at beginning of period            | 182,170   | 48,037    |
| Cash and cash equivalents at end of period                  | \$ 89,837 | \$ 53,341 |
| Supplemental disclosure:                                    |           |           |
| Cash paid for interest                                      | 4,279     | 1,153     |
| Cash paid for taxes   | 2,152     | 1,829     |

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(unaudited)

(1) Organization and Business Activities

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that restore function and improve the lives of people with neurological disorders.

Management 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, 2014 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 consolidated financial statements include certain amounts that are based on management’s best estimates and judgments. Estimates are used in determining such items as provisions for rebates and incentives, chargebacks, returns and other sales allowances, depreciable/amortizable lives, asset impairments, excess inventory, valuation allowance on deferred taxes, purchase price allocations and amounts recorded for contingencies and accruals. Because of the uncertainties inherent in such estimates, actual results may differ from these estimates. Management periodically evaluates estimates used in the preparation of the consolidated financial statements for reasonableness.

The use of forecasted financial information is inherent in many of our accounting estimates, including but not limited to, determining the estimated fair value of goodwill, intangible assets and contingent consideration, matching intangible amortization to underlying benefits (e.g. sales and cash inflows), establishing and evaluating inventory reserves, and evaluating the need for valuation allowances for deferred tax assets. Such forecasted financial information is comprised of numerous assumptions regarding our future revenues, cash flows, and operational results. Management believes that its financial forecasts are reasonable and appropriate based upon current facts and circumstances. Because of the inherent nature of forecasts, however, actual results may differ from these forecasts. Management regularly reviews the information related to these forecasts and adjusts the carrying amounts

of the applicable assets and liabilities prospectively when actual results differ from previous estimates.

#### Investments

Short-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 investments as available-for-sale. Available-for-sale securities are recorded at the 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 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 Loss

The Company's accumulated other comprehensive loss is comprised of unrealized 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 distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. 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 collectability is reasonably assured. The Company recognizes product sales of Ampyra following receipt of product by a network of specialty pharmacy providers, Kaiser Permanente, and ASD Specialty Healthcare, Inc. The specialty pharmacy providers, Kaiser Permanente, and ASD Specialty Healthcare, Inc. are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 calendar days.

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, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies, Kaiser Permanente and ASD Specialty Healthcare, Inc., an adjustment is recorded for estimated discounts, rebates and chargebacks. 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 discounts, rebates and chargebacks 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. The Company does not accept 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. Prior to the three-month period ended September 30, 2015, the Company accounted for Zanaflex tablet and capsule (Zanaflex products) shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company's sales and revenue recognition reflected the Company's estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company is recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. For the three-month period ended September 30, 2015, the Company recognized a one-time increase in net revenue of \$22.2 million, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, chargebacks 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 the wholesale distributors, an allowance is recorded for estimated discounts, rebates, chargebacks 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 discounts, rebates, chargebacks 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.

#### Qutenza

Qutenza is distributed in the United States by Besse Medical, Inc., a specialty distributor that furnishes the medication to physician offices; and by ASD Specialty Healthcare, Inc., a specialty distributor that furnishes the medication to hospitals and clinics. 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 receipt of product by its specialty distributors.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated rebates, chargebacks, 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, chargebacks, 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, chargebacks, 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 as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

#### 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 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 in the statement of operations. These assets are tested at least annually or sooner when a triggering event occurs that could indicate a potential impairment.

### Contingent Consideration

The Company records contingent consideration as part of its business acquisitions. Contingent consideration is recognized at fair value as of the date of acquisition and recorded as a liability on the consolidated balance sheet. The contingent consideration is re-valued on a quarterly basis using a probability weighted discounted cash-flow approach until fulfillment or expiration of the contingency. Changes in the fair value of the contingent consideration are recognized in the statement of operations.

### Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired.

### 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, 2015 were a network of specialty pharmacies, Kaiser Permanente, and ASD Specialty Healthcare, Inc. for Ampyra, wholesale pharmaceutical distributors for Zanaflex Capsules and Zanaflex tablets, and two specialty distributors 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 product revenue for the nine-month periods ended September 30, 2015 and 2014. Three and four customers individually accounted for more than 10% of the Company's accounts receivable as of September 30, 2015 and December 31, 2014, respectively. 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 to improve the lives of people with neurological disorders. 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 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 May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09). This new standard will replace all current U.S. GAAP guidance on this topic and eliminate all industry-specific guidance. In July 2015, the FASB decided to defer the effective date of the new revenue standard for interim and annual periods beginning after December 15, 2017 (previously December 15, 2016). The change will allow public entities to adopt the new standard as early as the original public entity effective date (i.e. annual reporting periods beginning after December 15, 2016 and interim periods therein). Early adoption prior to that date will not be permitted. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. The Company is evaluating the transition method that will be elected and the potential effects of adopting the provisions of ASU No. 2014-09.

In August 2014, the FASB issued Accounting Standards Update 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU 2014-05 is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. ASU-2014-15 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2015, with early adoption permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements or results of operations.

On June 12, 2015, the FASB issued ASU 2015-10, Technical Corrections and Improvements. With regard to fair value measurement disclosures, ASU 2015-10 clarified that, for nonrecurring measurements estimated at a date during the reporting period other than the end of the reporting period, an entity should clearly indicate that the fair value information presented is not as of the period's end as well as the date or period that the measurement was taken. This change was effective immediately upon issuance of ASU 2015-10. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements or disclosures.

In July 2015, the FASB issued Accounting Standards Update 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory (ASU 2015-11), which requires the measurement of inventory at the lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and interim periods therein with early adoption permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements or results of operations.

In September 2015, the FASB issued Accounting Standards update 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments (ASU 2015-16), which requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the period in which the adjustment amount is determined. The acquirer is required to also record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. In addition the acquirer is required to present separately on the face of the income statement or disclose in the notes to the financial statements the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as

of the acquisition date. This guidance is effective for fiscal years and interim periods beginning after December 15, 2015, and requires prospective application. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements or results of operations.

(3) Acquisitions

Civitas Therapeutics, Inc. Acquisition

On October 22, 2014, the Company completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation (Civitas). As a result of the acquisition, the Company acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease. The acquisition of Civitas also included rights to Civitas's proprietary ARCUS

pulmonary delivery technology, which management believes has potential applications in multiple disease areas, and a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Approximately 45 Civitas employees based at the Chelsea facility joined the Acorda workforce in connection with the acquisition.

The Civitas acquisition was completed under an Agreement and Plan of Merger, dated as of September 24, 2014 (the Merger Agreement), by and among Acorda, Five A Acquisition Corporation, a Delaware corporation and its wholly-owned subsidiary (Merger Sub), Civitas and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the security holders' representative (SRS). Pursuant to the terms of the Merger Agreement, Merger Sub has merged with and into Civitas, which is the surviving corporation in the Merger and which is continuing as a wholly-owned subsidiary of Acorda under the Civitas name.

Pursuant to the terms of the Merger Agreement, aggregate merger consideration was \$525 million plus \$4.5 million in Civitas transaction costs paid by the Company. Additionally and pursuant to the Merger Agreement, upon consummation of the merger, \$39.375 million of the aggregate merger consideration was deposited into escrow to secure representation and warranty indemnification obligations of Civitas and Civitas' security holders. The escrow amount was released in the fourth quarter of 2015 in accordance with the Merger Agreement. The transaction was financed with cash on hand. The Company incurred approximately \$7.2 million of its own transactions costs related to legal, valuation and other professional and consulting fees associated with the acquisition. These transaction costs have been expensed as selling, general and administrative expenses in the year ended December 31, 2014.

The fair value of consideration transferred as of the acquisition date of October 22, 2014 totaled approximately \$529.5 million summarized as follows:

|   |            |
|---|------------|
| (In thousands)                          |            |
| Cash paid                               | \$ 524,201 |
| Extinguishment of long-term debt        | 5,325      |
| Fair value of consideration transferred | \$ 529,526 |

In accordance with the acquisition method of accounting, the Company allocated the purchase price to the estimated fair values of the identifiable assets acquired and liabilities assumed, with any excess allocated to goodwill. The fair value of acquired IPR&D is classified as an indefinite lived intangible asset until the successful completion or abandonment of the associated research and development efforts. The Company accounted for the transaction as a business combination. The results of Civitas' operations have been included in the consolidated statements of operations from the date of acquisition.

Acquired contingent consideration represents the estimated fair value of certain royalty payments due under a prior acquisition agreement between Alkermes and Civitas pertaining to sales of licensed products using the ARCUS technology. The estimated fair value of the acquired contingent consideration was determined by applying a probability adjusted, discounted cash flow approach based on estimated future sales expected from CVT-301, a phase 3 candidate for the treatment of OFF episodes of Parkinson's disease and CVT-427, a pre-clinical development stage product. CVT-427 is an inhaled triptan intended to provide relief from acute migraine episodes by using the ARCUS delivery system.

Goodwill represents the amount of the purchase price paid in excess of the estimated fair value of the assets acquired and liabilities assumed. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the IPR&D intangible assets which have no tax basis and, therefore, will not result in a future tax

deduction.

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The following table presents the final allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date of October 22, 2014:

|   |           |
|---|-----------|
| (In thousands)                                |           |
| Current assets                                | \$54,911  |
| Property and equipment                        | 27,913    |
| Identifiable intangible assets:               |           |
| In-process research and development           | 423,000   |
| Other non-current assets                      | 1,002     |
| Current liabilities                           | (6,154 )  |
| Contingent consideration                      | (50,400 ) |
| Deferred taxes                                | (103,317) |
| Other non-current liabilities                 | (1,065 )  |
| Fair value of acquired assets and liabilities | 345,890   |
| Goodwill                                      | 183,636   |
| Aggregate purchase price                      | 529,526   |
| Amount paid to extinguish long-term debt      | (5,325 )  |
| Cash Paid                                     | \$524,201 |

In the three-month period ended September 30, 2015, the Company completed its purchase price allocation for the Civitas acquisition which resulted in an increase of approximately \$0.7 million to the provisional amount recorded for deferred tax liabilities, resulting in an increase to goodwill.

The following table presents the changes to the goodwill balance associated with the completion of the accounting for the Civitas acquisition:

|   |           |
|---|-----------|
| (In thousands)  |           |
| Goodwill – balance at October 22, 2014                      | \$182,952 |
| Increase to goodwill for final adjustment to deferred taxes | 684       |
| Goodwill – balance at September 30, 2015                    | \$183,636 |

#### Pro-Forma Financial Information Associated with the Civitas Acquisition (Unaudited)

The following table summarizes certain supplemental pro forma financial information for the three and nine-month periods ended September 30, 2015 and 2014 as if the acquisition of Civitas had occurred as of January 1, 2013. The unaudited pro forma financial information for the three and nine-month periods ended September 30, 2014 reflects (i) the impact to depreciation expense based on fair value adjustments to the property, plant and equipment acquired from Civitas; (ii) the effect to interest expense on a loan Civitas entered into at March 31, 2014; and (iii) the income tax benefit from Civitas net loss at the Company's effective income tax rate at September 30, 2014. 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)    | For the Three-Month<br>Period ended<br>September 30, 2015 |            | For the Three-Month<br>Period ended<br>September 30, 2014 |            |
|-------------------|---|------------|---|------------|
|                   | Reported  | Pro Forma  | Reported  | Pro Forma  |
| Net revenues      | \$ 148,199  | \$ 148,199 | \$ 105,961  | \$ 105,961 |
| Net income (loss) | 3,941   | 3,941      | 11,953  | (10,288)   |

| (In thousands)    | For the Nine-Month Period<br>ended<br>September 30, 2015 |            | For the Nine-Month Period<br>ended<br>September 30, 2014 |            |
|-------------------|--|------------|--|------------|
|                   | Reported   | Pro Forma  | Reported   | Pro Forma  |
| Net revenues      | \$ 361,758   | \$ 361,758 | \$ 283,608   | \$ 283,608 |
| Net income (loss) | 1,853  | 1,853      | 17,342   | (13,733)   |

#### (4) Share-based Compensation

During the three-month periods ended September 30, 2015 and 2014, the Company recognized share-based compensation expense of \$8.9 million and \$7.3 million, respectively. During the nine-month periods ended September 30, 2015 and 2014, the Company recognized share-based compensation expense of \$24.7 million and \$20.6 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2015 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, 2015 and 2014 were approximately \$14.74 and \$14.88, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2015 and 2014 were approximately \$15.89 and \$18.04, respectively.

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

| (In millions)                          | For the three-month<br>period ended<br>September 30, |        | For the nine-month<br>period ended<br>September 30, |         |
|--|--|--------|---|---------|
|  | 2015   | 2014   | 2015  | 2014    |
| Research and development               | \$ 2.2   | \$ 1.5 | \$ 6.2  | \$ 4.1  |
| Selling, general and<br>administrative | 6.7  | 5.8    | 18.5  | 16.5    |
| Total                                  | \$ 8.9   | \$ 7.3 | \$ 24.7   | \$ 20.6 |

A summary of share-based compensation activity for the nine-month period ended September 30, 2015 is presented below:

Stock Option Activity

|  | Number<br>of Shares<br>(In<br>thousands) | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term | Intrinsic<br>Value<br>(In<br>thousands) |
|--|--|--|---|---|
| Balance at January 1, 2015                           | 7,787                                    | \$ 29.05                                 |   |   |
| Granted  | 1,561                                    | 35.42                                    |   |   |
| Cancelled  | (261 )                                   | 34.75                                    |   |   |
| Exercised  | (327 )                                   | 24.49                                    |   |   |
| Balance at September 30, 2015                        | 8,760                                    | \$ 30.19                                 | 6.7   | \$ 14,685                               |
| Vested and expected to vest at<br>September 30, 2015 | 8,655                                    | \$ 30.12                                 | 6.7   | \$ 14,685                               |
| Vested and exercisable at<br>September 30, 2015      | 5,202                                    | \$ 27.05                                 | 5.4   | \$ 14,543                               |

Restricted Stock Activity

| (In thousands)<br>Restricted Stock | Number of<br>Shares |
|------------------------------------|---------------------|
| Nonvested at January 1,<br>2015    | 502                 |
| Granted                            | 219                 |
| Vested                             | (17)                |
| Forfeited                          | (30)                |
| Nonvested at September<br>30, 2015 | 674                 |

Unrecognized compensation cost for unvested stock options and restricted stock awards as of September 30, 2015 totaled \$66.0 million and is expected to be recognized over a weighted average period of approximately 2.5 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, 2015 and 2014:

| (In thousands, except per share<br>data) | 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, 2015 | September<br>30, 2014 | September<br>30, 2015 | September<br>30, 2014 |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
| <b>Basic and diluted</b>   |                       |                       |                       |                       |
| Net income   | \$ 3,941              | \$ 11,953             | \$ 1,853              | \$ 17,342             |
| Weighted average common<br>shares outstanding used in<br>computing net income per<br>share—basic   | 42,174                | 41,094                | 42,097                | 41,022                |
| Plus: net effect of dilutive<br>stock options and restricted<br>common shares                      | 1,258                 | 1,271                 | 1,337                 | 1,324                 |
| Weighted average common<br>shares outstanding used in<br>computing net income per<br>share—diluted | 43,432                | 42,365                | 43,434                | 42,346                |
| Net income per share—basic   | \$ 0.09               | \$ 0.29               | \$ 0.04               | \$ 0.42               |
| Net income per share—diluted   | \$ 0.09               | \$ 0.28               | \$ 0.04               | \$ 0.41               |

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  | Three-month  | Nine-month   | Nine-month   |
|--|--------------|--------------|--------------|--------------|
|  | period ended | period ended | period ended | period ended |
|  | September    | September    | September    | September    |
|  | 30, 2015     | 30, 2014     | 30, 2015     | 30, 2014     |
| <b>Denominator</b>                         |              |              |              |              |
| Stock options and restricted common shares | 4,630        | 4,380        | 4,517        | 3,959        |
| Convertible note – Saints Capital          | 19           | 29           | 19           | 29           |

Additionally, the impact of the convertible debt was determined to be anti-dilutive and excluded from the calculation of net income per diluted share for the three and nine-month periods ended September 30, 2015 and 2014.

#### (6) Income Taxes

For the three-month periods ended September 30, 2015 and 2014, the Company recorded a \$17.8 million and \$4.5 million provision for income taxes, respectively based upon its estimated tax liability for the year. For the nine-month periods ended September 30, 2015 and 2014, the Company recorded a \$16.9 million and \$13.4 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 three-month periods ended September 30, 2015 and 2014 were 82% and 28%, respectively. The effective income tax rates for the Company for the nine-month periods ended September 30, 2015 and 2014 were 90% and 44%, respectively. The variances in the effective tax rates for the three and nine-month periods ended September 30, 2015 as compared to the three and nine-month periods ended September 30, 2014 were due primarily to the non-deductible \$8.75 million payment in July 2015 to the former equity holders of Neuronex. As a result of the Federal research and development tax credit not being extended during the first three quarters of 2015, the Company was not able to receive a benefit in the effective tax rate for this in 2015. The Company, however, was able to receive a benefit in the effective tax rate for 2015 for the Massachusetts state research and development tax credit in addition to the Federal orphan drug 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 and liabilities 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, 2015 and December 31, 2014 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 observable market prices. The Company's Level 3 liabilities represent acquired contingent consideration related to the acquisition of Civitas and are valued using a probability weighted discounted cash flow valuation approach. No changes in valuation techniques occurred during the three or nine-month periods ended September 30, 2015. The estimated fair values of all of our financial instruments approximate their carrying values at September 30, 2015, except for the fair value of the Company's convertible senior notes, which was approximately \$314.4 million as of September 30, 2015. The Company estimates the fair value of its notes utilizing market quotations for the debt (Level 2).

| (In thousands)                            | Level 1    | Level 2 | Level 3 |
|---|------------|---------|---------|
| <b>September 30, 2015</b>                 |            |         |         |
| <b>Assets Carried at Fair Value:</b>      |            |         |         |
| Cash equivalents                          | \$ 50,142  | \$ —    | \$ —    |
| Short-term investments                    | —          | 233,593 | —       |
| <b>Liabilities Carried at Fair Value:</b> |            |         |         |
| Acquired contingent consideration         | —          | —       | 60,000  |
| Put/call liability                        | —          | —       | —       |
| <b>December 31, 2014</b>                  |            |         |         |
| <b>Assets Carried at Fair Value:</b>      |            |         |         |
| Cash equivalents                          | \$ 149,754 | \$ —    | \$ —    |
| Short-term investments                    | —          | 125,448 | —       |
| <b>Liabilities Carried at Fair Value:</b> |            |         |         |
| Acquired contingent consideration         | —          | —       | 52,600  |
| Put/call liability                        | —          | —       | —       |

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

#### Acquired contingent consideration

| (In thousands)   | Three-month<br>period<br>ended<br>September<br>30, 2015 | Three-month<br>period<br>ended<br>September<br>30, 2014 | Nine-month<br>period<br>ended<br>September<br>30, 2015 | Nine-month<br>period<br>ended<br>September<br>30, 2014 |
|--|---|---|--|--|
| <b>Acquired contingent consideration:</b>  |   |   |  |  |
| Balance, beginning of period   | \$ 56,800   | \$ —  | \$ 52,600  | \$ —   |
| Fair value change to contingent consideration (unrealized) included in the statement of operations | 3,200   | —   | 7,400  | —  |
| Balance, end of period   | \$ 60,000   | \$ —  | \$ 60,000  | \$ —   |

The Company estimates the fair value of its acquired contingent consideration using a probability weighted discounted cash flow valuation approach based on estimated future sales expected from CVT-301, a phase 3 candidate for the treatment of OFF episodes of Parkinson's disease and CVT-427, a pre-clinical development stage product. CVT-427 is an inhaled triptan intended to provide relief from acute migraine episodes using the ARCUS delivery system. Using this approach, expected future cash flows are calculated over the expected life of the agreement, are discounted, and then exercise scenario probabilities are applied. Some of the more significant assumptions made in the valuation

include (i) the estimated CVT-301 and CVT 427 revenue forecasts, (ii) probabilities of success, and (iii) discount periods and rate. The probability of achievement of revenue milestones ranged from 28.5% to 70% with milestone payment outcomes ranging from \$0 to \$60 million in the aggregate for CVT-301 and CVT-427. The valuation is performed quarterly. Gains and losses are included in the statement of operations. For the three-month period ended September 30, 2015, changes in the fair value of the acquired contingent consideration were due to the re-calculation of cash flows for the passage of time. For the nine-month period ended September 30, 2015, changes in the fair value of the acquired contingent consideration were due to the re-calculation of cash flows for the passage of time and updates to certain other estimated assumptions.

The acquired contingent consideration is 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 probability adjusted sales estimates for CVT-301 and CVT-427 and estimated discount rates, the estimated fair value could be significantly higher or lower than the fair value we determined.

## (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 |
|---------------------------|-------------------|------------------------------|-------------------------------|----------------------------|
| <b>September 30, 2015</b> |                   |                              |                               |                            |
| US Treasury bonds         | \$ 233,539        | \$ 57                        | \$ (3 )                       | \$ 233,593                 |
| <b>December 31, 2014</b>  |                   |                              |                               |                            |
| US Treasury bonds         | 125,443           | 14                           | (9 )                          | 125,448                    |

The contractual maturities of short-term available-for-sale debt securities at September 30, 2015 and December 31, 2014 are greater than 3 months but less than 1 year. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of September 30, 2015.

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$50.1 million and \$149.8 million as of September 30, 2015 and December 31, 2014, respectively.

Unrealized holding gains and losses are reported within accumulated other comprehensive income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the unrealized holding gains on available-for-sale investments during the nine-month period ended September 30, 2015, were as follows (in thousands):

| (In thousands)  | Net Unrealized<br>Gains (Losses) on<br>Marketable<br>Securities |
|---|---|
| Balance at December 31, 2014  | \$ (74 )  |
| Other comprehensive income before reclassifications:                | 31  |
| Amounts reclassified from accumulated other<br>comprehensive income | —   |
| Net current period other comprehensive income                       | 31  |
| Balance at September 30, 2015                                       | \$ (43 )  |

## (9) Collaborations, Alliances, and Other Agreements

## Biogen

On June 30, 2009, the Company entered into an exclusive collaboration and license agreement with Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen 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 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 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 (the "Supply Agreement"), pursuant to which the Company will supply Biogen 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 will be required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. In addition, the consideration that Biogen 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 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, will participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the United States pursuant to that agreement. Acorda will continue to develop and commercialize Ampyra independently in the United States.

As of June 30, 2009, the Company recorded deferred revenue of \$110.0 million for the upfront payment from Biogen under the Collaboration Agreement. Also, as a result of such payment to Acorda, a payment of \$7.7 million was made to Alkermes and recorded as a deferred expense.

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. 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 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 know-how 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 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, and \$0.2 million and \$0.5 million 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, 2015 and 2014, respectively. 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 owes Acorda royalties based on ex-U.S. net sales, and milestones based on ex-U.S. regulatory approval and new indications. 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 has determined this milestone to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangement as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in the research and development of new products and the uncertainty involved with obtaining regulatory approval. Biogen leveraged Acorda's U.S. Ampyra study results that contributed to the regulatory approval process. Therefore, the milestone was

achieved based in part on Acorda's past performance. The milestone was also reasonable relative to all deliverable and payment terms of the collaboration arrangement. Therefore, the payment was recognized in its entirety as revenue and the cost of the milestone revenue was recognized in its entirety as an expense during the three-month period ended September 30, 2011. The Company recognized \$2.5 million in royalty revenue, respectively, for the three-month periods ended September 30, 2015 and 2014 and \$7.3 million and \$7.7 million for the nine-month periods ended September 30, 2015 and 2014, respectively, related to ex-U.S. sales of Fampyra by Biogen.

#### 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 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, 2015 and 2014, the Company recognized royalty revenue of \$2.1 million and \$2.7 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the three-month periods ended September 30, 2015 and 2014, the Company also recognized revenue and a corresponding cost of sales of \$1.0 million and \$1.3 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Actavis, which is recorded in net product revenues and cost of sales.

During the nine-month periods ended September 30, 2015 and 2014, the Company recognized royalty revenue of \$5.3 million and \$6.4 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the nine-month periods ended September 30, 2015 and 2014, the Company also recognized revenue and a corresponding cost of sales of \$2.5 million and \$3.4 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Actavis, 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) developing Plumiaz (our trade name for Diazepam Nasal Spray). Plumiaz is a proprietary nasal spray formulation of diazepam that we are developing 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 experience intermittent bouts of increased seizure activity also known as seizure clusters or acute repetitive seizures, or ARS.

The Company completed the acquisition pursuant to a merger agreement with Neuronex and Moise A. Khayrallah, acting as the Stockholders' Representative on behalf of the former Neuronex equity holders. In July 2015, the Company entered into an amendment to the merger agreement (Amendment) with Mr. Khayrallah, as Stockholders' Representative. Pursuant to the Amendment, the Stockholders' Representative, acting on behalf of the former Neuronex equity holders, agreed to certain modifications to the Company's future contingent payment obligations regarding the development and potential commercialization of Plumiaz, described below. In consideration of those modifications, pursuant to the Amendment the Company paid the former Neuronex equity holders \$8.75 million in the three-month period ended September 30, 2015.

Under the terms of the Neuronex merger 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 Plumiaz pre-NDA meeting with the FDA. In December 2012, the Company completed the acquisition by paying \$6.8 million to former Neuronex equity holders less a \$0.3 million holdback provision. After adjustment for Neuronex's working capital upon closing of the acquisition, approximately \$0.1 million of the holdback amount was remaining as of December 31, 2013. This balance was paid to the former equity holders of Neuronex pursuant to the merger agreement in February 2014.

Under the merger agreement, the former equity holders of Neuronex will be entitled to receive payments from the Company, in addition to payments the Company has already made under the merger agreement, upon the achievement of specified regulatory, manufacturing-related, and sales milestones with respect to Diazepam Nasal Spray products (Plumiaz). Pursuant to the merger agreement as amended by the Amendment, the Company is obligated to pay (i) up

to \$3 million in specified regulatory and manufacturing-related milestone payments, a reduction from up to \$18 million in such payments that were originally specified in the merger agreement, and (ii) up to \$100 million upon the achievement of specified sales milestones, a reduction from up to \$105 million in such payments that were originally specified in the merger agreement. Under the merger agreement, the former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments on worldwide net sales of Diazepam Nasal Spray products (Plumiaz), if any. The rates for these payments pursuant to the merger agreement originally ranged from the upper single digits to lower double digits, but were modified pursuant to the Amendment and now range from the mid-single digits to mid double digits. 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 Diazepam Nasal Spray products 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 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product (including a \$1 million payment that was triggered during the three-month period ending September 30, 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz and paid during the three-month period ending December 31, 2013), and up to \$3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. 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 initial acquisition transaction based upon the guidance of ASC 805, Business Combinations, and concluded that it only acquired inputs and did not acquire any processes. The Company needed 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 year ended December 31, 2014. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

In March 2015, Civitas exercised its right to extend the term of a sublease for five additional years, until December 31, 2020, and Civitas retains the right to further extend the sublease beyond that date for another five year period. The base rent is currently \$0.7 million per year. For each extension period, the economic terms of the sublease will be determined by a process set forth in the sublease, and Civitas will be required to provide a letter of credit in an amount equal to the full five-year lease obligation for each lease extension period and additional security. Alkermes leases the building pursuant to an overlease with H&N Associates, LLC, and has extension rights pursuant to the overlease that correspond to Civitas' extension rights under the sublease. Alkermes has exercised a five-year extension option under the overlease that corresponds with Civitas' exercise of its five year extension option under the sublease. Pursuant to the sublease, Civitas has agreed to comply with all of Alkermes's obligations under the overlease.

The Company is currently party to various legal proceedings which are principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability or range of losses can be reasonably estimated. As a result, the Company did not record any loss contingencies for any of these matters. While it is not possible to determine the outcome of these matters the Company believes that the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to the Company's consolidated results of operations in any one accounting period. 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 biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that restore function and improve the lives of people with neurological disorders. We market three FDA-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. We have one of the leading pipelines in the industry of novel neurological therapies. We are currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders, including post-stroke walking deficits (PSWD), Parkinson's disease, epilepsy, heart failure, MS, and spinal cord injury.

### 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 drug 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 \$117.0 million for the three-month period ended September 30, 2015 and \$96.4 million for the three-month period ended September 30, 2014.

Since the March 2010 launch of Ampyra, more than 110,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is increasingly considered by many physicians a standard of care to improve walking in people with MS. As of June 30, 2015, 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. These refill rates exclude patients who started Ampyra through our First Step trial program. Our First Step program provides eligible patients with two months of Ampyra at no cost. Year to date, on average more than 70% of new Ampyra patients currently enroll in First Step. The program is in its fourth year, and data show that First step participants have higher compliance and persistency rates over time compared to non-First Step patients. Approximately 50% of patients who initiate Ampyra therapy with the First Step free trial program convert to paid prescriptions.

Ampyra is marketed in the U.S. 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 Market Access Account Directors who provide information and assistance to payers and physicians on Ampyra; National Trade Account Managers who work with our limited network of specialty pharmacies; 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 U.S. 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 distributes

Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. All of these customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 calendar 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.



Two of the largest national health plans in the U.S. – United Healthcare and Cigna – have listed Ampyra in the lowest competitive reimbursement tier, which means that it is listed in either the lowest branded copay 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 insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by health plans.

In October 2015, we presented 5-year post-marketing safety data for dalfampridine extended release tablets in MS at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. The data presented continue to be consistent with those reported in double-blind clinical trials, with incidence of reported seizure remaining stable over time.

#### License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen anticipates making Fampyra commercially available in additional markets in 2015. Under our agreement with Biogen, we are entitled to receive double-digit tiered royalties on sales of Fampyra and we are also entitled to receive additional payments based on achievement of certain regulatory and sales milestones. We received a \$25 million milestone payment from Biogen in 2011, which was triggered by Biogen's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters.

#### Ampyra Patent Update

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

- The first is U.S. Patent No. 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 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, this 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, this patent will 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 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 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.

- The fifth is U.S. Patent No. 8,663,685 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Absent patent term adjustment, the patent is set to expire in 2025.

Ampyra also has Orphan Drug designation, which gives it marketing exclusivity in the U.S. until January 2017.

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis Laboratories FL, Inc. (“Actavis”), Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies

had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits in the U.S. District Court for the District of Delaware against all of these companies alleging multiple counts of patent infringement. These lawsuits have been consolidated into a single case. The court has scheduled a Markman hearing on March 7, 2016, and has set a five day bench trial starting on September 19, 2016. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date. On October 1, 2015, we entered into a settlement agreement with Actavis to resolve the patent litigation against them described above. The settlement with Actavis does not resolve pending patent litigation that we brought against the other ANDA filers. This litigation and the Actavis settlement are further described below in Part II, Item 1 of this report.

On May 6, 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (“Sun”) advising that they had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and they also asserted that generic versions of their products may not infringe certain claims of these patents. In response to the filing, we filed a lawsuit against Sun in the U.S. District Court for the District of Delaware alleging multiple counts of patent infringement. On October 20, 2015, we entered into a settlement agreement with Sun to resolve this patent litigation. The settlement with Sun does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report. This litigation and the settlement are further described in Part II, Item 1 of this report.

On September 11, 2015, we received a Paragraph IV Certification Notice from Par Pharmaceutical, Inc. (“Par”) advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Par has challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and they have also asserted that generic versions of its products may not infringe certain claims of these patents. In response to the filing of the ANDA, in September 2015 we filed a lawsuit against Par in the U. S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685. We filed this lawsuit within 45 days from the date of receipt of the Paragraph IV Certification Notice, which instituted the 30 month statutory stay of approval period to the Par ANDA under the Hatch-Waxman Act. Since the Par ANDA was filed after January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra, the 30 month statutory stay of approval will start from the receipt of the Paragraph IV Certification Notice. This restricts the FDA from approving the ANDA until March 2018 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date. This litigation is further described in Part II, Item 1 of this report.

In February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. In August 2015, the U.S. Patent and Trademark Office Patent Trials and Appeals Board ruled that it would not institute inter partes review of either of these patents. On September 23, 2015, however, the hedge fund filed two motions for reconsideration to the U.S. Patent and Trademark Office Patent Trials and Appeals Board, requesting that the denial to institute these two IPRs be reversed.

On September 2 and 3, 2015, the same hedge fund filed four separate IPR petitions with the U.S. Patent and Trademark Office. These new IPR petitions challenge the same two patents that were the subject of the February 2015 IPR petitions and also U.S. Patent Nos. 8,354,437 and 8,440,703. The challenged patents are four of the five Ampyra Orange-book listed patents. We will oppose the requests to institute these IPRs, and if one or more is allowed to proceed, we will oppose the full proceedings and defend our patents. The 30 month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

In 2011, the European Patent Office, or EPO, granted EP 1732548, 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 the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation

of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthron B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthron B.V., neuraxpharm Arzneimittel GmbH and Actavis Group PTC ehf filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines.

We will vigorously defend our intellectual property rights.

#### 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 disorders, including MS and spinal cord injury. 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 \$22.8 million for the three-month period ended September 30, 2015 and \$0.5 million for the three-month period ended September 30, 2014. Net revenue for the quarter ended September 30, 2015, includes the impact of a one-time increase in net revenue of \$22.2 million, representing the cumulative impact of our conversion from the sell-through to the sell-in method of revenue recognition. Under the sell-in method of revenue recognition, revenue is recognized when the product is shipped to the distributor, whereas under the sell-through method, revenue is recognized when the product is prescribed to the patient. Going forward, Zanaflex revenue will be recognized under the sell-in method of revenue recognition.

In 2012, Apotex commercially launched a generic version of tizanidine hydrochloride capsules, and we also launched our own authorized generic version, which is being marketed by Watson Pharma (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 from the sale 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 2015 and beyond.

#### Qutenza

Qutenza is a dermal patch containing 8% prescription strength capsaicin the effects of which can last up to three months and is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain. We acquired commercialization rights to Qutenza in July 2013 from NeurogesX, Inc. These rights include the U.S., Canada, Latin America and certain other territories. Qutenza was approved by the FDA in 2010 and launched in April 2010 but NeurogesX discontinued active promotion of the product in March 2012. In January 2014, we re-launched Qutenza in the U.S. using our existing commercial organization, including our specialty neurology sales force as well as our medical and safety reporting infrastructure. Net revenue for Qutenza was \$0.4 million for the three-month period ended September 30, 2015 and \$0.3 million for the three-month period ended September 30, 2014.

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.

#### Research & Development Programs

We have one of the leading pipelines in the industry of novel neurological therapies. We are currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders, including post-stroke walking deficits (PSWD), Parkinson's disease, epilepsy, heart failure, MS, and spinal cord injury. Our pipeline includes the programs described below.

#### CVT-301 and ARCUS Technology

In October 2014, we completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation. As a result of the acquisition, we acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease. Our acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas, and a subleased manufacturing facility in

Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space.

CVT-301 is an inhaled formulation of levodopa, or L-dopa, for the treatment of OFF episodes in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease is characterized by symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care for the treatment of Parkinson's disease is oral levodopa (L-dopa), but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. The re-emergence of symptoms is referred to as an OFF episode, and despite optimized regimens with current therapeutic options and strategies, OFF episodes remain one of the most challenging aspects of the disease.

CVT-301 is based on the proprietary ARCUS technology platform that we acquired with Civitas. The ARCUS technology is a dry-powder pulmonary delivery system that we believe has potential applications in multiple disease areas. This platform allows delivery of significantly larger doses of medication than are possible with conventional dry powder formulations. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents.

In December 2014, we announced that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We expect results from the efficacy trial in 2016, and pending timely recruitment for clinical trials, our goal is to file a new drug application, or NDA, in the U.S. by the end of 2016 or early 2017. We expect that the NDA will be filed under section 505(b)(2) of the Food Drug and Cosmetic Act, referencing data from the branded L-dopa product Sinemet®. Based on Civitas's interactions with the FDA, we believe a single Phase 3 efficacy study will be needed for filing an NDA. A separate long term safety study will also be required. We are projecting that, if approved, annual peak sales of CVT-301 in the U.S. alone could exceed \$500 million.

In June 2015, we presented data from a Phase 2b clinical trial of CVT-301 at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS). The data showed that patients experiencing an OFF episode, treated with CVT-301, experienced significantly greater improvements in motor function than patients treated with an inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured.

In addition to CVT-301, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS technology can provide a significant therapeutic benefit to patients. For example, we are currently developing CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes by using the ARCUS delivery system. Triptans are the class of drug most commonly prescribed to treat acute migraine. Oral triptans, which account for approximately 98% of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. CVT-427 is currently in pre-clinical development, and we have selected zolmitriptan as the active ingredient for CVT-427. We are preparing an IND for and plan to initiate the first Phase 1 clinical trial of CVT-427 by the end of 2015.

In July 2015 the Bill & Melinda Gates Foundation awarded us a \$1.4 million grant to support the development of a formulation and delivery system for a dry powder version of lung surfactant, a treatment for neonatal respiratory distress syndrome (RDS). The formulation will be based on our proprietary ARCUS technology, and will be produced in collaboration with the Massachusetts Institute of Technology (MIT). RDS is a condition affecting newborns in

which fluid collects in the lungs' air sacs; it most commonly affects infants born prematurely. It can be fatal, or lead to severe, chronic health issues caused by a lack of oxygen getting to the baby's brain and other organs. The syndrome is caused by the infants' inability to produce enough surfactant, a liquid lining the inside of the lungs. Delivering liquid surfactant to the lungs via intubation is the standard of care. This grant will support the development of a portable and easily administered inhaled form of surfactant, which may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. This program is not aimed at developing a commercial product, but our work on this program could potentially generate information that is useful for adapting the ARCUS technology to commercial pediatric uses.

#### Ampyra/Dalfampridine Development Programs

We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. In December 2014, we announced that the first patient has been enrolled in a Phase 3 clinical trial evaluating the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from post-stroke walking



deficits (PSWD) after experiencing an ischemic stroke. As part of the trial design, we are planning to conduct an interim analysis of the trial data in 2016, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study, we determined that the initial QD formulation that we had been developing with an external partner was not practical for further testing. We are working with different external partners to develop a new QD formulation that could be included in future post-stroke studies. We currently have three prototypes from three different partners based on in vitro testing, and expect to move all three into Phase 1 clinical testing before the end of 2015.

#### Plumiaz

We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy currently on stable regimens of antiepileptic drugs (AEDs) who experience bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. In May 2015, we announced that we completed discussions with the FDA, and are advancing the development of Plumiaz. Based on interactions with the FDA, we are conducting three clinical trials prior to resubmitting the NDA for Plumiaz.

- The first trial is a long-term open-label study assessing safety and tolerability of Plumiaz over 52 weeks. This trial will enroll approximately 100 participants ages 12-65. We have initiated this trial and expect it will be completed in the second half of 2016.
- The second trial is assessing the bioavailability, safety and tolerability of Plumiaz compared to diazepam rectal gel (Diastat®). This open-label, randomized, crossover trial will enroll approximately 120 people with refractory epilepsy ages 12-65 who experience seizure clusters. We have initiated this trial and we expect that it will be completed in the fourth quarter of 2016.
- The third trial is a pharmacokinetic dose proportionality study in healthy adults; we expect this trial will be initiated in the first quarter of 2016 and will be completed in second half of 2016.

Pending the successful completion of these studies, we are planning to resubmit the NDA for Plumiaz in the first quarter of 2017. Based on FDA guidelines, the expected review period of the resubmitted NDA would be six months.

We have obtained orphan drug designation, which would confer seven years of market exclusivity from the date of approval for diazepam containing drug products for the same indication. We licensed two patent families relating to the clinical formulation for Diazepam Nasal Spray, including a granted U.S. patent that is set to expire in 2029. We anticipate that our current infrastructure can support sales and marketing of this product if it receives FDA approval. If approved, we project peak U.S. net sales revenue of more than \$200 million.

We acquired the Plumiaz program in December 2012 in connection with our acquisition of Neuronex, Inc., a privately-held development stage pharmaceutical company. We completed the acquisition pursuant to a merger agreement with Neuronex and Moise A. Khayrallah, acting as the Stockholders' Representative on behalf of the former Neuronex equity holders. In July 2015, we entered into an amendment to the merger agreement with Mr. Khayrallah, as Stockholders' Representative. Pursuant to the amendment, the Stockholders' Representative, acting on behalf of the former Neuronex equity holders, agreed to certain modifications to our future contingent payment obligations regarding the development and potential commercialization of Plumiaz, described below. In consideration of those

modifications, pursuant to the amendment we paid the former Neuronex equity holders \$8.75 million in the three-month period ended September 30, 2015.

Under the Merger Agreement, the former equity holders of Neuronex will be entitled to receive payments from us, in addition to payments we have already made under the merger agreement, upon the achievement of specified regulatory, manufacturing-related, and sales milestones with respect to Plumiaz. Pursuant to the merger agreement as amended by the amendment, we are obligated to pay (i) up to \$3 million in specified regulatory and manufacturing-related milestone payments, a reduction from up to \$18 million in such payments that were originally specified in the merger agreement, and (ii) up to \$100 million upon the achievement of specified sales milestones, a reduction from up to \$105 million in such payments that were originally specified in the merger agreement. Under the merger agreement, the former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments on worldwide net sales of Plumiaz, if any. The

rates for these payments pursuant to the merger agreement originally ranged from the upper single digits to lower double digits, but were modified pursuant to the amendment and now range from the mid-single digits to mid double digits. 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 Plumiaz 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 million upon the achievement of specified development milestones with respect to Plumiaz (including a \$1 million payment that was triggered in 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz), and up to \$3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Plumiaz.

#### Cimaglermin alfa/Neuregulins

Cimaglermin alfa is our lead product candidate for our neuregulin program. We have completed a cimaglermin 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. Data from this trial showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting toxicity was also identified in the highest planned dose cohort, specifically acute liver injury meeting Hy's Law for drug induced hepatotoxicity, which resolved within several days. In March 2015, we presented new analyses of data from this trial at the American College of Cardiology (ACC) 64th Annual Scientific Session and Expo. These analyses found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. In June 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to this clinical hold. The abnormal blood tests resolved within several days, as was the case with the one Hy's Law case reported in the previous Phase 1 study noted above. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up, including six minute walk and cardiac ejection fraction data. We expect to complete an analysis of data from the three-month follow up by the end of 2015. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we plan to review these and other data from the cimaglermin studies with the FDA.

#### Remyelinating Antibodies

rHIgM22 is the lead antibody in our remyelinating antibody program, and we are developing it as a potential therapeutic for MS. We believe a therapy that could repair myelin sheaths has the potential to restore neurological function to those affected by demyelinating conditions. In April 2013, we initiated a Phase 1 clinical trial of rHIgM22 to assess the safety and tolerability of rHIgM22 in patients with MS. The study also included several exploratory clinical, imaging and biomarker measures. We announced top-line safety and tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. In April 2015, we presented additional safety data from this trial at the 67th American Academy of Neurology Annual Meeting. The additional data showed that rHIgM22 was well-tolerated in each of the five doses, supporting additional clinical development. In October 2015, we

presented pharmacokinetics from the trial in patients with stable MS, confirming that rHIgM22 penetrates the central nervous system. This data was presented at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. Based on these data, we intend to advance clinical development of rHIgM22 for MS. We are currently enrolling a Phase 1, single ascending dose trial in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in late 2016 or early 2017.

## 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.

## NP-1998

NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we have been assessing for the treatment of neuropathic pain. We acquired rights to NP-1998 from NeurogesX, Inc. in 2013 in connection with our purchase of Qutenza, an FDA-approved dermal patch containing 8% prescription strength capsaicin. We acquired development and commercialization rights in the U.S., Canada, Latin America and certain other territories. Astellas Pharma Europe Ltd. has an option to develop NP-1998 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. We believe this liquid formulation of the capsaicin-based therapy has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, we have evaluated and reprioritized our research and development pipeline based on our 2014 acquisition of Civitas, and as a result we have no current plans to invest in further development of NP-1998 for neuropathic pain.

## Outlook for 2015

### Financial Guidance for 2015

We are providing the following guidance with respect to our 2015 financial performance:

- We expect 2015 net revenue from the sale of Ampyra to range from \$420 million to \$430 million. This guidance is raised from our prior guidance of \$410 million to \$420 million.
- We expect Zanaflex (tizanidine hydrochloride) and ex-U.S. Fampyra (prolonged-release fampridine tablets) 2015 revenue to be approximately \$25 million, which includes net sales of branded Zanaflex products and royalties from ex-U.S. Fampyra and authorized generic tizanidine hydrochloride capsule sales and excludes the one-time increase in net revenue of \$22.2 million associated with the change in revenue recognition policy from the sell-through to the sell-in method of revenue recognition for branded Zanaflex products.
- Research and development (R&D) expenses in 2015 are expected to range from \$140 million to \$150 million, excluding share-based compensation charges and expenditures related to the potential acquisition of new products or other business development activities. The increase in research and development expenses in 2015 compared to 2014 is primarily related to Phase 3 studies of dalfampridine and CVT-301. Additional expenses include continued development of Plumiaz, clinical trials for cimaglermin alfa, rHlgM22 and CVT-427, as well ongoing preclinical studies.
- Selling, general and administrative expenses (SG&A) in 2015 are expected to range from \$180 million to \$190 million, excluding share-based compensation charges. We have set a high priority on managing selling, general and administrative expenses in 2015.

The range of SG&A and R&D expenditures for 2015 are non-GAAP financial measures because they exclude share-based compensation charges and certain non-cash expenses related to the Civitas acquisition. The guidance for Zanaflex and ex-U.S. Fampyra 2015 revenue is a non-GAAP financial measure because it excludes the one-time,

non-recurring increase in net revenue associated with the change in revenue recognition policy for branded Zanaflex products. 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. We believe that non-GAAP financial measures that exclude share-based compensation charges, which are substantially dependent on changes in the market price of our common stock, certain non-cash expenses related to the Civitas acquisition, and the increase in net revenue related to the change in revenue recognition policy for Zanaflex which is a one-time, non-recurring event 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 pipeline during 2015 and beyond are as follows:

- Continue progressing our Phase 3 efficacy and safety studies of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We expect results from the efficacy trial in 2016, and pending timely recruitment for clinical trials, our goal is to file a new drug application, or NDA, in the U.S. by the end of 2016 or early 2017.
- Continue progressing our Phase 3 clinical trial assessing the use of a once-daily (BID) formulation of dalfampridine as a treatment for post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. As part of the trial design, we are planning to conduct an interim analysis of the trial data in 2016, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We are working with different external partners to develop a once-daily (QD) formulation that could be included in future post-stroke studies. We currently have three prototypes from three partners based on in vitro testing, and expect to move all three into Phase 1 clinical testing before the end of 2015.
- We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. In May 2015, we announced that we completed discussions with the FDA, and are advancing the development of Plumiaz. Based on interactions with the FDA, we are conducting three clinical trials prior to resubmitting the NDA for Plumiaz, described above in this report. Pending the successful completion of these studies, we are planning to resubmit the NDA for Plumiaz in the first quarter of 2017. Based on FDA guidelines, the expected review period of the resubmitted NDA would be six months.
- In June 2015 we announced that we had stopped enrollment in our second clinical trial of cimaglermin based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria (elevated ALT, AST and bilirubin), based on blood test results. We also received a notification of clinical hold from the FDA following submission of this information, and the trial remains subject to the clinical hold. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up, including six minute walk and cardiac ejection fraction data. We expect to complete an analysis of data from the three-month follow up by the end of 2015. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we plan to review these and other data from the cimaglermin studies with the FDA.
- Our Phase 1 clinical trial of rHIgM22 found no dose-limiting toxicities at any of, and was well tolerated in each of, the five dose levels studied. In October 2015, we presented pharmacokinetics from the trial in patients with stable MS, confirming that rHIgM22 penetrates the central nervous system. Based on these data, we intend to advance clinical development of rHIgM22 for MS. We are currently enrolling a Phase 1, single ascending dose trial in people with MS who are experiencing an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study includes exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. We expect to complete the trial in late 2016 or early 2017.
- We are preparing an IND for and plan to initiate the first Phase 1 clinical trial of CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes, by the end of 2015. We have selected zolmitriptan as the active ingredient for CVT-427.





## Results of Operations

Three-Month Period Ended September 30, 2015 Compared to September 30, 2014

### Net Product Revenues

#### Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of \$117.0 million as compared to \$96.4 million for the three-month periods ended September 30, 2015 and 2014, respectively, an increase of \$20.6 million, or 21%. The net revenue increase was comprised of net volume increases of \$9.9 million due to greater demand, due in part to the success of certain marketing programs such as our First Step and Step Together programs and price increases net of discount and allowance adjustments of \$10.8 million. Effective January 1, 2015, we increased our sale price to our customers by 10.95%.

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

#### Zanaflex

Prior to the three-month period ended September 30, 2015, the Company accounted for Zanaflex product shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company’s revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company’s sales and revenue recognition reflected the Company’s estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company is recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules. We recognized net revenue from the sale of Zanaflex products of \$22.8 million for the three-month period ended September 30, 2015, as compared to \$0.5 million for the three-month period ended September 30, 2014. For the three-month period ended September 30, 2015, the Company recognized a one-time increase in net revenue of \$22.2 million, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns. Net product revenues also include \$1.0 million which represents the sale of our Zanaflex Capsules authorized generic product to Actavis for the three-month period ended September 30, 2015 as compared to \$1.3 million for the three-month period ended September 30, 2014.

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

Qutenza

We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of \$0.4 million and \$0.3 million for the three-month periods ended September 30, 2015 and 2014, respectively. For the foreseeable future we do not expect that sales of this product will materially contribute to our revenues.

#### License Revenue

We recognized \$2.3 million in license revenue for the three-month periods ended September 30, 2015 and 2014, related to the \$110.0 million received from Biogen in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

#### Royalty Revenue

We recognized \$2.5 million in royalty revenue for the three-month periods ended September 30, 2015 and 2014, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$2.1 million and \$2.7 million in royalty revenue for the three-month periods ended September 30, 2015 and 2014, respectively, related to the authorized generic sale of Zanaflex Capsules.

#### Cost of Sales

We recorded cost of sales of \$24.7 million for the three-month period ended September 30, 2015 as compared to \$20.6 million for the three-month period ended September 30, 2014. Cost of sales for the three-month period ended September 30, 2015 consisted primarily of \$20.8 million in inventory costs related to recognized revenues. Cost of sales for the three-month period ended September 30, 2015 also consisted of \$2.6 million in royalty fees based on net product shipments, \$0.1 million in amortization of intangible assets, and \$0.1 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$1.0 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the three-month period ended September 30, 2015.

Cost of sales for the three-month period ended September 30, 2014 consisted primarily of \$16.8 million in inventory costs related to recognized revenues. Cost of sales for the three-month period ended September 30, 2014 also consisted of \$2.2 million in royalty fees based on net product shipments, \$0.2 million in amortization of intangible assets, and \$0.1 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$1.3 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the three-month period ended September 30, 2014.

#### Cost of License Revenue

We recorded cost of license revenue of \$0.2 million for the three-month periods ended September 30, 2015 and 2014, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen as a result of our collaboration agreement.

#### Research and Development

Research and development expenses for the three-month period ended September 30, 2015 were \$43.3 million as compared to \$16.6 million for the three-month period ended September 30, 2014, an increase of approximately \$26.7 million, or 162%. The increase was primarily due to \$15.1 million in CVT-301 and CVT-427 expenses incurred in 2015 after the acquisition of Civitas in October 2014. The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$1.7 million to support the research and development initiatives related to our product pipeline, as well as increases in expenses for certain research and development programs, including \$8.1 million related to our Plumiaz program which consists of the \$8.8 million payment to the former Neuronex equity holders, offset by a reduction in other research and development costs of \$0.6 million, \$2.5

million related to our life cycle management program for Ampyra and \$0.4 million related to our cimaglermin program. The increases in research and development expenses for the three-month period ended September 30, 2015 were partially offset by decreases in expenses in certain other research and development programs, including \$0.5 million related to the NP-1998 program and \$0.4 million related to the AC 105 program.

#### Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2015 were \$25.1 million compared to \$26.2 million for the three-month period ended September 30, 2014, a decrease of approximately \$1.1 million, or 4%. The decrease was primarily attributable to a decrease in overall marketing, selling, distribution, and market research expenses for Ampyra of \$1.2 million, a decrease in compensation expenses of \$0.2 million and a decrease of \$0.2 million for pre-launch

activities associated with the possible commercialization of Plumiaz, partially offset by expenses relating to the acquisition of Civitas in October 2014 of \$0.5 million.

General and administrative expenses for the three-month period ended September 30, 2015 were \$26.0 million compared to \$21.6 million for the three-month period ended September 30, 2014, an increase of approximately \$4.4 million, or 20%. This increase was primarily 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, including the acquisition of Civitas in October 2014, and an increase of \$1.5 million in legal fees, partially offset by a reduction in business development expenses of \$1.4 million.

#### Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Civitas products. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded a \$3.2 million expense pertaining to changes in the fair-value of our acquired contingent consideration for the three-month period ended September 30, 2015. The changes in the fair-value of the acquired contingent consideration were due to the re-calculation of discounted cash flows for the passage of time. There were no changes to the valuation techniques.

#### Other Income / Expense

Other expense was \$4.0 million for the three-month period ended September 30, 2015 compared to other expense of \$4.3 million for the three-month period ended September 30, 2014, a decrease of \$0.3 million. The decrease was due primarily to a decrease in interest expense of \$0.6 million, related to the Paul Royalty Fund, offset by an increase of \$0.1 million for the cash and non-cash portions of interest expense on the convertible senior notes issued in June 2014 (the Notes) and a decrease of \$0.1 million in interest income. Interest expense related to the Notes was \$3.7 million for the three-month period ended September 30, 2015, of which the non-cash portion was \$2.2 million.

#### Provision for Income Taxes

For the three-month periods ended September 30, 2015 and 2014, the Company recorded a \$17.8 million and \$4.5 million provision for income taxes 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, 2015 and 2014 were 82% and 28%, respectively. The variance in the effective tax rates for the three-month periods ended September 30, 2015 and 2014 is due primarily to the non-deductible \$8.8 million payment in July 2015 to the former equity holders of Neuronex. As a result of the Federal research and development tax credit not being extended during the third quarter of 2015, the Company was not able to receive a benefit in the effective tax rate for this in 2015. The Company, however, was able to receive a benefit in the effective tax rate for 2015 for the Massachusetts state research and development tax credit in addition to the Federal orphan drug credit.

We continue to evaluate the realizability of the Company's deferred tax assets and consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance will be required to reduce the deferred tax assets to the amount that is more likely than not to be realized in future periods. The Company maintains a valuation allowance on acquired state tax attributes expected to expire prior to their utilization.

#### Nine-Month Period Ended September 30, 2015 Compared to September 30, 2014

Net Product Revenues

Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of \$315.0 million as compared to \$256.3 million for the nine-month periods ended September 30, 2015 and 2014, respectively, an increase of \$58.7 million, or 23%. The net revenue increase was comprised of net volume increases of \$30.0 million, due in part to the success of certain marketing programs such as our First Step and Step Together programs and price increases net of discount and allowance adjustments of \$28.7 million. Effective January 1, 2015, we increased our sale price to our customers by 10.95%.

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

#### Zanaflex

Prior to the three-month period ended September 30, 2015, the Company accounted for Zanaflex product shipments using a deferred revenue recognition model (sell-through). Under the deferred revenue recognition model, the Company did not recognize revenue upon product shipment. For product shipments, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognized revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company’s revenue to be recognized was based on the estimated prescription demand, based on pharmacy sales for its products using third-party information, including third-party market research data. The Company’s sales and revenue recognition reflected the Company’s estimate of actual product prescribed to the end-user. Beginning in the third quarter of 2015, the Company is recognizing sales for Zanaflex products when the product is shipped to its wholesale distributors (sell-in), as the Company believes there is now sufficient history to reasonably estimate expected returns. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules. We recognized net revenue from the sale of Zanaflex products of \$24.0 million for the nine-month period ended September 30, 2015, as compared to \$2.2 million for the nine-month period ended September 30, 2014. For the nine-month period ended September 30, 2015, the Company recognized a one-time increase in net revenue of \$22.2 million, representing previously deferred product sales as of June 30, 2015, net of an allowance for estimated returns. Net product revenues also include \$2.5 million which represents the sale of our Zanaflex Capsules authorized generic product to Actavis for the nine-month period ended September 30, 2015, as compared to \$3.4 million for the nine-month period ended September 30, 2014.

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

#### Qutenza

We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of approximately \$0.9 million and \$0.8 million for the nine-month periods ended September 30, 2015 and 2014, respectively. For the foreseeable future we do not expect that sales of this product will materially contribute to our revenues.

#### License Revenue

We recognized \$6.8 million in license revenue for the nine-month periods ended September 30, 2015 and 2014, related to the \$110.0 million received from Biogen 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 \$7.3 million and \$7.7 million in royalty revenue for the nine-month periods ended September 30, 2015 and 2014, respectively related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$5.3 million and \$6.4 million in royalty revenue for the nine-month periods ended September 30, 2015 and 2014, respectively, related to the authorized generic sale of Zanaflex Capsules.

#### Cost of Sales

We recorded cost of sales of \$65.9 million for the nine-month period ended September 30, 2015 as compared to \$55.0 million for the nine-month period ended September 30, 2014. Cost of sales for the nine-month period ended September 30, 2015 consisted primarily of \$55.6 million in inventory costs related to recognized revenues. Cost of sales for the nine-month period ended September 30, 2015 also consisted of \$7.2 million in royalty fees based on net product shipments, \$0.4



million in amortization of intangible assets, and \$0.3 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$2.5 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the nine-month period ended September 30, 2015.

Cost of sales for the nine-month period ended September 30, 2014 consisted primarily of \$44.6 million in inventory costs related to recognized revenues. Cost of sales for the nine-month period ended September 30, 2014 also consisted of \$6.1 million in royalty fees based on net product shipments, \$0.5 million in amortization of intangible assets, and \$0.3 million in period costs related to freight, stability testing, and packaging. Cost of sales also included \$3.4 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the nine-month period ended September 30, 2014.

#### Cost of License Revenue

We recorded cost of license revenue of \$0.5 million for the nine-month periods ended September 30, 2015 and 2014, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen as a result of our collaboration agreement.

#### Research and Development

Research and development expenses for the nine-month period ended September 30, 2015 were \$105.2 million as compared to \$47.5 million for the nine-month period ended September 30, 2014, an increase of approximately \$57.7 million, or 121%. The increase was primarily due to \$39.2 million in CVT-301 and CVT-427 expenses incurred in 2015 after the acquisition of Civitas in October 2014 and an increase in overall research and development staff, compensation and related expenses of \$6.6 million to support the research and development initiatives related to our product pipeline. The increase was also due to increases in expenses for various other research and development programs, including \$8.4 million related to our Plumiaz program, \$3.9 million related to our life cycle management program for Ampyra, and \$1.1 million relating to our cimaglermin program. The increases in research and development expenses for the nine-month period ended September 30, 2015 were partially offset by a decrease of \$0.5 million related to our AC 105 program and \$0.3 million related to our rHlgM22 program.

#### Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2015 were \$76.2 million compared to \$81.8 million for the nine-month period ended September 30, 2014, a decrease of approximately \$5.6 million, or 7%. The decrease was primarily attributable to a decrease of \$4.0 million for pre-launch activities associated with the possible commercialization of Plumiaz, and a decrease in overall marketing, selling, distribution, and market research expenses for Ampyra of \$3.2 million. The decrease in sales and marketing expenses was partially offset by an increase in overall compensation, benefits, and other selling expenses of \$1.0 million, including sales force incentive compensation.

General and administrative expenses for the nine-month period ended September 30, 2015 were \$76.4 million compared to \$63.5 million for the nine-month period ended September 30, 2014, an increase of approximately \$12.9 million, or 20%. This increase was primarily the result of an increase of \$9.1 million for staff and compensation expenses and other expenses related to supporting the growth of the organization, including the acquisition of Civitas in October 2014, and an increase of \$5.1 million in legal fees. The increases in general and administrative expenses for the nine-month period ended September 30, 2015 were partially offset by a decrease of \$1.6 million for work on FDA post-approval requirements for the Zanaflex franchise.

Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Civitas products. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded a \$7.4 million expense pertaining to changes in the fair-value of our acquired contingent consideration for the nine-month period ended September 30, 2015. The changes in the fair-value of the acquired contingent consideration were due to the re-calculation of discounted cash flows for the passage of time and updates to certain other estimated assumptions. There were no changes to the valuation techniques.

#### Other Income / Expense

Other expense was \$11.4 million for the nine-month period ended September 30, 2015 compared to \$4.5 million for the nine-month period ended September 30, 2014, an increase of approximately \$6.9 million. The increase was due to an increase in interest expense of \$7.0 million, principally related to the cash and non-cash portions of interest expense for the convertible senior notes issued in June 2014 (the Notes). Interest expense related to the Notes was \$10.9 million for the nine-month period ended September 30, 2015, of which the non-cash portion was \$6.4 million.

#### Provision for Income Taxes

For the nine-month periods ended September 30, 2015 and 2014, the Company recorded a \$16.9 million and \$13.4 million provision for income taxes 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 nine-month periods ended September 30, 2015 and 2014 were 90% and 44%, respectively. The variances in the effective tax rates for the nine-month periods ended September 30, 2015 and 2014 were due primarily to the non-deductible \$8.8 million payment in July 2015 to the former equity holders of Neuronex. As a result of the Federal research and development tax credit not being extended during the first three quarters of 2015, the Company was not able to receive a benefit in the effective tax rate for this in 2015. The Company, however, was able to receive a benefit in the effective tax rate for 2015 for the Massachusetts state research and development tax credit in addition to the Federal orphan drug credit.

We continue to evaluate the realizability of the Company's deferred tax assets and consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance will be required to reduce the deferred tax assets to the amount that is more likely than not to be realized in future periods. The Company maintains a valuation allowance on acquired state tax attributes expected to expire prior to their utilization.

#### 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, a convertible debt offering, payments received under our collaboration and licensing agreements, sales of Ampyra, Zanaflex Tablets and Capsules and Qutenza, and, to a lesser extent, from loans, government and non-government grants and our financing arrangement with Paul Royalty Fund (PRF) (see below).

We were cash flow positive in 2014 and, at September 30, 2015, we had \$323.4 million of cash, cash equivalents and short-term investments, compared to \$307.6 million at December 31, 2014. We expect to remain cash flow positive in 2015. We believe that we have sufficient cash, cash equivalents and short-term investments on hand, in addition to cash expected to be generated from operations, to fund our operations, including our currently anticipated development pipeline activities as currently planned.

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 capital required or used for future acquisitions or to 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

### Saints Capital Notes

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, 2015, \$2.2 million of these promissory notes was outstanding, which amount includes accrued interest. The fifth of seven annual payments on this note was due and paid on the five year anniversary of Ampyra approval on January 22, 2015 and will continue to be paid annually until paid in full.

### Zanaflex Revenue Interests Assignment

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006. 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. In November 2014, PRF sold its Zanaflex revenue interest to Valeant Pharmaceuticals International, Inc.

Under the revenue interest assignment agreement and the amendment, PRF was entitled to, and now as PRF's successor, Valeant 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 and Valeant, as PRF's successor, have received and retained payments under the agreement that are at least 2.1 times the aggregate amount PRF paid us under the agreement, Valeant will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we recorded a liability as of September 30, 2015, referred to as the revenue interest liability, of approximately \$0.6 million. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 5.8%. Payments made to Valeant 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, Valeant 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 Valeant. Except in the case of certain bankruptcy events, if Valeant exercises its right, which we refer to as Valeant's put option, to cause us to repurchase the rights we assigned to it, Valeant 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 under the revenue interests assignment agreement 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/Valeant to us as of such date, less all

payments received by PRF/Valeant from us as of such date, and (ii) an amount that would generate an internal rate of return to PRF/Valeant of 25% on all payments made by PRF/Valeant to us as of such date, taking into account the amount and timing of all payments received by PRF/Valeant from us as of such date. We have determined that Valeant'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, 2015, we have no liability recorded related to the put/call option to reflect its current estimated fair value. This liability is revalued on an as needed basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings.

#### Convertible Senior Notes

In June 2014, the Company entered into an underwriting agreement (the Underwriting Agreement) with J.P. Morgan Securities LLC (the Underwriter) relating to the issuance by the Company of \$345 million aggregate principal amount of

1.75% Convertible Senior Notes due 2021 (the Notes) in an underwritten public offering pursuant to the Company's Registration Statement on Form S-3 (the Registration Statement) and a related preliminary and final prospectus supplement, filed with the Securities and Exchange Commission (the Offering). The principal amount of Notes included \$45 million aggregate principal amount of Notes that was purchased by the Underwriter pursuant to an option granted to the Underwriter in the Underwriting Agreement, which option was exercised in full. The net proceeds from the offering, after deducting the Underwriter's discount and the offering expenses paid by the Company, were approximately \$337.5 million.

The Notes are governed by the terms of an indenture, dated as of June 23, 2014 (the Base Indenture) and the first supplemental indenture, dated as of June 23, 2014 (the Supplemental Indenture, and together with the Base Indenture, the Indenture), each between the Company and Wilmington Trust, National Association, as trustee (the Trustee). The Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per \$1,000 principal amount of Notes (which represents an initial conversion price of approximately \$42.56 per share), only in the following circumstances and to the following extent: (1) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per \$1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (2) during any calendar quarter commencing after the calendar quarter ending on September 30, 2014 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (3) if the Company calls any or all of the Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; (4) upon the occurrence of specified events described in the Indenture; and (5) at any time on or after December 15, 2020 through the second scheduled trading day immediately preceding the maturity date.

The Company may not redeem the Notes prior to June 20, 2017. The Company may redeem for cash all or part of the Notes, at the Company's option, on or after June 20, 2017 if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending within five trading days prior to the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The Company will pay 1.75% interest per annum on the principal amount of the Notes, payable semiannually in arrears in cash on June 15 and December 15 of each year. The Company paid \$3.0 million on June 15, 2015 for interest due on the Notes. The Notes will mature on June 15, 2021.

If the Company undergoes a "fundamental change" (as defined in the Indenture), subject to certain conditions, holders may require the Company to repurchase for cash all or part of their Notes in principal amounts of \$1,000 or an integral multiple thereof. The fundamental change repurchase price will be equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. If a make-whole fundamental change, as described in the Indenture, occurs and a holder elects to convert its Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by

notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes by notice to the Company and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 270 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the Notes.

The Notes will be senior unsecured obligations and will rank equally with all of the Company's existing and future senior debt and senior to any of the Company's subordinated debt. The Notes will be structurally subordinated to all existing or future indebtedness and other liabilities (including trade payables) of the Company's subsidiaries and will be effectively



subordinated to the Company's existing or future secured indebtedness to the extent of the value of the collateral. The Indenture does not limit the amount of debt that the Company or its subsidiaries may incur.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the seven-year term of the Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

Our outstanding note balances as of September 30, 2015 consisted of the following:

| (In thousands)              | September<br>30, 2015 |
|-----------------------------|-----------------------|
| <b>Liability component:</b> |                       |
| Principal                   | \$ 345,000            |
| Less: debt discount, net    | (51,508)              |
| Net carrying amount         | \$ 293,492            |
| Equity component            | \$ 61,195             |

### Investment Activities

At September 30, 2015, cash, cash equivalents and short-term investments were approximately \$323.4 million, as compared to \$307.6 million at December 31, 2014. 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, 2015, our cash and cash equivalents were \$89.8 million, as compared to \$182.2 million as of December 31, 2014. 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 \$233.6 million as of September 30, 2015, as compared to \$125.4 million as of December 31, 2014.

### Net Cash Provided by Operations

Net cash provided by operations was \$16.2 million for the nine-month period ending September 30, 2015 while \$61.4 million was provided by operations for the nine-month period ended September 30, 2014. Cash provided by operations for the nine-month period ended September 30, 2015 was primarily due to non-cash share based compensation expense of \$24.7 million, a deferred tax provision of \$16.9 million, depreciation and amortization of \$11.2 million, changes in acquired contingent consideration of \$7.4 million, and debt discount and debt issuance costs of \$6.4 million, partially offset by the recognition of deferred product revenue of \$22.2 million associated with the change in revenue recognition policy for Zanaflex, increased inventory held by the Company of \$20.6 million, and a decrease in the non-current portion of deferred license revenue of \$6.8 million.

Cash provided by operations for the nine-month period ended September 30, 2014 was primarily due to non-cash share-based compensation expense of \$20.6 million, net income of \$17.3 million principally resulting from an increase net product revenues, a deferred tax provision of \$13.4 million, depreciation and amortization of \$5.4 million,

and amortization of net premiums and discounts on investments, debt discount and debt issuance costs of \$5.3 million. Cash provided by operations was partially offset by a decrease of \$6.8 million in the non-current portion of deferred license revenue.

#### Net Cash Used in Investing

Net cash used in investing activities for the nine-month period ended September 30, 2015 was \$116.3 million, which was due to purchases of investments of \$360.0 million, purchases of property and equipment of \$5.0 million, and purchases of intangible assets of \$0.8 million, partially offset by \$249.5 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, 2015 was \$7.8 million, which was due to \$8.0 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by \$0.2 million 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, 2014. 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, 2015, commitments related to the purchase of inventory decreased as compared to December 31, 2014. As of September 30, 2015, we have inventory-related purchase commitments totaling approximately \$40.6 million.

Under certain 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 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, 2015, we have committed to make potential future milestone payments to third parties of up to approximately \$149 million as part of our various collaborations, including licensing and development programs. This represents a decrease of approximately \$55 million as compared to December 31, 2014, due to the termination and/or modification of certain license agreements. 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, 2015, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

Our 2014 acquisition of Civitas included a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas subleases the Chelsea, Massachusetts facility from Alkermes, Inc. The sublease is an operating lease that was scheduled to expire on December 31, 2015. In March 2015, Civitas exercised its right to extend the term of the sublease for five additional years, until December 31, 2020, and Civitas retains the right to further extend the sublease beyond that date for another five year period. The base rent is currently \$0.7 million per year. For each extension period, the economic terms of the sublease will be determined by a process set forth in the sublease, and Civitas will be required to provide a letter of credit in an amount equal to the full five-year lease obligation for each lease extension period and additional security. Alkermes leases the building pursuant to an overlease with H&N Associates, LLC, and has extension rights pursuant to the overlease that correspond to Civitas' extension rights under the sublease. Alkermes has exercised a five-year extension option under the overlease that corresponds with Civitas' exercise of its five year extension option under the sublease. Pursuant to the sublease, Civitas has agreed to comply with all of Alkermes's obligations under the overlease.



### 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, 2014. As of September 30, 2015, we changed our revenue recognition policy with respect to Zanaflex products from a deferred revenue recognition model (sell-through) where revenue is recognized based upon prescriptions to end-users to a traditional revenue recognition model (sell-in) where revenue is recognized based upon shipments to the wholesale distributors. As a result of this policy change, we also established a reserve for estimated future product returns. With the exception of this change, our critical accounting policies have not changed materially from December 31, 2014.

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

Our financial instruments consist of cash equivalents, short-term investments, grants receivable, convertible senior notes, convertible notes payable and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying values at September 30, 2015, except for the fair value of the Company's convertible senior notes.

We have cash equivalents and short-term investments at September 30, 2015, 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 investments approximate their fair value at September 30, 2015. At September 30, 2015, we held \$323.4 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 0.1%.

We maintain an investment portfolio in accordance with our investment policy. The primary objective of our investment policy is 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, interest rate risk is mitigated due to the conservative nature and relatively short duration of our investments. 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 2015, 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, 2015, 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, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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

#### Apotex

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. In October 2014, the Court granted our motion for summary judgment against Apotex's remaining claim. Apotex has appealed both the motion to dismiss and summary judgment decisions to the Second Circuit Court of Appeals. The Company will defend itself vigorously throughout the appeal process.

#### Ampyra ANDA Litigation

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis Laboratories FL, Inc. ("Actavis"), Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to the filing of these ANDAs, in July 2014, we filed lawsuits against these generic pharmaceutical manufacturing companies in the U.S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 5,540,938, 8,007,826, 8,354,437, 8,440,703, and 8,663,685. Requested judicial remedies include recovery of litigation costs and injunctive relief, including a request that the effective date of any FDA approval for these generic companies to make, use, offer for sale, sell, market, distribute, or import the proposed generic products be no earlier than the dates on which the Ampyra Orange-book listed patents expire, or any later expiration of exclusivity to which we are or become entitled. These lawsuits with the eight ANDA filers have been consolidated into a single case. The U.S. District Court for the District of Delaware has scheduled a Markman hearing on March 7, 2016, and has set a five day bench trial starting on September 19, 2016. The Markman hearing will be conducted to determine the scope and limitations of certain patent claims that are asserted in the litigation. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for



Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

On October 1, 2015, we entered into a settlement agreement with Actavis to resolve the patent litigation that we brought against Actavis in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Actavis will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The parties have requested that the Court enter orders dismissing without prejudice our litigation against Actavis. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Actavis does not resolve pending patent litigation that we brought against the other ANDA filers, as described in this report.

In August 2014, Mylan Pharmaceuticals, Inc. and its parent, Mylan, Inc. (collectively, “Mylan”), filed a motion challenging the jurisdiction of the U.S. District Court for the District of Delaware. On January 14, 2015, the Court denied Mylan’s motion to dismiss with respect to the ANDA filer, Mylan Pharmaceuticals, Inc. On January 30, 2015, the Court granted Mylan’s request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit Court of Appeals. The Company will defend itself vigorously throughout the appeal process. Due to Mylan’s motion to dismiss, we also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. Patents and requesting the same judicial relief as in the Delaware action. On December 17, 2014, we filed a motion in the Northern District of West Virginia to stay that action in deference to the Delaware proceeding and until the issue of jurisdiction has been decided. On February 11, 2014, the District Court for the Northern District of West Virginia granted our motion to stay the proceeding in that district until the Federal Circuit Court of Appeals decides Mylan’s appeal of Delaware’s jurisdictional decision. The patent infringement case against Mylan, however, is still proceeding in Delaware along with the cases against the other eight ANDA filers (see below) at the present time.

On May 6, 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (“Sun”) advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun Pharmaceuticals challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and also asserted that generic versions of their products may not infringe certain claims of these patents. In response to the filing of the ANDA, in May 2015 we filed a lawsuit against Sun Pharmaceuticals in the U. S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685, which was within the 45 days from the date of receipt of Sun’s Paragraph IV Certification Notice which instituted the 30 month statutory stay of approval period to the Sun Pharmaceuticals ANDA under the Hatch-Waxman Act. On October 20, 2015, we entered into a settlement agreement with Sun to resolve this patent litigation. As a result of the settlement agreement, Sun will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The parties have requested that the Court enter a Consent Order, in which it will dismiss our litigation against Sun. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Sun does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

On September 11, 2015, we received a Paragraph IV Certification Notice from Par Pharmaceutical, Inc. (“Par”) advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Par has challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and they have also asserted that generic versions of its products may not infringe certain claims of these patents. In response to the filing of the ANDA, in September 2015 we filed a lawsuit against Par in the U. S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685. Requested judicial remedies include recovery of litigation costs and injunctive relief, including a request that the effective date of any FDA approval for Par to make, use, offer for sale, sell, market, distribute, or import the proposed generic product be no earlier than the dates on which the Ampyra Orange-book listed patents expire, or any later expiration of exclusivity to which we are or become entitled. We filed this lawsuit within 45 days from the date of receipt of the Paragraph IV Certification Notice, which instituted the 30 month statutory stay of approval period to the Par ANDA under the Hatch-Waxman Act. Since the Par ANDA was filed after January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra, the 30 month statutory stay of approval will start from the receipt of the Paragraph IV Certification Notice. This restricts the FDA from approving the ANDA until March 2018 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

Ampyra IPR Proceedings

In February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. In August 2015, the U.S. Patent and Trademark Office Patent Trials and Appeals Board ruled that it would not institute inter partes review of either of these patents. On September 23, 2015, however, the hedge fund filed two motions for reconsideration to the U.S. Patent and Trademark Office Patent Trials and Appeals Board, requesting that the denial to institute these two IPRs be reversed.

On September 2 and 3, 2015, the same hedge fund filed four separate IPR petitions with the U.S. Patent and Trademark Office. These new IPR petitions challenge the same two patents that were the subject of the February 2015 IPR petitions and also U.S. Patent Nos. 8,354,437 and 8,440,703. The challenged patents are four of the five Ampyra Orange-

book listed patents. We will oppose the requests to institute these IPRs, and if one or more is allowed to proceed, we will oppose the full proceedings and defend our patents. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

We will vigorously defend our intellectual property rights.

Item 1 of Part II of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2015, and June 30, 2015, include prior updates to the legal proceedings 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, 2014, as updated in our Quarterly Reports subsequently filed during the current fiscal year, 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 certain risk factors to report changes since our publication of risk factors in our 2014 Annual Report on Form 10-K and our subsequent Quarterly Reports on Form 10-Q.

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/aminopyridines, CVT-301 and our ARCUS inhaled therapeutic technology, cimaglermin alfa/neuregulins, remyelinating antibodies/antibodies relating to nervous system disorders, chondroitinase, Plumiaz/diazepam nasal spray, Qutenza and NP-1998/topical capsaicin formulations, comprised of both our own and in-licensed patents and patent applications. For some of our proprietary technologies, for example our ARCUS technology, we rely on a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property rights. Our intellectual property also includes copyrights 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, several generic drug manufacturers have already filed

Abbreviated New Drug Applications, or ANDAs, for generic versions of Ampyra with the FDA. In filing these ANDAs for Ampyra, the generic drug manufacturers have challenged all of the Orange Book-listed patents that protect the Ampyra franchise. As such, to protect our intellectual property rights we have initiated legal proceedings asserting the challenged Orange Book-listed patents against these generic drug manufacturers. Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Invents Act, specifically inter partes review and/or post grant review before the U.S. Patent and Trademark Office. For example, in February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging two of the five Ampyra Orange Book-listed patents. Although the U.S. Patent and Trademark Office Patent Trials and Appeals Board chose not to institute inter partes review of these patents, the hedge fund has filed motions for reconsideration requesting that the denial to institute these two IPRs be reversed. In addition, in September 2015 the same hedge fund filed four additional IPR petitions challenging four of the five listed Orange Book patents, including two

of the same patents that were the subject of the February 2015 IPR petitions. Patent litigation, IPR, and other legal proceedings involve complex legal and factual questions. 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 lawsuits and legal proceedings.

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

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

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 9, 2015

By:

/s/ Michael Rogers

Michael Rogers

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 9, 2015



## Exhibit Index

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