

ACORDA THERAPEUTICS INC  
Form 10-Q  
May 06, 2016

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 March 31, 2016

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 April 30, 2016
Common Stock, \$0.001 par value per share	46,067,276 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 complete the Biotie Therapies Corp. transaction on a timely basis; the ability to realize the benefits anticipated from the Biotie Therapies transaction and the Civitas Therapeutics transaction, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; the ability to successfully integrate Biotie Therapies' operations and Civitas's operations respectively, into our operations; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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 (diazepam) Nasal Spray, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; or the products that we will acquire when we complete the Biotie Therapies transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaborator 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," expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this report and in our Annual Report on Form 10-K for the year ended December 31, 2015, particularly in the "Risk Factors" section (as updated by the disclosures in our subsequent quarterly reports, including this report), 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)	March 31, 2016	December 31, 2015
	(unaudited)	
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 431,414	\$ 153,204
Restricted cash	190	6,032
Short-term investments	—	200,101
Trade accounts receivable, net of allowances of \$932 and \$884, as of March 31, 2016 and December 31, 2015, respectively	41,623	31,466
Prepaid expenses	14,312	16,079
Finished goods inventory	39,667	36,476
Other current assets	17,075	7,959
<b>Total current assets</b>	<b>544,281</b>	<b>451,317</b>
Property and equipment, net of accumulated depreciation	38,027	40,204
Goodwill	183,636	183,636
Deferred tax asset	12,273	2,128
Intangible assets, net of accumulated amortization	430,491	430,856
Non-current portion of deferred cost of license revenue	2,747	2,906
Other assets	239	247
<b>Total assets</b>	<b>\$ 1,211,694</b>	<b>\$ 1,111,294</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 21,355	\$ 14,233
Accrued expenses and other current liabilities	73,475	66,133
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interest liability	—	25
Current portion of convertible notes payable	1,117	1,144
<b>Total current liabilities</b>	<b>105,004</b>	<b>90,592</b>
Convertible senior notes (due 2021)	292,624	290,420
Acquired contingent consideration	69,700	63,500
Non-current portion of deferred license revenue	39,249	41,513
Non-current portion of convertible notes payable	—	1,107
Deferred tax liability	12,146	12,146

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Other non-current liabilities	8,959	8,991
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at March 31, 2016 and December 31, 2015; issued 45,974,953 and 43,440,324 shares, including those held in treasury, as of March 31, 2016 and December 31, 2015, respectively	46	43
Treasury stock at cost (12,420 shares at March 31, 2016 and December 31, 2015)	(329 )	(329 )
Additional paid-in capital	894,167	812,782
Accumulated deficit	(209,872 )	(209,352 )
Accumulated other comprehensive loss	—	(119 )
Total stockholders' equity	684,012	603,025
Total liabilities and stockholders' equity	\$ 1,211,694	\$ 1,111,294

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 March 31, 2016	Three-month period ended March 31, 2015
<b>Revenues:</b>		
Net product revenues	\$ 110,148	\$ 93,500
Royalty revenues	3,492	4,087
License revenue	2,264	2,264
<b>Total net revenues</b>	<b>115,904</b>	<b>99,851</b>
<b>Costs and expenses:</b>		
Cost of sales	23,186	18,446
Cost of license revenue	159	159
Research and development	44,570	30,636
Selling, general and administrative	58,980	48,769
Changes in fair value of acquired contingent consideration	6,200	3,100
<b>Total operating expenses</b>	<b>133,095</b>	<b>101,110</b>
Operating loss	(17,191 )	(1,259 )
<b>Other income (expense) (net):</b>		
Interest and amortization of debt discount expense	(3,723 )	(4,051 )
Interest income	215	66
Other income	10,442	121
<b>Total other income (expense) (net)</b>	<b>6,934</b>	<b>(3,864 )</b>
Loss before taxes	(10,257 )	(5,123 )
Benefit from income taxes	9,737	2,038
Net loss	\$ (520 )	\$ (3,085 )
<b>Net loss per share—basic</b>		
	\$ (0.01 )	\$ (0.07 )
<b>Net loss per share—diluted</b>		
	\$ (0.01 )	\$ (0.07 )
	44,815	42,031

Weighted average common shares outstanding used in computing net loss per share—basic		
Weighted average common shares outstanding used in computing net loss per share—diluted	44,815	42,031

See accompanying Unaudited Notes to Consolidated Financial Statements



ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(unaudited)

(In thousands)	Three-month period ended March 31, 2016	Three-month period ended March 31, 2015
Net loss	\$ (520 )	\$ (3,085 )
Other comprehensive loss:		
Unrealized losses on available for sale securities, net of tax	—	(17 )
Reclassification of net losses to net income	119	—
Other comprehensive income (loss), net of tax	119	(17 )
Comprehensive loss	\$ (401 )	\$ (3,102 )

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(unaudited)

(In thousands)	Three-month period ended March 31, 2016	Three-month period ended March 31, 2015
<b>Cash flows from operating activities:</b>		
Net loss	\$ (520 )	\$ (3,085 )
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation expense	8,159	7,126
Amortization of net premiums and discounts on investments	495	551
Amortization of debt discount and debt issuance costs	2,204	2,103
Amortization of revenue interest issuance cost	—	6
Depreciation and amortization expense	3,949	3,707
Change in acquired contingent consideration obligation	6,200	3,100
Unrealized gain on foreign currency transaction	(10,289 )	—
Deferred tax benefit	(10,172 )	(2,038 )
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(10,156 )	1,659
Decrease (increase) in prepaid expenses and other current assets	4,308	(3,190 )
Increase in inventory	(3,191 )	(18,996 )
Decrease in non-current portion of deferred cost of license revenue	159	159
Increase in accounts payable, accrued expenses, other current liabilities	11,969	7,099
Decrease in revenue interest liability interest payable	—	(41 )
Decrease in non-current portion of deferred license revenue	(2,264 )	(2,264 )
Increase in other non-current liabilities	4	—
Decrease in deferred product revenue—Zanaflex	—	(300 )
Decrease (Increase) in restricted cash	5,842	(4,846 )
Net cash provided by (used in) operating activities	6,697	(9,250 )
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,037 )	(2,571 )
Purchases of intangible assets	(406 )	(152 )
Purchases of investments	(40,214 )	(169,563)
Proceeds from maturities of investments	239,966	56,250
Net cash provided by (used in) investing activities	198,309	(116,036)
<b>Cash flows from financing activities:</b>		

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Proceeds from issuance of common stock and option exercises	73,229	4,741
Repayments of revenue interest liability	(25 )	(110 )
Net cash provided by financing activities	73,204	4,631
Net decrease in cash and cash equivalents	278,210	(120,655)
Cash and cash equivalents at beginning of period	153,204	182,170
Cash and cash equivalents at end of period	\$ 431,414	\$ 61,515
Supplemental disclosure:		
Cash paid for interest	21	463
Cash paid for taxes	157	743

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.

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information, Accounting Standards Codification (ASC) Topic 270-10 and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management’s opinion, all adjustments considered necessary for a fair presentation have been included in the interim periods presented and all adjustments are of a normal recurring nature. The Company has evaluated subsequent events through the date of this filing. Operating results for the three-month period ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. When used in these notes, the terms “Acorda” or “the Company” mean Acorda Therapeutics, Inc. The December 31, 2015 consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. You should read these unaudited interim condensed consolidated financial statements in conjunction with the consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Certain reclassifications were made to prior period amounts in the interim consolidated financial statements and accompanying notes to conform with the current presentation.

(2) Summary of Significant Accounting Policies

Our critical accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2015. As of March 31, 2016, with the exception of the adoption of ASU 2015-03, our critical accounting policies have not changed materially from December 31, 2015.

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 the following subsequent events required disclosure in these financial statements.

Biotie acquisition

On April 18, 2016, the Company closed a tender offer for all of the outstanding capital stock of Biotie Therapies Corp. (“Biotie”), a Finland based company, pursuant to which the Company acquired approximately 93% of the fully diluted capital stock of Biotie (See Note 3). On May 4, 2016, the Company acquired another approximately 4% of Biotie’s fully diluted capital stock pursuant to a subsequent public offer to Biotie stockholders that did not tender their shares in the initial tender offer. The Company funded the initial and subsequent tender offers with approximately \$357 million of existing cash on hand. As a result of funding the tender offer, the Company’s cash balance has decreased as

compared to the cash balance reported at March 31, 2016.

The Company will account for the transaction as a business combination following the acquisition method of accounting in accordance with ASC 805, Business Combinations. The preparation of the closing financial statements for Biotie is currently underway and the Company will perform valuation procedures to determine the fair value of the assets acquired and liabilities assumed upon completion of the closing financial statements. Therefore, the information necessary to determine the fair value of assets acquired and liabilities assumed is not available as of the date of these financial statements. The Company incurred approximately \$7.2 million in acquisition related expenses that are reflected in selling, general and administrative expenses for the three-month period ended March 31, 2016. With the exception of the acquisition related

expenses incurred, the acquisition of Biotie did not impact the Company's unaudited consolidated financial statements for the three-month periods ended March 31, 2016 and 2015.

#### Recently Issued / Adopted Accounting Pronouncements

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 therein beginning after December 15, 2015, with early adoption permitted. The Company adopted this guidance retrospectively effective in the three-month period ended March 31, 2016. The impact of the adoption of this guidance on the Company's consolidated balance sheet as of December 31, 2015 was a reclassification of approximately \$5.0 million representing the unamortized balance of debt issuance costs as of December 31, 2015 from Other Assets to the Convertible Senior Notes liability.

(In thousands)	Balance at December 31, 2015	
	Revised Reporting	As Previously Reported
Other assets	\$ 247	\$ 5,296
Convertible notes payable – due 2021	\$ (290,420 )	\$ (295,469 )

In March 2016, the FASB issued Accounting Standards Update 2016-09, "Compensation – Stock Compensation" (Topic 718). The main objective of this update is to simplify the accounting, and reporting classifications for certain aspects of share-based payment transactions. This ASU is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company is currently evaluating the new guidance to determine the impact it may have on its financial statements.

#### (3) Acquisitions

##### Biotie Therapies Corp. (Pending Acquisition)

In January 2016, the Company announced that it had entered into a combination agreement to acquire Biotie Therapies Corp. ("Biotie") for a cash purchase price of approximately \$363 million. In accordance with the combination agreement, on April 18, 2016, the Company closed a public tender offer for all of Biotie's capital stock, pursuant to which the Company acquired approximately 93% of the fully diluted capital stock of Biotie. On May 4, 2016, the Company acquired another approximately 4% of Biotie's fully diluted capital stock pursuant to a subsequent public offer to Biotie stockholders that did not tender their shares in the initial tender offer. Accordingly, the Company currently owns approximately 97% of the fully diluted capital stock of Biotie. The Company intends to acquire all remaining shares of Biotie capital stock that have not been tendered to the Company pursuant to compulsory redemption proceedings under Finnish law that the Company initiated in April 2016. The Company expects to complete the acquisition of 100% of Biotie pursuant to these compulsory redemption proceedings in the second half of 2016.

#### Financing Transactions

Concurrently with the announcement of the Biotie acquisition, the Company announced two separate financing transactions. The first was a private placement of 2,250,900 shares of the Company's common stock for an aggregate purchase price of approximately \$75 million. The Company paid discounts and commissions of \$2.3 million in connection with the private placement, which settled on January 26, 2016. The Company used the net proceeds from the private placement to fund, in part, the acquisition of Biotie. The Company also announced a commitment from JP Morgan Chase, N.A. for an asset-based credit facility for up to \$60 million. The closing of this credit facility is expected to occur in the second quarter of 2016.

## Financial Instruments

The Company does not enter into hedging transactions in the normal course of business. However, as a result of the Biotie acquisition which is to be completed in euros, the Company is exposed to fluctuations in exchange rates between the U.S. dollar and the euro until the completion of the transaction. To mitigate this risk, the Company entered into foreign currency options to limit its exposure to fluctuations in exchange rates between the U.S. dollar and the euro until the transaction is completed. The Company recorded the fair value of the options on its balance sheet and will recognize any gains or losses in earnings each period until the options expire or are canceled. As of May 2, 2016, there were no remaining foreign currency options outstanding. The Company currently owns approximately 97% of the fully diluted capital stock of Biotie, therefore, the risk of exposure to fluctuations in exchange rates between the U.S. dollar and the euro is no longer material to the Company.

The notional value of the foreign currency options was EUR 334 million (or approximately \$363 million based on an average exchange rate of 1.0864 USD to 1.00 EUR from the last 5 trading days prior to January 15, 2016) as of March 31, 2016.

As of March 31, 2016, the Company had an unrealized gain on the options of approximately \$10.3 million that is being reflected in other income. The Company recorded approximately \$11.6 million in other current assets and approximately \$1.3 million in other current liabilities related to the options in the consolidated balance sheet at March 31, 2016. The options which are subject to a master netting arrangement are presented on a gross basis in the consolidated balance sheet.

## (4) Share-based Compensation

During the three-month periods ended March 31, 2016 and 2015, the Company recognized share-based compensation expense of \$8.1 million and \$7.1 million, respectively. Activity in options and restricted stock during the three-month period ended March 31, 2016 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 March 31, 2016 and 2015 were approximately \$15.28 and \$16.25, respectively.

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

(In millions)	For the three-month period ended March 31,	
	2016	2015
Research and development	\$ 2.1	\$ 1.8
Selling, general and administrative	6.0	5.3
Total	\$ 8.1	\$ 7.1



A summary of share-based compensation activity for the three-month period ended March 31, 2016 is presented below:

#### Stock Option Activity

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value (In thousands)
Balance at January 1, 2016	8,223	\$ 30.97		
Granted	919	35.74		
Cancelled	(42 )	33.26		
Exercised	(68 )	17.09		
Balance at March 31, 2016	9,032	\$ 31.55	6.7	\$ 8,701
Vested and expected to vest at March 31, 2016	8,919	\$ 31.50	6.7	\$ 8,701
Vested and exercisable at March 31, 2016	5,408	\$ 28.99	5.5	\$ 8,660

#### Restricted Stock Activity

(In thousands) Restricted Stock	Number of Shares
Nonvested at January 1, 2016	441
Granted	486
Vested	(3)
Forfeited	(5)
Nonvested at March 31, 2016	919

Unrecognized compensation cost for unvested stock options, restricted stock awards and performance stock units as of March 31, 2016 totaled \$78.5 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-month periods ended March 31, 2016 and 2015:

(In thousands, except per share data)	Three-month period ended	Three-month period ended
---------------------------------------	--------------------------------	--------------------------------

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	March 31, 2016	March 31, 2015
<b>Basic and diluted</b>		
Net loss	\$ (520 )	\$ (3,085 )
Weighted average common shares outstanding used in computing net loss per share—basic	44,815	42,031
Plus: net effect of dilutive stock options and restricted common shares	—	—
Weighted average common shares outstanding used in computing net loss per share—diluted	44,815	42,031
Net loss per share—basic	\$ (0.01 )	\$ (0.07 )
Net loss per share—diluted	\$ (0.01 )	\$ (0.07 )

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 period ended March 31, 2016	Three-month period ended March 31, 2015
<b>Denominator</b>		
Stock options and restricted common shares	4,393	3,300
Convertible note – Saints Capital	10	19

Additionally, the impact of the convertible debt was determined to be anti-dilutive and excluded from the calculation of net loss per diluted share for the three-month periods ended March 31, 2016 and 2015.

#### (6) Income Taxes

For the three-month periods ended March 31, 2016 and 2015, the Company recorded a \$9.7 million benefit and \$2.0 million benefit from income taxes, respectively based upon its estimated annual effective tax rate. The benefit for income taxes is based on federal, state and Puerto Rico income taxes, net of any tax credits. The effective income tax rates for the Company for the three-month periods ended March 31, 2016 and 2015 were 95% and 40%, respectively. The variance in the effective tax rates for the three-month period ended March 31, 2016 as compared to the three-month period ended March 31, 2015 was due primarily to the Company being able to receive a benefit in 2016 for the Federal research and development tax as a result of passed legislation making the tax credit permanent. The Company was not able to benefit from the Federal research and development credit for the three-month period ending March 31, 2015, however, the Company was able to receive the benefit for this tax credit in the effective tax rate at December 31, 2015.

The Company continues to evaluate the realizability of its deferred tax assets and liabilities on a quarterly 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 March 31, 2016 and December 31, 2015 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, exchange 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 foreign currency options that are valued using market exchange rates which are observable and high-quality government bonds that 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-month period ended March 31, 2016. The estimated fair values of all of our financial instruments approximate their carrying values at March 31, 2016, except for the fair value of the Company's convertible senior notes, which was approximately \$305.5 million as of March 31, 2016. 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>March 31, 2016</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 357,687	\$ —	\$ —
Foreign currency option (asset)	—	11,650	—
<b>Liabilities Carried at Fair Value:</b>			
Acquired contingent consideration	—	—	69,700
Foreign currency option (liability)	—	1,361	—
<b>December 31, 2015</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 70,504	\$ 13,009	\$ —
Short-term investments	—	200,101	—
<b>Liabilities Carried at Fair Value:</b>			
Acquired contingent consideration	—	—	63,500

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 period ended March 31, 2016	Three-month period ended March 31, 2015
<b>Acquired contingent consideration:</b>		
Balance, beginning of period	\$ 63,500	\$ 52,600
Fair value change to contingent consideration (unrealized) included in the statement of operations	6,200	3,100
Balance, end of period	\$ 69,700	\$ 55,700

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 periods of Parkinson's disease and CVT-427, a Phase I candidate. CVT-427 is an inhaled triptan intended for acute treatment of migraine 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 43.9% 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 March 31, 2016, 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 determined.

(8) Investments

The Company held no short-term available-for-sale debt securities at March 31, 2016 as compared to \$200.1 million at December 31, 2015 as these investments were either sold or matured during the three-month period ended March 31, 2016

to facilitate the Biotie acquisition. As a result of the sale of certain available-for-sale debt securities, the Company recognized a gain of approximately \$0.03 million in the three-month period ended March 31, 2016. The contractual maturities of available-for-sale debt securities held at December 31, 2015 were greater than 3 months but less than 1 year.

(In thousands)	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
March 31, 2016				
U.S. Treasury bonds	\$ —	\$ —	\$ (— )	\$ —
December 31, 2015				
U.S. Treasury bonds	200,244	—	(143 )	200,101

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$357.7 million and \$83.5 million as of March 31, 2016 and December 31, 2015, respectively.

Unrealized holding gains and losses are reported within accumulated other comprehensive (loss) (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the unrealized holding (losses) on available-for-sale investments during the three-month period ended March 31, 2016, were as follows (in thousands):

(In thousands)	Net Unrealized Gains (Losses) on Marketable Securities
Balance at December 31, 2015	\$ (119 )
Other comprehensive loss before reclassifications:	—
Amounts reclassified from accumulated other comprehensive loss	119
Net current period other comprehensive income	119
Balance at March 31, 2016	\$ —

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

### Biogen

The Company has an exclusive collaboration and license agreement with Biogen Inc. (formerly Biogen Idec International GmbH), or Biogen, as of June 2009 to develop and commercialize Ampyra (known as Fampyra outside the U.S.) in markets outside the U.S. (the “Collaboration Agreement”). 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 received an upfront payment of \$110.0 million in June 2009, and a \$25 million milestone payment in August 2011. As a result of the upfront payment from Biogen, the Company also made a \$7.7 million payment to Alkermes. The upfront payment from Biogen was recorded as deferred revenue and the payment to Alkermes was recorded as deferred expense. The Company is also entitled to receive additional payments of up to \$10 million based on the successful achievement of future regulatory milestones and up to \$365 million based on the successful achievement of future sales milestones. Due to the uncertainty surrounding the

achievement of the future regulatory and sales milestones, these payments will not be recognized as revenue unless and until they are earned.

The Company recognized \$2.3 million in license revenue, a portion of the \$110.0 million received from Biogen, and \$0.2 million in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during the three-month periods ended March 31, 2016 and 2015, 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. The Company recognized \$2.5 million and \$2.3 million in royalty revenue, respectively, for the three-month periods ended March 31, 2016 and 2015, related to ex-U.S. sales of Fampyra by Biogen.



Allergan/Watson

The Company has an agreement with an Allergan plc subsidiary (originally Watson Pharma, Inc.), or Allergan, 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 Allergan's gross margin, as defined by the agreement, of the authorized generic product. During the three-month periods ended March 31, 2016 and 2015, the Company recognized royalty revenue of \$1.0 million and \$1.8 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the three-month periods ended March 31, 2016 and 2015, the Company also recognized revenue and a corresponding cost of sales of \$0.6 million and \$0.2 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Allergan, which is recorded in net product revenues and cost of sales.

(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, 2015. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

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 an industry leading pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, epilepsy, post-stroke walking difficulty, migraine, and MS.

### Biotie Acquisition

In January 2016, we announced that we had entered into a combination agreement to acquire Biotie Therapies Corp. for a cash purchase price of approximately \$363 million. In accordance with the combination agreement, on April 18, 2016, we closed a public tender offer for all of Biotie's capital stock, pursuant to which we acquired approximately 93% of the fully diluted capital stock of Biotie. On May 4, 2016, we acquired another approximately 4% of Biotie's fully diluted capital stock pursuant to a subsequent public offer to Biotie stockholders that did not tender their shares in the initial tender offer. Accordingly, we currently own approximately 97% of the fully diluted capital stock of Biotie. We intend to acquire all remaining shares of Biotie capital stock that have not been tendered to us pursuant to compulsory redemption proceedings under Finnish law that we initiated in April 2016. We expect to complete the acquisition of 100% of Biotie pursuant to these compulsory redemption proceedings in the second half of 2016.

Subject to completion of the acquisition, as described above, we will obtain worldwide rights to tozadenant, an oral adenosine A2a receptor antagonist currently in Phase 3 development as an adjunctive treatment to levodopa in Parkinson's disease patients to reduce OFF time. A2a receptor antagonists have the potential to be the first new class of drug for Parkinson's disease in over 20 years. We believe that tozadenant will be complementary to our other Phase 3 product for Parkinson's disease, CVT-301, because while tozadenant is aimed at reducing overall OFF time, CVT-301 is aimed at rapid improvement of OFF periods when they occur. We project that, if approved, tozadenant could generate peak annual U.S. net revenue of more than \$400 million. Further expanding our pipeline, when we complete the acquisition we will also obtain global rights to SYN120, an oral, 5-HT6/5-HT2A dual receptor antagonist for Parkinson's-related dementia, in Phase 2 development with support from the Michael J. Fox Foundation. Also, Biotie receives double digit royalties from sales of Selincro, a European Medicines Agency (EMA)-approved orally administered therapy for alcohol dependence therapy. Selincro has been introduced across Europe in 29 countries by Biotie's partner, H. Lundbeck A/S, a Danish pharmaceutical company specializing in central nervous system products. Selincro is not approved for use in the U.S. and is not under development for use in the U.S.

### 2016 Financing Transactions

Concurrently with the announcement of the Biotie transaction described above, we announced two separate financing transactions. The first was a private placement of 2,250,900 shares of our common stock for an aggregate purchase price of approximately \$75 million. We paid discounts and commissions of \$2,250,900 in connection with the private placement, which settled on January 26, 2016. We used the net proceeds from the private placement to fund, in part, the Biotie acquisition. We also announced a commitment from JPMorgan Chase, N.A. for an asset-based credit facility for up to \$60 million. The closing of this credit facility is expected to occur in the second quarter of 2016.

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 U.S. in March 2010. Net revenue for Ampyra was \$109.6 million for the three-months ended March 31, 2016 and \$92.4 million for the three-months ended March 31, 2015.

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 March 1, 2016, 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 60 day free trial program. Our 60 day free trial program provides eligible patients with two months of Ampyra at no cost. During 2015, on average more than 70% of new Ampyra patients were enrolled in our 60 day free trial program. The program is in its fifth year, and data show that participants in the 60 day free trial program have higher compliance and persistency rates over time compared to patients that are not in the program. Approximately 50% of patients who initiate Ampyra therapy with the 60 day 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 Directors 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 our 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.

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial 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.

#### License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen 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 available in additional markets in

2016. 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.

Our Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from several generic drug manufacturers, and also inter partes review (IPR) petitions filed by a hedge fund with the U.S. Patent and Trademark Office. An adverse outcome in these legal proceedings could result in our loss of some or all Orange-Book listed patents that we rely on for Ampyra. These legal proceedings are described in Part II, Item 1 of this report.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), 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 Synthon B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthon 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. On February 24, 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

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. 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 an Allergan subsidiary as part of its Actavis business (originally Watson Pharma, Inc.). 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 our net revenue from Zanaflex Capsules to decline further in 2016 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.

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 an industry leading pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, epilepsy, post-stroke walking difficulty, migraine, and MS. Our pipeline includes the programs described below as well as the programs we are acquiring with Biotie described above.

### CVT-301, CVT-427 and ARCUS Technology

We acquired CVT-301 in October 2014 with our acquisition of Civitas Therapeutics, Inc. CVT-301 is a Phase 3 inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods 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 period, and despite optimized regimens with current therapeutic options and strategies, OFF periods 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 was enrolled in a Phase 3 study of CVT-301 for the treatment of OFF periods in Parkinson's disease. We expect the last patient out of the efficacy trial in the fourth quarter of 2016, and subject to successful completion, our goal to file a new drug application, or NDA, in the U.S. in the first quarter of 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, supported by existing Phase 2b data. A separate long-term safety study is also required and is ongoing. We are projecting that, if approved, annual peak net revenue 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 period,



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 April 2016, data from this clinical trial were one of six platform presentations highlighted during the Movement Disorders Invited Science Session at the 68th Annual Meeting of the American Academy of Neurology.

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 (zolmitriptan) intended for acute treatment of migraine by using the ARCUS delivery system. Triptans are the class of drug most commonly prescribed for the acute treatment of migraine. Oral triptans,

which account for the majority 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. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in a nasally-delivered formulation. However, based on available data, we believe that nasally-delivered triptans generally have an onset of action similar to orally administered triptans.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427 for acute treatment of migraine. Based on initial study analyses, we are planning to advance the development program and are designing protocols for the next studies. There were no dose-limiting toxicities in the safety data from this trial. We will present data from the trial in a peer-reviewed forum. We are planning to initiate special population studies to evaluate safe inhalation in patients with asthma and in smokers in the second half of 2016.

### 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, or NDA, 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 development of Plumiaz. Based on these discussions, we are conducting three clinical trials for Plumiaz:

- The first trial is a long-term open-label study assessing safety and tolerability of Plumiaz over 52 weeks.
- The second trial is assessing the bioavailability, safety and tolerability of Plumiaz compared to diazepam rectal gel (Diastat®).
- The third trial is a pharmacokinetic dose proportionality study in healthy adults.

Subject to positive data, 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 annual U.S. net 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.

#### 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 was 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 chronic post-stroke walking difficulty (PSWD) after experiencing an ischemic stroke. This clinical trial has reached 50% of its target enrollment, or 270 subjects.

We have been exploring a once-daily (QD) formulation of dalfampridine for use in the post-stroke clinical program. We currently have three prototype formulations from three different companies based on in vitro testing, which do not have the alcohol dose dumping issue we identified in a prior QD formulation we had been developing. In March 2016, we completed Phase 1 pharmacokinetic studies for these formulations, at least one of which has met all of our success criteria. We expect to move forward with multi-dose pharmacokinetic studies for one or more of these formulations in the second quarter of 2016 and we expect study results in the third quarter of 2016.

Given the progress of our development of a once-daily (QD) formulation of dalfampridine, we have made the decision to stop enrollment of the Phase 3 clinical trial and conduct an unblinded analysis of the trial data. Data are expected by the fourth quarter of 2016, and will be used to inform the design of planned Phase 3 trials. Subject to positive results from this data, the pharmacokinetic studies on the QD formulation described above, and manufacturing scale up work, we are planning to move forward with two concurrent pivotal Phase 3 clinical trials in mid-2017.

#### rHIgM22

We are developing rHIgM22, a remyelinating antibody, 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 includes 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. We are advancing clinical development of rHIgM22 for MS. We are currently enrolling a Phase 1 trial using one of two doses of rHIgM22 or placebo 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 the first half of 2017.

#### 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 report of hepatotoxicity (liver injury) was also identified in the highest planned dose cohort 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 cimagermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In October 2013, we commenced a second clinical trial of cimagermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimagermin, 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) (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 case of hepatotoxicity 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. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimagermin studies and to request that the program be removed from clinical hold.

#### 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 no current plans to invest in further development of NP-1998 for neuropathic pain.

#### Outlook for 2016

#### Financial Guidance for 2016

We are providing the following guidance with respect to our 2016 financial performance:

- We expect 2016 net revenue from the sale of Ampyra to range from \$475 million to \$485 million.
- Research and development (R&D) expenses in 2016 are expected to range from \$165 million to \$175 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 2016 is primarily related to Phase 3 studies of CVT-301, Plumiaz and dalfampridine and continuing development costs for rHIgM22 and CVT-427, as well ongoing preclinical studies.

- Selling, general and administrative (SG&A) expenses in 2016 are expected to range from \$195 million to \$205 million, excluding share-based compensation charges. We are setting a high priority on managing selling, general and administrative expenses in 2016.

The range of SG&A and R&D expenditures for 2016 excludes potential expenses related to the acquisition of Biotie as we are unable to make a determination about the potential expenses for Biotie until the acquisition is completed.

The range of SG&A and R&D expenditures for 2016 are non-GAAP financial measures because they exclude share-based compensation charges. Non-GAAP financial measures are not an alternative for financial measures prepared in

accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures, when viewed in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe that non-GAAP financial measures that exclude share-based compensation charges help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses non-GAAP financial measures that exclude share-based compensation charges to establish budgets and operational goals, and to manage our business and to evaluate its performance.

#### Development Pipeline Goals

Our planned goals and key initiatives with respect to our pipeline during 2016 and beyond are as follows:

- Continue progressing our Phase 3 clinical trial of CVT-301 for the treatment of OFF periods in Parkinson's disease. We expect the last patient out of the efficacy trial in the fourth quarter of 2016, and subject to successful completion, our goal is to file a new drug application, or NDA, in the U.S. in the first quarter of 2017.
- Proceed with an unblinded analysis of clinical trial data from our Phase 3 clinical trial assessing the use of a twice-daily (BID) formulation of dalfampridine as a treatment for chronic post-stroke walking difficulty (PSWD) after experiencing an ischemic stroke. Data are expected by the fourth quarter of 2016 and will be used to inform the design of planned Phase 3 trials in post-stroke walking difficulty. We currently have three prototype formulations of a once-daily (QD) formulation of dalfampridine that could be included in future post-stroke trials. We completed Phase 1 pharmacokinetic studies for these formulations, at least one of which has met all of our success criteria. We expect to move forward with multi-dose pharmacokinetic studies for one or more of these formulations in the second quarter of 2016 and we expect study results in the third quarter of 2016. Subject to positive results from the unblinded trial data, the pharmacokinetic studies on the QD formulation, and manufacturing scale up work, we are planning to move forward with two concurrent pivotal Phase 3 clinical trials in mid-2017.
- We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters or acute repetitive seizures. We are conducting three clinical trials for continuing development of Plumiaz. Subject to positive data, we are planning to resubmit an NDA for Plumiaz in the first quarter of 2017.
- Based on initial study analyses of a completed Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427, we are planning to advance the development program and are designing protocols for the next studies. We will present data from the Phase 1 trial in a peer-reviewed forum. We are planning to initiate special population studies to evaluate inhalation in patients with asthma and in smokers in the second half of 2016.
- 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) (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. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with our first Phase 1 trial, but efficacy data was inconclusive which we believe was in part due to the very small number of patients in the trial. We have ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and we will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.



- We are currently enrolling a Phase 1 trial of rHIgM22 using one of two doses of rHIgM22 or placebo 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 the first half of 2017.

## Results of Operations

Three-Month Period Ended March 31, 2016 Compared to March 31, 2015

### 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 \$109.6 million as compared to \$92.4 million for the three-month periods ended March 31, 2016 and 2015, respectively, an increase of \$17.2 million, or 18.6%. The net revenue increase was comprised of net volume increases of \$10.0 million due to greater demand, due in part to the success of certain marketing programs such as our 60 day free trial program and price increases net of discount and allowance adjustments of \$7.2 million. Effective January 1, 2016, 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 and discounts. 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.

The net revenue for the three-month period ended March 31, 2016 decreased from net revenue of \$122.0 million for the three-month period ended December 31, 2015. We believe that the decrease in net revenue between the fourth quarter of 2015 and the first quarter of 2016 reflects certain recurring seasonal factors relating to the commencement of a new calendar year. These factors include patients switching insurance plans or pharmacy benefit providers at year-end. Consequently, many patients must re-establish eligibility during the first few months of the calendar year. Also, when deductibles and the Medicare donut hole reset at the beginning of the calendar year, it can affect timely refills for consumers with financial constraints. In addition, as in previous years, there was some inventory build in the fourth quarter of 2015 that was destocked during the first quarter.

#### Other Product Revenues

We recognized net revenue from the sale of Other products of \$0.5 million for the three-month period ended March 31, 2016, as compared to \$1.1 million for the three-month period ended March 31, 2015, a decrease of \$0.6 million.

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.

#### License Revenue

We recognized \$2.3 million in license revenue for the three-month periods ended March 31, 2016 and 2015, 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 and \$2.3 million in royalty revenue for the three-month periods ended March 31, 2016 and 2015, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$1.0 million and \$1.8 million in royalty revenue for the three-month periods ended March 31, 2016 and 2015, respectively, related to the authorized generic sale of Zanaflex Capsules.

#### Cost of Sales

We recorded cost of sales of \$23.2 million for the three-month period ended March 31, 2016 as compared to \$18.4

million for the three-month period ended March 31, 2015. Cost of sales for the three-month period ended March 31, 2016 consisted primarily of \$19.8 million in inventory costs related to recognized revenues and \$2.5 million in royalty fees based on net product shipments.

Cost of sales for the three-month period ended March 31, 2015 consisted primarily of \$15.9 million in inventory costs related to recognized revenues and \$2.1 million in royalty fees based on net product shipments.

#### Cost of License Revenue

We recorded cost of license revenue of \$0.2 million for the three-month periods ended March 31, 2016 and 2015, 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 March 31, 2016 were \$44.6 million as compared to \$30.6 million for the three-month period ended March 31, 2015, an increase of approximately \$14.0 million, or 46%. The increase was due primarily to an increase in spending for CVT-301 of approximately \$10.0 million. The increase was also due to increased spending on other programs, including \$2.0 million for our Ampyra life cycle management program, and \$1.0 million for our Plumiaz program, plus additional research and development staffing costs of \$1.8 million, partially offset by reduced spending for the NP-1998 program of \$0.8 million.

#### Selling, General and Administrative

Sales and marketing expenses for the three-month period ended March 31, 2016 were \$27.2 million compared to \$25.0 million for the three-month period ended March 31, 2015, an increase of approximately \$2.2 million, or 9%. The increase was attributable to an increase in overall marketing, selling, distribution, and market research expenses of \$1.6 million, and increases in compensation and other selling related expenses of \$0.6 million.

General and administrative expenses for the three-month period ended March 31, 2016 were \$31.8 million compared to \$23.8 million for the three-month period ended March 31, 2015, an increase of approximately \$8.0 million, or 34%. This increase was primarily due to increased spending related to the Biotie acquisition including Business Development expenses \$6.9 million and Legal and Finance related expenses \$3.3 million, partially offset by reductions in staff compensation and other expenses \$2.0 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 expenses pertaining to changes in the fair-value of acquired contingent consideration of \$6.2 million for the three-month period ended March 31, 2016 compared to \$3.1 million for the three-month period ended March 31, 2015. 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.

#### Other Income / Expense

Other income was \$6.9 million for the three-month period ended March 31, 2016 compared to other expense of \$3.9 million for the three-month period ended March 31, 2015, a difference of \$10.8 million. The difference is due primarily to the unrealized gain on the foreign currency options associated with the Biotie acquisition of \$10.3 million. Interest expense related to our convertible senior notes was \$3.7 million for the three-month period ended March 31, 2016, of which the non-cash portion was \$2.2 million.

### Benefit from Income Taxes

For the three-month periods ended March 31, 2016 and 2015, the Company recorded a \$9.7 million benefit and \$2.0 million benefit from income taxes, respectively based upon its estimated annual effective tax rate. The benefit for income taxes is based on federal, state and Puerto Rico income taxes, net of any tax credits. The effective income tax rates for the Company for the three-month periods ended March 31, 2016 and 2015 were 95% and 40%, respectively. The variance in the effective tax rates for the three-month period ended March 31, 2016 as compared to the three-month period ended March 31, 2015 was due primarily to the Company being able to receive a benefit for the Federal research and development tax during 2016 as a result of passed legislation making the tax credit permanent. The Company was not able to benefit from the Federal research and development credit for the three-month period ending March 31, 2015, however, the Company was able to receive the benefit for this tax credit in the effective tax rate at December 31, 2015.

The Company continues to evaluate the realizability of its deferred tax assets and liabilities on a quarterly 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.

### 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 other financing arrangements.

At March 31, 2016, we had \$431.4 million of cash, cash equivalents and short-term investments, compared to \$353.3 million at December 31, 2015. Following the closing of the Biotie transaction, we expect that our existing cash, the cash balance of Biotie, any cash flows from operations, and the expected availability under the asset-based credit facility, will be sufficient to fund our ongoing operations. The closing of this credit facility is expected to occur in the second quarter of 2016.

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

As of March 31, 2016, we had \$1.1 million of outstanding convertible promissory notes, which amount includes accrued interest payable to Saints Capital. The sixth of seven annual payments on this note was due and paid on the six year anniversary of Ampyra approval on January 22, 2016 and will continue to be paid annually until paid in full

in 2017.

#### 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.

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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.

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 March 31, 2016 consisted of the following:

(In thousands)	March 31, 2016
<b>Liability component:</b>	
Principal	\$ 345,000
Less: debt discount and debt issuance costs, net	(52,376)
Net carrying amount	\$ 292,624
<b>Equity component</b>	<b>\$ 61,195</b>

### Investment Activities

At March 31, 2016, cash and cash equivalents were approximately \$431.4 million, as compared to \$153.2 million at December 31, 2015. Our cash equivalents consists of highly liquid investments with original maturities of three months or less at date of purchase and consists of time deposits and investments in a money market fund. At December 31, 2015, we held \$200.1 million of short-term investments which consisted of U.S. Treasury bonds with original maturities greater than three months and less than one year. 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.

### Net Cash Provided by Operations

Net cash provided by operations was \$6.7 million for the three-month period ending March 31, 2016 while \$9.3 million was used in operations for the three-month period ended March 31, 2015. Cash provided by operations for the three-month period ended March 31, 2016 was primarily due to an increase in accounts payable, accrued expenses and other current liabilities of \$12.0 million, non-cash share based compensation expense of \$8.2 million, changes in acquired contingent consideration of \$6.2 million, a decrease in restricted cash of \$5.8 million, and a decrease in prepaid expenses and other current assets of \$4.3 million, partially offset by an unrealized gain on foreign currency options of \$10.3 million related to the Biotie acquisition, an increase in accounts receivable of \$10.2 million, and a deferred tax benefit of \$10.2 million.

### Net Cash Provided by Investing

Net cash provided by investing activities for the three-month period ended March 31, 2016 was \$198.3 million, which was due primarily to proceeds from maturing investments of \$240.0 million, partially offset by purchases of investments of \$40.2 million.

### Net Cash Provided by Financing

Net cash provided by financing activities for the three-month period ended March 31, 2016 was \$73.2 million, which was due to \$72.1 million in net proceeds from the issuance of common stock and \$1.1 million in proceeds from the exercise of stock options.

### 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, 2015. 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 three-month period ended March 31, 2016, commitments related to the purchase of inventory increased as compared to December 31, 2015. As of March 31, 2016, we have inventory-related purchase commitments totaling approximately \$62.3 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.

#### 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, 2015. As of March 31, 2016, with the exception of the adoption of ASU 2015-03, our critical accounting policies have not changed materially from December 31, 2015.

#### 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, foreign currency options and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying values at March 31, 2016, except for the fair value of the Company's convertible senior notes which was approximately \$305.5 million as of March 31, 2016.

We have cash equivalents at March 31, 2016, 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, the carrying value of our cash equivalents approximates their fair value at March 31, 2016. At March 31, 2016, we held \$431.4 million in cash and cash equivalents which had an average interest rate of approximately 0.2%.

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 enter into hedging transactions in the normal course of business. However, as a result of the Biotie acquisition which is to be completed in euros, the Company is exposed to fluctuations in exchange rates between the U.S. dollar and the euro until the completion of the transaction. To mitigate this risk, the Company entered into foreign currency options to limit its exposure to fluctuations in exchange rates between the U.S. dollar and the euro until the transaction is completed.

#### 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 first quarter of 2016, 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 March 31, 2016, 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 March 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

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. In September 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. In December 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. In January 2012, we moved to dismiss or stay Apotex's suit. In February 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. Also in February 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 briefing period and oral argument have been completed and we are now awaiting a decision from 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. ("Aurobindo"), 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 ANDA filers have been consolidated into a single case. The U.S. District Court for the District of Delaware issued a Markman ruling in March, 2016, determining the scope and limitations of certain patent claims asserted in the litigation, 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.

In October and December 2015, we entered into settlement agreements with Actavis and Aurobindo to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreements, Actavis and Aurobindo will be permitted to market generic versions of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The Court entered an order dismissing the case against Actavis without prejudice in October 2015. As a result of the settlement agreement with Aurobindo, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Aurobindo in December 2015. The parties have submitted the agreements to the Federal Trade Commission and the Department of Justice,



as required by federal law. The settlements with Actavis and Aurobindo do 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. In January 2015, the Court denied Mylan's motion to dismiss with respect to the ANDA filer, Mylan Pharmaceuticals, Inc. Subsequently, in January 2015, the Court granted Mylan's request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit Court of Appeals. In March 2016, the Court of Appeals denied Mylan's appeal, and the case remains in the U.S. District Court for the District of Delaware. Mylan, however, has requested the Federal Circuit Court of Appeals to reconsider its decision. The Federal Circuit Court has not decided whether or not it will grant Mylan's request. 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. In December 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. In February 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 ANDA filers.

In May 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals 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 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 May 2015 we filed a lawsuit against Sun 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. In October 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. As a result of the settlement agreement, and upon request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Sun in October 2015. 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.

In September 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 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 it 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. In January 2016, we entered into a settlement agreement with Par to resolve this patent litigation. As a result of the settlement agreement, Par 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. As a result of the settlement agreement, and upon the request of the parties, the Court entered a Consent Order, in which it dismissed our litigation against Par in January 2016. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Par does not resolve pending patent litigation that we brought against the other ANDA filers, described in this report.

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, or PTO, 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, or PTAB, ruled that it would not institute inter partes review of either of these patents. In September 2015, the hedge fund filed two motions for reconsideration to the PTAB, requesting that the denial to institute these two IPRs be reversed. However, in April 2016 the PTAB denied these motions thus denying the hedge fund's two IPR proceedings.

In September 2015, the same hedge fund filed four separate IPR petitions with the PTO. These later 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 opposed the requests to institute these IPRs, but in March 2016 the PTAB decided to institute the IPR proceedings on all four patents. A ruling on the IPR petitions is expected within one year from that determination. We are opposing those IPRs and defending 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 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, 2015, 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 2015 Annual Report on Form 10-K.

We are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to other regulatory requirements that apply to drugs manufactured or distributed by us.

If we receive a notice of inspectional observations or deficiencies from the FDA or foreign regulatory authorities, we may be required to undertake corrective and preventive actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses. Failure to adequately address the FDA's, or foreign regulatory agency's, concerns could expose us to enforcement and administrative actions.

For example, the FDA conducted two inspections beginning in July 2011. The first inspection focused on our Ampyra REMS (which we are no longer subject to), and the second inspection focused on our adverse event reporting system. The REMS inspection resulted in verbal comments pertaining to formalization of procedures and enhanced quality assurance responsibilities. The adverse event reporting inspection resulted in a September 2011 FDA Form 483 focused primarily on timeliness of reporting, formalization and enhancement of certain procedures and processes, communication of Ampyra post-marketing commitments, and Acorda access to source documentation. Acorda provided the FDA with formal responses to the inspectional observations as well as to the verbal comments and commenced the process of implementing specific actions to address the FDA's concerns and enhance our overall pharmacovigilance process. However, in May 2012 the FDA issued a written warning letter based on some of the adverse event reporting issues identified in the 2011 inspection. The FDA warning letter identified some of the FDA's observations as repeat observations from prior FDA inspections. We responded to the warning letter, advising the FDA of the corrective actions we were taking to address all of the matters covered in the warning letter.

The FDA also conducted two inspections in December 2012 through January 2013. The first inspection focused on Ampyra REMS adherence and resulted in the issuance of an FDA Form 483 with one written observation and six verbal comments. The written observation described a lack of timely distribution of REMS required letters to prescribers and pharmacists. The verbal comments pertained to verification and document control processes for REMS required letters, process control for creation and distribution of these letters and the medication guide, and the timing of prescriber surveys in relation to mailing of letters to the prescribers. The second inspection focused on adverse event reporting and was a follow-up to our responses to the 2011 FDA Form 483 and warning letter. This

inspection resulted in an FDA Form 483 with six written observations and three verbal comments. The written observations noted late adverse event reporting, one late quarterly Periodic Adverse Experience Report, or PADER, and one late field alert. The FDA also noted that certain solicited adverse events were not reported in our PADERS and there was a lack of consistent adherence to procedures for timely case follow-up and investigations. The verbal comments covered the completeness and timeliness of investigations as well as need for further clarification of an existing procedure. We responded to the Form 483s and oral comments, and took corrective actions. The FDA also conducted a routine inspection in December 2013. This inspection focused on Quality Unit procedures, especially those related to handling of product complaints and field alerts as well as on adverse event reporting. An FDA Form 483 was issued with two findings. The first Form 483 finding pertained to late adverse event reporting and the second finding pertained to lack of sufficient investigation of Ampyra “lack of effect” complaint trends. We responded to the Form 483, and have taken corrective actions. In February 2016, the FDA conducted what it classified as a biennial

routine inspection. The inspection focused on pharmacovigilance reporting and product complaint handling. This inspection resulted in one FDA Form 483 observation related to Ampyra “lack of effect” complaint trends analysis. We responded to the Form 483, and have taken or will take corrective actions. We continue to monitor and enhance our adverse event and product complaint reporting systems to ensure continued adherence to regulatory requirements. However, the FDA may conclude in subsequent inspections that we have not demonstrated adequate control over our current processes or have not demonstrated adequate closure of our response commitments, and could take action against us without further notice. Action by the FDA against us could require us to take further corrective actions or even that we stop marketing Ampyra and/or result in monetary fines, and any of such actions by the FDA could harm our business.

In addition, our third-party suppliers’ drug product manufacturing sites are subject to inspection by the FDA. Some of these sites have been inspected by the FDA and could be inspected by the FDA in the future. If the FDA inspects the process validation efforts and manufacturing process at these sites, the FDA might find what it considers to be deficiencies in the manufacturing process or process validation efforts, which could negatively impact the availability of product supply or, in the case of a potential new product, delay or prevent commercial launch of that product. For example, although we have not yet contracted with the manufacturer of Plumiaz, we have named a potential manufacturer in the NDA that has limited experience with FDA inspections and no prior experience with commercial manufacturing. If serious concerns are identified during the manufacturing process inspection, this could delay the launch of Plumiaz, if it is approved, which could harm our business. In some cases, our third-party suppliers’ drug manufacturing sites may also be subject to inspection by foreign regulatory authorities. We face similar risks to our business if those third-party manufacturers are unable to comply with foreign regulatory requirements. We and our third-party suppliers are generally required to maintain compliance with cGMPs and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. In addition, the FDA must approve certain changes to our suppliers or manufacturing methods. If we or our third-party suppliers cannot demonstrate ongoing cGMP compliance, we may be required to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of our third-party suppliers, to pass regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties, shut-down of manufacturing facilities, or other civil or criminal sanctions. Non-compliance could increase our costs, cause us to lose revenue, and damage our reputation.

Even if our suppliers or manufacturing methods are in compliance with applicable requirements, we may encounter problems with the manufacture of our products. To investigate and/or resolve these problems, we may be required to withdraw or recall product and interrupt commercial supply of our products. These events could increase our costs, cause us to lose revenue, and damage our reputation. We are required to submit field alert reports to the FDA if we learn of certain reported problems with our products, and we are required to investigate the causes of the reported problems. Issues identified in field alerts could lead to product recalls and interruption of supplies, which in turn could harm our business.

Also, effective January 2015, the Federal Food, Drug & Cosmetic Act requires that trading partners such as our manufacturers, repackagers, wholesale distributors, and dispensers, take certain actions upon determining that a product in their possession or control is suspected to be: counterfeit; diverted; stolen; intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; is the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences to humans. The suspect product is required to be quarantined while an investigation is promptly conducted to determine whether the product meets any of the above criteria. Once a product is determined to meet any of the above-listed criteria, it will be deemed an illegitimate product. Upon such a determination, the FDA and all trading partners in the supply chain must be notified within 24 hours. The notification

and quarantine of product during an investigation could impact product availability for commercial distribution and harm our business.

Item 6. Exhibits

Exhibit No.	Description
2.1	Combination Agreement, dated as of January 19, 2016, by and between the Registrant and Biotie Therapies Corp. Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on January 19, 2016.
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: May 6, 2016

By:

/s/ Michael Rogers

Michael Rogers

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: May 6, 2016



## Exhibit Index

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