ACORDA THERAPEUTICS INC
Form 10-Q
November 06, 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 September 30, 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 every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth 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	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 October 31, 2018
Common Stock, $0.001 par value	47,558,339 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; increasing competition and accompanying loss of revenues in the U.S. from generic versions of Ampyra (dalfampridine) following our loss of patent exclusivity; 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," "p "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," 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)	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 321,011	$ 307,068
Restricted cash	365	410
Short term investments	139,935	—
Trade accounts receivable, net of allowances of $2,336 and $845, as of September 30, 2018 and December 31, 2017, respectively	51,461	81,403
Prepaid expenses	16,221	13,333
Finished goods inventory held by the Company	10,800	37,501
Other current assets	6,802	1,983
Total current assets	546,595	441,698
Property and equipment, net of accumulated depreciation	52,061	36,669
Goodwill	283,435	286,611
Intangible assets, net of accumulated amortization	428,575	430,603
Non-current portion of deferred cost of license revenue	—	1,638
Other assets	419	750
Total assets	$ 1,311,085	$ 1,197,969
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 29,554	$ 27,367
Accrued expenses and other current liabilities	97,816	100,128
Current portion of deferred license revenue	—	9,057
Current portion of loans payable	624	645
Current portion of liability related to sale of future royalties	7,714	6,763
Total current liabilities	135,708	143,960
Convertible senior notes (due 2021)	316,160	308,805
Non-current portion of acquired contingent consideration	131,229	112,722
Non-current portion of deferred license revenue	—	23,398
Non-current portion of loans payable	24,673	25,670
Deferred tax liability	70,656	22,459
Non-current portion of liability related to sale of future royalties	24,251	29,025
Other non-current liabilities	9,783	11,943
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value. Authorized 20,000,000 shares at September 30,	—	—

2018 and December 31, 2017; no shares issued as of September 30, 2018 and December 31, 2017, respectively		
Common stock, $0.001 par value. Authorized 80,000,000 shares at September 30, 2018 and December 31, 2017; issued 47,310,300 and 46,441,428 shares, including those held in treasury, as of September 30, 2018 and December 31, 2017, respectively	47	46
Treasury stock at cost (79,275 shares at September 30, 2018 and 16,151 shares at December 31, 2017)	(1,976)	(389)
Additional paid-in capital	999,880	968,580
Accumulated deficit	(403,439)	(455,108)
Accumulated other comprehensive income	4,113	6,858
Total stockholders' equity	598,625	519,987
Total liabilities and stockholders' equity	$ 1,311,085	$ 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 September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Revenues:				
Net product revenues	$ 139,973	$ 134,357	$ 393,388	$ 379,705
Royalty revenues	2,841	4,444	8,893	13,391
License revenue	—	2,264	—	6,793
Total net revenues	142,814	141,065	402,281	399,889
Costs and expenses:				
Cost of sales	25,391	29,992	77,834	84,840
Cost of license revenue	—	159	—	476
Research and development	22,855	33,286	79,325	130,963
Selling, general and administrative	43,571	40,741	135,435	142,100
Asset impairment	—	39,446	—	39,446
Changes in fair value of acquired contingent consideration	22,700	(400)	21,900	16,800
Total operating expenses	114,517	143,224	314,494	414,625
Operating income (loss)	28,297	(2,159)	87,787	(14,736)
Other (expense) income, net:				
Interest and amortization of debt discount expense	(5,415)	(4,180)	(16,326)	(13,783)
Interest income	1,176	30	2,412	103
Realized loss on foreign currency transactions	(1)	(18)	(8)	(458)
Other income	—	—	24	—
Total other expense, net	(4,240)	(4,168)	(13,898)	(14,138)
Income (loss) before taxes	24,057	(6,327)	73,889	(28,874)
Provision for income taxes	(37,968)	(18,868)	(49,802)	(23,421)
Net (loss) income	$ (13,911)	$ (25,195)	$ 24,087	$ (52,295)
Net (loss) income per share—basic	$ (0.29)	$ (0.55)	$ 0.51	$ (1.14)
Net (loss) income per share—diluted	$ (0.29)	$ (0.55)	$ 0.51	$ (1.14)
Weighted average common shares outstanding used in computing net (loss) income per share—basic	47,184	46,002	46,840	45,918
Weighted average common shares outstanding used in computing net (loss) income per share—diluted	47,184	46,002	47,251	45,918

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)

(unaudited)

(In thousands)	Three-month period ended September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Net (loss) income	$ (13,911)	$ (25,195)	$ 24,087	$ (52,295)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustment	(721)	7,266	(2,703)	19,838
Unrealized income (loss) on available for sale debt securities	35	—	(42)	—
Other comprehensive (loss) income, net of tax	(686)	7,266	(2,745)	19,838
Comprehensive (loss) income	$ (14,597)	$ (17,929)	$ 21,342	$ (32,457)

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Cash flows from operating activities:		
Net income (loss)	$ 24,087	$ (52,295)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Share-based compensation expense	16,246	25,264
Amortization of net premiums and discounts on investments	(807)	—
Amortization of debt discount and debt issuance costs	11,917	8,918
Depreciation and amortization expense	9,118	17,484
Change in acquired contingent consideration obligation	21,900	16,800
Unrealized foreign currency transaction loss	—	247
Intangible asset impairment	—	39,446
Non-cash royalty revenue	(7,826)	—
Deferred tax provision	42,565	16,746
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	29,942	(1,505)
(Increase) decrease in prepaid expenses and other current assets	(5,319)	1,614
Decrease in inventory	26,701	3,266
Decrease in non-current portion of deferred cost of license revenue	—	476
Decrease (increase) in other assets	25	(3,610)
Decrease in accounts payable, accrued expenses and other current liabilities	(5,508)	(29,557)
Decrease in non-current portion of deferred license revenue	—	(6,793)
Increase in other non-current liabilities	90	102
Net cash provided by operating activities	163,131	36,603
Cash flows from investing activities:		
Purchases of property and equipment	(22,548)	(10,370)
Purchases of intangible assets	(375)	(294)
Purchases of investments	(191,652)	—
Proceeds from maturities of investments	52,539	—
Net cash used in investing activities	(162,036)	(10,664)
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	14,978	7,001
Refund of deposit for purchase of noncontrolling interest	—	2,722
Purchase of treasury stock	(1,587)	(60)
Repayment of loans payable	(656)	(2,409)

Net cash provided by financing activities	12,735	7,254
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(238)	1,060
Net increase in cash, cash equivalents and restricted cash	13,592	34,253
Cash, cash equivalents and restricted cash at beginning of period	308,039	158,871
Cash, cash equivalents and restricted cash at end of period	$ 321,631	$ 193,124
Supplemental disclosure:		
Cash paid for interest	$ 3,045	$ 3,047
Cash paid for taxes	16,665	11,363

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 and nine-month periods ended September 30, 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 and Stockholders' Equity			
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 September 30, 2018 was as follows:

(In thousands)	Balance as of September 30, 2018 Prior to Adoption of ASC 606	Net Adjustments	Balance as of September 30, 2018 as Reported Under ASC 606
Assets			
Other current assets	$7,436	$ (634)	$6,802
Non-current portion of deferred cost of license revenue	1,161	(1,161)	—
Total Assets	$1,312,880	$ (1,795)	$1,311,085

Liabilities and Stockholders’ Equity			
Current portion of deferred license revenue	$9,057	$ (9,057)	$—
Non-current portion of deferred license revenue	16,606	(16,606)	—
Deferred tax liability	68,056	2,600	70,656
Accumulated deficit	(424,707)	21,268	(403,439)
Total liabilities and stockholders' equity	$1,312,880	$ (1,795)	$1,311,085

The impact of the adoption of ASC 606 on the Company's consolidated statement of operations for the three-month period ended September 30, 2018 was as follows:

(In thousands)	Three-Month Period Ended September 30, 2018 Balance Prior to Adoption of ASC 606	Effect of Change	Three-Month Period Ended September 30, 2018 Balance as Reported Under ASC 606
License revenue	$ 2,264	$(2,264)	$ —
Cost of license revenue	159	(159)	—
Operating income (loss)	$ 30,402	$(2,105)	$ 28,297
Net (loss) income	$ (11,806)	$(2,105)	$ (13,911)
Net (loss) income per share—basic	$ (0.25)	$(0.04)	$ (0.29)
Net (loss) income per share—diluted	$ (0.25)	$(0.04)	$ (0.29)

The impact of the adoption of ASC 606 on the Company's consolidated statement of operations for the nine-month period ended September 30, 2018 was as follows:

(In thousands)	Nine-Month Period Ended September 30, 2018 Balance Prior to Adoption of ASC 606	Effect of Change	Nine-Month Period Ended September 30, 2018 Balance as Reported Under ASC 606
License revenue	$ 6,792	$(6,792)	$ —
Cost of license revenue	477	(477)	—
Operating income (loss)	$ 94,102	$(6,315)	$ 87,787
Net income (loss)	$ 30,402	$(6,315)	$ 24,087
Net income (loss) per share—basic	$ 0.65	$(0.14)	$ 0.51
Net income (loss) per share—diluted	$ 0.64	$(0.13)	$ 0.51

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.

ASC 606 requires entities to record a contract asset when a performance obligation has been satisfied or partially satisfied, but the amount of consideration has not yet been received because the receipt of the consideration is conditioned on something other than the passage of time. ASC 606 also requires an entity to present a revenue contract as a contract liability in instances when a customer pays consideration, or an entity has a right to an amount of consideration that is unconditional (e.g. receivable), before the entity transfers a good or service to the customer.

We currently do not have any contract assets. We recognize contract liabilities when a customer pays an upfront deposit upon contract execution for future obligations to be performed by us. As of September 30, 2018, we had a contract liability in the amount of $5.5 million which reflects an upfront deposit paid by a customer upon contract execution for future obligations to be performed by us. The amount is currently reported in accrued expenses and other current liabilities in the Balance Sheet. If the contract is canceled, these upfront deposits are refundable only if certain obligations have not been performed by us. We did not have any contract liability as of December 31, 2017.

Product Revenue, Net

Net revenue from product sales is recognized at the transaction price when the customer obtains control of the Company's products, which occurs at a point in time, typically upon receipt of the product by the customer. The Company's products are sold primarily to a network of specialty providers which are contractually obligated to hold no more than an agreed upon number of days of inventory. The Company's payment terms are between 30 to 35 days.

The Company's net revenues represent total revenues adjusted for discounts and allowances, including estimated cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. These adjustments represent variable consideration under ASC 606 and are recorded for the Company's estimate of cash consideration expected to be 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. Actual 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 companies in our distribution network, which primarily includes specialty pharmacies and ASD Specialty Healthcare, Inc. 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 Services 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 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 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 September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Revenues:				
Net product revenues	$ 139,973	$ 134,357	$ 393,388	$ 379,705
Royalty revenues	2,841	4,444	8,893	13,391
License revenue	—	2,264	—	6,793
Total net revenues	$ 142,814	$ 141,065	$ 402,281	$ 399,889

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 losses and gains are recognized in the period incurred and are reported as other (expense) income, net 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 the following subsequent events required disclosure in these financial statements.

On October 30, 2018, we sold our Qutenza assets and NP-1998 development program. 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. NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we were previously assessing for the treatment of neuropathic pain. Under the asset purchase agreement, the buyer made aggregate cash payments to us of approximately $7.9 million for the assets.

Accounting Pronouncements Adopted

As noted above, in May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers" (Topic 606). 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 November 2016, the FASB issued 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:

	Nine-month period ended September 30, 2018		Nine-month period ended September 30, 2017	
(In thousands)	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$307,068	$321,011	$158,537	$192,496
Restricted cash	410	365	79	68
Restricted cash included in Other assets	561	255	255	560
Total Cash, cash equivalents and restricted cash per statement of cash flows	$308,039	$321,631	$158,871	$193,124

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 June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. Currently, share-based payment arrangements with employees are accounted for under ASC 718, while nonemployee share-based payments issued for goods and services are accounted for under ASC 505-50. ASC 505-50, before the amendments, differed significantly from ASC 718. However, FASB concluded that awards granted to employees are economically similar to awards granted to nonemployees and therefore two different accounting models were not justified. This ASU is effective for fiscal years beginning after December 15, 2018, and interim periods therein with early adoption permitted. The Company early adopted this guidance beginning April 1, 2018. The adoption of this guidance did not have an impact on its consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 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. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification

Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use model ("ROU") that requires a lessee to recognize an ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.

This ASU is effective for the Company on January 1, 2019. We expect to adopt the new standard on its effective date. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. We expect to adopt the new standard on January 1, 2019 and use the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019.

The new standard provides a number of optional practical expedients in transition. We expect to elect the 'package of practical expedients', which permits us not to reassess under the new standard our prior conclusions about lease

identification, lease classification and initial direct costs. We do not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

While we continue to assess all of the effects of adoption, we currently believe the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on our balance sheet for our real estate operating leases and (2) providing significant new disclosures for our leasing activities. While we continue to assess our contracts, we do not expect a significant change in our leasing activities between now and adoption. The new standard also provides practical expedients for an entity's ongoing accounting. We currently expect to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. We also currently expect to elect the practical expedient to not separate lease and non-lease components for all of our leases.

In January 2017, the FASB issued ASU 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 its consolidated financial statements.

In February 2018, the FASB issued ASU 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 ASU 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.

In July 2018, the FASB issued ASU 2018-09, “Codification Improvements.” The ASU’s amendments clarify, correct errors in, or make minor improvements to a variety of ASC topics. The changes in ASU 2018-09 are not expected to have a significant effect on current accounting practices. Some of the amendments in this update do not require transition guidance and will be effective upon issuance of this update. However, many of the amendments in this update do have transition guidance with effective dates for annual periods beginning after December 15, 2018, for public business entities. The Company is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13 “Fair Value Measurement (Topic 820): “Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.” The amendment in this ASU eliminate, add and modify certain disclosure requirements for fair value measurements as part of its disclosure framework project. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value

hierarchy, but public business entities will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, 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 August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.” The ASU clarifies certain aspects of ASU 2015-05, “Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement,” which was issued in April 2015. Specifically, the ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license).” The ASU is effective for all entities for fiscal years beginning after December 15, 2019, 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 August 2018, the Securities Exchange Commission (“SEC”) adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders’ equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. The Company anticipates its first presentation of changes in stockholders’ equity as required under the new SEC guidance will be included in its Form 10-Q for the three-month period ended March 31, 2019.

(3) Share-based Compensation

During the three month periods ended September 30, 2018 and 2017, the Company recognized share-based compensation expense of $5.1 million and $6.7 million, respectively. During the nine month periods ended September 30, 2018 and 2017, the Company recognized share-based compensation expense of $16.3 million and $26.2 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 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 September 30, 2018 and 2017 were approximately $12.39 and $9.46, respectively The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2018 and 2017 were approximately $12.81 and $10.68, respectively.

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

	For the three-month period ended September 30,		For the nine-month period ended September 30,	
(In millions)	2018	2017	2018	2017
Research and development expense	$ 1.1	$ 2.0	$ 4.4	$ 8.4
Selling, general and administrative expense	4.0	4.7	11.9	17.8
Total	$ 5.1	$ 6.7	$ 16.3	$ 26.2

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A summary of share-based compensation activity for the nine-month period ended September 30, 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	8,930	$ 29.46		
Granted	748	25.04		
Cancelled	(595)	28.07		
Exercised	(721)	20.78		
Balance at September 30, 2018	8,362	$ 29.91	5.6	$ 2,163
Vested and expected to vest at September 30, 2018	8,328	$ 29.93	5.6	$ 2,159
Vested and exercisable at September 30, 2018	6,763	$ 30.52	5.0	$ 1,857

Restricted Stock and Performance Stock Unit Activity

(In thousands) Restricted Stock and Performance Stock Units	Number of Shares
Nonvested at January 1, 2018	697
Granted	(148)
Vested	—
Forfeited	(127)
Nonvested at September 30, 2018	422

Unrecognized compensation cost for unvested stock options, restricted stock awards and performance stock units as of September 30, 2018 totaled $24.3 million and is expected to be recognized over a weighted average period of approximately 1.7 years.

The Company did not repurchase shares of common stock during the thee-month period ended September 30, 2018. During the nine month period ended September 30, 2018, the Company repurchased 63,124 shares of common stock at an average price of $25.15 per share or approximately $1.6 million. The share repurchase consists primarily

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 nine-month period ended September 30, 2018.

(4) (Loss) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings (loss) per share for the three and nine-month periods ended September 30, 2018 and 2017:

(In thousands, except per share data)	Three-month period ended September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Basic and diluted				
Net (loss) income	$ (13,911)	$ (25,195)	$ 24,087	$ (52,295)
Weighted average common shares outstanding used in computing net (loss) income per share—basic	47,184	46,002	46,840	45,918
Plus: net effect of dilutive stock options and restricted common shares	—	—	411	—
Weighted average common shares outstanding used in computing net (loss) income per share—diluted	47,184	46,002	47,251	45,918
Net (loss) income per share—basic	$ (0.29)	$ (0.55)	$ 0.51	$ (1.14)
Net (loss) income per share—diluted	$ (0.29)	$ (0.55)	$ 0.51	$ (1.14)

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

The following amounts were not included in the calculation of net (loss) income per diluted share because their effects were anti-dilutive:

(In thousands)	Three-month period ended September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Denominator				
Stock options and restricted common shares	8,825	9,147	7,262	9,232

Additionally, the impact of the convertible debt was determined to be anti-dilutive and excluded from the calculation of net (loss) income per diluted share for the three and nine-month periods ended September 30, 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 September 30, 2018 and 2017, the Company recorded a provision of $38.0 million and $18.9 million for income taxes, respectively. The effective income tax rates for the Company for the three-month periods ended September 30, 2018 and 2017 were 157.8% and (298.2%), respectively. The variance in the effective tax rates for the three-month period ended September 30, 2018 as compared to the three-month period ended September 30, 2017 was due primarily to differences in pre-tax book income between the periods, 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.

For the nine-month periods ended September 30, 2018 and 2017, the Company recorded a provision of $49.8 million and $23.4 million for income taxes, respectively. The effective income tax rates for the Company for the nine-month periods ended September 30, 2018 and 2017 were 67.4% and (81.1%), respectively. The variance in the effective tax rates for the nine-month period ended September 30, 2018 as compared to the nine-month period ended September 30, 2017 was due primarily to differences in pre-tax book income between the periods, 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 and nine-month periods ended September 30, 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 three-month period ending December 31, 2018 when the analysis is complete. The Company did not make any adjustments in the nine-month period ended September 30, 2018.

The Internal Revenue Service completed its examination of the Company’s U.S. income tax return for 2015 in the second quarter of 2018 with no material impact.

The Internal Revenue Service commenced its examination of the Company’s wholly-owned subsidiary, Biotie Therapies, Inc.’s, U.S. income tax return for the short period ended December 31, 2016 in the third quarter of 2018. There have been no proposed adjustments at this stage of the examination.

The New York State Department of Tax commenced an examination of the Company's income tax returns for the years 2014-2016. There have been no proposed adjustments at this stage of the examination.

(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 September 30, 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 short-term investments for 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 or nine-month periods ended September 30, 2018. The estimated fair values of all of our financial instruments approximate their carrying values at September 30, 2018, except for the fair value of the Company's convertible senior notes, which was approximately $298.4 million as of September 30, 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
September 30, 2018			
Assets Carried at Fair Value:			
Cash equivalents	$20,729	$—	$—
Short-term investments	—	139,935	—
Liabilities Carried at Fair Value:			
Acquired contingent consideration	—	—	134,900
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 September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Acquired contingent consideration:				
Balance, beginning of period	$ 112,200	$ 89,300	$ 113,000	$ 72,100
Fair value change to contingent consideration	22,700	(400)	21,900	16,800

included in the statement of operations				
Balance, end of period	$ 134,900	$ 88,900	$ 134,900	$ 88,900

- 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), our most advanced development program for the treatment of OFF periods in people with Parkinson's taking a carbidopa/levodopa regimen 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 $60.0 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 and nine-month periods ended September 30, 2018 and 2017, changes in the fair value of the acquired contingent consideration were due to the re-calculation of cash flows for the passage of time and updates to certain other estimated assumptions.

The acquired contingent consideration is classified as a Level 3 liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the various inputs to the valuation approach, including but not limited to, assumptions involving probability adjusted sales estimates for 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 on quoted market prices. Available-for-sale investments consisted of the following at September 30, 2018:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short Term Investments	$ 139,977	$ 4	$ (46)	$ 139,935

Short-term investments with maturities of three months or less from date of purchase have been classified as cash equivalents, and amounted to approximately $20.7 million as of September 30, 2018. Short-term investments have original maturities of greater than 3 months but less than 1 year and amounted to approximately $139.9 million as of September 30, 2018. The aggregate fair value of short-term investments in an unrealized loss position amounted to approximately $104.9 million as of September 30, 2018. The Company held no short-term investments at December 31, 2017. Short-term investments at September 30, 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 September 30, 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 September 30, 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 losses on available-for-sale investments during the nine-month period ended September 30, 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		(42)
Amounts reclassified from accumulated other comprehensive income		—
Net current period other comprehensive loss		(42)
Balance at September 30, 2018	$	(42)

(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 $2.5 million, non-cash interest expense of approximately $1.1 million and debt discount amortization costs of approximately $0.2 million for the three-month period ended September 30, 2018. The Company recognized non-cash royalty revenue of approximately $7.8 million, non-cash interest expense of approximately $3.4 million and debt discount amortization costs of approximately $0.6 million for the nine-month period ended September 30, 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 September 30, 2018	Nine-month period ended September 30, 2018
Liability related to sale of future royalties - beginning balance	$ 33,183	$ 35,788
Deferred transaction costs recognized	195	596
Non-cash royalty revenue payable to HCRP	(2,500)	(7,826)
Non-cash interest expense recognized	1,087	3,407
Liability related to sale of future royalties - ending balance	$ 31,965	$ 31,965

(9) Convertible Senior Notes

On June 17, 2014, the Company issued $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021 (the Notes) in an underwritten public offering. The net proceeds from the offering were $337.5 million after deducting the Underwriter’s discount and offering expenses paid by the Company.

The Notes are 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, under certain circumstances as outlined in the indenture, based on an initial conversion rate, subject to adjustment, of 23.4968 shares per $1,000 principal amount of Notes (representing an initial conversion price of approximately $42.56 per share).

The Company may not redeem the Notes prior to June 20, 2017. The Company may redeem for cash all or part of the Notes, at the Company's option, on or after June 20, 2017, under certain circumstances as outlined in the indenture.

The Company pays 1.75% interest per annum on the principal amount of the Notes, payable semiannually in arrears in cash on June 15 and December 15 of each year. The Notes will mature on June 15, 2021.

If the Company undergoes a "fundamental change" (as defined in the Indenture), subject to certain conditions, holders may require the Company to repurchase for cash all or part of their Notes in principal amounts of $1,000 or an integral multiple thereof. The 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 equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The outstanding note balance as of September 30, 2018 and December 31, 2017 consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Liability component:		
Principal	$ 345,000	$ 345,000
Less: debt discount and debt issuance costs, net	(28,840)	(36,195)
Net carrying amount	$ 316,160	$ 308,805
Equity component	$ 61,195	$ 61,195

In connection with the issuance of the Notes, the Company incurred approximately $7.5 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total $7.5 million of debt issuance costs, $1.3 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and $6.2 million were allocated to the liability component and recorded as a reduction in the carrying amount of the debt liability on the balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the Notes using the effective interest method.

As of September 30, 2018, the remaining contractual life of the Notes is approximately 2.75 years. The effective interest rate on the liability component was approximately 4.8% for the period from the date of issuance through September 30, 2018.

The following table sets forth total interest expense recognized related to the Notes for the three and nine months ended September 30, 2018 and 2017:

(In thousands)	Three-month period ended September 30, 2018	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2018	Nine-month period ended September 30, 2017
Contractual interest expense	$ 1,509	$ 1,509	$ 4,528	$ 4,528
Amortization of debt issuance costs	229	219	680	649
Amortization of debt discount	2,252	2,147	6,675	6,367
Total interest expense	$ 3,990	$ 3,875	$ 11,883	$ 11,544

(10) 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. Inbrija (levodopa inhalation powder), our most advanced development program, is an investigational inhaled formulation of levodopa for symptoms of OFF periods for people with Parkinson's on a carbidopa/levodopa regimen. Inbrija utilizes our innovative ARCUS pulmonary delivery system, a technology platform designed to deliver medication through inhalation that we believe has potential applications in multiple disease areas. We market branded Ampyra (dalfampridine) Extended Release Tablets, 10 mg, as well as an authorized generic version of Ampyra marketed through Mylan AG.

In February 2018, our New Drug Application, or NDA, for Inbrija was accepted for filing by the FDA, and the FDA set a goal date of October 5, 2018, under the Prescription Drug User Fee Act, or PDUFA, for review of the NDA. On September 13, 2018 we announced that the FDA extended the PDUFA date to January 5, 2019. This extension is related to recent submissions that we made in response to requests from the FDA for additional information on chemistry, manufacturing and controls (CMC). The FDA determined that these submissions constitute a major amendment and will take additional time to review. Our commercial preparations for the potential launch of Inbrija continue, including sales force training and education, managed care discussions, market research, disease state awareness and social media initiatives. We are progressing development of a pricing strategy and analyzing expected product margins, which we plan to finalize near launch, if Inbrija is approved. We are projecting that, if approved, annual peak net revenue of Inbrija in the U.S. alone could exceed $800 million. We have received letters from the FDA regarding the FDA's pre-approval inspections of our Chelsea, Massachusetts manufacturing facility and the Inbrija inhaler device manufacturer's facility, indicating that the FDA's inspections of these facilities are successfully closed, without need for any further action by the FDA.

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, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines, with an opinion of the Committee for Medicinal Products for Human Use, or CHMP, expected within 210 days of the May 24, 2018 validation notification date (plus any clock-stops to provide answers to questions which may arise during the review). After the adoption of a CHMP opinion, a final decision regarding the MAA is carried out by the European Commission. We are in discussions with potential partners regarding Inbrija outside of the U.S.

We currently derive substantially all of our revenue from the sale of Ampyra. We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the "District Court") issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), which issued a ruling on September 10, 2018 upholding the District Court's decision (the "Appellate Decision"). In October 2018, we filed a petition for rehearing en banc regarding the Appellate Decision at the Federal Circuit, which subsequently invited the generic drug manufacturers to respond to our petition. We are experiencing a rapid and significant decline in Ampyra sales due to competition from generic

versions of Ampyra that are being marketed following the Appellate Decision, including our own authorized generic version being marketed by Mylan AG. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales.

Our strategic priorities for the remainder of 2018 and 2019 are as follows:

- Attain approval for and initiate the U.S. launch of Inbrija. Importantly, we kept our commercial team intact despite a 2017 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.

- Subject to attaining approval for and launching Inbrija in the U.S., accelerate our efforts to develop additional therapeutics based on our proprietary ARCUS pulmonary drug delivery technology, looking at central nervous system, or CNS, as well as non-CNS opportunities. We expect our first priority in further ARCUS development to be accelerating our CVT-427 program to develop an inhalable triptan for treatment of acute migraine, which is further described below. A Phase 1 clinical trial of CVT-427 showed increased bioavailability and faster absorption compared to oral and nasal administration of the same active ingredient in healthy adults. However, our next step for this program is to reformulate to address evidence of bronchoconstriction shown in some subjects in a 2016 special population study of safe inhalation in people with asthma and in smokers.
- We are also continuing to evaluate business development opportunities for late stage neurology assets that would leverage our neurology expertise and commercial capabilities.

As of September 30, 2018, we had cash, cash equivalents and short-term investments of approximately $460.9 million and we are projecting a 2018 year-end cash balance in excess of $400.0 million. We have $345 million of convertible senior notes due in 2021 with a conversion price of $42.56. We believe that we are sufficiently capitalized to fund operations through the launch of Inbrija in the U.S., pending approval from the FDA.

On October 30, 2018, we sold our Qutenza assets and NP-1998 development program. 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. NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we were previously assessing for the treatment of neuropathic pain. Under the asset purchase agreement, the buyer made aggregate cash payments to us of approximately $7.9 million for the assets and we are entitled to receive up to an additional $35.0 million in cash based on achievement of specified U.S. sales milestones for Qutenza and, if it receives FDA approval, NP-1998.

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 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). Net revenue for Ampyra was $137.8 million for the three-month period ended September 30, 2018 and $132.6 million for the three-month period ended September 30, 2017.

We have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. In 2017, the United States District Court for the District of Delaware (the “District Court”) issued a ruling that upheld our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidated our four other Orange Book-listed patents pertaining to Ampyra that were set to expire between 2025 and 2027. Under this decision, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the District Court decision to the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”), which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). In October 2018, we filed a petition for rehearing en banc regarding the Appellate Decision at the Federal Circuit, which subsequently invited the generic drug manufacturers to respond to our petition. This litigation is discussed in further detail in Part II, Item 1 of this report. We are experiencing a rapid and significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision, including our own authorized generic version being marketed by Mylan AG. Mylan announced the launch of the authorized generic in mid-September 2018. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales.

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. We have a 60-day free trial program that provides eligible patients with two months of Ampyra at no cost.

Ampyra is distributed in the U.S. primarily through a limited network of specialty pharmacy providers, which deliver the medication to patients by mail, 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. 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. We recently established relationships with six new pharmacies through which Ampyra is available, each of which is either affiliated with an integrated health delivery network or an academic medical center. These pharmacies are not part of our specialty pharmacy network, but rather receive prescriptions for Ampyra directly from prescribers without first being routed through APSS.

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

Six issued Ampyra patents have been listed in the Orange Book. The five initial Orange Book-listed patents have been the subject of litigation with certain generic drug manufacturers, as described above. In connection with the litigation, our Orange Book-listed patent that expired on July 30, 2018, was upheld, but four other Ampyra patents set to expire between 2025 and 2027 were invalidated. The litigation is discussed in further detail in Part II, Item 1 of 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 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 described in this report.

In 2011, the European Patent Office, or EPO, granted EP 1732548, with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine (known under the trade name Fampyra in the European Union), to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmBH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmBH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmBH and Actavis Group PTC EHF filed oppositions with the EPO challenging our EP

2377536 patent, which is a divisional of the EP 1732548 patent. 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.

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. This program 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.

In February 2018, our Inbrija NDA was accepted for filing by the FDA, and the FDA set a goal date of October 5, 2018, under the Prescription Drug User Fee Act, or PDUFA, for review of the NDA. On September 13, 2018, we announced that the FDA extended the PDUFA date to January 5, 2019. This extension is related to recent submissions we made in response to requests from the FDA for additional information on chemistry, manufacturing and controls (CMC). The FDA determined that these submissions constitute a major amendment and will take additional time to review.

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, including sales force training and education, managed care discussions, market research, disease state awareness and social media initiatives. We are progressing development of a pricing strategy and analyzing expected product margins, which we plan to finalize near launch, if Inbrija is approved. 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 have received letters from the FDA regarding the FDA's pre-approval inspections of our Chelsea, Massachusetts manufacturing facility and the Inbrija inhaler device manufacturer's facility, indicating that the FDA's inspections of these facilities are successfully closed, without need for any further action by the FDA.

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, or EMA, in March 2018. In May 2018, we announced that the EMA completed formal validation of the MAA for Inbrija, and that the review of the MAA will be according to standard timelines, with an opinion of the Committee for Medicinal Products for Human Use, or CHMP, expected within 210 days of the May 24, 2018 validation notification date (plus any clock-stops to provide answers to questions which may arise during the review). After the adoption of a CHMP opinion, a final decision regarding the MAA is carried out by the European Commission. 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, our strategic priorities include 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. We are also considering non-CNS opportunities for ARCUS.

CVT-427 is our most advanced ARCUS program other than Inbrija, and one of our strategic priorities. CVT-427 is 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 accelerate work on reformulating to move the program forward as a strategic priority, subject attaining approval for and launching Inbrija in the U.S.

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.
- 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 fourth 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.

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 be more than $400 million. This guidance is raised from or prior guidance of $330 million to $350 million.
- 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 pre-launch 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 have increased our projected 2018 year-end cash balance from our prior guidance of more than $300 million to more than $400 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 September 30, 2018 Compared to September 30, 2017

Net Product Revenues

Ampyra

We recognize product sales of Ampyra following receipt of product by companies in our distribution network, which primarily includes specialty pharmacy providers and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra of $137.8 million and $132.6 million for the three-month periods ended September 30, 2018 and 2017, respectively, an increase of $5.2 million, or 3.9%. The net revenue increase is comprised of net price increases,

net of discount and allowance adjustments of $7.3 million offset by decreased net volume of $2.1 million. Effective January 1 and July 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 customers. 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.

Other Net Product Revenues

We recognized net revenue from the sale of other products of $2.2 million for the three-month period ended September 30, 2018, as compared to $1.8 million for the three-month period ended September 30, 2017, an increase 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.

Royalty Revenue

We recognized $2.8 million and $3.1 million in royalty revenue for the three-month periods ended September 30, 2018 and 2017, respectively related to ex-U.S. sales of Fampyra by Biogen.

We recognized $0.5 million and $0.8 million in royalty revenue for the three-month period ended September 30, 2017, related to the authorized generic sale of Zanaflex Capsules and Selincro, respectively. We sold Zanaflex and monetized Selincro in fiscal 2017.

License Revenue

We recognized $2.3 million in license revenue for the three-month period ended September 30, 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.

Cost of Sales

We recorded cost of sales of $25.4 million for the three-month period ended September 30, 2018 as compared to $30.0 million for the three-month period ended September 30, 2017. Cost of sales for the three-month period ended September 30, 2018 consisted primarily of $23.1 million in inventory costs related to recognized revenues, $1.7 million in royalty fees based on net product shipments, $0.2 million for costs related to the amortization of intangible assets and $0.2 million for costs related to sales of the authorized generic version of Ampyra. Cost of sales for the three-month period ended September 30, 2017 consisted primarily of $22.8 million in inventory costs related to recognized revenues, $3.0 million in royalty fees based on net product shipments, $2.4 million for costs related to Selincro, $0.9 million related to the cost of Zanaflex Capsules authorized generic product sold and $0.7 million related to the amortization of intangible assets.

Cost of License Revenue

We recorded cost of license revenue of $0.2 million for the three-month period ended September 30, 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 September 30, 2018 were $22.9 million as compared to $33.3 million for the three-month period ended September 30, 2017, a decrease of approximately $10.4 million, or 31%. The decrease was due primarily to reductions in spending of $11.6 million due to the termination of tozadenant development program and $0.8 million in reduced spending for certain other programs partially offset by an increase of $1.9 million related to manufacturing cost in preparation for the upcoming Inbrija launch.

Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2018 were $22.7 million compared to $20.8 million for the three-month period ended September 30, 2017, an increase of approximately $1.9 million, or 9.1%. The increase was attributable to an increase in overall salaries and benefits of $1.1 million, an increase in marketing related spending of $0.5 million and an increase in other selling related expenses of $0.3 million.

General and administrative expenses for the three-month period ended September 30, 2018 were $20.9 million compared to $20.0 million for the three-month period ended September 30, 2017, an increase of approximately $0.9 million, or 4.5%. This increase was primarily due to an increase in legal costs of $0.9 million and certain other costs of $0.5 million, partially offset by a decrease in salaries and benefits related costs of $0.4 million.

Asset Impairments

We recognized an asset impairment charge of $39.4 million in the three-month period ended September 30, 2017 related to our intangible asset for Selincro. We reviewed the intangible asset for impairment due to a downward revision to the projected royalty revenue we expect to receive. As a result of the review, we determined that the carrying value of the asset was greater than the estimated fair market value as of September 30, 2017. We did not recognize any asset impairment charge in the three-month period ended September 30, 2018.

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 expense pertaining to changes in the fair-value of acquired contingent consideration of $22.7 million for the three-month period ended September 30, 2018 as compared to an income of $0.4 million for the three-month period ended September 30, 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 and changes to certain other estimated assumptions.

Other Expense, Net

Other expense, net was $4.2 million for the three-month periods ended September 30, 2018 and September 30, 2017. This was due primarily to an increase in interest income of $1.0 million offset by an increase in interest and amortization of debt discount expense of $1.2 million.

Provision for Income Taxes

For the three-month periods ended September 30, 2018 and 2017, the Company recorded a $38.0 million and $18.9 million provision for income taxes, respectively. The effective income tax rates for the Company for the three-month periods ended September 30, 2018 and 2017 were 157.8% and (298.2%), respectively. The variance in the effective tax rates for the three-month period ended September 30, 2018 as compared to the three-month period ended September 30, 2017 was due primarily to differences in pre-tax book income between the periods, 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.

Nine-Month Period Ended September 30, 2018 Compared to September 30, 2017

Net Product Revenues

Ampyra

We recognize product sales of Ampyra following receipt of product by companies in distribution network, which primarily includes specialty pharmacy providers and ASD Specialty Healthcare, Inc. We recognized net revenue from the sale of Ampyra of $390.9 million and $376.1 million for the nine-month periods ended September 30, 2018 and 2017, respectively, an increase of $14.8 million, or 4%. The net revenue increase is comprised of net price increases, net of discount and allowance adjustments of $20.2 million, offset by decreased net volume of $5.4 million. Effective January 1 and July 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 customers. 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.

Other Net Product Revenues

We recognized net revenue from the sale of other products of $2.5 million for the nine-month period ended September 30, 2018, as compared to $3.6 million for the nine-month period ended September 30, 2017, a decrease of $1.1 million. The decrease was due primarily to the sale of Zanaflex assets in fiscal 2017.

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.

Royalty Revenue

We recognized $8.9 million and $8.5 million in royalty revenue for the nine-month periods ended September 30, 2018 and 2017, respectively, related to ex-U.S. sales of Fampyra by Biogen.

We recognized $2.6 million and $2.3 million in royalty revenue for the nine-month period ended September 30, 2017, related to the authorized generic sale of Zanaflex Capsules and Selincro, respectively. We sold Zanaflex and monetized Selincro in fiscal 2017.

License Revenue

We recognized $6.8 million in license revenue for the nine-month period ended September 30, 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.

Cost of Sales

We recorded cost of sales of $77.8 million for the nine-month period ended September 30, 2018 as compared to $84.8 million for the nine-month period ended September 30, 2017. Cost of sales for the nine-month period ended September 30, 2018 consisted primarily of $68.2 million in inventory costs related to recognized revenues, $7.5 million in royalty fees based on net product shipments, $1.6 million for costs related to the amortization of intangible assets and $0.2 million for costs related to sales of the authorized generic version of Ampyra. Cost of sales for the nine-month period ended September 30, 2017 consisted primarily of $66.0 million in inventory costs related to recognized revenues, $8.5 million in royalty fees based on net product shipments, costs related to Selincro of $6.9 million, the cost of Zanaflex Capsules authorized generic product sold of $1.6 million and 1.6 million related to the amortization of intangible assets.

Cost of License Revenue

We recorded cost of license revenue of $0.5 million for the nine-month period ended September 30, 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 nine-month period ended September 30, 2018 were $79.3 million as compared to $131.0 million for the nine-month period ended September 30, 2017, a decrease of approximately $51.7 million, or 39.5%. The decrease was due primarily to reductions in spending of $26.8 million due to the termination of the tozadenant development program, $6.8 million primarily for Inbrija as the clinical trials for Inbrija are winding down, $4.4 million for Ampyra life cycle management program, $6.7 million for salaries and benefits related costs, $4.3 million decrease in restructuring costs and $2.4 million for certain other programs.

Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2018 were $68.7 million compared to $71.8 million for the nine-month period ended September 30, 2017, a decrease of approximately $3.1 million, or 4.3%. The decrease was attributable primarily to a decrease in marketing related spending of $3.7 million, partially offset by an increase in overall salaries and benefits of $0.8 million.

General and administrative expenses for the nine-month period ended September 30, 2018 were $66.7 million compared to $70.3 million for the nine-month period ended September 30, 2017, a decrease of approximately $3.6 million, or 5.1%. This decrease was primarily due to a decrease in restructuring costs of $2.0 million, a decrease in salaries and benefits related costs of $2.4 million, partially offset by an increase in legal and other related cost of $0.6 million.

Asset Impairment

We recognized an asset impairment charge of $39.4 million in the nine-month period ended September 30, 2017 related to our intangible asset for Selincro. We reviewed the intangible asset for impairment due to a downward revision to the projected royalty revenue we expect to receive. As a result of the review, we determined that the carrying value of the asset was greater than the estimated fair market value as of September 30, 2017. We did not

recognize an asset impairment charge in the nine-month period ended September 30, 2018.

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 expense pertaining to changes in the fair-value of acquired contingent consideration of $21.9 million for the nine-month period ended September 30, 2018 as compared to an expense of $16.8 million for the nine-month period ended September 30, 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 and changes to certain other estimated assumptions.

Other Expense, Net

Other expense was $13.9 million for the nine-month period ended September 30, 2018 compared to other expense of $14.1 million for the nine-month period ended September 30, 2017, a decrease in expense of $0.2 million. The decrease was due primarily to an increase in interest income of approximately $2.3 million and a decrease in realized losses on foreign currency exchange of approximately $0.4 million partially offset by an increase in interest and amortization of debt discount expense of $2.5 million.

Provision for Income Taxes

For the nine-month periods ended September 30, 2018 and 2017, the Company recorded a $49.8 million and $23.4 million provision for income taxes, respectively. The effective income tax rates for the Company for the nine-month periods ended September 30, 2018 and 2017 were 67.4% and (81.1%), respectively. The variance in the effective tax rates for the nine-month period ended September 30, 2018 as compared to the nine-month period ended September 30, 2017 was due primarily to differences in pre-tax book income between the periods, 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, Fampyra, Zanaflex and Qutenza, and, to a lesser extent, from loans, government and non-government grants and other financing arrangements.

At September 30, 2018, we had $460.9 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 September 30, 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 September 30, 2018 consisted of the following:

(In thousands)	September 30, 2018
Liability component:	
Principal	$ 345,000
Less: debt discount and debt issuance costs, net	(28,840)
Net carrying amount	$ 316,160
Equity component	$ 61,195

Non-Convertible Capital Loans

The Non-Convertible Capital Loans ("Tekes Loans") which were granted to Biotie 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 $23.4 million as of September 30, 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 to Biotie 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 $1.9 million as of September 30, 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 September 30, 2018, cash, cash equivalents and short-term investment were approximately $460.9 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. 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 $163.1 million for the nine-month period ending September 30, 2018. Cash provided by operations for the nine-month period ended September 30, 2018 was primarily due to net income of $24.1 million, a decrease in accounts receivable of $29.9 million, a change in contingent consideration liability of $21.9 million, stock compensation expense of $16.2 million, depreciation and amortization of $9.1 million, amortization of debt discount and debt issuance costs of $11.9 million, deferred tax provision of $42.6 million and a decrease in inventory of $26.7 million. This was partially offset by a decrease in accounts payable and accrued expenses of $5.5 million, non-cash royalty revenue of $7.8 million, and an increase in other current assets of $5.3 million

Net Cash Used in Investing

Net cash used in investing activities for the nine-month period ended September 30, 2018 was $162.0 million, which was due primarily to purchases of short-term investments and property and equipment of $191.7 million and $22.5 million, respectively. This was partially offset by proceeds from maturities of investments of $52.5 million.

Net Cash Provided by Financing

Net cash provided by financing activities for the nine-month period ended September 30, 2018 was $12.7 million, which was due to $15.0 million in net proceeds from the issuance of common stock and stock option exercises, partially offset by the repurchase of treasury stock of $1.6 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 nine-month period ended September 30, 2018, commitments related to the purchase of inventory increased as compared to December 31, 2017. As of September 30, 2018, we have inventory-related purchase commitments totaling approximately $30.4 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 September 30, 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 September 30, 2018, except for the fair value of the Company's convertible senior notes which was approximately $298.4 million as of September 30, 2018.

We have cash equivalents and short-term investments at September 30, 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 September 30, 2018. At September 30, 2018, we held $460.9 million in cash, cash equivalents and short-term investments which had an average interest rate of approximately 1.9%.

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 third 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 September 30, 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 September 30, 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, we have been engaged in litigation with certain generic drug manufacturers relating to our five initial Orange Book-listed Ampyra patents. We filed lawsuits against these generic drug manufacturers in response to their submitting Abbreviated New Drug Applications, or ANDAs, to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. As previously reported, we settled with some, but not all, of these companies. 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 Ampyra Orange Book-listed patent that expired in July 2018, but invalidated the four other Orange Book-listed patents pertaining to Ampyra that are the subject of the litigation that were set to expire between 2025 and 2027. We appealed the decision on the four invalidated patents to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), which issued a ruling on September 10, 2018 upholding the District Court's decision (the "Appellate Decision"). In October 2018, we filed a petition for rehearing en banc regarding the Appellate Decision at the Federal Circuit, which subsequently invited the generic drug manufacturers to respond to our petition.

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 separate Paragraph IV Certification Notices from Accord Healthcare, Inc. ("Accord"), Actavis Laboratories FL, Inc. ("Actavis"), Alkem Laboratories Ltd. and its affiliate Ascend Laboratories, LLC ("Alkem"), Apotex Inc. ("Apotex"), Aurobindo Pharma Ltd. ("Aurobindo"), Mylan Pharmaceuticals Inc. ("Mylan"), 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 drug manufacturers and certain affiliates in the District Court 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 expired on July 30, 2018, but invalidated U.S. Patent Nos. 8,663,685, 8,007,826, 8,440,703, and 8,354,437. In May 2017, we appealed the ruling on these patents to the Federal Circuit. The Federal Circuit issued a decision on September 10, 2018 upholding the District Court's decision. We are experiencing a rapid and significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the decision of the Federal Circuit, including our own authorized generic version being marketed by Mylan AG. Mylan announced the U.S. launch of the authorized generic in mid-September 2018. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales. In October 2018, we filed a petition for rehearing en banc regarding the Appellate Decision at the Federal Circuit, which subsequently invited the generic drug manufacturers to respond to our petition.

As previously reported, prior to the 2017 District Court decision, we entered into settlement agreements with Accord, Actavis, Alkem, Apotex and Aurobindo (and certain affiliates). More recently, in August 2018, we reported a conditioned settlement agreement with Mylan.

Second ANDA Filers. In 2015 and 2017, we received Paragraph IV Certification Notices from Sun Pharmaceutical Industries Limited, Sun Pharmaceuticals Industries Inc., Par Pharmaceutical, Inc., and Micro Labs Ltd. advising that each of these companies had submitted ANDAs to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. These ANDA filers 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 their products may not infringe certain claims of these patents. In response to the filing of the ANDAs, as previously reported, we filed lawsuits against these companies that were subsequently settled.

We will vigorously defend our intellectual property rights.

Item 1 of Part II of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31 and June 30, 2018, include prior updates to the legal proceedings described above.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A. Risk Factors, in our Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A for the year ended December 31, 2017, as updated in our Quarterly Reports subsequently filed during the current fiscal year, all of which could materially affect our business, financial condition or future results. These risks are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Following is the restated text of certain risk factors to report changes since our publication of risk factors in our 2017 Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A and our updates in subsequent Quarterly Reports on Form 10-Q.

Risks related to our business

We have a history of operating losses and may not be able to achieve or sustain profitability in the future; we are and will remain substantially dependent on revenues from the sale of Ampyra, which are rapidly and significantly declining due to generic competition, unless and until we obtain marketing approval for, and can commercially launch, Inbrija (levodopa inhalation powder).

We have been highly dependent on the sales of Ampyra in the U.S. and derive substantially all of our revenue from the sale of Ampyra. Our Orange Book-listed patents have been the subject of litigation with certain generic drug manufacturers, who submitted Abbreviated New Drug Applications, or ANDAs, to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10mg. In 2017, the United States District Court for the District of Delaware (the “District Court”) issued a ruling upholding our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidating our four other Orange Book-listed patents pertaining to Ampyra set to expire between 2025 and 2027. Under this ruling, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. We appealed the decision on the four invalidated patents to the United States Court of Appeals for the Federal Circuit, which issued a ruling on September 10, 2018 upholding the District Court’s decision (the “Appellate Decision”). We are experiencing a rapid and significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales.

As of September 30, 2018, we had an accumulated deficit of approximately $403.4 million. We had net losses of $223.4 million for the year ended December 31, 2017 and $34.6 million for the year ended December 31, 2016. Our prospects for achieving and sustaining profitability in the future will depend primarily on how successful we are in:

- obtaining NDA approval for Inbrija (levodopa inhalation powder), a self-administered, inhaled formulation of levodopa using our proprietary ARCUS drug delivery technology, for the treatment of OFF periods in people with Parkinson’s taking a carbidopa/levodopa regimen;
- successfully launching Inbrija in the U.S., if approved;

- obtaining MAA approval in the E.U. for Inbrija and commercializing through potential ex-U.S. partner
- continuing to advance and/or out-license our earlier-stage clinical development programs; and
- expanding our product development pipeline through the potential in-licensing and/or acquisition of additional products and technologies.

If we are not successful in executing our business plan, we may not achieve or sustain profitability and even if we do so, we may not meet sales expectations. Also, even if we are successful in executing our business plan, our profitability may

fluctuate from period to period due to our level of investments in sales and marketing, research and development, and product and product candidate acquisitions. For example, in 2018 and 2019 we expect to invest a significant amount to support our most advanced program, Inbrija.

Our restructuring may not adequately reduce our expenses, and we may encounter difficulties associated with the related organizational change.

In April 2017, following a decision by the United States District Court for the District of Delaware to invalidate certain patents relating to Ampyra, which has been upheld by the Court of Appeals for the Federal Circuit, (the "Federal Circuit"), we implemented a corporate restructuring to reduce our cost structure and focus our resources on Inbrija (levodopa inhalation powder) and our other strategic priorities. As part of this restructuring, we reduced headcount by approximately 20%. If our restructuring does not adequately reduce our expenses, further restructuring activities may be required in the future. In any event, the benefits of the restructuring are not expected to offset the loss of revenues from decreased long-term Ampyra sales following the invalidation of our patents. We are experiencing a rapid and significant decline in revenues due to competition from generic versions of Ampyra that are being marketed following the decision of the Federal Circuit. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in revenues.

Our restructuring may have other unintended consequences as well, including, for example, making it more difficult for us to attract and retain highly skilled personnel in a competitive environment. We may also experience operational disruptions from our reduction in personnel. The loss of key personnel such as regulatory or manufacturing functions could disrupt our operations and sales force attrition could harm our ability to maintain Ampyra sales and, if we obtain FDA approval for Inbrija, commercialize that product.

We operate in the highly-regulated pharmaceutical industry.

Our research, development, preclinical and clinical trial activities, as well as the manufacture and marketing of any products that we have developed or in the future may successfully develop, are subject to an extensive regulatory approval process by the FDA and other regulatory agencies abroad.

In order to conduct clinical trials to obtain FDA approval to commercialize any drug or biological product candidate, an investigational new drug, or IND, application must first be submitted to the FDA and must become effective before clinical trials may begin. Subsequently, if the product candidate is regulated as a drug, a new drug application, or NDA, must be submitted to the FDA and approved before commercial marketing may begin. The NDA must include the results of adequate and well-controlled clinical trials demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. If the product candidate, such as an antibody, is regulated as a biologic, a biologic license application, or BLA, must be submitted and approved before commercial marketing may begin. Extensive submissions of preclinical and clinical trial data are required to demonstrate the safety, potency and purity for each intended use. The FDA may refuse to accept our regulatory submissions for filing if they are incomplete. For example, in August 2017, we received a "Refuse to File," or RTF, letter from the FDA regarding the NDA we had submitted in June 2017 for Inbrija (levodopa inhalation powder), to treat symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen. The FDA specified two reasons for the RTF: first, the date when the manufacturing site would be ready for inspection, and second, a question regarding the submission of the drug master production record. The FDA also requested that we submit additional information when we resubmit the NDA, though this was not part of the basis for the RTF. We resubmitted the Inbrija NDA in December 2017. In February 2018, the resubmitted NDA was accepted for filing by the FDA, and under the Prescription Drug User Fee Act, or PDUFA, the FDA set a goal date of October 5, 2018 for its review of the NDA. On September 13, 2018, we announced that the FDA extended the PDUFA date to January 5, 2019. Of the large number of drugs in development, only a small percentage result in the submission of an NDA or BLA to the FDA, and even

fewer are approved for commercialization.

The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Any regulatory approvals may be for fewer or narrower indications than we request, may include distribution restrictions, or may be conditioned on burdensome post-approval study or other requirements, including the requirement that we institute and follow a special risk evaluation and mitigation strategy, or REMS, to monitor and manage potential safety issues, all of which may eliminate or reduce the drug's market potential. Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Investigational products, such as Inbrija, are regulated as combination products and require that we satisfy FDA that both the drug and device component of the products satisfy FDA requirements. Failure to satisfy the FDA's requirements for either the drug or device component of Inbrija or other such combination products could delay approval of these products or result in these products not receiving FDA approval.

Any product for which we currently have or may in the future obtain marketing approval is subject to continual post-approval requirements including, among other things, record-keeping and reporting requirements, packaging and labeling requirements, requirements for reporting adverse drug experiences, import/export controls, restrictions on advertising and promotion, cGMP requirements as well as any other requirements imposed by the applicants NDA or BLA. All of our products and operations are subject to periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, any approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Post-market evaluation of a product could result in marketing restrictions or withdrawal from the market.

We may fail to comply with existing legal or regulatory requirements or be slow to adapt, or be unable to adapt, to new legal or regulatory requirements. We may encounter problems with our manufacturing processes, and we may discover previously unknown problems with our products. These circumstances could result in:

- voluntary or mandatory recalls;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- shut-down of manufacturing facilities;
- receipt of warning letters or untitled letters;
- product seizures;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on importation of our product candidates;
- fines and injunctions;
- civil and criminal penalties;
- exclusion from participation in government programs; and
- suspension of review or refusal to approve pending applications.

In addition, we are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, controlled substances and we may be subject to other local, state, federal and foreign regulations. We cannot predict the impact of those regulations on us, although they could impose significant restrictions on our business and we may have to incur additional expenses to comply with them.

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. Ampyra has become subject to competition from generic drug manufacturers. In 2017, in litigation with certain generic drug manufacturers, the United States District Court for the District of Delaware (the "District Court") issued a ruling upholding our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidating four other Orange Book-listed patents that were set to expire between 2025 and 2027. Under this ruling, our patent exclusivity with respect to Ampyra terminated on July 30, 2018. The United States Court of Appeals for the Federal Circuit issued a ruling on September 10, 2018 upholding the District Court's decision (the "Appellate Decision"). We are experiencing a rapid and significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales. Our litigation with the generic drug manufacturers is described in further detail in Part II, Item I of this report.

In addition to competition from generic versions of Ampyra, 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.

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. In March 2018, Sunovion submitted a New Drug Application, or NDA, to the FDA, and in June 2018 they reported that the FDA accepted the NDA and that the expected action date by the FDA under the Prescription Drug User Fee Act is January 29, 2019.

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. Amneal Pharmaceuticals, Inc. (formerly 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 Intec Pharma and Mitsubishi Tanabe Pharma Corporation. 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 operations could be curtailed if we are unable to obtain any necessary additional financing on favorable terms or at all.

As of September 30, 2018, we had approximately $460.9 million in cash and cash equivalents. We have product candidates in various stages of development, and each will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. In connection with our corporate restructuring announced in 2017, we are focusing our resources on Inbrija (levodopa inhalation powder) and other strategic priorities. While we believe that the cost savings from the restructuring and subsequent operating expense reductions, as well as the cost savings from the discontinuation of our tozadenant program, will enable us to fund operations through the commercial launch of Inbrija, if approved by the FDA, there can be no guarantee that we will have sufficient funding to do so. We are experiencing a rapid and significant decline in Ampyra revenue due to the marketing of generic versions of Ampyra following the September 10, 2018 decision of the United States Court of Appeals for the Federal Circuit which upheld the United States District Court for the District of Delaware's decision to invalidate certain Ampyra patents. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales. Also, on September 13, 2018, we announced that the FDA extended the PDUFA goal date for its review of the NDA of Inbrija from October 5, 2018 to January 5, 2019. If there are further delays in the approval of Inbrija, or it fails to receive FDA approval, 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.

To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote fewer resources to marketing Ampyra or our other commercial products.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including our convertible senior notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. For example, we are experiencing a rapid and significant decline in Ampyra revenue due to the marketing of generic versions of Ampyra following the September 2018 decision of the United States Court of Appeals for the Federal Circuit to uphold the United States District Court for the District of Delaware's decision to invalidate certain Ampyra patents. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive.

Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

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 (which has been upheld by the United States Court of Appeals for the Federal Circuit), 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.

Risks related to our intellectual property

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

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent and trademark protection for the technologies, compounds and products, if any, resulting from our licenses and research and development programs. Without protection for the intellectual property we use or intend to use, other companies could offer substantially identical products for sale without incurring the sizable discovery, research, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

We have patent portfolios relating to Ampyra/aminopyridines, Inbrija (levodopa inhalation powder), CVT-427 and our ARCUS drug delivery technology, SYN120, BTT1023, cimaglermin alfa/neuregulins, remyelinating antibodies/antibodies relating to nervous system disorders, Qutenza and NP-1998/topical capsaicin formulations, comprised of both our own and in-licensed patents and patent applications. For some of our proprietary technologies, for example our ARCUS drug delivery technology, we rely on a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property rights. Our intellectual property also includes copyrights and a portfolio of trademarks.

The process of obtaining patents and trademarks can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent or trademark may not issue, it may not issue in a timely manner, or it may not have sufficient scope or strength to protect the technology it was intended to protect or to provide us with any commercial advantage. We may never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because patent applications are confidential until they are published, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not allowed or issued for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or trademarks or the patents or trademarks of our licensors.

For example, in 2014 and 2015, several generic drug manufacturers filed Abbreviated New Drug Applications, or ANDAs, for generic versions of Ampyra to the FDA and challenged the Orange Book-listed patents that protected the Ampyra franchise. As such, to protect our intellectual property rights we filed lawsuits against the ANDA filers (other than those with whom we settled), which were consolidated into a single case, asserting the challenged Orange Book-listed patents against these generic drug manufacturers. In March 2017, the United States District Court for the District of Delaware (the "District Court") issued a ruling upholding our Ampyra Orange Book-listed patent that expired on July 30, 2018, but invalidating four other Orange Book-listed patents pertaining to Ampyra set to expire between 2025 and 2027. In September 2018, the United States Court of Appeals for the Federal Circuit issued a ruling upholding the District Court's decision (the "Appellate Decision"). We are experiencing a rapid and significant decline in Ampyra sales due to competition from generic versions of Ampyra that are being marketed following the Appellate Decision. We expect that additional manufacturers will market generic versions of Ampyra, which may accelerate the decline in Ampyra sales.

Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Invents Act, specifically inter partes review and/or post grant review before the U.S. Patent and Trademark Office. For

example, in February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging two of our Ampyra Orange Book-listed patents. The U.S. Patent and Trademark Office Patent Trials and Appeals Board, or PTAB, chose not to institute inter partes review of these patents. The hedge fund filed motions for reconsideration requesting that the denial to institute these two IPRs be reversed, but the motions were denied in April 2016. In addition, in September 2015 the same hedge fund filed four additional IPR petitions challenging four of our Orange Book-listed patents, including two of the same patents that were the subject of the February 2015 IPR petitions. We opposed the requests to institute these IPRs, but in March 2016 the PTAB decided to institute the IPR proceedings on all four patents. In March 2017 the PTAB issued a ruling and upheld all four of the challenged patents. The ruling has become final, as the hedge fund did not appeal the ruling before the May 2017 appeal deadline. However, the PTAB decision does not prevent parties from filing additional IPR petitions challenging our patents. Also, the PTAB's decision does not affect the District Court's decision invalidating the four patents in the ANDA litigation described above.

Patent litigation, IPR proceedings, and other legal proceedings involve complex legal and factual questions. We need to devote significant resources to the existing ANDA and IPR legal proceedings, and we may need to devote significant resources to other legal proceedings that arise in the future. If we are not successful, we could lose some or all of our Orange Book listed patents and our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of any such lawsuits and legal proceedings.

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

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

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

the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

Item 6. Exhibits

Exhibit No.	Description
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the 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.

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: November 6, 2018 President, Chief Executive Officer and Director

By: /s/ David Lawrence
David Lawrence

Date: November 6, 2018 Chief, Business Operations and Principal Accounting Officer