

ACORDA THERAPEUTICS INC  
Form 10-Q  
May 08, 2015

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

FORM 10-Q

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended March 31, 2015
- OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 000-50513

ACORDA THERAPEUTICS, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

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

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

10502  
(Zip Code)

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

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

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

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

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

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

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, 2015
Common Stock, \$0.001 par value per share	42,790,888 shares

---

This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: The ability to realize the benefits anticipated from the Civitas Therapeutics, Inc. transaction and to successfully integrate Civitas's operations into our operations; our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Bioge 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," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements in this report and in our Annual Report on Form 10-K for the year ended December 31, 2014, particularly in the "Risk Factors" section, 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.

---

ACORDA THERAPEUTICS, INC.  
TABLE OF CONTENTS

	Page
<b>PART I—FINANCIAL INFORMATION</b>	
Item 1.	1
Financial Statements	
Consolidated Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014	1
Consolidated Statements of Operations (unaudited) for the Three-month Period Ended March 31, 2015 and 2014	2
Consolidated Statements of Comprehensive Income (Loss) (unaudited) for the Three-month Period Ended March 31, 2015 and 2014	3
Consolidated Statements of Cash Flows (unaudited) for the Three-month Period Ended March 31, 2015 and 2014	4
Notes to Consolidated Financial Statements (unaudited)	5
Management’s Discussion and Analysis of Financial Condition and Results of Operations	18
Item 2.	18
Item 3.	32
Item 4.	32
Quantitative and Qualitative Disclosures About Market Risk	
Controls and Procedures	
<b>PART II—OTHER INFORMATION</b>	
Item 1.	33
Legal Proceedings	
Item 1A.	34
Risk Factors	
Item 6.	36
Exhibits	

---

## PART I

## Item 1. Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

(In thousands, except share data)	March 31, 2015	December 31, 2014
	(unaudited)	
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$61,515	\$ 182,170
Restricted cash	1,243	1,205
Short-term investments	238,182	125,448
Trade accounts receivable, net of allowances of \$739 and \$771, as of March 31, 2015 and December 31, 2014, respectively	30,551	32,211
Prepaid expenses	19,050	15,523
Finished goods inventory held by the Company	45,268	26,256
Finished goods inventory held by others	563	581
Deferred tax asset	20,469	18,420
Other current assets	6,995	7,324
<b>Total current assets</b>	<b>423,836</b>	<b>409,138</b>
Property and equipment, net of accumulated depreciation	45,919	46,090
Goodwill	182,952	182,952
Intangible assets, net of accumulated amortization	432,155	432,822
Non-current portion of deferred cost of license revenue	3,381	3,540
Restricted cash	4,809	—
Other assets	5,930	6,137
<b>Total assets</b>	<b>\$1,098,982</b>	<b>\$ 1,080,679</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$21,886	\$ 17,751
Accrued expenses and other current liabilities	60,208	56,118
Deferred product revenue—Zanaflex	29,121	29,420
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interest liability	749	893
Current portion of convertible notes payable	1,144	1,144
<b>Total current liabilities</b>	<b>122,165</b>	<b>114,383</b>
Convertible senior notes (due 2021)	289,607	287,699
Acquired contingent consideration	55,700	52,600
Non-current portion of deferred license revenue	48,306	50,570
Non-current portion of convertible notes payable	1,058	2,184
Deferred tax liability	23,885	23,885

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

Other non-current liabilities	9,241	9,103
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at March 31, 2015 and December 31, 2014; issued and outstanding 42,797,996 and 41,883,843 shares, including those held in treasury, as of March 31, 2015 and December 31, 2014, respectively	43	42
Treasury stock at cost (12,420 shares at March 31, 2015 and December 31, 2014)	(329 )	(329 )
Additional paid-in capital	772,892	761,026
Accumulated deficit	(223,495 )	(220,410 )
Accumulated other comprehensive income	(91 )	(74 )
Total stockholders' equity	549,020	540,255
Total liabilities and stockholders' equity	\$1,098,982	\$ 1,080,679

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(unaudited)

(In thousands, except per share data)	Three-month period ended March 31, 2015	Three-month period ended March 31, 2014
<b>Revenues:</b>		
Net product revenues	\$ 93,500	\$ 74,463
Royalty revenues	4,087	3,791
License revenue	2,264	2,264
<b>Total net revenues</b>	<b>99,851</b>	<b>80,518</b>
<b>Costs and expenses:</b>		
Cost of sales	18,446	15,529
Cost of license revenue	159	159
Research and development	30,636	14,522
Selling, general and administrative	48,769	46,892
Changes in fair value of acquired contingent consideration	3,100	—
<b>Total operating expenses</b>	<b>101,110</b>	<b>77,102</b>
Operating (loss) income	(1,259 )	3,416
<b>Other (expense) income, net:</b>		
Interest and amortization of debt discount expense	(4,051 )	(92 )
Interest income	66	172
Other income	121	—
<b>Total other (expense) income, net</b>	<b>(3,864 )</b>	<b>80</b>
(Loss) income before taxes	(5,123 )	3,496
(Provision for) benefit from income taxes	2,038	(2,793 )
<b>Net (loss) income</b>	<b>\$ (3,085 )</b>	<b>\$ 703</b>
<b>Net (loss) income per share—basic</b>		
	<b>\$ (0.07 )</b>	<b>\$ 0.02</b>
<b>Net (loss) income per share—diluted</b>		
	<b>\$ (0.07 )</b>	<b>\$ 0.02</b>
<b>Weighted average common shares outstanding used in computing net (loss) income per share—basic</b>		
	<b>42,031</b>	<b>40,934</b>
<b>Weighted average common shares outstanding used in computing net (loss) income per share—diluted</b>		
	<b>42,031</b>	<b>42,235</b>

See accompanying Unaudited Notes to Consolidated Financial Statements





## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Comprehensive Income (Loss)

(unaudited)

(In thousands)	Three-month period ended March 31, 2015	Three-month period ended March 31, 2014
Net (loss) income	\$ (3,085 )	\$ 703
Other comprehensive (loss) income:		
Unrealized (losses) gains on available-for-sale securities, net of tax	(17 )	45
Other comprehensive (loss) income, net of tax	(17 )	45
Comprehensive (loss) income	\$ (3,102 )	\$ 748

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, 2015	Three-month period ended March 31, 2014
Cash flows from operating activities:		
Net (loss) income	\$ (3,085 )	\$ 703
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Share-based compensation expense	7,126	5,757
Amortization of net premiums and discounts on investments	551	735
Amortization of debt discount and debt issuance costs	2,103	—
Amortization of revenue interest issuance cost	6	8
Depreciation and amortization expense	3,707	1,759
Change in acquired contingent consideration obligation	3,100	—
Loss on put/call liability	—	20
Deferred tax (benefit) provision	(2,038 )	2,821
Changes in assets and liabilities:		
Decrease in accounts receivable	1,659	1,518
(Increase) decrease in prepaid expenses and other current assets	(3,198 )	1,031
Increase in inventory held by the Company	(19,013 )	(5,010 )
Decrease in inventory held by others	17	28
Decrease in non-current portion of deferred cost of license revenue	159	159
Decrease in other assets	8	8
Increase (decrease) in accounts payable, accrued expenses, other current liabilities	7,099	(1,774 )
Decrease in revenue interest liability interest payable	(41 )	(348 )
Decrease in non-current portion of deferred license revenue	(2,264 )	(2,264 )
Increase in other non-current liabilities	—	9
Decrease in deferred product revenue—Zanaflex	(300 )	(873 )
(Increase) decrease in restricted cash	(4,846 )	18
Net cash (used in) provided by operating activities	(9,250 )	4,305
Cash flows from investing activities:		
Purchases of property and equipment	(2,571 )	(942 )
Purchases of intangible assets	(152 )	(1,198 )
Purchases of investments	(169,563 )	(93,797 )
Proceeds from maturities of investments	56,250	84,500
Net cash used in investing activities	(116,036 )	(11,437 )
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	4,741	3,662
Repayments of revenue interest liability	(110 )	(212 )
Net cash provided by financing activities	4,631	3,450

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

Net (decrease) in cash and cash equivalents	(120,655 )	(3,682 )
Cash and cash equivalents at beginning of period	182,170	48,037
Cash and cash equivalents at end of period	\$ 61,515	\$ 44,355
Supplemental disclosure:		
Cash paid for interest	463	415
Cash paid for taxes	743	460

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 neurological function and improve the lives of people with neurological disorders.

Management is responsible for the accompanying unaudited interim consolidated financial statements and the related information included in the notes to the consolidated financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, including normal recurring adjustments necessary for the fair presentation of the Company’s financial position and results of operations and cash flows for the periods presented. Results of operations for interim periods are not necessarily indicative of the results to be expected for the entire year.

These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company as of and for the year ended December 31, 2014 included in the Company’s Annual Report on Form 10-K for such year, as filed with the Securities and Exchange Commission (the SEC).

(2) Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America and include the results of operations of the Company and its majority owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

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

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

## Investments

Short-term investments consist of US Treasury bonds. The Company classifies marketable securities available to fund current operations as short-term investments in current assets on its consolidated balance sheets. Marketable securities are classified as long-term investments in long-term assets on the consolidated balance sheets if the Company has the ability and intent to hold them and such holding period is longer than one year. The Company classifies its short-term and long-term investments as available-for-sale. Available-for-sale securities are recorded at the fair value of the investments based on quoted market prices.

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

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

#### Accumulated Other Comprehensive Income

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

#### Revenue Recognition

##### Ampyra

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. Ampyra is not available in retail pharmacies. The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. The Company recognizes product sales of Ampyra following receipt of product by a network of specialty pharmacy providers, Kaiser Permanente, and ASD Specialty Healthcare, Inc. The specialty pharmacy providers, Kaiser Permanente, and ASD Specialty Healthcare, Inc. are contractually obligated to hold no more than an agreed number of days of inventory, ranging from 10 to 30 days.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies, Kaiser Permanente and ASD Specialty Healthcare, Inc., an adjustment is recorded for estimated discounts, rebates and chargebacks. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for discounts, rebates and chargebacks are established based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales. The Company does not accept returns of Ampyra with the exception of product damages that occur during shipping.

##### Zanaflex

The Company applies the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules.

The Company has accumulated some sales history with Zanaflex Capsules; however, due to existing and potential generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, management is unable to determine a return rate at this time. As a result, the Company accounts for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the cost basis of the product held by the wholesaler as a separate component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized is based on (1) the estimated prescription demand, based on pharmacy sales for its products; and (2) the Company's analysis of third-party information, including third-party market research data. The Company's estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information is itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition reflects the Company's estimates of actual product prescribed to the end-user. The Company expects to be able to apply a more traditional revenue recognition policy such that revenue is

recognized following shipment to the customer when it believes it has sufficient data to develop reasonable estimates of expected returns based upon historical returns and greater certainty regarding generic competition.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's statement of operations. Adjustments are recorded for estimated discounts, rebates and chargebacks. These allowances are established by management as its best estimate based on available information and are adjusted to reflect known changes in the factors that impact such allowances. Allowances for discounts, rebates and chargebacks are established based on the contractual terms with customers, analysis of historical levels of discounts, rebates and chargebacks, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. In addition, the Company records a charge to cost of goods sold for the cost basis of the estimated product returns the Company believes may ultimately be realized at the time of product shipment to wholesalers. The Company has recognized this charge at the date of shipment since it is probable that it will receive a level of returned products; upon the return of such product it will be unable to resell the product considering its expiration dating; and it can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns. Product shipping and handling costs are included in cost of sales.

#### Qutenza

Qutenza is distributed in the United States by Besse Medical, Inc., a specialty distributor that furnishes the medication to physician offices; and by ASD Specialty Healthcare, Inc., a specialty distributor that furnishes the medication to hospitals and clinics. The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. This means that, for Qutenza, the Company recognizes product sales following receipt of product by its specialty distributors.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated rebates, chargebacks, and returns. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped, an adjustment is recorded for estimated rebates, chargebacks, and returns. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for rebates, chargebacks, and returns are established based on the contractual terms with customers, historical trends, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

#### Milestones and royalties

In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards (FASB) guidance on the milestone method of revenue recognition. At the inception of a collaboration agreement, the Company evaluates if payments are substantive. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be



reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

#### In-Process Research and Development

The cost of in-process research and development (IPR&D) acquired directly in a transaction other than a business combination is capitalized if the projects have an alternative future use; otherwise they are expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. The Company utilizes the "income method", and uses estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on

factors such as relevant market size, patent protection, historical pricing and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. IPR&D intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense recognized in the statement of operations. These assets are tested at least annually or sooner when a triggering event occurs that could indicate a potential impairment.

#### Contingent Consideration

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

#### Goodwill

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

#### Collaborations

The Company recognizes collaboration revenues and expenses by analyzing each element of the agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

#### Concentration of Credit Risk

The Company's principal direct customers as of March 31, 2015 were a network of specialty pharmacies, Kaiser Permanente, and ASD Specialty Healthcare, Inc. for Ampyra, wholesale pharmaceutical distributors for Zanaflex Capsules and Zanaflex tablets, and two specialty distributors for Qutenza. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary. Four customers individually accounted for more than 10% of the Company's product revenue in 2015 and 2014. Four customers individually accounted for more than 10% of the Company's accounts receivable as of March 31, 2015 and December 31, 2014, respectively. The Company's net product revenues are generated in the United States.

#### Segment and Geographic Information

The Company is managed and operated as one business which is focused on the identification, development and commercialization of novel therapies to improve the lives of people with neurological disorders. The entire business is managed by a single management team that reports to the Chief Executive Officer. The Company does not operate separate lines of business with respect to any of its products or product candidates and the Company does not prepare

discrete financial information with respect to separate products or product candidates or by location. Accordingly, the Company views its business as one reportable operating segment. Net product revenues reported to date are derived from sales of Ampyra, Zanaflex and Qutenza in the United States.

#### Subsequent Events

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

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU No. 2014-09). This new standard will replace all current U.S. GAAP guidance on this topic and eliminate all industry-specific guidance. In April 2015, the FASB issued an exposure draft proposing to defer the effective date of the new revenue standard for interim and annual periods beginning after December 15, 2017 (previously December 15, 2016). The proposal will allow public entities to adopt the new standard as early as the original public entity effective date (i.e. annual reporting periods beginning after December 15, 2016 and interim periods therein). Early adoption prior to that date will not be permitted. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. The Company is evaluating the transition method that will be elected and the potential effects of adopting the provisions of ASU No. 2014-09..

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

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

### (3) Acquisitions

#### Civitas Therapeutics, Inc. Acquisition

On October 22, 2014, the Company completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation (Civitas). As a result of the acquisition, the Company acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease. The acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which management believes has applications in multiple disease areas, and a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Approximately 45 Civitas employees based at the Chelsea facility joined the Acorda workforce in connection with the acquisition.

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

Pursuant to the terms of the Merger Agreement, aggregate merger consideration was \$525 million plus \$4.5 million in Civitas transaction costs paid by the Company. Additionally and pursuant to the Merger Agreement, upon

consummation of the merger, \$39.375 million of the aggregate merger consideration was deposited into escrow to secure representation and warranty indemnification obligations of Civitas and Civitas' securityholders. The transaction was financed with cash on hand. The Company incurred approximately \$7.2 million of its own transactions costs related to legal, valuation and other professional and consulting fees associated with the acquisition. These transaction costs have been expensed as selling, general and administrative expenses in the year ended December 31, 2014.

The fair value of consideration transferred totaled approximately \$529.5 million summarized as follows:

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

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

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

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

The following table presents the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

(In thousands)	
Current assets	\$54,911
Property and equipment	27,913
Identifiable intangible assets:	
In-process research and development	423,000
Other non-current assets	1,002
Current liabilities	(6,154 )
Contingent consideration	(50,400 )
Deferred taxes	(102,633)
Other non-current liabilities	(1,065 )
Fair value of acquired assets and liabilities	346,574
Goodwill	182,952
Aggregate purchase price	529,526
Amount paid to extinguish long-term debt	(5,325 )
Cash Paid	\$524,201

The Company may update its preliminary acquisition accounting for provisional amounts for which the accounting is incomplete during the reporting period in which the acquisition occurred, and may continue to update the provisional

amounts until the amounts are no longer provisional, but for no longer than one year from the date of the acquisition. Any updates to the fair value of consideration given or fair value assigned to assets acquired and liabilities assumed during the measurement period would be adjusted through goodwill.

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

The following table summarizes certain supplemental pro forma financial information for the three months ended March 31, 2015 and 2014 as if the acquisition of Civitas had occurred as of January 1, 2013. The unaudited pro forma financial information for the three months ended March 31, 2014 reflects (i) the impact to depreciation expense based on fair value adjustments to the property, plant and equipment acquired from Civitas; and (ii) the income tax benefit from Civitas net

loss at the Company's effective income tax rate at March 31, 2014. The unaudited pro forma financial information was prepared for comparative purposes only and is not necessarily indicative of what would have occurred had the acquisition been made at that time or of results which may occur in the future.

(In thousands)	Three Month Period ended March 31, 2015		Three Month Period ended March 31, 2014	
	Reported	Pro Forma	Reported	Pro Forma
Net revenues	\$ 99,851	\$ 99,851	\$ 80,518	\$ 80,518
Net (loss) income	(3,085 )	(3,085 )	703	(2,267 )

#### (4) Share-based Compensation

During the three-month periods ended March 31, 2015 and 2014, the Company recognized share-based compensation expense of \$7.1 million and \$5.8 million, respectively. Activity in options and restricted stock during the three-month period ended March 31, 2015 and related balances outstanding as of that date are reflected below. The weighted average fair value per share of options granted to employees for the three-month periods ended March 31, 2015 and 2014 were approximately \$16.25 and \$18.81, respectively.

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

(In thousands)	For the three-month period ended March 31,	
	2015	2014
Research and development	\$ 1,822	\$ 1,104
Selling, general and administrative	5,304	4,653
Total	\$ 7,126	\$ 5,757

A summary of share-based compensation activity for the three-month period ended March 31, 2015 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, 2015	7,786	\$ 29.05		
Granted	1,285	36.13		
Cancelled	(24 )	34.14		
Exercised	(191 )	24.82		
Balance at March 31, 2015	8,856	\$ 30.16	7.2	\$ 40,889
	8,698	\$ 30.06	7.1	\$ 40,802



Vested and expected to vest at  
March 31, 2015

Vested and exercisable at March 31, 2015	4,598	\$ 26.06	5.4	\$ 35,703
---	-------	----------	-----	-----------

## Restricted Stock Activity

(In thousands) Restricted Stock	Number of Shares
Nonvested at January 1, 2015	518
Granted	219
Vested	-
Forfeited	(2)
Nonvested at March 31, 2015	735

Unrecognized compensation cost for unvested stock options and restricted stock awards as of March 31, 2015 totaled \$83.5 million and is expected to be recognized over a weighted average period of approximately 2.8 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, 2015 and 2014:

(In thousands, except per share data)	Three-month period ended March 31, 2015	Three-month period ended March 31, 2014
Basic and diluted		
Net (loss) income	\$ (3,085 )	\$ 703
Weighted average common shares outstanding used in computing net (loss) income per share—basic	42,031	40,934
Plus: net effect of dilutive stock options and restricted common shares	—	1,301
Weighted average common shares outstanding used in computing net (loss) income per share—diluted	42,031	42,235
Net (loss) income per share—basic	\$ (0.07 )	\$ 0.02
Net (loss) income per share—diluted	\$ (0.07 )	\$ 0.02

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 (loss) income per diluted share because their effects were anti-dilutive:

(In thousands)	Three-month	
	period ended	period ended
	March 31,	March 31,
	2015	2014
<b>Denominator</b>		
Stock options and restricted common shares	3,300	2,764
Convertible note	19	29

Additionally, the impact of the convertible debt was determined to be anti-dilutive and excluded from the calculation of net income per diluted share.

## (6) Income Taxes

For the three-month periods ended March 31, 2015 and 2014, the Company recorded a \$2.0 million benefit from and \$2.8 million provision for income taxes, respectively, based upon its estimated tax liability for the year. The benefit from/ provision for income taxes is based on federal, state and Puerto Rico income taxes. The effective income tax rates for the Company for the three-month periods ended March 31, 2015 and 2014 were 40% and 80%, respectively. As a result of the Federal research and development tax credit not being extended during the first quarter of 2015, the Company was not able to receive a benefit in the effective tax rate for this in 2015. The Company, however, was able to receive a benefit in the effective tax rate for 2015 for the Massachusetts state research and development tax credit in addition to the Federal orphan drug credit.

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

## (7) Fair Value Measurements

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of March 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 and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability. The Company's Level 1 assets consist of time deposits and investments in a Treasury money market fund and the Company's Level 2 assets consist of high-quality government bonds and are valued using observable market prices. Level 1 instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets and Level 2 assets are valued using quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves. The Company's Level 3 liabilities represent 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 or inputs occurred during the three months ended March 31, 2015. The estimated fair values of all of our financial instruments approximate their carrying values at March 31, 2015.

(In thousands)	Level 1	Level 2	Level 3
<b>March 31, 2015</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 45,393	\$ —	\$ —
Short-term investments	—	238,182	—
<b>Liabilities Carried at Fair Value:</b>			
Acquired contingent consideration	—	—	55,700
Put/call liability	—	—	—
<b>December 31, 2014</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 149,754	\$ —	\$ —

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

Short-term investments	—	125,448	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	52,600
Put/call liability	—	—	—

The fair value of the Company's convertible senior notes was approximately \$351.7 million as of March 31, 2015. The Company estimates the fair value of its Notes utilizing market quotations for the debt (Level 2).

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, 2015	Three-month period ended March 31, 2014
<b>Acquired contingent consideration:</b>		
Balance, beginning of period	\$ 52,600	\$ —
Fair value change to contingent consideration (unrealized) included in the statement of operations	3,100	—
Balance, end of period	\$ 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 episodes of Parkinson's Disease and CVT-427, a pre-clinical development stage product intended to provide relief from acute migraine episodes. Using this approach, expected future cash flows are calculated over the expected life of the agreement, are discounted, and then exercise scenario probabilities are applied. Some of the more significant assumptions made in the valuation include (i) the estimated CVT-301 and CVT 427 revenue forecasts, (ii) probabilities of success, and (iii) discount periods and rate. The probability of achievement of revenue milestones ranged from 28.5% to 70% with milestone payment outcomes ranging from \$0 to \$60 million in the aggregate for CVT-301 and CVT-427. The valuation is performed quarterly. Gains and losses are included in the statement of operations.

The acquired contingent consideration is classified as a Level 3 liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the various inputs to the valuation approach, including but not limited to, assumptions involving probability adjusted sales estimates for CVT-301 and CVT-427 and estimated discount rates, the estimated fair value could be significantly higher or lower than the fair value we determined.

#### (8) Investments

The Company has determined that all of its investments are classified as available-for-sale. Available-for-sale securities are carried at fair value with interest on these securities included in interest income and are recorded based primarily on quoted market prices. Available-for-sale securities consisted of the following:

(In thousands)	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
<b>March 31, 2015</b>				
US Treasury bonds	\$ 238,204	\$ 7	\$ (29 )	\$ 238,182
<b>December 31, 2014</b>				
US Treasury bonds	125,443	14	(9 )	125,448

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

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$45.4 million and \$149.8 million as of March 31, 2015 and December 31, 2014, respectively.

Unrealized holding gains and losses are reported within accumulated other comprehensive income (AOCI) in the statements of comprehensive income (loss). The changes in AOCI associated with the unrealized holding loss on available-for-sale investments during the three months ended March 31, 2015, were as follows (in thousands):

(In thousands)	Net Unrealized Gains on Marketable Securities
Balance at December 31, 2014	\$ (74 )
Other comprehensive income before reclassifications:	(17 )
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive income	(17 )
Balance at March 31, 2015	\$ (91 )

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

##### Biogen

On June 30, 2009, the Company entered into an exclusive collaboration and license agreement with Biogen International GmbH (formerly Biogen Idec International GmbH), or Biogen to develop and commercialize Ampyra (known as Fampyra outside the U.S.) in markets outside the United States (the “Collaboration Agreement”). Under the Collaboration Agreement, Biogen was granted the exclusive right to commercialize Ampyra and other products containing aminopyridines developed under that agreement in all countries outside of the United States, which grant includes a sublicense of the Company’s rights under an existing license agreement between the Company and Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan). Biogen has responsibility for regulatory activities and future clinical development of Fampyra in ex-U.S. markets worldwide. The Company also entered into a related supply agreement with Biogen (the “Supply Agreement”), pursuant to which the Company will supply Biogen with its requirements for the licensed products through the Company’s existing supply agreement with Alkermes.

Under the Collaboration Agreement, the Company was entitled to an upfront payment of \$110.0 million as of June 30, 2009, which was received in July 2009, and a \$25.0 million milestone payment upon approval of the product in the European Union, which was received in August 2011. The Company is also entitled to receive additional payments of up to \$10.0 million based on the successful achievement of future regulatory milestones and up to \$365.0 million based on the successful achievement of future sales milestones. Due to the uncertainty surrounding the achievement of the future regulatory and sales milestones, these payments will not be recognized as revenue unless and until they are earned. The Company is not able to reasonably predict if and when the milestones will be achieved. Under the Collaboration Agreement, Biogen will be required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. In addition, the consideration that Biogen will pay for licensed products under the Supply Agreement will reflect the price owed to the Company’s suppliers under its supply arrangements with Alkermes or other suppliers for ex-U.S. sales. The Company and Biogen may also carry out future joint development activities regarding licensed product under a cost-sharing arrangement. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen, will participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the United States pursuant to that agreement. Acorda will continue to develop and commercialize Ampyra independently in the United States.

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



The Company considered the following deliverables with respect to the revenue recognition of the \$110.0 million upfront payment: (1) the license to use the Company's technology, (2) the Collaboration Agreement to develop and commercialize licensed product in all countries outside the U.S., and (3) the Supply Agreement. Due to the inherent uncertainty in obtaining regulatory approval, the applicability of the Supply Agreement is outside the control of the Company and Biogen. Accordingly, the Company has determined the Supply Agreement is a contingent deliverable at the onset of the agreement. As a result, the Company has determined the Supply Agreement does not meet the definition of a deliverable that needs to be accounted for at the inception of the arrangement. The Company has also determined that there is no significant

and incremental discount related to the supply agreement since Biogen will pay the same amount for inventory that the Company would pay and the Company effectively acts as a middle man in the arrangement for which it adds no significant value due to various factors such as the Company does not have any manufacturing capabilities or other know how with respect to the manufacturing process.

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and reliable evidence of fair value for the deliverables. Accordingly, the non-contingent deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen as revenue and the associated payment to Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company had determined this was the most probable expected benefit period. The Company recognized \$2.3 million in license revenue, a portion of the \$110.0 million received from Biogen, and \$159,000 in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during the three-month periods ended March 31, 2015 and 2014. The Company currently estimates the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

On January 21, 2011 Biogen announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of Fampryra to improve walking ability in adult patients with multiple sclerosis. Biogen, working closely with the Company, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization, and in July 2011 Biogen received conditional approval from the European Commission for, Fampryra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7).

As part of its ex-U.S. license agreement, Biogen owes Acorda royalties based on ex-U.S. net sales, and milestones based on ex-U.S. regulatory approval and new indications. These milestones included a \$25.0 million payment for approval of the product in the European Union which was recorded and paid in the three month period ended September 30, 2011. Based on Acorda's worldwide license and supply agreement with Alkermes, Alkermes received 7% of this milestone payment from Acorda during the same period. For revenue recognition purposes, the Company has determined this milestone to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangement as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in the research and development of new products and the uncertainty involved with obtaining regulatory approval. Biogen leveraged Acorda's U.S. Ampyra study results that contributed to the regulatory approval process. Therefore, the milestone was achieved based in part on Acorda's past performance. The milestone was also reasonable relative to all deliverable and payment terms of the collaboration arrangement. Therefore, the payment was recognized in its entirety as revenue and the cost of the milestone revenue was recognized in its entirety as an expense during the three-month period ended September 30, 2011. The Company recognized \$2.3 million and \$2.4 million in royalty revenue for the three-month periods ended March 31, 2015 and 2014, respectively, related to ex-U.S. sales of Fampryra by Biogen.

#### Actavis/Watson

The Company has an agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules which was launched in February 2012. In accordance with the agreement, the Company receives a royalty based on Watson's gross margin, as defined by the agreement, of the authorized generic product. During the three-month periods ended March 31, 2015 and 2014, the Company recognized royalty revenue of \$1.8 million and \$1.4 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the three-month periods ended March 31, 2015 and 2014, the Company also recognized revenue and a corresponding cost

of sales of \$179,000 and \$830,000, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Actavis, which is recorded in net product revenues and cost of sales.

Neuronex

In December 2012, the Company acquired Neuronex, Inc., a privately-held development stage pharmaceutical company (Neuronex) developing Plumiaz (our trade name for Diazepam Nasal Spray). Plumiaz is a proprietary nasal spray formulation of diazepam that we are developing under Section 505(b)(2) of the Food, Drug and Cosmetic Act as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who experience

intermittent bouts of increased seizure activity also known as seizure clusters or acute repetitive seizures, or ARS.

Under the terms of the agreement, the Company made an upfront payment of \$2.0 million in February 2012. The Company also paid \$1.5 million during the twelve month period ended December 31, 2012 pursuant to a commitment under the agreement to fund research to prepare for the Plumiaz pre-NDA meeting with the FDA. In December 2012, the Company completed the acquisition by paying \$6.8 million to former Neuronex shareholders less a \$300,000 holdback provision. After adjustment for Neuronex's working capital upon closing of the acquisition, approximately \$120,000 of the holdback amount was remaining as of December 31, 2013. This balance was paid to the former equity holders of Neuronex pursuant to the merger agreement in February 2014.

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

The patent and other intellectual property and other rights relating to Diazepam Nasal Spray products are licensed from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which granted worldwide rights to Neuronex, except certain specified Asian countries, the Company's subsidiary Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product (including a \$1 million payment that was triggered during the three-month period ending September 30, 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz and paid during the three-month period ending December 31, 2013), and up to \$3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

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

#### (10) Commitments and Contingencies

A summary of the Company's commitments and contingencies was included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

In March 2015, Civitas exercised its right to extend the term of a sublease for five additional years, until December 31, 2020, and Civitas retains the right to further extend the sublease beyond that date for another five year period. The base rent is currently \$722,000 per year. For each extension period, the economic terms of the sublease will be determined by a process set forth in the sublease, and the Company will be required to provide a letter of credit in an amount equal to the full five-year lease obligation for each lease extension period and additional security. Alkermes leases the building pursuant to an overlease with H&N Associates, LLC, and has extension rights pursuant to the

overlease that correspond to Civitas' extension rights under the sublease. Alkermes has exercised a five-year extension option under the overlease that corresponds with Civitas' exercise of its five year extension option under the sublease. Pursuant to the sublease, Civitas has agreed to comply with all of Alkermes's obligations under the overlease.

The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. While losses, if any, are possible, the Company is not able to estimate any ranges of losses as of March 31, 2015. 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 neurological function and improve the lives of people with neurological disorders. We market three FDA-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. We have one of the leading pipelines in the industry of novel neurological therapies. We are currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders, including chronic post-stroke walking deficits (PSWD), Parkinson's disease, epilepsy, heart failure, MS, and spinal cord injury.

Ampyra

General

Ampyra was approved by the FDA in January 2010 for the improvement of walking in people with MS. To our knowledge, Ampyra is the first and only drug approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the United States in March 2010. Net revenue for Ampyra was \$92.4 million for the three months ended March 31, 2015 and \$72.5 million for the three months ended March 31, 2014.

Since the March 2010 launch of Ampyra, more than 100,000 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 December 2014, approximately 70% of all people with MS who were prescribed Ampyra received a first refill, and approximately 40% of all people with MS who were prescribed Ampyra have been dispensed at least six months of the medicine through refills, consistent with previously reported trends. These refill rates exclude patients who started Ampyra through our First Step trial program. Our First Step program provides eligible patients with two months of Ampyra at no cost. More than 65% of new Ampyra patients currently enroll in First Step. The program is in its fourth year, and data show that First step participants have higher compliance and persistency rates over time compared to non-First Step patients. Approximately 50% of patients who initiate Ampyra therapy with the First Step free trial program convert to paid prescriptions.

Ampyra is marketed in the United States through our own specialty sales force and commercial infrastructure. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, Managed Markets Account Directors who provide information and assistance to payers and physicians on Ampyra, National Trade Account Managers who work with wholesalers and our limited network of specialty pharmacies, and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Ampyra is distributed in the United States exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which 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 between 10 to 30 days.

We have contracted with a third party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, or APSS, a dedicated resource that coordinates the prescription process among healthcare providers, people with MS, and insurance carriers. Processing of most incoming requests for prescriptions by APSS begins within 24 hours of receipt. Patients will experience a range of times to receive their first shipment based on the processing time for insurance requirements. As with any prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription.

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

#### License and Collaboration Agreement with Biogen

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

#### Ampyra Patent Update

We have five issued patents listed in the Orange Book for Ampyra, one of which issued in 2014, 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, which issued in January 2013, is U.S. Patent No. 8,354,437, which includes claims relating to methods to improve walking, increase walking speed, and treat walking disability in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2026.
- The fourth, which issued in May 2013, is U.S. Patent No. 8,440,703, which includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with MS by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2025.
- The fifth, which issued in March of 2014, is U.S. Patent No. 8,663,685 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Absent patent term adjustment, the patent is set to expire in 2025.

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

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis FL, Inc., Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. This litigation is further described





above in Part II, Item 1 of this report. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

On May 6, 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Limited, or Sun Pharmaceuticals, advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun Pharmaceuticals has challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and they have also asserted that generic versions of their products may not infringe certain claims of these patents. We have 45 days from the date of receipt of this Paragraph IV Certification Notice to file suit in U.S. District Court, which will institute a 30 month statutory stay of approval period to the Sun Pharmaceuticals ANDA under the Hatch-Waxman Act. Since the Sun Pharmaceuticals ANDA was filed after January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra, the 30 month statutory stay of approval will start from the receipt of the Paragraph IV Certification Notice. This restricts the FDA from approving the ANDA until November 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. We are currently reviewing the Paragraph IV Certification Notice.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings and defend our patents. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

In 2011, the European Patent Office, or EPO, granted EP 1732548, the counterpart European patent to U.S. Patent No. 8,354,437 with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both 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. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines.

We will vigorously defend our intellectual property rights.

#### Zanaflex

Zanaflex Capsules and Zanaflex tablets are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many central nervous system disorders, including MS and spinal cord injury. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. We launched Zanaflex Capsules in April 2005 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. Combined net revenue of Zanaflex Capsules and Zanaflex tablets was \$691,000 for the three months ended March 31, 2015 and \$900,000 for the three months ended March 31, 2014. In 2012, Apotex commercially launched a generic version of tizanidine hydrochloride capsules, and we also launched our own authorized generic version, which is being marketed by Watson Pharma (a subsidiary of Actavis). In March 2013, Mylan Pharmaceuticals commercially launched their own generic version of Zanaflex Capsules. The commercial launch of generic tizanidine hydrochloride capsules has caused a significant decline in net revenue from the sale of Zanaflex Capsules, and the launch of these generic versions and the potential launch of other generic versions is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2015 and beyond.

#### Qutenza

Qutenza is a dermal patch containing 8% prescription strength capsaicin the effects of which can last up to three months and is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain. We acquired commercialization rights to Qutenza in July 2013 from NeurogesX, Inc. These rights include the United States, 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 United States using our existing commercial organization, including our specialty neurology sales force as well as our medical and safety reporting infrastructure. Net revenue for Qutenza was \$222,000 for the three months ended March 31, 2015 and \$209,000 for the three months ended March 31, 2014.

Astellas Pharma Europe Ltd. has exclusive commercialization rights for Qutenza in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland, certain countries in Eastern Europe, the Middle East and Africa.

#### Research & Development Programs

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

#### CVT-301 and ARCUS Technology

On October 22, 2014, we completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation. As a result of the acquisition, we acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease. Our acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas, and a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space.

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

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

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

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

#### Ampyra/Dalfampridine Development Programs

We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. In December 2014, we announced that the first patient has been enrolled in a Phase 3 clinical trial evaluating the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. As part of the trial design, we are planning to conduct an interim analysis of the trial data, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study, we determined that the initial QD formulation that we had been developing with an external partner was not practical for further testing. We are working with different external partners to develop a new QD formulation that could be included in future post-stroke studies.

#### Plumiaz

We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We have engaged with the FDA regarding Plumiaz and expect to provide an update on this program in the second quarter of 2015.

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. We believe this product has the potential to generate peak annual sales significantly higher than \$100 million.

#### Cimaglermin alfa (also known as GGF2)/Neuregulins

Cimaglermin alfa, which we previously referred to as GGF2, is our lead product candidate for our neuregulin program. We have completed a cimaglermin Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. Data from this trial showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting toxicity was also identified in the highest planned dose cohort, specifically acute liver injury meeting Hy's Law for drug induced hepatotoxicity. In March 2015, we presented new analyses of data from this trial at the American College of Cardiology (ACC) 64th Annual Scientific Session and Expo. These analyses found that cimaglermin produced a dose-dependent benefit at multiple time points for up to three months following a single infusion.

In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product independently or to enter into a partnership, most likely with a cardiovascular-focused company.

#### Remyelinating Antibodies

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

## Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

Based on these data, we intend to advance clinical development of rHIgM22 for MS. We expect to begin a second Phase 1 trial in relapsing MS patients in the second quarter of 2015, and we expect trial results in 2016.

### 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 United States, Canada, Latin America and certain other territories. Astellas Pharma Europe Ltd. has an option to develop NP-1998 in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland, certain countries in Eastern Europe, the Middle East and Africa. We believe this liquid formulation of the capsaicin-based therapy has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, we have evaluated and reprioritized our research and development pipeline based on our recent acquisition of Civitas, and as a result we have no current plans to invest in further development of NP-1998 for neuropathic pain.

### Corporate Facilities Update

We currently lease approximately 138,000 square feet of office and laboratory space in Ardsley, NY. Our lease for this facility includes options to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. In May 2014, we notified the landlord that we were exercising our option to expand into an additional 25,405 square feet of office space. We occupied the additional space in the first quarter of 2015.

Our 2014 acquisition of Civitas Therapeutics, Inc. included a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas subleases the Chelsea, Massachusetts facility from Alkermes, Inc. The sublease is an operating lease that was scheduled to expire on December 31, 2015. In March 2015, Civitas exercised its right to extend the term of the sublease for five additional years, until December 31, 2020, and Civitas retains the right to further extend the sublease beyond that date for another five year period. The base rent is currently \$722,000 per year. For each extension period, the economic terms of the sublease will be determined by a process set forth in the sublease, and we will be required to provide a letter of credit in an amount equal to the full five-year lease obligation for each lease extension period and additional security. Alkermes leases the building pursuant to an overlease with H&N Associates, LLC, and has extension rights pursuant to the overlease that correspond to Civitas' extension rights under the sublease. Alkermes has exercised a five-year extension option under the overlease that corresponds with Civitas' exercise of its five year extension option under the sublease. Pursuant to the sublease, Civitas has agreed to comply with all of Alkermes' obligations under the overlease.

### Outlook for 2015

#### Financial Guidance for 2015

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

- We expect 2015 net revenue from the sale of Ampyra to range from \$405 million to \$420 million.
- We expect Zanaflex (tizanidine hydrochloride) and ex-U.S. Fampyra (prolonged-release fampridine tablets) 2015 revenue to be approximately \$25 million, which includes net sales of branded Zanaflex products and royalties from ex-U.S. Fampyra and authorized generic tizanidine hydrochloride capsule sales.
- Research and development (R&D) expenses in 2015 are expected to range from \$150 million to \$160 million, excluding share-based compensation charges and expenditures related to the potential acquisition of new products or other business development activities. The increase in research and development expenses in 2015 is primarily related to Phase 3 studies of dalfampridine and CVT-301. Additional expenses include continued development of



Plumiaz, clinical trials for cimaglermin alfa (previously GGF2) and rHlgM22 and CVT-427, as well ongoing preclinical studies.

- Selling, general and administrative expenses (SG&A) in 2015 are expected to range from \$180 million to \$190 million, excluding share-based compensation charges. We are setting a high priority on managing selling, general and administrative expenses in 2015.

We are evaluating the impact of recent events on both R&D and SG&A expenses for 2015, and will provide an update on our next earnings call if there are any changes to guidance.

The range of SG&A and R&D expenditures for 2015 are non-GAAP financial measures because they exclude share-based compensation charges and certain non-cash expenses related to the Civitas acquisition. 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 and certain non-cash expenses related to the Civitas acquisition 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 and certain non-cash expenses related to the Civitas acquisition to establish budgets and operational goals, and to manage our business and to evaluate its performance.

#### Development Pipeline Goals

Our planned goals and key initiatives with respect to our pipeline during 2015 and beyond are as follows:

- Continue progressing our Phase 3 efficacy and safety studies of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We expect results from the efficacy trial in 2016, and plan to file a new drug application, or NDA, in the U.S. by the end of 2016.
  - Continue progressing our Phase 3 clinical trial assessing the use of a once-daily (BID) formulation of dalfampridine as a treatment for chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. As part of the trial design, we are planning to conduct an interim analysis of the trial data, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We are working with different external partners to develop a once-daily (QD) formulation that could be included in future post-stroke studies.
- We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We have engaged with the FDA regarding Plumiaz and expect to provide an update on this program in the second quarter of 2015.
- Complete our second clinical trial of cimaglermin alfa (previously GGF2), a Phase 1b single-infusion trial in people with heart failure assessing the tolerability of three dose levels of cimaglermin, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. In October 2013, we announced that the first patient had been enrolled in this clinical trial. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015.
- Our Phase 1 clinical trial of rHlgM22 found no dose-limiting toxicities at any of the five dose levels studied. In addition, testing detected rHlgM22 in cerebrospinal fluid (CSF), indicating the drug's access to the central nervous system. Based on these data, we intend to advance clinical development of rHlgM22 for MS. We expect to begin a second Phase 1 trial in relapsing MS patients in the second quarter of 2015, and we expect trial results in 2016.

•

We are preparing an IND for and to initiate the first Phase 1 clinical trial of CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes.

Results of Operations

Three-Month Period Ended March 31, 2015 Compared to March 31, 2014

Net Product Revenues

Ampyra

We recognize product sales of Ampyra following receipt of product by our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra to these customers of \$92.4 million as compared to \$72.5 million for the three-month periods ended March 31, 2015 and 2014, respectively, an increase of \$19.9 million, or 27.4%. The net revenue increase was comprised of net volume increases of \$11.1 million due to greater demand we believe due to, in part, the success of certain marketing programs such as our First Step and Step Together programs and price increases net of discount and allowance adjustments of \$8.8 million. Effective January 1, 2015, we increased our sale price to our customers by 10.95%.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers, Kaiser Permanente and ASD Specialty Healthcare, Inc. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances also consist of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

The net revenue for the three-month period ended March 31, 2015 decreased from net revenue of \$109.9 million for the three-month period ended December 31, 2014. We believe that the decrease in net revenue between the fourth quarter of 2014 and the first quarter of 2015 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 2014 that was destocked during the first quarter.

Zanaflex

We recognize product sales of Zanaflex Capsules and Zanaflex tablets using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$691,000 for the three-month period ended March 31, 2015, as compared to \$900,000 for the three-month period ended March 31, 2014. Net product revenues also include \$179,000 which represents the sale of our Zanaflex Capsules authorized generic product to Actavis for the three-month period ended March 31, 2015 as compared to \$830,000 for the three-month period ended March 31, 2014. Generic competition has caused a significant decline in sales of Zanaflex Capsules and is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2015 and beyond. The decrease in net revenues was also the result of a disproportionate increase in discounts and allowances due to the mix of customers continuing to purchase our product. These customers receive higher levels of rebates and allowances.

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

Qutenza

We recognize product sales of Qutenza following receipt of product by our specialty distributors. We recognized net revenue from the sale of Qutenza of \$222,000 and \$209,000 for the three-month periods ended March 31, 2015 and 2014, respectively. For the foreseeable future we do not expect that sales of this product will materially contribute to our revenues.



#### License Revenue

We recognized \$2.3 million in license revenue for the three-month periods ended March 31, 2015 and 2014, related to the \$110.0 million received from Biogen in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

#### Royalty Revenue

We recognized \$2.3 million and \$2.4 million in royalty revenue for the three-month periods ended March 31, 2015 and 2014, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized \$1.8 million and \$1.4 million in royalty revenue for the three-month periods ended March 31, 2015 and 2014, respectively, related to the authorized generic sale of Zanaflex Capsules.

#### Cost of Sales

We recorded cost of sales of \$18.4 million for the three-month period ended March 31, 2015 as compared to \$15.5 million for the three-month period ended March 31, 2014. 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. Cost of sales for the three-month period ended March 31, 2015 also consisted of \$2.1 million in royalty fees based on net product shipments, \$147,000 in amortization of intangible assets, and \$85,000 in period costs related to freight, stability testing, and packaging. Cost of sales also included \$179,000, which represents the cost of Zanaflex Capsules authorized generic product sold for the three-month period ended March 31, 2015.

Cost of sales for the three-month period ended March 31, 2014 consisted primarily of \$12.7 million in inventory costs related to recognized revenues. Cost of sales for the three-month period ended March 31, 2014 also consisted of \$1.7 million in royalty fees based on net product shipments, \$179,000 in amortization of intangible assets, and \$88,000 in period costs related to freight, stability testing, and packaging. Cost of sales also included \$830,000, which represents the cost of Zanaflex Capsules authorized generic product sold for the three-month period ended March 31, 2014.

#### Cost of License Revenue

We recorded cost of license revenue of \$159,000 for the three-month periods ended March 31, 2015 and 2014, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen as a result of our collaboration agreement.

#### Research and Development

Research and development expenses for the three-month period ended March 31, 2015 were \$30.6 million as compared to \$14.5 million for the three-month period ended March 31, 2014, an increase of approximately \$16.1 million, or 111%. The increase was primarily due to \$11.3 million in CVT-301 and CVT-427 expenses incurred in 2015 after the acquisition of Civitas in October 2014. The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$2.7 million to support the various research and development initiatives related to our product pipeline, as well as increases in expenses for various other research and development programs, including \$1.5 million related to our life cycle management program for Ampyra, \$795,000 in expenses relating to our NP-1998 program, and \$333,000 related to our Chondroitinase program. The increase in expenses related to our NP-1998 program is primarily attributable to drug supply purchase commitments made earlier in 2014 prior to the program re-prioritization. The increases in research and development expenses for the three-month period ended March 31, 2015 were partially offset by a decrease of \$359,000 related to the Plumiaz program.

#### Selling, General and Administrative

Sales and marketing expenses for the three-month period ended March 31, 2015 were \$25.0 million compared to \$26.6 million for the three-month period ended March 31, 2014, a decrease of approximately \$1.6 million, or 6%. The decrease was attributable to a decrease of \$1.8 million for pre-launch activities associated with the possible commercialization of Plumiaz and a decrease in overall marketing, selling, distribution, and market research expenses for Ampyra of \$921,000. The decrease in sales and marketing expenses was partially offset by an increase in overall compensation, benefits, and other selling expenses of \$1.1 million, including sales force incentive compensation.

General and administrative expenses for the three-month period ended March 31, 2015 were \$23.8 million compared to \$20.3 million for the three-month period ended March 31, 2014, an increase of approximately \$3.5 million, or 17%. This increase was primarily the result of an increase of \$4.2 million for staff and compensation expenses and other expenses related to supporting the growth of the organization, including the acquisition of Civitas in October 2014, and an increase of \$836,000 in legal fees. The increases in general and administrative expenses for the three-month period ended March 31, 2015 were partially offset by a decrease of \$1.1 million for work on FDA post-approval requirements for the Zanaflex franchise and \$588,000 in drug safety and surveillance expenses.

#### 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 will be assessed quarterly. We recorded a \$3.1 million expense pertaining to changes in the fair-value of our acquired contingent consideration as of March 31, 2015. The changes in the fair-value of the acquired contingent consideration were due to the re-calculation of discounted cash flows for the passage of time. There were no other changes to the valuation techniques or assumptions.

#### Other Income / Expense

Other expense was \$3.9 million for the three-month period ended March 31, 2015 compared to other income of \$80,000 for the three-month period ended March 31, 2014, an increase of \$3.9 million. The increase was due to an increase in interest expense of \$4.0 million, principally related to the cash and non-cash portions of interest expense for the convertible senior notes issued in June 2014 (the Notes). Interest expense related to the Notes was \$3.6 million for the three-month period ended March 31, 2015, of which the non-cash portion was \$2.1 million. We will report interest expense in future quarters of between \$3.6 million and \$4.3 million related to the Notes.

#### Provision for Income Taxes

For the three-month periods ended March 31, 2015 and 2014, the Company recorded a \$2.0 million benefit from and \$2.8 million provision for income taxes, respectively, based upon its estimated tax liability for the year. The provision for income taxes is based on federal, state and Puerto Rico income taxes. The effective income tax rates for the Company for the three-month periods ended March 31, 2015 and 2014 were 40% and 80%, respectively. As a result of the Federal research and development tax credit not being extended during the first quarter of 2015, the Company was not able to receive a benefit in the effective tax rate for this in 2015. The Company, however, was able to receive a benefit in the effective tax rate for 2015 for the Massachusetts state research and development tax credit in addition to the Federal orphan drug credit.

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

#### 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 and Zanaflex Capsules, and, to a lesser extent, from loans, government grants and our financing arrangement with Paul Royalty Fund (PRF).

We were cash flow positive in 2014 and, at March 31, 2015, we had \$299.7 million of cash, cash equivalents and short-term investments, compared to \$307.6 million at December 31, 2014. We expect to remain cash flow positive in 2015. We believe that we have sufficient cash, cash equivalents and short-term investments on hand, in addition to cash expected to be generated from operations, to fund our operations, including our currently anticipated development pipeline activities as currently planned.

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Ampyra, the continued progress of our research and development activities, the amount and timing of milestone or other payments payable under collaboration, license and acquisition agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, and capital required or

used for future acquisitions or to in-license new products and compounds including the development costs relating to those products or compounds. To the extent our capital resources are insufficient to meet future operating requirements we will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund our operations. If we require additional financing in the future, we cannot assure you that it will be available to us on favorable terms, or at all.

#### Financing Arrangements

##### Saints Capital Notes

In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, Elan transferred these promissory notes to funds affiliated with Saints Capital. As of March 31, 2015, \$2.2 million of these promissory notes was outstanding, which amount includes accrued interest. The fifth of seven annual payments on this note was due and paid on the five year anniversary of Ampyra approval on January 22, 2015 and will continue to be paid annually until paid in full.

##### Zanaflex Revenue Interests Assignment

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006. An additional \$5.0 million was due to us if net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in our December 31, 2006 financial statements. Under the terms of the amendment, we repaid PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met. In November 2014, PRF sold its Zanaflex revenue interest to Valeant Pharmaceuticals International, Inc.

Under the revenue interests assignment agreement and the amendment, PRF was entitled to, and now as PRF's successor, Valeant is entitled to the following portion of Zanaflex net revenues:

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

Notwithstanding the foregoing, once PRF and Valeant, as PRF's successor, have received and retained payments under the agreement that are at least 2.1 times the aggregate amount PRF paid us under the agreement, Valeant will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we recorded a liability as of March 31, 2015, referred to as the revenue interest liability, of approximately \$749,000. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 5.8%. Payments made to Valeant as a result of Zanaflex sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability.

Upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain of the covenants, representations or warranties we make under the agreement, Valeant may (i) require us to repurchase the rights we sold them at the "put/call price" in effect on the date such right is exercised or (ii) foreclose on the Zanaflex assets that secure our obligations to Valeant. Except in the case of certain bankruptcy events, if Valeant exercises its right, which we



refer to as Valeant's put option, to cause us to repurchase the rights we assigned to it, Valeant may not foreclose unless we fail to pay the put/call price as required. If we experience a change of control we have the right, which we refer to as our call option, to repurchase the rights we sold under the revenue interests assignment agreement at the "put/call price" in effect on the date such right is exercised. The put/call price on a given date is the greater of (i) all payments made by PRF/Valeant to us as of such date, less all payments received by PRF/Valeant from us as of such date, and (ii) an amount that would generate an internal rate of return to PRF/Valeant of 25% on all payments made by PRF/Valeant to us as of such date, taking into account the amount and timing of all payments received by PRF/Valeant from us as of such date. We have determined that Valeant's put option and our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. As of March 31, 2015, we have no liability recorded related to the put/call option to reflect its current estimated fair value. This liability is revalued on an as needed basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings.

#### Convertible Senior Notes

In June 2014, the Company entered into an underwriting agreement (the Underwriting Agreement) with J.P. Morgan Securities LLC (the Underwriter) relating to the issuance by the Company of \$345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the Notes) in an underwritten public offering pursuant to the Company's Registration Statement on Form S-3 (the Registration Statement) and a related preliminary and final prospectus supplement, filed with the Securities and Exchange Commission (the Offering). The principal amount of Notes included \$45 million aggregate principal amount of Notes that was purchased by the Underwriter pursuant to an option granted to the Underwriter in the Underwriting Agreement, which option was exercised in full. The net proceeds from the offering, after deducting the Underwriter's discount and the offering expenses paid by the Company, were approximately \$337.5 million.

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

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

The Company will pay 1.75% interest per annum on the principal amount of the Notes, payable semiannually in arrears in cash on June 15 and December 15 of each year. The first payment was made in December 2014 in the amount of \$2.9 million. The Notes will mature on June 15, 2021.

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

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

The Notes will be senior unsecured obligations and will rank equally with all of the Company's existing and future senior debt and senior to any of the Company's subordinated debt. The Notes will be structurally subordinated to all existing or future indebtedness and other liabilities (including trade payables) of the Company's subsidiaries and will be effectively subordinated to the Company's existing or future secured indebtedness to the extent of the value of the collateral. The Indenture does not limit the amount of debt that the Company or its subsidiaries may incur.

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

Our outstanding note balances as of March 31, 2015 consisted of the following:

(In thousands)	March 31, 2015
<b>Liability component:</b>	
Principal	\$ 345,000
Less: debt discount, net	(55,393)
Net carrying amount	\$ 289,607
Equity component	\$ 61,195

#### Investment Activities

At March 31, 2015, cash, cash equivalents and short-term investments were approximately \$299.7 million, as compared to \$307.6 million at December 31, 2014. Our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in a Treasury money market fund and US Treasury bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of March 31, 2015, our cash and cash equivalents were \$61.5 million, as compared to \$182.2 million as of December 31, 2014. Our short-term investments consist of US Treasury bonds with original maturities greater than three months and less than one year. The balance of these investments was \$238.2 million as of March 31, 2015, as compared to \$125.4 million as of December 31, 2014.

#### Net Cash (Used in) / Provided by Operations

Net cash used in operations was \$9.2 million for the three-month period ending March 31, 2015 while \$4.3 million was provided by operations in the three-month period ended March 31, 2014. Cash used in operations for the three-month period ended March 31, 2015 was primarily due to a net increase in working capital items of \$13.8 million primarily attributable to an increase in inventory held by the company, a net loss of \$3.1 million principally resulting from an overall increase in operating expenses, a decrease in deferred license revenue of \$2.3 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009, and a deferred tax benefit of \$2.0 million. Cash used in operations was partially offset by a non-cash share-based compensation expense of \$7.1 million, depreciation and amortization of \$3.7 million, a non-cash charge for the change in the contingent consideration obligation of \$3.1 million, and amortization of the debt discount and debt issuance costs of \$2.1 million.

Cash provided by operations for the three-month period ended March 31, 2014 was primarily due to a non-cash share-based compensation expense of \$5.8 million, a deferred tax provision of \$2.8 million, depreciation and amortization of \$1.8 million, and net income of \$0.7 million principally resulting from an increase in net product revenues. Cash provided by operations was partially offset by a net increase in working capital items of \$5.4 million primarily attributable to an increase in inventory held by the company and a decrease in accounts payable resulting from payment timing.

#### Net Cash Used in Investing

Net cash used in investing activities for the three-month period ended March 31, 2015 was \$116.0 million, primarily due to \$169.6 million in purchases of investments, purchases of property and equipment of \$2.6 million, and purchases of intangible assets of \$0.2 million, partially offset by \$56.3 million in proceeds from maturities and sales of investments.

#### Net Cash Provided by Financing

Net cash provided by financing activities for the three-month period ended March 31, 2015 was \$4.6 million, primarily due to \$4.7 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by \$0.1 million in repayments to PRF.

#### Contractual Obligations and Commitments

A summary of our minimum contractual obligations related to our major outstanding contractual commitments is included in our Annual Report on Form 10-K for the year ended December 31, 2014. Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. Under certain supply agreements and other agreements with manufacturers and suppliers, we are required to make payments for the manufacture and supply of our clinical and approved products. During the three-month period ended March 31, 2015, commitments related to the purchase of inventory decreased as compared to December 31, 2014. As of March 31, 2015, we have inventory-related purchase commitments totaling approximately \$29.3 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. As of March 31, 2015, we have committed to make potential future milestone payments to third parties of up to approximately \$169 million as part of our various collaborations, including licensing and development programs. This represents a decrease of approximately \$35 million as compared to December 31, 2014, due to the termination of certain license agreements. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of March 31, 2015, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

Our 2014 acquisition of Civitas included a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas subleases the Chelsea, Massachusetts facility from Alkermes, Inc. The sublease is an operating lease that was scheduled to expire on December 31, 2015. In March 2015, Civitas exercised its right to extend the term of the sublease for five additional years, until December 31, 2020, and Civitas retains the right to further extend the sublease beyond that date for another five year period. The base rent is currently \$722,000 per year. For each extension period, the economic terms of the sublease will be determined by a process set forth in the sublease, and we will be required to provide a letter of credit in an amount equal to the full five-year lease obligation for each lease extension period and additional security. Alkermes leases the building pursuant to an overlease with H&N Associates, LLC, and has extension rights pursuant to the overlease that correspond to Civitas' extension rights under the sublease. Alkermes has exercised a five-year extension option under the overlease that corresponds with Civitas' exercise of its five year extension option under the sublease. Pursuant to the sublease, Civitas has agreed to comply with all of Alkermes's obligations under the overlease.

### Critical Accounting Policies and Estimates

Our critical accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2014. As of March 31, 2015, our critical accounting policies have not changed materially from December 31, 2014.

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

Our financial instruments consist of cash equivalents, short-term investments, grants receivable, convertible notes payable and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying values at March 31, 2015.

We have cash equivalents and short-term investments at March 31, 2015, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds and US Treasury bonds, the carrying value of our cash equivalents and short-term investments approximate their fair value at March 31, 2015. At March 31, 2015, we held \$299.7 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 0.1%.

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

### Item 4. Controls and Procedures

#### Evaluation of disclosure controls and procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act") we carried out an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the first quarter of 2015, the period covered by this report. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of March 31, 2015, our disclosure controls and procedures were effective to achieve their stated purpose.

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

#### Change in internal control over financial reporting

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our chief executive officer and chief financial officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended March 31, 2015, 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. On September 6, 2011, we filed a citizen petition with the FDA requesting that the FDA not approve Apotex's ANDA because of public-safety concerns about Apotex's proposed drug. On December 2, 2011, Apotex filed suit against us in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleged, among other claims, that we engaged in anticompetitive behavior and false advertising in connection with the development and marketing of Zanaflex Capsules, including that the citizen petition we filed with the FDA delayed FDA approval of Apotex's generic tizanidine capsules. On January 26, 2012, we moved to dismiss or stay Apotex's suit. On February 3, 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. On February 21, 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. Following our filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed five of the six counts in the amended complaint, including all of the antitrust claims, leaving only a claim under the Lanham Act relating to alleged product promotional activities. In October 2014, the Court granted our motion for summary judgment against Apotex's remaining claim. On November 20, 2014, Apotex filed a Notice of Appeal to the Second Circuit Court of Appeals seeking an appeal of both the motion to dismiss and summary judgment decisions. The Company will defend itself vigorously throughout the appeal process.

Ampyra Patents

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis FL, Inc., Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to the filing of these ANDAs, in July 2014, we filed lawsuits against these generic pharmaceutical manufacturing companies in the U.S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 5,540,938, 8,007,826, 8,354,437, 8,440,703, and 8,663,685. Requested judicial remedies include recovery of litigation costs and injunctive relief, including a request that the effective date of any FDA approval for these generic companies to make, use, offer for sale, sell, market, distribute, or import the proposed generic products be no earlier than the dates on which the Ampyra Orange-book listed patents expire, or any later expiration of exclusivity to which we are or become entitled. On April 22, 2015, the District Court issued a scheduling order with respect to all eight generic challengers. Pursuant to the scheduling order, a Markman hearing is currently scheduled for March 7, 2016, and the patent trial is scheduled to start 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 August 2014, Mylan Pharmaceuticals, Inc. and its parent, Mylan, Inc. (collectively, “Mylan”), filed a motion challenging the jurisdiction of the U.S. District Court for the District of Delaware. On January 14, 2015, the Court denied Mylan’s motion to dismiss with respect to the ANDA filer, Mylan Pharmaceuticals, Inc. On January 30, 2015, the Court granted Mylan’s request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit Court of Appeals. The Company will defend itself vigorously throughout the appeal process. Due to Mylan’s motion to dismiss, we also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. Patents and requesting the same judicial relief as in the Delaware action. On December 17, 2014, we filed a motion in the Northern District of West Virginia to stay that action in deference to the Delaware proceeding and until the issue of jurisdiction has been decided. On February 11, 2014, the District Court for the Northern District of West Virginia granted Acorda’s 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 other seven generics at the present time.

On May 6, 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Limited, or Sun Pharmaceuticals, advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun Pharmaceuticals has challenged the validity of four of our five Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and they have also asserted that generic versions of their products may not infringe certain claims of these patents. We have 45 days from the date of receipt of this Paragraph IV Certification Notice to file suit in U.S. District Court, which will institute a 30 month statutory stay of approval period to the Sun ANDA under the Hatch-Waxman Act. Since the Sun Pharmaceuticals ANDA was filed after January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra, the 30 month statutory stay of approval will start from the receipt of the Paragraph IV Certification Notice. This restricts the FDA from approving the ANDA until November 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. We are currently reviewing the Paragraph IV Certification Notice.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings and defend our patents. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

We will vigorously defend our intellectual property rights.

#### Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A. Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2014, as updated by this Item 1A, all of which could materially affect our business, financial condition or future results. These risks are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Following is the restated text of certain risk factors, and additional risk factors, to report changes since our publication of risk factors in our 2014 Annual Report on Form 10-K.

The approval of Zanaflex Capsules is subject to certain post-approval regulatory requirements that we have not completed, and we may be subject to penalties if we fail to comply with these requirements and our Zanaflex products could be subject to enforcement actions or withdrawal from the market.

We have an outstanding FDA commitment, inherited from Alkermes (formerly Elan), to provide an assessment of the safety and effectiveness of Zanaflex Capsules in pediatric patients. This commitment, which is included in the NDA approval for Zanaflex Capsules, was to be satisfied by February 2007. We provided retrospective pediatric safety data to the FDA in April 2007. However, we were not able to complete the pediatric pharmacokinetic study by the February 2007 deadline due to delays in investigator recruitment and obtaining Institutional Review Board approvals. The study was completed and the final report submitted to the FDA in April 2008. The FDA reviewed our report against new standards set out in the Pediatric Research Equity Act (PREA) and reauthorized by both the 2007 FDA Amendments Act (FDAAA) and the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) and concluded that the report did not satisfy the commitment. The FDA has informed us that a series of studies designed to further characterize the pharmacokinetics and demonstrate the efficacy and long-term safety of Zanaflex Capsules in

children are required to fulfill the pediatric commitment for Zanaflex Capsules. In June 2011, the FDA informally advised us that it would be amending the pediatric commitment for Zanaflex Capsules to require a non-clinical juvenile toxicology study, as well as formalize the timeline for the required pediatric studies. In December 2012, the FDA issued a formal written request that confirmed the information in its informal June 2011 request, and set forth specific deadlines for the required pediatric nonclinical and clinical studies. In January 2013, we submitted a request in writing to the FDA to extend the deadlines for these studies, and in September 2014 we received a “Denial of Deferral Request” letter from the FDA. We responded to this denial letter in October 2014, requesting the FDA to reconsider the denial, which FDA again denied in March 2015. Subsequently in March 2015, we received a notice of non-compliance with PREA. In April 2015, we responded in writing to this notice and also submitted a request for waiver from the pediatric commitments, and we await a further response from the FDA. Additionally, and

separate from the pediatric commitment, the FDA asked for, and we have completed, a clinical electrocardiogram study in adult humans to investigate potential QT prolongation (heart rhythm measure). The clinical study report has been submitted to the FDA and remains subject to FDA review and potential FDA action based on its review of the data. The remaining studies could be more extensive and more costly than our prior studies and might result in new data that are not consistent with the current safety and efficacy profile of the drug, which might require us to change our product labeling and could harm product sales. We also may be subject to penalties for not meeting our pediatric study commitments, including a court-imposed injunction to conduct studies.

Our business could be harmed by requirements to publicly disclose our clinical trial data.

There is an increasing trend across multiple jurisdictions, including the United States and the EU, towards requiring greater transparency, particularly in the area of clinical trial results. In the EU, for example, the European Medicines Agency, or EMA, has instituted a new policy on transparency of clinical trial data submitted to the agency in applications for marketing authorization. These data traditionally have been regarded as confidential commercial information not subject to disclosure. Although the precise implementation of the EMA's new policy remains in flux and subject to legal challenge, it ultimately could result in the EMA's public disclosure of sponsor clinical study reports and/or patient level data in some circumstances. This could negatively impact our business in a variety of ways, including for example through disclosure of our trade secret methodologies for clinical development of our products, and/or by potentially enabling competitors to use our clinical data to gain approvals for their own products in the same or other jurisdictions. Regardless of how the EMA institutes its new policy, the trend across governments is for increased transparency, which could diminish our ability to protect our confidential commercial information.

Item 6. Exhibits

Exhibit No.	Description
10.1	Letter agreement dated March 25, 2015 between Civitas Therapeutics, Inc. and Alkermes, Inc. regarding extension of the Sublease dated December 27, 2010, by and between Civitas Therapeutics, Inc. and Alkermes, Inc.
10.2*	Employment Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\* Indicates management contract or compensatory plan or arrangement.

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

SIGNATURES

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

Acorda Therapeutics, Inc.

By:

/s/ Ron Cohen

Ron Cohen, M.D.

President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: May 8, 2015

By:

/s/ Michael Rogers

Michael Rogers

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: May 8, 2015

## Exhibit Index

Exhibit No.	Description
10.1	Letter agreement dated March 25, 2015, between Civitas Therapeutics, Inc. and Alkermes, Inc. regarding extension of the Sublease dated December 27, 2010, by and between Civitas Therapeutics, Inc. and Alkermes, Inc.
10.2*	Employment Agreement, dated as of May 13, 2014, by and between the Registrant and Andrew Hindman.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\* Indicates management contract or compensatory plan or arrangement.

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