ACORDA THERAPEUTICS INC
Form 10-Q
May 09, 2018

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, 2018

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	13-3831168
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

420 Saw Mill River Road, Ardsley, New York	10502
(Address of principal executive offices)	(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,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a small reporting company)	Small reporting company
Emerging growth company		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

Class	Outstanding at May 7, 2018
Common Stock, $0.001 par value	47,066,476 shares

per share

ACORDA THERAPEUTICS, INC.

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This Quarterly Report on Form 10-Q contains forward looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: the ability to realize the benefits anticipated from acquisitions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; we may need to raise additional funds to finance our operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg in the U.S., which will likely be materially adversely affected by the March 2017 court decision in our litigation against filers of Abbreviated New Drug Applications to market generic versions of Ampyra in the U.S.; the risk of unfavorable results from future studies of Inbrija (levodopa inhalation powder) or from our other research and development programs, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Inbrija, or any other products under development; risks associated with complex, regulated manufacturing processes for pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand, if it receives regulatory approval; third party payers (including governmental agencies) may not reimburse for the use of Ampyra, Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the occurrence of adverse safety events with our products; the outcome (by judgment or settlement) and costs of legal, administrative or regulatory proceedings, investigations or inspections, including, without limitation, collective, representative or class action litigation; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this report and in our Annual Report on Form 10-K, as amended by Amendment No.1 on Form 10-K/A, for the year ended December 31, 2017, particularly in the "Risk Factors" section (as updated by the disclosures in our subsequent quarterly reports, including this report), that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.

We and our subsidiaries own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks "Acorda Therapeutics," our stylized Acorda Therapeutics logo, "Biotie Therapies," "Ampyra" "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., "Inbrija") in the U.S. and worldwide for potential product names or for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.

PART I

Item 1. Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share data)	March 31, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$226,276	$ 307,068
Restricted cash	460	410
Short term investments	106,767	—
Trade accounts receivable, net of allowances of $2,129 and $845, as of March 31, 2018 and December 31, 2017, respectively	50,787	81,403
Prepaid expenses	14,782	13,333
Finished goods inventory held by the Company	27,662	37,501
Other current assets	1,454	1,983
Total current assets	428,188	441,698
Property and equipment, net of accumulated depreciation	39,023	36,669
Goodwill	289,577	286,611
Intangible assets, net of accumulated amortization	429,791	430,603
Non-current portion of deferred cost of license revenue	—	1,638
Other assets	494	750
Total assets	$1,187,073	$ 1,197,969
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$18,377	$ 27,367
Accrued expenses and other current liabilities	91,782	100,128
Current portion of deferred license revenue	—	9,057
Current portion of loans payable	663	645
Current portion of liability related to sale of future royalties	6,536	6,763
Total current liabilities	117,358	143,960
Convertible senior notes (due 2021)	311,228	308,805
Non-current portion of acquired contingent consideration	117,983	112,722
Non-current portion of deferred license revenue	—	23,398
Non-current portion of loans payable	25,900	25,670
Deferred tax liability	24,936	22,459
Non-current portion of liability related to sale of future royalties	27,859	29,025
Other non-current liabilities	11,884	11,943
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value. Authorized 1,000,000 shares at March 31,	—	—

2018 and December 31, 2017; no shares issued as of March 31, 2018 and December 31, 2017, respectively		
Common stock, $0.001 par value. Authorized 80,000,000 shares at March 31, 2018 and December 31, 2017; issued 46,724,546 and 46,441,428 shares, including those held in treasury, as of March 31, 2018 and December 31, 2017, respectively	47	46
Treasury stock at cost (62,936 shares at March 31, 2018 and 16,151 shares at December 31, 2017)	(1,591)	(389)
Additional paid-in capital	977,881	968,580
Accumulated deficit	(435,725)	(455,108)
Accumulated other comprehensive income	9,313	6,858
Total stockholders' equity	549,925	519,987
Total liabilities and stockholders' equity	$1,187,073	$1,197,969

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, 2018	Three-month period ended March 31, 2017
Revenues:		
Net product revenues	$ 103,003	$ 112,593
Royalty revenues	3,162	4,528
License revenue	—	2,265
Total net revenues	106,165	119,386
Costs and expenses:		
Cost of sales	21,350	25,183
Cost of license revenue	—	159
Research and development	30,560	46,493
Selling, general and administrative	47,601	52,024
Changes in fair value of acquired contingent consideration	6,200	10,800
Total operating expenses	105,711	134,659
Operating income (loss)	454	(15,273)
Other (expense) income, (net):		
Interest and amortization of debt discount expense	(5,497)	(4,143)
Interest income	326	38
Realized loss on foreign currency transactions	(5)	(444)
Total other expense, (net)	(5,176)	(4,549)
Loss before taxes	(4,722)	(19,822)
(Provision for) benefit from income taxes	(3,477)	918
Net loss	$ (8,199)	$ (18,904)
Net loss per share—basic and diluted	$ (0.18)	$ (0.41)
Weighted average common shares outstanding used in computing net loss per share—basic and diluted	46,529	45,808

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(unaudited)

(In thousands)	Three-month period ended March 31, 2018	Three-month period ended March 31, 2017
Net loss	$ (8,199)	$ (18,904)
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustment	2,547	2,402
Unrealized losses on available for sale debt securities	(92)	—
Other comprehensive income, net of tax	2,455	2,402
Comprehensive loss	$ (5,744)	$ (16,502)

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, 2018	Three-month period ended March 31, 2017
Cash flows from operating activities:		
Net loss	$ (8,199)	$ (18,904)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation expense	5,867	7,872
Amortization of net premiums and discounts on investments	(92)	—
Amortization of debt discount and debt issuance costs	4,003	2,580
Depreciation and amortization expense	3,310	5,647
Change in acquired contingent consideration obligation	6,200	10,800
Unrealized foreign currency transaction loss	—	247
Non-cash royalty revenue	(2,782)	—
Deferred tax benefit	(293)	(4,673)
Changes in assets and liabilities:		
Decrease in accounts receivable	30,616	2,011
(Increase) decrease in prepaid expenses and other current assets	(1,535)	497
Decrease (increase) in inventory	9,839	(2,918)
Decrease in non-current portion of deferred cost of license revenue	—	159
Decrease (increase) in other assets	8	(3,415)
Decrease in accounts payable, accrued expenses, other current liabilities	(18,271)	(23,093)
Decrease in non-current portion of deferred license revenue	—	(2,264)
Increase in other non-current liabilities	30	35
Net cash provided by (used in) operating activities	28,701	(25,419)
Cash flows from investing activities:		
Purchases of property and equipment	(4,807)	(5,773)
Purchases of intangible assets	(5)	(76)
Purchases of investments	(106,767)	—
Net cash used in investing activities	(111,579)	(5,849)
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	3,367	5,474
Refund of deposit for purchase of noncontrolling interest	—	2,722
Purchase of treasury stock	(1,202)	—
Repayment of loans payable	(656)	(2,225)
Net cash provided by financing activities	1,509	5,971
Effect of exchange rate changes on cash, cash equivalents and restricted cash	378	361
Net decrease in cash, cash equivalents and restricted cash	(80,991)	(24,936)
Cash, cash equivalents and restricted cash at beginning of period	308,039	158,871

Cash, cash equivalents and restricted cash at end of period	$ 227,048	$ 133,935
Supplemental disclosure:		
Cash paid for interest	$ 26	$ 29
Cash paid for taxes	465	1,915

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 focused on developing therapies that restore function and improve the lives of people with neurological disorders.

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information, Accounting Standards Codification (ASC) Topic 270-10 and with the instructions to Form 10-Q. Accordingly, these financial statements do not include all of the information and footnotes required by GAAP for complete financial statements. In management’s opinion, all adjustments considered necessary for a fair presentation have been included in the interim periods presented and all adjustments are of a normal recurring nature. The Company has evaluated subsequent events through the date of this filing. Operating results for the three-month period ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. When used in these notes, the terms “Acorda” or “the Company” mean Acorda Therapeutics, Inc. The December 31, 2017 consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. You should read these unaudited interim condensed consolidated financial statements in conjunction with the consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A, for the year ended December 31, 2017.

Certain reclassifications were made to prior period amounts in the consolidated financial statements and accompanying notes to conform with the current year presentation due to the adoption of ASU 2016-18 “Statement of Cash Flows” and Topic 230: Restricted Cash. See Note 2.

(2) Summary of Significant Accounting Policies

Our critical accounting policies are detailed in our Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A, for the year ended December 31, 2017. Effective January 1, 2018, the Company adopted ASU 2014-09, “Revenue from Contracts with Customers” (Topic 606), ASU 2016-01, “Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities”, ASU 2016-15 “Statement of Cash Flows” (Topic 230): Classification of Certain Cash Receipts and Cash Payments, ASU 2016-18 “Statement of Cash Flows” (Topic 230): Restricted Cash, ASU 2017-01, “Business Combinations” (Topic 805): Clarifying the Definition of a Business, and ASU 2017-09, “Compensation – Stock Compensation” (Topic 718): Scope of Modification Accounting and ASU 2017-01. Other than the adoption of the new accounting guidance, our critical accounting policies have not changed materially from December 31, 2017.

Revenue Recognition

On January 1, 2018, we adopted the new accounting standard ASC 606, “Revenue from Contracts with Customers” (Topic 606) (“ASC 606”) and the related amendments to all contracts with customers that were not completed as of the date of adoption using the modified retrospective method. ASC 606 supersedes prior revenue guidance under ASC 605 “Revenue Recognition” (“ASC 605”) and requires entities to recognize revenue to depict the transfer of promised goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company completed its assessment of the new guidance and evaluated the

new requirements as applied to its existing revenue contracts not completed as of the date of initial application. As a result of the assessment, with the exception of the changes to our recognition of license revenue as further described below, the Company determined that adoption of the new standard did not have a significant impact on its revenue recognition methodology. In accordance with ASC 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for the good or service.

The Company determined that the revenue recognition methodology for the deferred license revenue changed as a result of the adoption of ASC 606. License revenue recorded by the Company prior to January 1, 2018 related exclusively to the recognition of the upfront payment received from Biogen upon the execution of the License and Collaboration agreement

that granted Biogen an exclusive non sub-licensable license to sell Fampyra outside of the U.S. License revenue recorded prior to January 1, 2018 was recognized under ASC 605 on a pro rata basis as the Company's obligations were satisfied throughout the duration of the license and collaboration agreement. As of January 1, 2018, the Company adopted ASC 606 which changed the Company's determination of its distinct performance obligations resulting in an acceleration of the recognition of the revenue in the arrangement. The material performance obligations were completed prior to January 1, 2018, and as a result, the Company recognized its previously deferred revenue as a cumulative effect adjustment of $27.6 million within the accumulated deficit on the consolidated balance sheet as of January 1, 2018.

The cumulative effect of applying ASC 606 to the company's consolidated balance sheet was as follows:

(In thousands)	Balance as of December 31, 2017	Net Adjustments	Balance as of January 1, 2018
Assets			
Other current assets	$1,983	$ (634)	$1,349
Non-current portion of deferred cost of license revenue	1,638	(1,638)	—
Total Assets	$1,197,969	$ (2,272)	$1,195,697
Liabilities			
Current portion of deferred license revenue	$9,057	$ (9,057)	$—
Non-current portion of deferred license revenue	23,398	(23,398)	—
Deferred tax liability	22,459	2,600	25,059
Accumulated deficit	(455,108)	27,583	(427,525)
Total liabilities and stockholders' equity	$1,197,969	$ (2,272)	$1,195,697

The impact of the adoption of ASC 606 on the Company's consolidated balance sheet as of March 31, 2018 was as follows:

(In thousands)	Balance as of March 31, 2018 Prior to Adoption of ASC 606	Net Adjustments	Balance as of March 31, 2018 as Reported Under ASC 606
Assets			
Other current assets	$2,088	$ (634)	$1,454
Non-current portion of deferred cost of license revenue	1,479	(1,479)	—
Total Assets	$1,189,186	$ (2,113)	$1,187,073

Liabilities			
Current portion of deferred license revenue	$9,057	$ (9,057)	$—
Non-current portion of deferred license revenue	21,134	(21,134)	—
Deferred tax liability	22,336	2,600	24,936
Accumulated deficit	(461,203)	25,478	(435,725)
Total liabilities and stockholders' equity	$1,189,186	$ (2,113)	$1,187,073

The impact of the adoption of ASC 606 on the Company’s consolidated statement of operations for the three-month period ended March 31, 2018 was as follows:

(In thousands)	Three-Month Period Ended March 31, 2018 Balance Prior to Adoption of ASC 606	Effect of Change	Three-Month Period Ended March 31, 2018 Balance as Reported Under ASC 606
License revenue	$ 2,264	$(2,264)	$ —
Cost of license revenue	159	(159)	—
Operating income	$ 2,559	$(2,105)	$ 454
Net loss	$ (6,094)	$(2,105)	$ (8,199)
Net loss per share (basic and diluted)	$ (0.13)	$(0.05)	$ (0.18)

ASC 606 did not have an aggregate impact on the Company’s net cash provided by operating activities.

ASC 606 outlines a five-step process for recognizing revenue from contracts with customers: i) identify the contract with the customer, ii) identify the performance obligations in the contract, (iii) determine the transaction price, iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon receipt of the product by the customer.

Product Revenue, Net

Net revenue from product sales is recognized at the transaction price when the customer obtains control of the Company’s product, which occurs at a point in time, typically upon receipt of the product by the customer. The Company’s products are sold to a network of specialty providers which are contractually obligated to hold no more than an agreed upon number of days inventory. The Company’s payment terms are between 30 to 34 days.

The Company’s net revenues represent total revenues adjusted for discounts and allowances, including estimated price discounts, rebates and chargebacks. These adjustments represent variable consideration under ASC 606 and are recorded for cash consideration given by the Company to a customer that is presumed to be a reduction of the transaction price of the Company’s products and, therefore, are characterized as a reduction of revenue. These adjustments 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. Adjustments for variable consideration are determined 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.

Discounts and Allowances

Revenue from product sales are recorded at the transaction price, which includes estimates for discounts and allowances for which reserves are established and includes cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. Discounts and allowances are recorded following shipment of product and the appropriate reserves are credited. These reserves are classified as reductions of accounts receivable (if the amount is payable to the Customer and right of offset exists) or a current liability (if the amount is payable to a party other than a Customer). These allowances are established by management as its best estimate based on historical experience and data points available and are adjusted to reflect known changes in the factors that impact such reserves. Allowances for customer credits, chargebacks, rebates, data fees and wholesaler fees for services, returns, and discounts are established based on contractual terms with customers and analyses of historical usage of these items. Actual amounts of consideration ultimately received may differ from the Company’s estimates. If actual results in the future vary from the Company’s estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. The nature of our allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows:

Government Chargebacks and Rebates: We contract for Medicaid and other U.S. Federal government programs to allow for our products to remain eligible for reimbursement under these programs. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. Based upon our contracts and the most recent experience with respect to sales through each of these channels, we provide an allowance for chargebacks and rebates. We monitor the sales trends and adjust the chargeback and rebate percentages on a regular basis to reflect the most recent chargebacks and rebate experience. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current

quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Managed Care Contract Rebates: We contract with various managed care organizations including health insurance companies and pharmacy benefit managers. These contracts stipulate that rebates and, in some cases, administrative fees, are paid to these organizations provided our product is placed on a specific tier on the organization's drug formulary. Based upon our contracts and the most recent experience with respect to sales through managed care channels, we provide an allowance for managed care contract rebates. We monitor the sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Copay Mitigation Rebates: We offer copay mitigation to commercially insured patients who have coverage for our products (in accordance with applicable law) and are responsible for a cost share. Based upon our contracts and the most recent experience with respect to actual copay assistance provided, we provide an allowance for copay mitigation rebates. We monitor the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience.

Cash Discounts: We sell directly to our network of specialty pharmacies, Kaiser and the specialty distributor to the U.S. Department of Veterans Affairs. We generally provide invoice discounts for prompt payment for our products. We estimate our cash discounts based on the terms offered to our customers. Discounts are estimated based on rates that are explicitly stated in the Company's contracts as it is expected they will take the discount and are recorded as a reduction of revenue at the time of product shipment when product revenue is recognized. We adjust estimates based on actual activity as necessary.

Product Returns: We either offer customers no return except for products damaged in shipping or consistent with industry practice, a limited right of return based on the product's expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The company currently estimates product return liabilities using historical sales information and inventory remaining in the distribution channel.

Data Fees and Fees for Service Payable to Specialty Pharmacies: We have contracted with certain specialty pharmacies to obtain transactional data related to our products in order to develop a better understanding of our selling channel as well as patient activity and utilization by the Medicaid program and other government agencies and managed care organizations. We pay a variable fee to the specialty pharmacies to provide us the data. We also pay the specialty pharmacies a flat fee in exchange for providing distribution and inventory management services, including the provision of inventory management data to the Company. We estimate our fee for service accruals and allowances based on sales to each specialty pharmacy and the applicable contracted rate.

Royalty Revenue

Royalty revenue recorded by the Company relates exclusively to the Company's License and Collaboration agreement with Biogen which provides for ongoing royalties based on sales of Fampyra outside of the U.S. The Company recognizes revenue for royalties under ASC 606, which provides revenue recognition constraints by requiring the recognition of revenue at the later of the following: 1) sale or usage of the products or 2) satisfaction of the performance obligations. The Company has satisfied its performance obligations and therefore recognizes royalty revenue when the sales to which the royalties relate are completed.

Milestone Revenue

Milestone revenue relates to the License and Collaboration agreement with Biogen which provides for milestone payments for the achievement of certain regulatory and sales milestones during the term of the agreement. Regulatory milestones are contingent upon the approval of Fampyra for new indications outside of the U.S. Sales milestones are contingent upon the achievement of certain net sales targets for Fampyra sales outside of the U.S. The Company recognizes milestone revenue under ASC 606, which provides constraints for entities to recognize milestone revenue which is deemed to be variable by requiring the Company to estimate the amount of consideration to which it is entitled in exchange for transferring the promised goods or services to a customer. The Company recognizes an estimate of revenue to the extent that

it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the milestone is achieved. For regulatory milestones, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. For sales-based milestones, the Company has satisfied its performance obligations and, therefore, recognizes revenue upon the achievement of the specific sale milestones.

The following table disaggregates our revenue by major source (in thousands):

	Three-month period ended March 31, 2018	Three-month period ended March 31, 2017
Revenues:		
Net product revenues	$ 103,003	$ 112,593
Royalty revenues	3,162	4,528
License revenue	—	2,265
Total net revenues	$ 106,165	$ 119,386

Foreign Currency Translation

The functional currency of operations outside the United States of America is deemed to be the currency of the local country, unless otherwise determined that the United States dollar would serve as a more appropriate functional currency given the economic operations of the entity. Accordingly, the assets and liabilities of the Company's foreign subsidiary, Biotie, are translated into United States dollars using the period-end exchange rate; income and expense items are translated using the average exchange rate during the period; and equity transactions are translated at historical rates. Cumulative translation adjustments are reflected as a separate component of equity. Foreign currency transaction gains and losses are recognized in the period incurred and are reported as other income (expense) in the statement of operations.

Segment and Geographic Information

The Company is managed and operated as one business which is focused on developing therapies that restore function and 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 the sales of Ampyra and Qutenza in the U.S.

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 these financial statements.

Accounting Pronouncements Adopted

As noted above, in May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers" (Topic 606) (ASU 2014-09). This new standard replaced all previous U.S. GAAP guidance on this topic and eliminated all industry-specific guidance. The new standard requires the application of a five-step model to determine the amount and timing of revenue to be recognized. The underlying principle is that revenue is to be recognized for the transfer of goods or services to customers that reflects the amount of consideration that the Company expects to be entitled to in exchange for those goods or services. The Company adopted the new standard effective January 1, 2018 using the modified retrospective transition method. See discussion of the adoption above in Revenue Recognition.

In January 2016, the FASB issued Accounting Standards Update 2016-01, “Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities.” The main objective of this update is to enhance the reporting model for financial instruments to provide users of financial statements with more decision-useful information. The new guidance addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In August 2016, the FASB issued Accounting Standards Update ASU 2016-15 “Statement of Cash Flows” (Topic 230): Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15), which specifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This ASU requires retrospective application to all periods presented. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In November 2016, the FASB issued Accounting Standards Update ASU 2016-18 “Statement of Cash Flows” (Topic 230); Restricted Cash (ASU 2016-18), which defines new requirements for the presentation of restricted cash and restricted cash equivalents in the statement of cash flows. The amendments in this ASU require retrospective application to each period presented. The Company adopted this guidance effective January 1, 2018 retrospectively. This ASU requires the entities to present statement of cash flows in a manner such that it reconciles beginning and ending totals of cash, cash equivalents, restricted cash or restricted cash equivalents. Also, when cash, cash equivalents, restricted cash or restricted cash equivalents are presented in more than one line item within the statement of financial position, an entity should, for each period that a statement of financial position is presented, present on the face of the statement of cash flows or disclose in the notes to the financial statements, the line items and amounts of cash, cash equivalents, and restricted cash or restricted cash equivalents reported within the statement of financial position. The amounts, disaggregated by the line item in which they appear within the statement of financial position, shall sum to the total amount of cash, cash equivalents, and restricted cash or restricted cash equivalents at the end of the corresponding period shown in the statement of cash flows.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the statement of financial position that sum to the total of the same amounts shown in the statement of cash flows:

	Three months ended March 31, 2018		Three months ended March 31, 2017	
(In thousands)	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$307,068	$226,276	$158,537	$133,619
Restricted cash	410	460	79	61
Restricted cash included in Other assets	561	312	255	255
Total Cash, cash equivalents and restricted cash per statement of cash flows	$308,039	$227,048	$158,871	$133,935

Amounts included in restricted cash represent those amounts required to be set aside to cover the Company’s self-funded employee health insurance. Restricted cash included in other assets on the statement of financial position relates to cash collateralized standby letters of credit in connection with obligations under facility leases, which is included with other assets in the consolidated balance sheet due to the long-term nature of the letters of credit.

In January 2017, the FASB issued Accounting Standards Update 2017-01, “Business Combinations” (Topic 805): Clarifying the Definition of a Business (ASU 2017-01), which provides additional clarification to aid in determining when a set of assets and activities is not a business. The amendments in this update require prospective applications. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In May 2017, the FASB issued Accounting Standards Update 2017-09, “Compensation – Stock Compensation” (Topic 718): Scope of Modification Accounting (ASU 2017-09). This new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU 2017-09 allows for prospective application and is effective for fiscal years beginning after December 15, 2017, and interim periods therein with early adoption permitted for interim or annual periods. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued Accounting Standards Update 2016-02, “Leases” (Topic 842). The main objective of this update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact it may have on its consolidated financial statements.

In January 2017, the FASB issued Accounting Standards Update 2017-04, “Intangibles – Goodwill and Other” (Topic 350): Simplifying the Test for Goodwill Impairment (ASU 2017-04). This new standard simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. ASU 2017-04 allows for prospective application and is effective for fiscal years beginning after December 15, 2019, and interim periods therein with early adoption permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating whether it will adopt this guidance early. The Company does not expect the adoption of this guidance to have a significant impact on the consolidated financial statements.

In February 2018, the FASB issued Accounting Standards Update 2018-02, ‘Income Statement—Reporting Comprehensive Income’ (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (ASU 2018-02). This new standard provides entities with an option to reclassify stranded tax effects within AOCI to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (or portion thereof) is recorded. ASC 740-10-35-4 requires that deferred tax assets and liabilities should be adjusted to account for any changes in tax laws or rates within the period that the enactment of these changes occurs and any adjustments to flow through income from continuing operations. Since the adjustments due to the Tax Cuts and Jobs Act are required to flow through income from continuing operations, the tax effects of items within accumulated other comprehensive income known now as “stranded tax effects,” do not reflect the appropriate tax rate. As such, FASB issued ASU 2018-02, in order to address these stranded income tax effects. The new standard requires entities to disclose the following:

- A description of the accounting policy for releasing income tax effects from AOCI;
- Whether they elect to reclassify the stranded income tax effects from the Tax Cuts and Jobs Act, and
- Information about the other income tax effects that are reclassified.

The ASU is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact it may have on its consolidated financial statements.

In March 2018, the FASB issued Accounting Standards Update 2018-05, “Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin (SAB) No. 118’. The ASU adds seven paragraphs to ASC 740, Income Taxes, that contain SEC guidance related to SAB 118 (codified as SEC SAB Topic 5.EE, “Income Tax Accounting Implications of the Tax Cuts and Jobs Act”), which provides guidance for companies that are not able to complete their accounting for the income tax effects of the Tax Cuts and Jobs Act in the period of enactment which is the period that includes December 22, 2017. The measurement period should not extend beyond one year from the enactment date. The Company is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

(3) Share-based Compensation

During the three month periods ended March 31, 2018 and 2017, the Company recognized share-based compensation expense of $5.9 million and $7.8 million, respectively. Activity in options and restricted stock during the three-month period ended March 31, 2018 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, 2018 and 2017 were approximately $12.37 and $13.02, respectively.

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

	For the three-month period ended March 31,	
(In millions)	2018	2017
Research and development	$ 1.7	$ 2.5
Selling, general and administrative	4.2	5.3
Total	$ 5.9	$ 7.8

A summary of share-based compensation activity for the three-month period ended March 31, 2018 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, 2018	8,929	$ 29.46		
Granted	536	24.39		
Cancelled	(201)	23.89		
Exercised	(172)	19.61		
Balance at March 31, 2017	9,092	$ 29.47	6.0	$ 8,141
Vested and expected to vest at March 31, 2018	9,032	$ 29.50	6.0	$ 8,068
Vested and exercisable at March 31, 2018	6,728	$ 30.49	5.1	$ 4,605

Restricted Stock and Performance Stock Unit Activity

(In thousands)	
Restricted Stock and Performance Stock Units	Number of Shares
Nonvested at January 1, 2018	698
Granted	—
Vested	(111)
Forfeited	(71)
Nonvested at March 31, 2018	516

Unrecognized compensation cost for unvested stock options, restricted stock awards and performance stock units as of March 31, 2018 totaled $33.7 million and is expected to be recognized over a weighted average period of approximately 1.9 years.

During the three month period ended March 31, 2018, the Company repurchased 46,785 shares of common stock at an average price of $25.69 per share or approximately $1.2 million. The share repurchase consists of common stock withheld to cover the tax liability in connection with the settlement of vested restricted stock units and stock options that were exercised in the there-month period ended March 31, 2018.

(4) Loss Per Share

The following table sets forth the computation of basic and diluted loss per share for the three-month periods ended March 31, 2018 and 2017:

(In thousands, except per share data)	Three-month period ended March 31, 2018	Three-month period ended March 31, 2017
Basic and diluted		
Net loss	$ (8,199)	$ (18,904)
Weighted average common shares outstanding used in computing net loss per share—basic and diluted	46,529	45,808
Net loss per share—basic and diluted	$ (0.18)	$ (0.41)

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 per diluted share because their effects were anti-dilutive:

(In thousands)	Three-month period ended March 31, 2018	Three-month period ended March 31, 2017
Denominator		
Stock options and restricted common shares	7,504	8,258

Additionally, the impact of the convertible debt and the impact of the convertible capital loan assumed from Biotie were determined to be anti-dilutive and excluded from the calculation of net loss per diluted share for the three-month periods ended March 31, 2018 and 2017.

(5) Income Taxes

The Company's effective income tax rate differs from the U.S. statutory rate principally due to state taxes, Federal research and development tax credits, jurisdictions with pretax losses for which no tax benefit can be recognized, changes in the valuation allowance and the effects of share based compensation which are recorded discretely in the quarters in which they occur

For the three-month periods ended March 31, 2018 and 2017, the Company recorded a $(3.5) million provision and $0.9 million benefit for income taxes, respectively. The effective income tax rates for the Company for the

three-month periods ended March 31, 2018 and 2017 were (74%) and 5%, respectively. The variance in the effective tax rates for the three-month period ended March 31, 2018 as compared to the three-month period ended March 31, 2017 was due primarily to the decrease in the federal statutory tax rate as a result of tax reform, the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, state taxes, and the reduction in the research & development tax credit.

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

The Tax Cuts and Jobs Act of 2017 (the “Act”) was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21% effective for tax years beginning after December 31, 2017, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously deferred and includes a variety of other changes.

On December 22, 2017, Staff Accounting Bulletin No. 118 (“SAB 118”) was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. For the three months

ended March 31, 2018, the Company has not completed its accounting for the tax effects of the enactment of the Act; however, in certain cases, we have made a reasonable estimate of the effects on our existing deferred tax balances. In other cases, we have not been able to make a reasonable estimate and continue to account for those items based on our existing accounting under ASC 740, Income Taxes, and the provisions of the tax laws that were in effect immediately prior to the enactment. The Company has not obtained additional information affecting the provisional amounts initially recorded. The Company did not record a provision related to the one-time transition tax on mandatory repatriation of undistributed foreign earnings and profits per the Act, since a preliminary analysis has determined that there is no accumulated earnings and profits.

Additional work is still necessary for a more detailed analysis of the Company's deferred tax assets and liabilities and its historical foreign earnings as well as potential correlative adjustments. Any subsequent adjustment to these amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete.

The Internal Revenue Service commenced an examination of the Company’s US income tax return for 2015 in the third quarter of 2017.

(6) Fair Value Measurements

The following table presents information about the Company’s assets and liabilities measured at fair value on a recurring basis as of March 31, 2018 and December 31, 2017 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices, interest rates, exchange rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability. The Company’s Level 1 assets consist of time deposits and investments in a Treasury money market fund. The Company’s level 2 assets consist of investments in corporate bonds and commercial paper which are categorized as cash equivalents for those investments with original maturities of three months or less and short-term investments for those investments with original maturities between three months and one year. The Company’s Level 3 liabilities represent acquired contingent consideration related to the acquisition of Civitas and are valued using a probability weighted discounted cash flow valuation approach. No changes in valuation techniques occurred during the three-month period ended March 31, 2018. The estimated fair values of all of our financial instruments approximate their carrying values at March 31, 2018, except for the fair value of the Company’s convertible senior notes, which was approximately $313.1 million as of March 31, 2018. The Company estimates the fair value of its notes utilizing market quotations for the debt (Level 2).

(In thousands)	Level 1	Level 2	Level 3
March 31, 2018			
Assets Carried at Fair Value:			
Cash equivalents	$19,621	$32,452	$—
Short-term investments	—	106,767	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	119,200
December 31, 2017			

Assets Carried at Fair Value:			
Cash equivalents	$9,163	$—	$—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	113,000

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, 2018	Three-month period ended March 31, 2017
Acquired contingent consideration:		
Balance, beginning of period	$ 113,000	$ 72,100
Fair value change to contingent consideration included in the statement of operations	6,200	10,800
Balance, end of period	$ 119,200	$ 82,900

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 Inbrija (levodopa inhalation powder), a potential new drug candidate for the treatment of OFF periods of Parkinson's disease and CVT-427, a Phase I candidate. CVT-427 is an inhaled triptan intended for acute treatment of migraine using the ARCUS drug delivery technology. Using this approach, expected probability adjusted future cash flows are calculated over the expected life of the agreement and discounted to estimate the current value of the liability at the period end date. Some of the more significant assumptions made in the valuation include (i) the estimated Inbrija and CVT-427 revenue forecasts, (ii) probabilities of success, and (iii) discount periods and rate. The probability of achievement of revenue milestones ranged from 26.3% to 85.0% with milestone payment outcomes ranging from $0 to $69 million in the aggregate for Inbrija and CVT-427. The valuation is performed quarterly. Gains and losses are included in the statement of operations. For the three-month period ended March 31, 2018, changes in the fair value of the acquired contingent consideration were due to the re-calculation of cash flows for the passage of time.

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 Inbrija and CVT-427 and estimated discount rates, the estimated fair value could be significantly higher or lower than the fair value determined.

(7) Investments

The Company has determined that all of its investments are classified as available-for-sale. Available-for-sale debt securities are carried at fair value with interest on these investments included in interest income and are recorded based primarily on quoted market prices. Available-for-sale investments consisted of the following at March 31, 2018:

	Gross	Gross	Estimated

(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash Equivalents	$ 32,457	$ 1	$ (6)	$ 32,452
Short Term Investments	106,854	6	(93)	106,767
Total	$ 139,311	$ 7	$ (99)	$ 139,219

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to approximately $32.5 million as of March 31, 2018. Short-term investments have original maturities of greater than 3 months but less than 1 year and amounted to approximately $106.8 million as of March 31, 2018. The Company held no short-term investments at December 31, 2017. Short-term investments at March 31, 2018 primarily consisted of high-grade commercial paper and corporate bonds. Long-term investments have original maturities of greater than 1 year. There were no investments classified as long-term at March 31, 2018 or December 31, 2017. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of March 31, 2018 as the Company does not intend to sell its investments and it is not more likely than not that the Company will be required to sell its investments prior to the recovery of its amortized cost basis.

Unrealized holding gains and losses, which relate to debt instruments, are reported within accumulated other comprehensive income (AOCI) in the statements of comprehensive income. The changes in AOCI associated with the unrealized holding gains on available-for-sale investments during the three-month period ended March 31, 2018, were as follows (in thousands):

(In thousands)	Net Unrealized Gains (Losses) on Marketable Securities
Balance at December 31, 2017	$ —
Other comprehensive loss before reclassifications	(92)
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive loss	(92)
Balance at March 31, 2018	$ (92)

(8) Liability Related to Sale of Future Royalties

As of October 1, 2017, the Company completed a royalty purchase agreement with HealthCare Royalty Partners, or HCRP (“Royalty Agreement”). In exchange for the payment of $40 million to the Company, HCRP obtained the right to receive Fampyra royalties payable by Biogen under the License and Collaboration Agreement between the Company and Biogen, up to an agreed upon threshold of royalties. When this threshold is met, if ever, the Fampyra royalties will revert back to the Company and the Company will continue to receive the Fampyra royalties from Biogen until the revenue stream ends. The transaction does not include potential future milestones to be paid.

The Company maintained the rights under the license and collaboration agreement with Biogen, therefore, the Royalty Agreement has been accounted for as a liability that will be amortized using the effective interest method over the life of the arrangement, in accordance with the relevant accounting guidance. The Company recorded the receipt of the $40 million payment from HCRP and established a corresponding liability in the amount of $40 million, net of transaction costs of approximately $2.2 million. The net liability is classified between the current and non-current portion of liability related to sale of future royalties in the consolidated balance sheets based on the recognition of the interest and principal payments to be received by HCRP in the next 12 months from the financial statement reporting date. The total net royalties to be paid, less the net proceeds received will be recorded to interest expense using the effective interest method over the life of the Royalty Agreement. The Company will estimate the payments to be made to HCRP over the term of the Agreement based on forecasted royalties and will calculate the interest rate required to discount such payments back to the liability balance. Over the course of the Royalty Agreement, the actual interest rate will be affected by the amount and timing of net royalty revenue recognized and changes in forecasted revenue. On a quarterly basis, the Company will reassess the effective interest rate and adjust the rate prospectively as necessary.

The Company recognized non-cash royalty revenue of approximately $2.8 million, non-cash interest expense of approximately $1.2 million and debt discount amortization costs of approximately $0.2 million for the three-month period ended March 31, 2018. The interest and debt discount amortization expense is reflected as interest and amortization of debt discount expense in the Statement of Operations.

(In thousands)	Three-month period ended March 31, 2018
Liability related to sale of future royalties - beginning balance	$ 35,788
Deferred transaction costs recognized	202
Non-cash royalty revenue payable to HCRP	(2,781)
Non-cash interest expense recognized	1,186
Liability related to sale of future royalties - ending balance	$ 34,395

(9) Commitments and Contingencies

The Company is currently party to various legal proceedings which are principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability or range of losses can be reasonably estimated. As a result, the Company did not record any loss contingencies for any of these matters. 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 focused on developing therapies that restore function and improve the lives of people with neurological disorders. We market two FDA-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in adult patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. We have a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease and MS.

We currently derive substantially all our revenue from the sale of Ampyra. In March 2017, we announced a decision by the United States District Court for the District of Delaware in litigation with certain generic drug manufacturers upholding our Ampyra Orange Book-listed patent set to expire on July 30, 2018, but invalidating our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, we expect to maintain patent exclusivity with respect to Ampyra at least through July 30, 2018, depending on the outcome of appeal of the District Court's decision. The defendant generic drug manufacturers have appealed the District Court's decision upholding the patent that expires in July 2018, and we have appealed the ruling on the four invalidated patents. We expect the appeals process to take approximately 12 to 18 months from the filing of the appeal in May 2017. The appellate court has scheduled oral argument for June 7, 2018.

We expect to experience a rapid and significant decline in Ampyra sales beyond July 2018 due to competition from generic versions of Ampyra that may be marketed after the expiration of our remaining Ampyra patent, unless the District Court's decision on the four invalidated patents is overturned on appeal, which could include reversal or remand by the appeals court back to the District Court. If the appeals court does not overturn the District Court's decision by July 30, 2018, multiple ANDA filers may be able to launch generic versions of Ampyra absent injunctive relief.

Inbrija, our most advanced development program, is a self-administered, inhaled formulation of levodopa, or L-dopa, being investigated for the treatment of OFF periods in people with Parkinson's disease who are taking a carbidopa/levodopa regimen. Inbrija is based on our proprietary ARCUS platform, a dry-powder pulmonary drug delivery technology that we believe has potential applications in multiple disease areas. We announced positive Phase 3 efficacy and safety data for this program in 2017. On February 20, 2018, we announced that our New Drug Application, or NDA for Inbrija was accepted for filing by the FDA, and that under the Prescription Drug User Fee Act, or PDUFA, the FDA has set a target date of October 5, 2018, for issuing its decision on the NDA. Our commercial preparations for the launch of Inbrija continue. We are projecting that, if approved, annual peak net revenue of Inbrija in the U.S. alone could exceed $800 million. We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency in March 2018. We are in discussions with potential partners regarding Inbrija outside of the U.S.

As of March 31, 2018, we had cash, cash equivalents and short-term investments of approximately $333.0 million and we are projecting a 2018 year-end cash balance in excess of $300.0 million. We have $345 million of convertible senior notes due in 2021 with a conversion price of $42.56. We believe that operating expense reductions from a 2017 restructuring, as well as additional expense reductions due to the termination of the tozadenant development program in November 2017, will enable us to fund operations through the launch of Inbrija in the U.S., pending approval from the FDA. Importantly, we have kept our commercial team intact despite the restructuring. We believe we have built a

leading neuro-specialty sales and marketing team through our commercialization of Ampyra, and that our commercial launch of Inbrija in the U.S., if approved, will benefit from the experiences and capabilities of this team.

Ampyra

General

Ampyra was approved by the FDA in January 2010 to improve walking in adults 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 $102.8 million for the three-month period ended March 31, 2018 and $112.0 million for the three-month period ended March 31, 2017.

Since the March 2010 launch of Ampyra, approximately 132,000 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 adults with MS. Eight years after approval, Ampyra continues to grow, reflecting the continued unmet medical need among adults with MS for a treatment to improve walking. As of March 31, 2018, approximately 70% of all people with MS who were prescribed Ampyra received a first refill, and approximately 40% of all people with MS who were prescribed Ampyra have been dispensed at least six months of the medicine through refills, consistent with previously reported trends. These refill rates exclude patients who started Ampyra through our 60-day free trial program. Our 60-day free trial program which provides eligible patients with two months of Ampyra at no cost. During 2017, on average, approximately 80% of new Ampyra patients enrolled in 60-day free trial. The program is in its seventh year, and data show that 60-day free trial participants have higher compliance and persistency rates over time compared to patients not in the program. Approximately 50% of patients who initiate therapy with the 60-day free trial free trial program convert to paid prescriptions.

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

Ampyra is distributed in the U.S. exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. The specialty pharmacy providers that deliver Ampyra by mail, and Kaiser Permanente, are contractually obligated to hold no more than a specified maximum amount of inventory, the highest being 20 business days of inventory, and some have agreed to hold a minimum of 8 to 10 business days of inventory.

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

Three of the largest national health plans in the U.S. – Aetna, Cigna and United Healthcare – have listed Ampyra on their commercial formulary. Approximately 75% of insured individuals in the U.S. continue to have no or limited prior authorizations, or PA’s, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by health plans.

License and Collaboration Agreement with Biogen

Ampyra is marketed as Fampyra outside the U.S. by Biogen International GmbH, or Biogen, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. 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. In November 2017, we announced a $40 million Fampyra royalty monetization transaction with HealthCare Royalty Partners, or HCRP. In return for the payment to us, HCRP obtained the right to receive these Fampyra royalties up to an agreed-upon threshold. Until this threshold is met, if ever, we will not receive Fampyra royalties although we have retained the right to receive any potential future milestone

payments, described above. The HCRP transaction is accounted for as a liability, as described in Note 8 to our Consolidated Financial Statements included in this report.

Ampyra Patent Update

We have six issued patents listed in the Orange Book for Ampyra. The five initial Orange Book-listed patents are the subject of litigation in U.S. District Court for the District of Delaware commenced in 2014 with certain generic drug manufacturers, as further described below in this report. The sixth Orange Book-listed patent, not involved in the litigation, was issued more recently and was listed in the Orange Book in April 2018.

The first of the five Orange Book-listed patents involved in the litigation 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 on July 30, 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). This patent was held valid by the District Court in the litigation, although in June 2017 the defendant generic drug manufacturers with whom we have not reached settlements appealed the District Court's decision upholding this patent.

The other four Orange Book-listed patents involved in the litigation were held invalid by the District Court in the litigation with generic drug manufacturers. These patents, which had been set to expire in 2025 through 2027, consist of 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; 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; 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; and 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.

The sixth Orange Book-listed patent is U.S. Patent No. 9,918,973, the claims of which relate to methods of increasing walking speed in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent will expire in 2024. We note that this patent does not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that are involved in the patent litigation referenced above.

The patent litigation relates to Paragraph IV Certification Notices received from ten generic drug manufacturers in 2014 and 2015, who submitted Abbreviated New Drug Applications, or ANDAs, with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. The ANDA filers challenged the validity of the five initial Orange Book-listed patents for Ampyra, and they also asserted that generic versions of their products do not infringe certain claims of these patents. In 2015 and 2016, we reached settlement agreements with six of the generic companies. A bench trial against the remaining four generic companies was completed in September 2016. In February 2017, we announced that we had reached a settlement agreement with one of those four generic companies. In March 2017, the U.S. District Court for the District of Delaware rendered a decision upholding our Orange Book-listed patent for Ampyra set to expire in July 2018, but invalidating the four other initial Orange Book-listed patents. In May 2017, we appealed the ruling on these four patents, and as described above, in June 2017 the other non-settling parties appealed the decision on the patent set to expire in July 2018. We

expect the appeals process to take approximately 12 to 18 months from the filing of the appeal in May 2017. Both the Biotechnology Innovation Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) filed amicus briefs in support of our appeal, raising important issues in conjunction with biopharmaceutical innovation. The appellate court has scheduled oral argument for June 7, 2018, and we are expecting a decision on the appeal in the second half of 2018. We expect to experience a rapid and significant decline in Ampyra sales beyond July 2018 due to competition from generic versions of Ampyra that may be marketed after the expiration of the Ampyra patent that expires in July 2018, unless the District Court's decision on the four invalidated patents is overturned on appeal, which could include reversal or remand by the appeals court back to the District Court. If the appeals court does not overturn the District Court's decision by July 30, 2018, multiple ANDA filers may be able to launch generic versions of Ampyra absent injunctive relief.

In April 2017, we received a Paragraph IV Certification Notice from an additional generic drug manufacturer, Micro Labs Ltd. (“Micro”), advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10mg. In response to the filing of the ANDA, in May 2017 we filed a lawsuit against Micro in the U.S. District Court for the District of New Jersey. In January 2018, we reached a settlement agreement with Micro.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmBH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmBH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmBH and Actavis Group PTC EHF filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. In February 2016, the EPO Opposition Division rendered a decision that revoked the EP 2377536 patent. We believe the claims of this patent are valid and we have appealed the decision. Both European patents, if upheld as valid, are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines. Fampyra also has 10 years of market exclusivity in the European Union that is set to expire in 2021.

We will vigorously defend our intellectual property rights.

Legal proceedings relating to our Ampyra patents are described in further detail in Part II, Item 1 of this report.

Qutenza

Qutenza is a dermal patch containing 8% prescription strength capsaicin the effects of which can last up to three months and is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain. We acquired commercialization rights to Qutenza in July 2013 from NeurogesX, Inc. These rights include the U.S., Canada, Latin America and certain other territories. Grunenthal GmbH (as the assignee of 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 a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson’s disease and MS. Inbrija (levodopa inhalation powder) is our most advanced development program and our highest priority. These programs and the other programs in our pipeline are described below.

Inbrija (levodopa inhalation powder)/Parkinson’s Disease

Inbrija is a self-administered, inhaled formulation of levodopa, or L-dopa, for the treatment of OFF periods in people with Parkinson’s disease who are taking a carbidopa/levodopa regimen. 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 causes a range of symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care for the treatment of Parkinson’s disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and amount of absorption and there are significant challenges in creating a regimen that consistently maintains therapeutic effects as Parkinson’s disease progresses. The re-emergence of

symptoms is referred to as an OFF period, and despite optimized regimens with current therapeutic options and strategies, OFF periods remain one of the most challenging aspects of the disease.

Inbrija delivers a precise dose of dry-powder formulation of L-dopa to the lung using a breath-actuated proprietary inhaler. Oral medication can be associated with slow and variable onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before reaching the brain. Inhaled treatments enter the body through the lungs and reach the brain shortly thereafter, bypassing the digestive system. Inbrija is based on our proprietary ARCUS platform, a dry-powder pulmonary drug delivery technology that we believe has potential applications in multiple disease areas. A key feature of our ARCUS technology is the large porous particles that allow for consistent and precise delivery of significantly larger doses of

medication than are possible with conventional dry powder pulmonary systems. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents. We have worldwide rights to our ARCUS drug delivery technology, which is protected by extensive know-how and trade secrets and various U.S. and foreign patents, including patents that protect the Inbrija dry powder capsules beyond 2030.

In 2016, we completed a Phase 3 efficacy and safety clinical trial of Inbrija for the treatment of OFF periods in Parkinson's disease. In February 2017, we announced efficacy and safety data from this clinical trial, showing a statistically significant improvement in motor function in people with Parkinson's experiencing OFF periods. The clinical trial had three arms: Inbrija 84 mg and 60 mg doses (equivalent to 50 mg and 35 mg fine particle doses, respectively), and placebo. The trial met its primary outcome measure of improvement in motor function as measured by the Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS Part III) in people with Parkinson's experiencing OFF periods. UPDRS III is a validated scale, which measures Parkinson's disease motor impairment. The primary endpoint was measured at 30 minutes post-treatment for the 84 mg dose at the 12-week visit. UPDRS Part III change was -9.83 compared to -5.91 for placebo with a p value of 0.009. The magnitude of Inbrija's benefit versus baseline was consistent with the data from the prior Phase 2b clinical trial, further described below, and represents a statistically significant, clinically meaningful improvement in motor function. The placebo-adjusted difference was lower in the Phase 3 clinical trial than the Phase 2b clinical trial but still represented a clinically important difference. In June 2017, we announced additional data from the Inbrija Phase 3 efficacy and safety trial at the International Congress of Parkinson's Disease and Movement Disorders (MDS). The secondary endpoints of achievement of an ON state with maintenance through 60 minutes (statistically significant), Patient Global Impression of Change (PGIC), and reduction in UPDRS III score at 10 minutes were supportive of the primary endpoint result.

The safety profile of Inbrija in the trial was consistent with that observed in a prior Phase 2b clinical trial:

- 84 mg, 60 mg and Placebo: Adverse events reported in any study arm at greater than 5% were cough, upper respiratory tract infection, throat irritation, nausea and sputum discoloration. Cough was the most common adverse event, reported by approximately 15% of subjects who received Inbrija. When reported, it was typically mild and reported once per participant during the course of treatment. Three of 227 participants receiving Inbrija discontinued the study due to cough. Reports of serious adverse events were: 3, or 2.7% in the placebo arm, 6, or 5.3% in the 60 mg arm, and 2, or 1.8% in the 84 mg arm. There was one death in the study, a suicide in the 60 mg group, judged by the investigator not to be related to drug.
- 84 mg: The most commonly reported adverse events in the Inbrija 84 mg group compared to the placebo group were: cough (14.9% vs. 1.8%, reported mostly once/subject), upper respiratory tract infection (6.1% vs. 2.7%), nausea (5.3% vs. 2.7%), sputum discoloration (5.3% vs. 0%) and dyskinesia (3.5% vs. 0.0%). When cough was reported, it was typically characterized as mild. Two of 114 participants receiving Inbrija 84 mg discontinued the study due to cough.

Results from a separate Phase 3 study to assess the long-term safety profile of Inbrija in people with Parkinson's showed no statistical difference in pulmonary function between the group receiving Inbrija and an observational control group. These results are consistent with the previously reported Phase 2b and Phase 3 clinical trials. In March 2017, we announced results from separate clinical studies that assessed the safety profile of Inbrija in people with asthma, smokers and early morning OFF.

On February 20, 2018, we announced that our Inbrija NDA was accepted for filing by the FDA, and that under the Prescription Drug User Fee Act, or PDUFA, the FDA has set a target date of October 5, 2018, for issuing its decision on the NDA. The NDA was submitted under section 505(b)(2) of the Food Drug and Cosmetic Act, referencing data from the branded L-dopa product Sinemet®. We believe the Phase 3 efficacy and safety clinical trial, combined with data from additional Phase 3 long-term safety studies and supported by existing Phase 2b data, are sufficient for the NDA filing. Our commercial preparations for the launch of Inbrija continue. We believe we have built a leading neuro-specialty sales and marketing team through our commercialization of Ampyra, and that our launch of Inbrija in

the U.S., if approved, will benefit from the experiences and capabilities of this team. We are projecting that, if approved, annual peak net revenue of Inbrija in the U.S. alone could exceed $800 million. We are seeking approval to market Inbrija in the European Union, and accordingly we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency in March 2018. We are in discussions with potential partners regarding Inbrija outside of the U.S.

In April 2018, we presented new Inbrija data from four accepted abstracts during two oral platform presentations at the American Academy of Neurology Annual Meeting. These presentations included a safety assessment in early morning OFF

symptoms in patients with Parkinson's disease and long-term pulmonary safety and efficacy of inhaled levodopa in Parkinson's disease.

ARCUS Product Development

In addition to Inbrija (levodopa inhalation powder), discussed above, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS drug delivery technology can provide a significant therapeutic benefit to patients.

Disorders of the central nervous system, or CNS, in addition to Parkinson's disease, may be addressed by ARCUS products with the delivery of active agents to the CNS with rapid onset and reduced systemic exposure. For example, we are currently developing CVT-427, an inhaled triptan (zolmitriptan) intended for acute treatment of migraine by using the ARCUS drug delivery technology. Triptans are the class of drug most commonly prescribed for acute treatment of migraine. Oral triptans, which account for the majority of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. Triptans delivered subcutaneously (injection) provide the most rapid onset of action, but are not convenient for patients. Many triptans are also available in nasally delivered formulations. However, based on available data, we believe that nasally delivered triptans generally have an onset of action similar to orally administered triptans.

In December 2015, we initiated and completed a Phase 1 safety/tolerability and pharmacokinetic clinical trial of CVT-427 for acute treatment of migraine. In June 2016, at the 58th Annual Scientific Meeting of the American Headache Society, we presented pharmacokinetic data from the Phase 1 trial which showed increased bioavailability and faster absorption compared to oral and nasal administration of the same active ingredient in healthy adults. In particular, the data showed that CVT-427 had a median Tmax of about 12 minutes for all dose levels compared to 1.5 hours for the oral tablet and 3.0 hours for the nasal spray. There were no serious adverse events, dose-limiting toxicities, evidence of bronchoconstriction or discontinuations due to adverse events reported in this study. The most commonly reported treatment-emergent adverse events were cough, chest discomfort, headache, and feeling hot. Apart from cough, single dose CVT-427 tolerability was generally consistent with the known safety profile of zolmitriptan. In December 2016, we completed a special population study to evaluate safe inhalation of CVT-427 in people with asthma and in smokers. Some subjects showed evidence of acute, reversible bronchoconstriction, post-inhalation. We plan to work on reformulating to move the program forward, once we have made more progress on the approval and launch of Inbrija.

In July 2015, the Bill & Melinda Gates Foundation awarded us a $1.4 million grant to support the development of a formulation and delivery system for a dry powder version of lung surfactant, a treatment for neonatal respiratory distress syndrome, or nRDS. In collaboration with the Massachusetts Institute of Technology, we developed a novel formulation and delivery device based on our proprietary ARCUS drug delivery technology. nRDS is a condition affecting prematurely born infants in which their lungs are underdeveloped and thus lack a sufficient amount of lung surfactant. It can be fatal, or lead to severe, chronic health issues caused by a lack of oxygen getting to the baby's brain and other organs. Delivering liquid surfactant to the lungs via intubation is the standard of care. We believe that our formulation and delivery system may present a more practical alternative for use in developing areas of the world, where intubation poses numerous problems. This program is not aimed at developing a commercial product, but our work on this program could potentially generate information that is useful for adapting the ARCUS drug delivery technology to commercial pediatric uses.

We are also beginning to formulate potential ARCUS products for two different rare lung diseases.

Other Research and Development Programs

Following is a description of our other research and development programs.

- SYN120: SYN120 is a potential treatment for Parkinson's-related dementia, which we acquired with Biotie Therapies. Data from a Phase 2 exploratory study that we completed in 2017 showed that several of the outcome measures trended in favor of drug versus placebo, particularly with respect to neuropsychiatric symptoms. However, neither the primary nor key secondary endpoints achieved statistical significance. We are continuing to review the data, which will be presented at an upcoming medical meeting.

- BTT1023: Through Biotie Therapies, we are also developing BTT1023 (timolumab), a product candidate for the orphan disease Primary Sclerosing Cholangitis, or PSC, a chronic and progressive liver disease. There are no approved drug therapies for PSC and liver transplant is the only treatment. Interim data from an ongoing Phase 2 proof-of-concept clinical trial of BTT1023 for PSC are expected in the second quarter of 2018.
- rHIgM22: We are developing rHIgM22, a remyelinating antibody, as a potential therapeutic for MS. We believe a therapy that could repair myelin sheaths has the potential to restore neurological function to those affected by demyelinating conditions. We have completed and analyzed data from a Phase 1 trial using one of two doses of rHIgM22 or placebo in 27 people with MS who experienced an acute relapse. In addition to assessing safety and tolerability during an acute relapse, the study included exploratory efficacy measures such as a timed walk, magnetization transfer ratio imaging of lesion myelination in the brain and various biomarkers. Data from the trial showed that a single dose of rHIgM22 was not associated with any safety signals. The trial's primary objectives were safety and tolerability of a single dose following a relapse. The study was not powered to show efficacy and exploratory measures showed no difference between the treatment groups. We are considering next steps for the program.
- Cimaglermin alfa: Cimaglermin alfa is a member of the neuregulin growth factor family, and has been shown to promote recovery after neurological injury, as well as enhance heart function in animal models of heart failure. In 2013, we commenced a Phase 1b single-infusion trial in people with heart failure, which assessed the tolerability of three dose levels of cimaglermin, and also included an assessment of drug-drug interactions and several exploratory measures of efficacy. In 2015 we announced that we had stopped enrollment in this trial based on the occurrence of a case of hepatotoxicity (liver injury) manifested by clinical symptoms and an elevation in liver chemistry tests meeting the FDA Drug-Induced Liver Injury Guidance (FDA 2009) stopping rules. We also received a notification of clinical hold from the FDA following submission of this information. The abnormal blood tests resolved within two to three weeks. We subsequently conducted additional analyses and non-clinical studies to further define the nature of the hepatoxicity, and met with the FDA to present these data as part of our request that the program be removed from the clinical hold. The FDA lifted the clinical hold in April 2017. We are seeking to partner or out-license this program.

NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we were previously assessing for the treatment of neuropathic pain. In 2013, we acquired development and commercialization rights in the U.S., Canada, Latin America and certain other territories. We believe NP-1998 has the potential to treat multiple neuropathies, but we have not invested in further development of NP-1998 for several years and we are seeking to partner or out-license this program.

Financial Guidance for 2018

We are providing the following guidance with respect to our 2018 financial performance:

- We expect 2018 net revenue from the sale of Ampyra to range from $330 million to $350 million. This guidance is subject to change based on the decision of the United States Court of Appeals for the Federal Circuit in our appeal of a March 2017 District Court decision invalidating certain Ampyra patents, as further described above in this report.
- Research and development (R&D) expenses in 2018 are expected to range from $100 million to $110 million, excluding share-based compensation charges and including manufacturing expenses associated with Inbrija.
- Selling, general and administrative (SG&A) expenses in 2018 are expected to range from $170 million to $180 million, excluding share-based compensation charges.

We are projecting a 2018 year-end cash balance in excess of $300 million.

The projected range of R&D and SG&A expenses in 2018 are provided on a non-GAAP basis, as both excluding share-based compensation charges. Due to the forward looking nature of this information, the amount of compensation charges and benefits needed to reconcile these measures to the most directly comparable GAAP financial measures is dependent on future changes in the market price of our common stock and is not available at this

time. 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 these non-GAAP financial measures help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses these non-GAAP financial measures to establish budgets and operational goals, and to manage our business and to evaluate its performance.

Results of Operations

Three-Month Period Ended March 31, 2018 Compared to March 31, 2017

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 $102.8 million and $112.0 million for the three-month periods ended March 31, 2018 and 2017, respectively, a decrease of $9.2 million, or 8.2%. The net revenue decrease comprised net price increases, net of discount and allowance adjustments of $71.8 million, offset by decreased net volume of $81.0 million. Effective January 1, 2018, we increased our list sale price to our customers by 9.5%.

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

The net revenue for the three-month period ended March 31, 2018 decreased from net revenue of $167.2 million for the three-month period ended December 31, 2017. We believe that the decrease in net revenue between the fourth quarter of 2017 and the first quarter of 2018 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, there was a modest expansion in customer inventories in the fourth quarter of 2017 which normalized by the end of the first quarter of 2018.

Other Net Product Revenues

We recognized net revenue from the sale of other products of $0.2 million for the three-month period ended March 31, 2018, as compared to $0.6 million for the three-month period ended March 31, 2017, a decrease of $0.4 million.

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

License Revenue

We recognized $2.3 million in license revenue for the three-month period ended March 31, 2017, related to the $110.0 million received from Biogen in 2009 as part of our collaboration agreement. As of January 1, 2018, we adopted ASC 606 “Revenue from Contracts with Customers” (“ASC 606). Under ASC 606, revenue related to the upfront payment is recognized at a point in time rather than over time. As a result of adopting ASC 606, we recognized the remaining deferred revenue as of January 1, 2018 as a cumulative effect adjustment to the accumulated deficit on the consolidated balance sheet as of January 1, 2018.

Royalty Revenue

We recognized $3.2 million and $2.5 million in royalty revenue for the three-month periods ended March 31, 2018 and 2017, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized $1.3 million in royalty revenue for the three-month period ended March 31, 2017, related to the authorized generic sale of Zanaflex Capsules and $0.7 million in royalty revenue for the three-month period ended March 31, 2017, related to sales of Selincro. The assets, Zanaflex and Selincro were monetized in fiscal 2017.

Cost of Sales

We recorded cost of sales of $21.3 million for the three-month period ended March 31, 2018 as compared to $25.2 million for the three-month period ended March 31, 2017. Cost of sales for the three-month period ended March 31, 2018 consisted primarily of $18.1 million in inventory costs related to recognized revenues, $2.4 million in royalty fees based on net product shipments, and $0.7 million for costs related to the amortization of intangible assets. Cost of sales for the three-month period ended March 31, 2017 consisted primarily of $20.2 million in inventory costs related to recognized revenues, $2.5 million in royalty fees based on net product shipments and costs related to Biotie of $2.2 million.

Cost of License Revenue

We recorded cost of license revenue of $0.2 million for the three-month period ended March 31, 2017. Cost of license revenue represented 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. As of January 1, 2018, we adopted ASC 606 “Revenue from Contracts with Customers” (“ASC 606). As a result of adopting ASC 606, we recognized the remaining deferred cost of license revenue as of January 1, 2018 as a cumulative effect adjustment to the accumulated deficit on the consolidated balance sheet as of January 1, 2018.

Research and Development

Research and development expenses for the three-month period ended March 31, 2018 were $30.6 million as compared to $46.5 million for the three-month period ended March 31, 2017, a decrease of approximately $15.9 million, or 34.2%. The decrease was due primarily to reductions in spending of $4.4 million for Inbrija (levodopa inhalation powder) as the clinical trials for Inbrija have closed out and we are approaching the potential approval, $3.0 million for our Ampyra life cycle management program, $4.9 million for salaries and benefits related costs and $3.7 million for our discontinued programs, partially offset by certain other expenses.

Selling, General and Administrative

Sales and marketing expenses for the three-month period ended March 31, 2018 were $22.9 million compared to $25.1 million for the three-month period ended March 31, 2017, a decrease of approximately $2.2 million, or 8.8%. The decrease was attributable to a decrease in marketing, trade and sales related spending of $3.1 million, partially offset by an increase in overall salaries and benefits of $1.0 million.

General and administrative expenses for the three-month period ended March 31, 2018 were $24.7 million compared to $26.9 million for the three-month period ended March 31, 2017, a decrease of approximately $2.2 million, or 8.2%. This decrease was primarily due to a decrease in business development, legal, finance and other related expenses of $2.5 million and a decrease in Biotie spending of $0.8 million, partially offset by an increase in salaries and benefits related costs of $1.1 million.

Changes in Fair Value of Acquired Contingent Consideration

As a result of the original Civitas spin out of Alkermes, part of the consideration to Alkermes was a future royalty to be paid to Alkermes on Civitas products. Acorda acquired this contingent consideration as part of the Civitas acquisition. The fair value of that future royalty is assessed quarterly. We recorded an expense pertaining to changes in the fair-value of acquired contingent consideration of $6.2 million for the three-month period ended March 31, 2018 as compared to $10.8

million for the three-month period ended March 31, 2017. 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.

Other Expense

Other expense was $5.2 million for the three-month period ended March 31, 2018 compared to other expense of $4.5 million for the three-month period ended March 31, 2017, an increase in expense of $0.7 million. The increase was due primarily to an increase in interest and amortization of debt discount expense of $1.4 million, partially offset by an increase in interest income of approximately $0.3 million and a decrease in realized losses on foreign currency exchange of approximately $0.4 million

(Provision) for Benefit from Income Taxes

For the three-month periods ended March 31, 2018 and 2017, the Company recorded a ($3.5) million provision for and $0.9 million benefit from income taxes, respectively. The effective income tax rates for the Company for the three-month periods ended March 31, 2018 and 2017 were (74%) and 5%, respectively. The variance in the effective tax rates for the three-month period ended March 31, 2018 as compared to the three-month period ended March 31, 2017 was due primarily to the decrease in the federal statutory tax rate as a result of tax reform, the valuation allowance recorded on deferred tax assets for which no tax benefit can be recognized, state taxes, and the reduction in the research and development tax credit.

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

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of our common stock and preferred stock, a convertible debt offering, payments received under our collaboration and licensing agreements, sales of Ampyra, and Qutenza, and, to a lesser extent, from loans, government and non-government grants and other financing arrangements.

At March 31, 2018, we had $333.0 million of cash, cash equivalents and short-term investments, compared to $307.1 million at December 31, 2017. We expect that our existing cash and cash flows from operations will be sufficient to fund our ongoing operations over the next 12 months from the financial statement filing date.

In April 2017, following a Federal District Court’s decision which invalidated certain of the Company’s patents relating to Ampyra, we implemented a corporate restructuring to reduce our cost structure and focus our resources on our most important and valuable initiatives, including our Inbrija development program and maximizing Ampyra value. As part of this restructuring, we reduced headcount by approximately 20%. The majority of the reduction was completed in April 2017. We believe that the operating expense reductions from the restructuring, as well as additional expense reductions due to the termination of our tozadenant development program in November 2017, will enable us to fund operations through the launch of Inbrija, pending approval from the FDA. However, there can be no guarantee that we will have sufficient funding to do so. We may need to seek additional equity or debt financing or strategic collaborations to complete our product development activities, and could require substantial funding to commercialize

any products that we successfully develop. We may not be able to raise additional capital on favorable terms, or at all.

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Ampyra, the time of approval (if ever) and launch of Inbrija, 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

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 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. As of March 31, 2018, the Notes did not meet the criteria to be convertible.

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

The Company will pay 1.75% interest per annum on the principal amount of the Notes, payable semiannually in arrears in cash on June 15 and December 15 of each year.

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

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

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

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

Our outstanding note balances as of March 31, 2018 consisted of the following:

(In thousands)	March 31, 2018
Liability component:	
Principal	$345,000
Less: debt discount and debt issuance costs, net	(33,772)
Net carrying amount	$311,228
Equity component	$61,195

Non-Convertible Capital Loans

The Non-Convertible Capital Loans ("Tekes Loans") which were granted by Tekes, a Finnish Funding Agency for Technology and Innovation, had a fair value of $20.5 million (€18.2 million) at the date of acquisition. The Tekes loans have a carrying value of approximately $24.6 million as of March 31, 2018. The Tekes Loans consist of fourteen non-convertible loans that bear interest based on the greater of 3% or the base rate set by Finland's Ministry of Finance minus one (1) percentage point. The maturity dates for these loans range from eight to ten years from the date of issuance, however, according to certain terms and conditions of the loans, Biotie may repay the principal and accrued and unpaid interest of the loans only when the consolidated retained earnings of Biotie is sufficient to fully repay the loans.

Research and Development Loans

The Research and Development Loans ("R&D Loans") which were granted by Tekes had a fair value of $2.9 million (€2.6 million) at the date of acquisition. The R&D Loans have a carrying value of approximately $2.0 million as of March 31, 2018. The R&D Loans bear interest based on the greater of 1% or the base rate set by Finland's Ministry of Finance minus three (3) percentage points. The principal on these loans will be paid in five equal annual installments beginning in 2017 through 2021.

Investment Activities

At March 31, 2018, cash, cash equivalents and short-term investment were approximately $333.0 million, as compared to $307.1 million at December 31, 2017. Our 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 money market funds, high-grade corporate debt securities and commercial paper. Our short term investments consist of high-grade corporate debt securities and commercial paper with original maturities of twelve months or less at date of purchase. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances.

Net Cash Provided by Operations

Net cash provided by operations was $28.7 million for the three-month period ending March 31, 2018. Cash provided by operations for the three-month period ended March 31, 2018 was primarily due to a net loss of $8.2 million, a decrease in accounts payable and accrued expenses of $18.3 million, non-cash royalty revenue of $2.8 million and an increase in other

assets of $1.5 million. This was partially offset by a decrease in accounts receivable of $30.6 million, stock compensation expense of $5.9 million, depreciation and amortization of $3.3 million, a change in contingent consideration liability of $6.2 million, amortization of debt discount and debt issuance costs of $4.0 million, and a decrease in inventory of $9.8 million.

Net Cash Used in Investing

Net cash used in investing activities for the three-month period ended March 31, 2018 was $111.6 million, which was due primarily to purchases of short-term investments and property and equipment of $106.8 million and $4.8 million, respectively.

Net Cash Provided by Financing

Net cash provided by financing activities for the three-month period ended March 31, 2018 was $1.5 million, which was due to $3.4 million in net proceeds from the issuance of common stock and stock option exercises, partially offset by the repurchase of treasury stock of $1.2 million and repayment of loans payable of $0.7 million.

Contractual Obligations and Commitments

A summary of our minimum contractual obligations related to our material outstanding contractual commitments is included in Note 14 of our Annual report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A, for the year ended December 31, 2017. Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

Under certain agreements, we are required to pay royalties or license fees and milestones 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. During the three-month period ended March 31, 2018, commitments related to the purchase of inventory increased as compared to December 31, 2017. As of March 31, 2018, we have inventory-related purchase commitments totaling approximately $24.5 million.

Critical Accounting Policies and Estimates

Our critical accounting policies are detailed in our Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A, for the year ended December 31, 2017. As of March 31, 2018, with the exception of the adoption of ASU 2014-09, “Revenue from Contracts with Customers” (Topic 606), ASU 2016-15 and ASU 2016-18 “Statement of Cash Flows” (Topic 230), ASU 2017-09, “Compensation – Stock Compensation” (Topic 718): Scope of Modification Accounting and ASU 2017-01, and “Business Combinations” (Topic 805): Clarifying the Definition of a Business, our critical accounting policies have not changed materially from December 31, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash equivalents, short-term investments, convertible senior notes, non-convertible capital loans, research and development loans and accounts payable. The estimated fair values of all of our financial instruments approximate their carrying values at March 31, 2018, except for the fair value of the Company’s convertible senior notes which was approximately $313 million as of March 31, 2018.

We have cash equivalents and short-term investments at March 31, 2018, 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, high-grade corporate bonds and commercial paper, the carrying value of our cash equivalents and short-term investments approximate their fair value at March 31, 2018. At March 31, 2018, we held $333 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 1.2%.

We maintain an investment portfolio in accordance with our investment policy. The primary objective of our investment policy is to preserve principal, maintain proper liquidity and to meet operating needs. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of

credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, interest rate risk is mitigated due to the conservative nature and relatively short duration of our investments.

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 2018, 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, Business Operations and Principal Accounting Officer. Based on that evaluation, these officers have concluded that, as of March 31, 2018, 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, Business Operations and Principal Accounting 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, Business Operations and Principal Accounting Officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended March 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Beginning January 1, 2018, we implemented ASC 606 - Revenue from Contracts with Customers. As a result of our implementation of ASC 606, we enhanced our control documentation related to revenue, although, with the exception of the adjustments to the recognition of our license revenue, the adoption of ASC 606 did not have a significant impact on our results of operations, cash flows, or financial position. The enhancements included revisions to our revenue recognition policy to apply the five-step model provided for in ASC 606 and other documentation enhancements to support ongoing monitoring activities in order to provide reasonable assurance regarding the fair presentation of our consolidated financial statements and related disclosures.

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

Ampyra ANDA Litigation

Overview. As further described below, our five initial Orange Book-listed patents for Ampyra are the subject of lawsuits relating to Paragraph IV Certification Notices received from ten generic drug manufacturers in 2014 and 2015, who submitted Abbreviated New Drug Applications, or ANDAs, with the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. In 2015 and 2016, we reached settlement agreements with six of the generic companies, and in February 2017, we announced that we had reached a settlement agreement with one additional generic company. As to the remaining three generic manufacturers, in March 2017, the U.S. District Court for the District of Delaware (the "District Court") rendered a decision from a bench trial held in September 2016. The District Court upheld our Orange Book-listed patent for Ampyra set to expire in July 2018, but invalidated the four other Orange Book-listed patents for Ampyra that are the subject of the litigation. We have appealed the decision on the four invalidated patents, and the non-settling generic drug manufacturers have appealed the decision upholding the patent set to expire in July 2018. As further described below, in April 2017 we received a Paragraph IV Certification Notice from an additional generic drug manufacturer, who submitted an ANDA with the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10mg., but we have reached a settlement with this generic drug manufacturer.

A sixth Ampyra patent was recently issued and listed in the Orange Book. We note that this patent does not entitle us to any additional statutory stay of approval under the Hatch-Waxman Act against the generic drug manufacturers that are involved in the patent litigation.

First ANDA Filers. In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis Laboratories FL, Inc. ("Actavis"), Alkem Laboratories Ltd. and its affiliate Ascend Laboratories, LLC ("Alkem"), Apotex Inc., Aurobindo Pharma Ltd. ("Aurobindo"), Mylan Pharmaceuticals, Inc., Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers challenged the validity of the five initial Orange Book-listed patents for Ampyra, and they 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 and certain affiliates 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 included recovery of litigation costs and injunctive relief, including a request that the effective date of any FDA approval for these generic companies to make, use, offer for sale, sell, market, distribute, or import the proposed generic products be no earlier than the dates on which the Ampyra Orange Book-listed patents expire, or any later expiration of exclusivity to which we are or become entitled. These lawsuits with the ANDA filers were consolidated into a single case. A bench trial was completed in September 2016, and the District Court issued a decision in March 2017. The District Court upheld U.S. Patent No. 5,540,938 (the '938 patent), which is set to expire in July 2018. The claims of the '938 patent 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. The District Court invalidated U.S. Patent Nos. 8,663,685, 8,007,826, 8,440,703, and 8,354,437 which pertain to Ampyra. In May 2017, we appealed the ruling on these patents. As a result of the District Court's ruling, no generic version of Ampyra will be marketed in the U.S. at least until July 31, 2018, although in June 2017 the non-settling ANDA filers appealed the District Court's decision upholding the '938 patent. Generic versions of Ampyra may be further delayed if the United States Court of Appeals for the Federal Circuit (the "Appellate Court") overturns the District Court's decision on the four invalidated patents, which could include reversal or

remand of the case back to the District Court. If the Appellate Court does not overturn the District Court's decision by July 30, 2018, multiple ANDA filers may be able to launch generic versions of Ampyra absent injunctive relief. We expect the appeals process to take approximately 12 to 18 months from the filing of the appeal in May 2017. Both the Biotechnology Innovation Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) filed amicus briefs in support of our appeal, raising important issues in conjunction with biopharmaceutical innovation. The appellate court has scheduled oral argument for June 7, 2018, and we are expecting a decision on the appeal in the second half of 2018.

In October and December 2015, we entered into settlement agreements with Actavis and Aurobindo to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreements, Actavis and Aurobindo will be permitted to market generic versions of Ampyra in the

U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The District Court entered an order dismissing the case against Actavis without prejudice in October 2015. As a result of the settlement agreement with Aurobindo, and upon the request of the parties, the District Court entered a Consent Order, in which it dismissed our litigation against Aurobindo in December 2015. The parties have submitted the agreements to the Federal Trade Commission and the Department of Justice, as required by federal law.

In August 2016, we entered into a settlement agreement with Alkem to resolve the patent litigation that we brought against Alkem in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Alkem will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. As a result of the settlement agreement with Alkem, and upon the request of the parties, the District Court entered a Consent Order, in which it dismissed our litigation against Alkem in August of 2016. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by Federal law.

In August 2016, we entered into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Limited (collectively "Accord") to resolve the patent litigation that we brought against Accord in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Accord will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. As a result of the settlement agreement with Accord, and upon the request of the parties, the District Court entered a Consent Order, in which it dismissed our litigation against Accord in August of 2016. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by state law. The settlements with Actavis, Aurobindo, Alkem and Accord do not resolve the patent litigation that we brought against the other ANDA filers, as described in this report.

In February 2017, we entered into a settlement agreement with Apotex Inc. and its subsidiary Apotex Corporation (collectively “Apotex”) to resolve the patent litigation that we brought against them in the U.S. District Court for the District of Delaware, described above. As a result of the settlement agreement, Apotex will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2025, or potentially earlier under certain circumstances. The District Court has entered a Consent Order, in which it has dismissed our litigation against Apotex referred to above. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Apotex does not resolve the patent litigation that we brought against other ANDA filers, as described in this report.

Second ANDA Filers. In May 2015, we received a Paragraph IV Certification Notice from Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. ("Sun") advising that they had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Sun challenged the validity of four of the five initial Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and also asserted that generic versions of its products may not infringe certain claims of these patents. In response to the filing of the ANDA, in May 2015 we filed a lawsuit against Sun in the U.S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685. In October 2015, we entered into a settlement agreement with Sun to resolve this patent litigation. As a result of the settlement agreement, Sun will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially 181 days after a first ANDA filer has entered the market. As a result of the settlement agreement, and upon request of the parties, the District Court entered a Consent Order, in which it dismissed our litigation against Sun in October 2015. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Sun does not resolve the patent litigation that we brought against the other ANDA filers, described in this report.

In September 2015, we received a Paragraph IV Certification Notice from Par Pharmaceutical, Inc. ("Par") advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. Par challenged the validity of four of the five initial Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and it also asserted that generic versions of its products may not infringe certain claims of these patents. In response to the filing of the ANDA, in September 2015 we filed a lawsuit against Par in the U.S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685. In January 2016, we entered into a settlement agreement with Par to resolve this patent litigation. As a result of the settlement agreement, Par will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially 181 days after a first ANDA filer has entered the market. As a result of the settlement agreement, and upon the request of the parties, the District Court entered a Consent Order, in which it dismissed our litigation

against Par in January 2016. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Par does not resolve the patent litigation that we brought against the other ANDA filers, described in this report.

In April 2017, we received a Paragraph IV Certification Notice from Micro Labs Ltd. ("Micro") advising that it had submitted an ANDA to the FDA seeking marketing approval for a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10mg. Micro challenged the validity of four of the five initial Orange Book-listed patents for Ampyra, and did not file against our U.S. Patent No. 5,540,938, and it also asserted that a generic version of its product does not infringe certain claims of these patents. In response to the filing of the ANDA, in May 2017 we filed a lawsuit against Micro in the U.S. District Court for the District of New Jersey, asserting infringement of our U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685. In January 2018, we entered into a settlement agreement with Micro to resolve this patent litigation. As a result of the settlement agreement, Micro will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2026, or potentially earlier under certain circumstances. As a result of the settlement agreement, and upon the request of the parties, the U.S. District Court for the District of New Jersey entered a Dismissal Order, in which it dismissed our litigation against Micro in January 2018. The parties have submitted the agreement to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlement with Micro does not resolve the patent litigation that we brought against the other ANDA filers, described in this report.

We will vigorously defend our intellectual property rights.

Shareholder Litigation

On November 17, 2017, a purported class action lawsuit was filed against us and certain of our current and former officers in the United States District Court for the Southern District of New York, by Michael Hague on behalf of stockholders who purchased or otherwise acquired our common stock between April 18, 2016 through November 14, 2017, which we refer to as the purported class period. The complaint asserted claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, including allegations that our stock was artificially inflated during the class period because we and certain current and former officers allegedly made misrepresentations or did not make proper disclosures regarding tozadenant, a pharmaceutical product candidate we acquired with Biotie Therapies in 2016. Specifically, the lawsuit alleged that we failed to disclose, throughout the class period, tozadenant's safety risks and approval prospects, and also that we overstated the benefits of the Biotie Therapies acquisition. The complaint sought, among other relief, class certification of the lawsuit, unspecified damages, interest, attorneys' fees, expert fees and other costs. On March 13, 2018, the District Court granted the plaintiffs' motion to voluntarily dismiss the class action without prejudice. There is no settlement agreement between us and the plaintiff, and each party is responsible for its own costs and attorneys' fees.

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, as amended by Amendment No. 1 on Form 10-K/A for the year ended December 31, 2017, all of which could materially affect our business, financial condition or future results. These risks are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Following is the restated text of certain risk factors to report changes since our publication of risk factors in our 2017 Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A.

We rely on our Chelsea manufacturing facility for the manufacture of Inbrija (levodopa inhalation powder) and other ARCUS inhaled therapeutic product candidates, and our business could be harmed if we do not obtain required regulatory approval to manufacture commercial product at that facility, if there is an interruption in operations at the facility, or if the facility does not have manufacturing capacity needed to meet product demand.

We currently manufacture all clinical supply of Inbrija at our Chelsea, Massachusetts manufacturing facility that we occupy under a lease that expires in December 2025, which we may extend for up to ten years. We intend to manufacture all commercial supplies of Inbrija, if approved for commercial sale, as well as supplies of all additional ARCUS inhaled therapeutic candidates that we may develop, in this manufacturing facility. However, our Chelsea manufacturing facility has not been inspected by the FDA. Prior to commercialization of Inbrija, the FDA will likely conduct a pre-approval inspection. If, during this inspection, the FDA determines that the systems or facility do not meet FDA current good manufacturing practices, or cGMP, requirements, the FDA may not grant marketing approval for our product. If we obtain approval from the

FDA for Inbrija, we anticipate the need to expand our manufacturing operations at the Chelsea facility after product launch to meet demand depending on the timing and extent of sales growth. Our inability to expand the facility in a timely manner or unexpected demand for commercial quantities of Inbrija could cause a supply shortage that would harm our commercialization of Inbrija.

Furthermore, if we were to lose the use of our facility or equipment, our manufacturing facility and manufacturing equipment would be difficult to replace and could require substantial replacement lead time and substantial additional funds. Our facility may be affected by natural disasters, such as floods or fire, or we may lose the use of our facility due to manufacturing issues that arise at our facility, such as contamination or regulatory concerns following a regulatory inspection of our facility. We may also unexpectedly experience these types of manufacturing issues as the unintended result of the construction and other activities occurring at the facility needed for expansion. In the event of a loss of the use of all or a portion of our facility or equipment for the reasons stated above or any other reason, we would be unable to manufacture Inbrija or any other ARCUS inhaled therapeutic products or product candidates until such time as our facility could be repaired, rebuilt or we are able to address other manufacturing issues at our facility. Any such interruptions in our ability to manufacture these products or product candidates would harm our business. Even if we do not suffer a loss of the facility or equipment within the facility, manufacturing operations can experience intermittent interruptions due to the need for routine or unexpected maintenance, inspection and repairs of the facility or the equipment, and, depending on their frequency and duration, these intermittent interruptions could also harm our business.

We do not currently have back-up manufacturing capability at another facility and there are only limited third-party manufacturers that we believe would be capable of manufacturing Inbrija or other ARCUS inhaled therapeutic products or product candidates. If the need arises to obtain supply from a third party manufacturer, there can be no assurance that we could identify a third party that would be capable and willing to manufacture for us on reasonable terms, if at all, or that they could supply us in sufficient quantities on a timely basis to meet our needs. Engaging a third party manufacturer to supply ARCUS products or product candidates would likely be a lengthy process involving the transfer of a proprietary, specialized and regulated manufacturing processes and which would be subject to the FDA regulatory approval requirements described above. Also, this would require that we share proprietary trade secrets and know-how with the third party manufacturer relating to Inbrija and our ARCUS platform. When our business requires that we share that type of information, we seek to protect it, in part, with confidentiality agreements, but those agreements may not provide adequate protection or prevent the unauthorized use or disclosure of the information. The unauthorized use or disclosure of our proprietary information could harm its value by enabling others to copy or use our information for their own products, methods or technologies, and we may not have an adequate remedy for the harm caused. If we are successful in engaging a third party manufacturer, they may not perform their obligations to us and/or they may be unable or unwilling to establish or increase production capacity commensurate with our needs. Also, third party manufacturers and suppliers are subject to their own operational and financial risks that are outside of our control, including macro-economic conditions that may cause them to suffer liquidity or operational problems and that could interfere with their business operations.

Expanding our Chelsea manufacturing capacity will be costly and involves numerous risks, and if Inbrija receives FDA approval, our efforts to commercialize the product could be harmed if we cannot complete expansion of the facility in a timely manner.

If Inbrija receives FDA approval, we anticipate the need to expand our manufacturing capacity at the Chelsea facility after product launch to meet demand depending on the timing and extent of sales growth. The ARCUS dry powder aerosol particles are generated by applying our proprietary and multi-step spray drying process to active pharmaceutical ingredient. The application of spray drying in the pharmaceutical industry is highly specialized, and the process of manufacturing ARCUS particles requires significant expertise in dry powder manufacture and handling and capsule filling. Expanding our manufacturing capacity will require substantial additional expenditures and various

regulatory approvals and permits. Further, we may need to hire and train additional employees and managerial personnel to staff our expanding manufacturing operations. Manufacturing scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology. Our expanded Chelsea facility will have to continue to comply with cGMP requirements, as described above in these risk factors, as well as other applicable environmental, safety, and other governmental permitting requirements. These challenges could delay or prevent us from successfully expanding our Chelsea manufacturing capacity. If we are delayed in or prevented from expanding our Chelsea facility, we may need to seek a third party to manufacturer additional Inbrija supply for us. As described above in these risk factors, there can be no assurance that we could identify a third party that would be capable and willing to manufacture for us on reasonable terms, if at all, or that they could supply us with product in sufficient quantities on a timely basis to meet our needs. If we cannot increase our supply of Inbrija by expanding our capacity in Chelsea or

engaging a third party manufacturer, we may not be able to meet demand for Inbrija and our ability to commercialize Inbrija could be harmed.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate false claims laws or fail to comply with our reporting and payment obligations under the Medicaid drug rebate program or other governmental pricing programs, or other applicable legal requirements, we may be subject to civil or criminal penalties or additional reimbursement requirements and sanctions, which could harm our business, financial condition, results of operations and growth prospects.

The distribution, sale and promotion of drug and biological products are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, the Federal Trade Commission, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, and are affected by the privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act, as amended and similar state laws. Because of the breadth of these laws and the narrowness of safe harbors under these laws, it is possible that some of our business activities could be subject to challenge under one or more of these laws. All of these activities are also subject to federal and state consumer protection and unfair competition laws.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Industry relationships with specialty pharmacies have also recently been scrutinized under these provisions. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce or facilitate prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. By statute, a violation of the federal anti-kickback statute may serve as the basis for a false claim under the false claims act. Numerous pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing kickbacks, such as free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; and engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Sanctions under these federal and state laws may include requirements to make payments to government-funded health plans to correct for insufficient rebates paid by us or overpayments made to us, civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines and imprisonment. We may also be subject to a corporate integrity agreement, deferred prosecution agreement, or similar arrangement.

Under the federal Sunshine Act, pharmaceutical manufacturers are required to collect information on payments or other transfers of value made to “covered recipients,” which are defined as physicians and teaching hospitals. The collected information has to be disclosed in annual reports that are placed on a public database. Similarly, pharmaceutical manufacturers are also required to annually report samples of prescription drugs requested by and distributed to healthcare providers. The law does not state whether these disclosures regarding samples will be made publicly available, and the FDA has not provided any guidance. If we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties.

We participate in the federal Medicaid drug rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid drug rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. Federal law requires that any company

that participates in the Medicaid drug rebate program extend comparable discounts to qualified purchasers under the Public Health Service Act pharmaceutical pricing program, which requires us to sell our products to certain customers at prices lower than we otherwise might be able to charge. The minimum basic Medicaid rebate for branded prescription drugs is 23.1%, and pharmaceutical manufacturers must pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, manufacturers must pay an additional Medicaid rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products.

For products to be made available to authorized users of the Federal Supply Schedule, additional pricing laws and requirements apply, as do certain obligations imposed by the Federal Acquisition Regulations. Under the Veterans Health Care Act of 1992, as amended (VHCA), we are required to offer certain drugs at a reduced price to a number of federal agencies, including the Veterans Administration, the Department of Defense (DOD), the Public Health Service and certain private Public Health Service designated entities, in order to participate in other federal funding programs including Medicare and Medicaid. Also, legislative changes enacted in 2009 require that discounted prices be offered for certain DOD purchases for its TRICARE retail program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

Pharmaceutical companies have been prosecuted under federal and state false claims laws for manipulating information submitted to the Medicaid drug rebate program or for knowingly submitting or using allegedly inaccurate pricing information in connection with federal pricing and discount programs.

Pricing and rebate calculations vary among products and programs. The laws and regulations governing the calculations are complex and are often subject to interpretation by us or our contractors, governmental or regulatory agencies and the courts. Our methodologies for calculating these prices could be challenged under false claims laws or other laws. We or our contractors could make a mistake in calculating reported prices and required discounts, revisions to those prices and discounts, or determining whether a revision is necessary, which could result in retroactive rebates (and interest and penalties, if any). Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. If we make these mistakes or if governmental agencies make these changes, we could face, in addition to prosecution under federal and state false claims laws, substantial liability and civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines or imprisonment or prosecutors may impose a Corporate Integrity Agreement, Deferred Prosecution Agreement, or similar arrangement.

Under the Affordable Care Act (ACA), drug manufacturers are required to provide a 50% discount (increasing to 70% in 2019) on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." In addition, the ACA imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U.S. government programs.

Also, Qutenza differs from Ampyra because it may be administered only by a healthcare professional. For this reason, it is treated as a "buy-and-bill" product by most payers, including Medicare, most Medicaid programs, and private payers. Buy-and-bill products must be purchased by healthcare providers before they can be administered to patients. Under the buy-and-bill model, healthcare providers subsequently bill the product to the patient's insurer, which may be a government healthcare program or private health plan. Purchasers of buy-and-bill products that are administered to Medicare patients are reimbursed under that program's Average Sales Price, or ASP, payment model. Because reimbursement for these patients is based on ASP and not the healthcare provider's actual purchase price for the

prescription drug, the reimbursement often differs somewhat from the actual price paid by the healthcare provider. Acorda does not sell Qutenza directly to healthcare providers, but rather, healthcare providers purchase this drug from a specialty distributor, who in turn acquires the product from us.

Historically, some pharmaceutical manufacturers have been accused by the government of “marketing the spread” between the healthcare provider’s purchase price and the reimbursement price, by allegedly promoting the potential to earn profit on each administration of the drug. Alternatively, other manufacturers have been alleged to have “manipulated” that spread by manipulating the determination of reimbursement rates by artificially inflating reported prices. We have adopted policies and training programs for our employees intended to prevent marketing or manipulating the spread between the price at which Qutenza is purchased and the price reimbursed by federal healthcare programs. However, if our actions are viewed by government regulators or qui tam relators as inappropriately marketing or manipulating that spread, we could be

investigated and, potentially, charged with violations of the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, the Medicaid drug rebate statute, and similar state laws.

In addition, if the actions we take by providing background educational material and other information to healthcare providers concerning billing for Qutenza are viewed as encouraging healthcare providers to misrepresent the professional services provided to beneficiaries of federal healthcare programs or to otherwise submit claims to federal healthcare programs that are designed to maximize reimbursement inappropriately, this could result in investigations, and possible charges of violating, these same laws.

Our existing or potential products may not be commercially viable if we fail to obtain or maintain an adequate level of reimbursement for these products by Medicaid, Medicare or other third-party payers.

Our ability to maintain and increase sales and profitability will depend in part on third-party payers, such as government or government-sponsored health administrative authorities, including Medicaid and Medicare Parts B and D, private health insurers and other such organizations, agreeing to reimburse patients for the cost of our products. Significant uncertainty exists as to the reimbursement status of newly approved drug products. Third-party payers are increasingly challenging the pricing of medical products and services and their reimbursement practices may affect the price levels for Ampyra or potential products such as Inbrija (levodopa inhalation powder) if it receives marketing approval. Our business could be materially harmed if the Medicaid program, Medicare program or other third-party payers were to deny reimbursement for our products or provide reimbursement only on unfavorable terms. Our business could also be harmed if the Medicaid program, Medicare program or other reimbursing bodies or payers limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate.

Third-party payers frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. We have agreed to provide such discounts and rebates to some third-party payers in relation to Ampyra. We expect increasing pressure to offer larger discounts and discounts to a greater number of third-party payers to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable. There is no guarantee that we would be able to negotiate agreements with third-party payers at price levels that are profitable to us, or at all. A number of third-party payers also implement utilization management techniques, such as prior authorization or quantity limits for Ampyra, or even refuse to provide reimbursement for Ampyra, and others may do so in the future. Patients who cannot meet the conditions of prior authorizations are often prevented from obtaining the prescribed medication, because they cannot afford to pay for the medication without reimbursement. If we are unsuccessful in maintaining reimbursement for our products at acceptable levels, or if reimbursement for our products by third-party payers is subject to overly restrictive utilization management, our business will be harmed. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and harm our results of operations.

The Medicare Part D outpatient prescription drug benefit is provided primarily through private entities, which attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations increase pressure to lower prescription drug prices or increase rebate payments to offset price. While the law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress support legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies. In addition, the Affordable Care Act contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. The Affordable Care Act requires drug manufacturers to provide a 50% discount (increasing to 70% in 2019) on prescriptions for

branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “donut hole.” Legislative or regulatory revisions to the Medicare Part D outpatient prescription drug benefit, as well as additional healthcare legislation that may be enacted at a future date, could reduce our sales and harm our results of operations.

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

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological conditions, including Parkinson's disease, or PD, and multiple sclerosis, or MS.

Our competitors may succeed in developing products that are more effective, safer or more convenient than our products or the ones we have under development or that render our approved or proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective, safer or more convenient for patients, or is able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would harm our ability to generate revenues and recover the substantial development costs we have incurred and will continue to incur.

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

Ampyra. In addition to the potential introduction of generic versions of Ampyra after July 30, 2018, further described below, we are aware of other companies developing products that may compete with Ampyra. These include Adamas Pharmaceuticals, Inc., which is developing ADS-5102 (amantadine hydrochloride) for patients with MS who have walking impairment, and Catalyst Pharmaceuticals, Inc., which is developing a 3,4-diaminopyridine product, licensed from Biomarin. Furthermore, several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Ampyra or some of our product candidates. In addition, in certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis, which is referred to as compounding. We are aware that at present compounded dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available.

Ampyra could become subject to competition from generic drug manufacturers. In March 2017, we announced a decision by the United States District Court for the District of Delaware in litigation with certain generic drug manufacturers upholding our Ampyra Orange Book-listed patent set to expire on July 30, 2018, but invalidating our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, we expect to maintain patent exclusivity with respect to Ampyra at least through July 30, 2018, depending on the outcome of appeal of the District Court's decision. The defendant generic drug manufacturers have appealed the District Court's decision upholding the patent that expires in July 2018, and we have appealed the ruling on the four invalidated patents. We expect the appeals process to take approximately 12 to 18 months from the filing of the appeal in May 2017. We expect to experience a rapid and significant decline in Ampyra sales beyond July 2018 due to competition from generic versions of Ampyra that may be marketed after the expiration of our remaining Ampyra patent, unless the District Court's decision on the four invalidated patents is overturned on appeal, which could include reversal or remand by the appeals court back to the District Court. If the appeals court does not overturn the District Court's decision by July 30, 2018, multiple ANDA filers may be able to launch generic versions of Ampyra absent injunctive relief. Our litigation with these generic drug manufacturers is described in further detail in Part I, Item 3 of this report. We will need to continue devoting significant resources to this litigation, and we can provide no assurance concerning its duration or outcome.

Inbrija (levodopa inhalation powder). If approved for the treatment of OFF periods, (re-emergence of symptoms) Inbrija would compete against on-demand therapies that aim to specifically address Parkinson's disease symptoms. Apokyn, an injectable formulation of apomorphine, is approved for the treatment of OFF periods. Apokyn was approved for this use in the U.S. in 2004 and in Europe in 1993. Also, Sunovion Pharmaceuticals Inc. is developing a sublingual, or under the tongue, formulation of apomorphine. This program is in Phase 3 clinical development and could potentially be commercially launched ahead of Inbrija. In January 2018, Sunovion announced positive topline results from their pivotal Phase 3 study for this program, and in March 2018 they submitted a New Drug Application to the FDA.

The standard of care for the treatment of Parkinson's disease is oral carbidopa/levodopa, but oral medication can be associated with wide variability in the timing and the amount of absorption and there are significant challenges in creating a

regimen that consistently maintains therapeutic effects as Parkinson's disease progresses. Inbrija may face competition from therapies that can limit the occurrence of OFF periods. Approaches to achieve consistent levodopa plasma concentrations include new formulations of carbidopa/levodopa, such as extended-release and intestinal infusions, and therapies that prolong the effect of levodopa. Impax Laboratories has received FDA approval for RYTARY, an extended-release formulation of oral carbidopa/levodopa, and extended release formulations of oral and patch carbidopa/levodopa are being developed by others including Impax Depomed Inc., Intec Pharma and NeuroDerm Ltd. Also, Abbvie Inc. has developed a continuous administration of a gel-containing levodopa through a tube that is surgically implanted into the intestine. This therapy, known as Duopa, has been approved by the FDA and is approved in the EU.

One or more of our competitors may utilize their expertise in pulmonary delivery of drugs to develop and obtain approval for pulmonary delivery products that may compete with Inbrija and any other of our other ARCUS drug delivery technology product candidates. These competitors may include smaller companies such as Alexza Pharmaceuticals, Inc., MannKind Corporation, Pulmatrix, Inc. and Vectura Group plc and larger companies such as Allergan, Inc., GlaxoSmithKline plc and Novartis AG. If approved, our product candidates may face competition in the target commercial areas.

Our inability to attract and retain key management and other personnel, or maintain access to expert advisors, may hinder our ability to execute our business plan.

We are highly dependent on the services of Dr. Ron Cohen, our President and Chief Executive Officer, as well as the other principal members of our management and scientific, regulatory, manufacturing and commercial personnel. Our success depends in large part upon our ability to attract and retain highly qualified personnel with the knowledge and experience needed for these and other areas of our business. We face intense competition in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. In addition, the discontinuation of our tozadenant program, the United States District Court for the District of Delaware's decision to invalidate certain Ampyra patents and our 2017 reduction in force may impede our ability to attract and retain highly qualified personnel. We do not maintain "key man" life insurance policies on the lives of our officers, directors or employees. The loss of one or more of our key employees, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan, particularly our efforts to obtain regulatory approval for, and if approved, manufacture and successfully launch Inbrija.

We also have scientific, medical, clinical, marketing and other advisors who assist us in our research and development, clinical, and commercial strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Similarly, they may have arrangements with other companies to assist in the development and commercialization of products that may compete with ours.

We depend on sophisticated information technology systems to operate our business and a cyber attack or other breach of these systems, or a system error, could have a material adverse effect on our business and results of operations.

We are increasingly dependent upon information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information) and confidential information with respect to our employees, customers, clinical trial patients and our business partners. In the ordinary course of our business, this type of data is also collected, stored, processed and transmitted on the networks and systems of our business partners and vendors from whom we purchase software

and/or technology-based services.

The size and complexity of our and any third party information technology systems and infrastructure, and their connection to the Internet, make such systems potentially vulnerable to service interruptions, system errors leading to data loss, data theft and/or cyber attacks. These incidents could result from inadvertent or intentional actions or omissions by our employees and consultants, or those of our business partners and vendors, or from the actions of third parties with malicious or criminal intent. To date, we have not experienced any material impact to our business or operations resulting from any of these occurrences affecting our or third party information technology systems; however, there is a growing risk of harm from these types of incidents because of rapid evolution of information technology systems, and because cyber attacks are increasing in frequency and in sophistication over time.

Data breaches or unauthorized data access or disclosure of our confidential information could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of

personal information of our clinical trial patients, employees and others. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation and business, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. Data breaches or unauthorized data access could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Data breaches or unauthorized data access could also result in liability to others, if these incidents involve the data of others that we have agreed, or are otherwise legally responsible, to keep confidential and protect.

Data breaches and unauthorized data access can be difficult to detect, and any delay in identifying any such incidents may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, and monitor such systems and infrastructure on an ongoing basis for any current or potential threats, there can be no assurance that these measures will prevent the type of incidents that could have a material adverse effect on our business and results of operations. Also, we rely on the security measures and monitoring activities of our business partners and vendors who may collect, store, process and transmit data on their networks and systems. In the event they experience a service issue or security incident: we may not receive timely notice from them of the issue or incident; they may not take adequate steps to remediate the issue or incident and protect against future occurrences; we may not have any remedy against them for losses and liabilities that we suffer, or if we have a remedy it may be inadequate, even though they are or may be at fault; and we may become subject to legal claims from others whose information has been compromised regardless of whether we are at fault.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

This table provides information about our purchases of shares of Acorda stock during the three-month period ended March 31, 2018.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
January 1-31, 2018	-	-	-	-
February 1-28, 2018	-	-	-	-
March 1-31, 2018	46,785	$25.69	-	-
Total	46,785	$25.69	-	-

(1)

Share repurchases reported in this column consist of shares of Acorda's common stock withheld to cover tax liability in connection with the settlement of vested restricted stock units (11,825 shares) and shares of Acorda's common stock withheld to cover the exercise price of stock options that were exercised prior to their 2018 expiration date (34,960 shares).

Item 6. Exhibits

Exhibit No.	Description
10.1	Cooperation Agreement dated February 27, 2018, by and between Registrant and Scopia Capital Management LP. Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed February 28, 2018.
10.2	Amendment D, dated March 29, 2018, by and between North River Everett Ave, LLC and Civitas Therapeutics, Inc.
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 Principal 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 Principal 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.

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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.

Date: May 9, 2018 President, Chief Executive Officer and Director

By: /s/ David Lawrence
David Lawrence

Date: May 9, 2018 Chief, Business Operations and Principal Accounting Officer