Assertio Therapeutics, Inc
Form 10-Q
November 09, 2018

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

FORM 10-Q

x 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 001-13111

ASSERTIO THERAPEUTICS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	94-3229046
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NUMBER)

100 South Saunders Road, Suite 300
Lake Forest, Illinois 60045
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES; ZIP CODE)

(224) 419-7106
(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 x 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 x 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 x Accelerated filer

Non-accelerated filer Smaller 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 x

The number of issued and outstanding shares of the registrant's Common Stock, no par value, as of November 5, 2018 was 63,939,066.

ASSERTIO THERAPEUTICS, INC.
Quarterly Report on Form 10-Q
For the Quarterly Period Ended September 30, 2018

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
ASSERTIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 121,904	$126,884
Short-term investments	—	1,205
Accounts receivable, net	43,912	72,482
Inventories, net	4,255	13,042
Prepaid and other current assets	57,297	17,238
Total current assets	227,368	230,851
Property and equipment, net	11,808	13,024
Intangible assets, net	717,542	793,873
Other long-term assets	26,789	869
Total assets	$ 983,507	$1,038,617
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,394	$14,732
Accrued rebates, returns and discounts	80,913	135,828
Accrued liabilities	26,075	60,496
Income taxes payable	—	126
Current portion of Senior Notes	125,000	82,500
Contingent consideration liability, current portion	—	156
Interest payable	10,260	13,220
Other current liabilities	1,432	3,522
Total current liabilities	261,074	310,580
Contingent consideration liability, long-term portion	877	1,457
Senior Notes	177,466	274,720
Convertible Notes	283,061	269,510
Other long-term liabilities	18,620	12,842
Total liabilities	741,098	869,109
Commitments and contingencies		
Shareholders' equity:		
Common stock	6	6
Additional paid-in capital	400,869	389,015
Accumulated deficit	(158,462)	(219,508)
Accumulated other comprehensive loss, net of tax	(4)	(5)
Total shareholders' equity	242,409	169,508
Total liabilities and shareholders' equity	$ 983,507	$1,038,617

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ASSERTIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$29,435	$95,204	$100,627	$285,721
Commercialization agreement, net	27,781	—	142,760	—
Royalties and milestones	20,277	209	25,784	596
Total revenues	77,493	95,413	269,171	286,317
Costs and expenses:				
Cost of sales (excluding amortization of intangible assets)	2,975	17,396	17,772	54,895
Research and development expenses	2,127	1,761	5,835	12,459
Selling, general and administrative expenses	33,409	48,850	93,750	147,379
Amortization of intangible assets	25,443	25,734	76,331	77,204
Restructuring charges	3,911	434	18,742	3,875
Total costs and expenses	67,865	94,175	212,430	295,812
Income (loss) from operations	9,628	1,238	56,741	(9,495)
Other income (expense):				
Litigation settlement	62,000	—	62,000	—
Interest and other income	677	72	973	604
Loss on prepayment of Senior Notes	—	—	—	(5,364)
Interest expense	(17,190)	(17,815)	(52,268)	(55,697)
Total other income (expense)	45,487	(17,743)	10,705	(60,457)
Income (loss) before income taxes	55,115	(16,505)	67,446	(69,952)
Benefit (expense) from income taxes	(6,845)	513	(6,400)	560
Net income (loss)	$48,270	$(15,992)	$61,046	$(69,392)
Basic net income (loss) per share	$0.76	$(0.25)	$0.96	$(1.11)
Diluted net income (loss) per share	$0.65	$(0.25)	$0.93	$(1.11)
Shares used in computing basic net income (loss) per share	63,917	62,997	63,714	62,556
Shares used in computing diluted net income (loss) per share	82,690	62,997	82,282	62,556

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ASSERTIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income (loss)	$48,270	$(15,992)	$61,046	$(69,392)
Unrealized (loss) gain on available-for-sale securities, net of tax	—	(5)	1	12
Comprehensive income (loss)	$48,270	$(15,997)	$61,047	$(69,380)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ASSERTIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Operating Activities		
Net income (loss)	$61,046	$(69,392)
Adjustments for non-cash items:		
Depreciation and amortization	80,729	79,031
Accretion of debt discount and debt issuance costs	16,298	14,249
Loss on prepayment of Senior Notes	—	5,364
Provision for inventory obsolescence	244	2,345
Gain on disposal of property and equipment	659	(275)
Stock-based compensation	10,275	9,922
Change in fair value of contingent consideration	(552)	(7,517)
Other	34	244
Changes in assets and liabilities:		
Accounts receivable	28,570	24,864
Receivables from collaborative partners	—	27
Inventories	8,543	272
Prepaid and other assets	(63,039)	(4,428)
Accounts payable and other accrued liabilities	(28,071)	(20,648)
Accrued rebates, returns and discounts	(54,915)	5,463
Interest payable	(2,960)	(4,616)
Income taxes payable	(126)	—
Net cash provided by operating activities	56,735	34,905
Investing Activities		
Purchases of property and equipment	(3,987)	(563)
Proceeds from disposal of property and equipment	145	281
Proceeds from sale of other assets	80	—
Investment in convertible instrument	(3,000)	—
Purchases of marketable securities	—	(7,074)
Maturities of marketable securities	1,200	60,681
Net cash (used in) investing activities	(5,562)	53,325
Financing Activities		
Payment of contingent consideration liability	(184)	(1,673)
Repayment of Senior Notes	(57,500)	(100,000)
Fees for early repayment and modifications of Senior Notes	—	(4,000)
Proceeds from issuance of common stock	1,852	7,529
Shares withheld for payment of employee's withholding tax liability	(321)	(210)
Net cash (used in) financing activities	(56,153)	(98,354)
Net (decrease) in cash and cash equivalents	(4,980)	(10,124)
Cash and cash equivalents at beginning of year	126,884	117,709
Cash and cash equivalents at end of period	$121,904	$107,585
Supplemental Disclosure of Cash Flow Information		
Net cash paid for income taxes	$4,871	$121
Cash paid for interest	$38,811	$44,832

Capital expenditures incurred but not yet paid	$30	$87

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ASSERTIO THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Assertio Therapeutics, Inc. (Assertio or the Company) is a specialty pharmaceutical company focused on neurology, orphan and specialty medicines. The Company's current specialty pharmaceutical business includes the following three products which we market in the United States (U.S.):

- Gralise® (gabapentin), a once daily product for the management of postherpetic neuralgia (PHN), was launched in October 2011.

- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, was acquired in December 2013.

- Zipsor® (diclofenac potassium) liquid filled capsules, a non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain, was acquired in June 2012.

Assertio was formerly known as Depomed, Inc., a California corporation (Depomed). On August 14, 2018, Depomed reincorporated from California to Delaware and changed its name to Assertio Therapeutics, Inc. The use of the term "Company" in this filing refers to Depomed any time prior to the Effective Time and to Assertio any time after the Effective Time.

In January 2018, pursuant to the terms of an agreement the Company entered into with Collegium Pharmaceutical, Inc. (Collegium) in December 2017, the (Commercialization Agreement), the Company granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the U.S. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. The Company will receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of $132.0 million for the year ended December 31, 2018. The parties amended the Commercialization Agreement in November 2018 (Amendment) as described in Note 17. The Company expects to receive royalties from Collegium of $132 million for 2018 and royalties based on certain annual NUCYNTA net sales thresholds for future years. Both the Company and Collegium may terminate the Commercialization Agreement under certain circumstances, provided that Collegium may not terminate the agreement prior to the end of 2021. The NUCYNTA franchise includes two products currently marketed in the U.S. by Collegium:

- NUCYNTA® ER (tapentadol extended release tablets), a product for the management of pain severe enough to require daily, around the clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults, and for which alternate treatment options are inadequate; and

- NUCYNTA® IR (NUCYNTA) (tapentadol), an immediate release version of tapentadol for the management of moderate to severe acute pain in adults.

In November 2017, the Company entered into definitive agreements with Slán Medicinal Holdings Limited (Slán) pursuant to which the Company acquired Slán's rights to market the specialty drug cosyntropin depot (synthetic ACTH Depot) in the U.S., and Slán acquired the Company's rights to Lazanda® (fentanyl) nasal spray. The Company believes cosyntropin depot can be second-to-market behind Mallinckrodt plc's marketed product, H-P Acthar gel. The

Company expects Slán to file an NDA for cosyntropin depot in late 2018.

The Company actively seeks to expand its product portfolio through acquiring or in licensing commercially available products or late stage product candidates that may be marketed and sold effectively with its existing products through its sales and marketing capabilities.

The Company also has royalty and milestone producing license arrangements based on its proprietary Acuform® gastroretentive drug delivery technology, including with Ironwood Pharmaceuticals, Inc. (Ironwood).

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Basis of Presentation

The unaudited condensed consolidated financial statements and the related footnote information of the Company have been prepared pursuant to the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (GAAP) have been condensed or omitted pursuant to such rules and regulations. In the opinion of the Company's management, the accompanying interim unaudited condensed consolidated financial statements include all adjustments necessary for a fair presentation of the information for the periods presented. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the entire year ending December 31, 2018 or future operating periods.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K filed with the SEC (the 2017 Form 10-K). The balance sheet as of December 31, 2017 has been derived from the audited financial statements at that date, as filed in the Company's 2017 Form 10-K.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Depomed Bermuda Ltd (Depo Bermuda), Depo NF Sub, LLC (Depo NF Sub) and Depo DR Sub, LLC (Depo DR Sub). These subsidiaries were established historically to facilitate transactions. All intercompany accounts and transactions have been eliminated on consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as sales discounts and returns, depreciable and amortizable lives, share-based compensation assumptions and taxes on income. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of the Company's business and operations, actual results could differ materially from these estimates.

Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at date of acquisition at their respective fair values. The fair value of the consideration paid, including contingent consideration, is assigned to the underlying net assets of the acquired business based on their respective fair values. Any excess or shortfall of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill or bargain purchase, as applicable.

Significant judgments are used in determining the estimated fair values assigned to the assets acquired and liabilities assumed and in determining estimates of useful lives of long-lived assets. Fair value determinations and useful life estimates are based on, among other factors, estimates of expected future net cash flows, estimates of appropriate discount rates used to present value expected future net cash flows, the assessment of each asset's life cycle, and the impact of competitive trends on each asset's life cycle and other factors. These judgments can materially impact the estimates used to allocate acquisition date fair values to assets acquired and liabilities assumed and the resulting timing and amounts charged to, or recognized in current and future operating results. For these and other reasons,

actual results may vary significantly from estimated results.

Any changes in the fair value of contingent consideration resulting from a change in the underlying inputs is recognized in operating expenses until the contingent consideration arrangement is settled. Changes in the fair value of contingent consideration resulting from the passage of time are recorded within interest expense until the contingent consideration is settled.

If the acquired net assets do not constitute a business under the acquisition method of accounting, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, the amount allocated to acquired in-process research and development (IPR&D) with no alternative future use is charged to expense at the acquisition date.

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Revenue Recognition

The Company accounts for revenue arising from contracts and customers in accordance with Accounting Standards Update (ASU or Update) 2014-9, Revenue from Contracts with Customers (ASC 606), which was adopted on January 1, 2018 using the modified retrospective transition method. There was no adjustment to the Company's opening balance of accumulated deficit resulting from the adoption of this guidance.

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation, when (or as) the performance obligation is satisfied.

Variable consideration arising from sales or usage-based royalties, promised in exchange for a license of the Company's Intellectual Property, is recognized at the later of (i) when the subsequent product sales occur or (ii) the performance obligation, to which some or all of the sales-based royalty has been allocated, has been satisfied.

The Company recognizes a contract asset relating to its conditional right to consideration for completed performance obligations. Accounts receivable are recorded when the right to consideration becomes unconditional. A contract liability is recorded for payments received in advance of the related performance obligation being satisfied under the contract.

The Company derives revenue from license fees, under its Commercialization Agreement with Collegium, sale of its products, and from license fees, milestones and royalties earned on license and collaborative arrangements. Royalty payments made on products that the Company is not actively commercializing, which are remitted to the licensor on a pass through basis, are recorded by the Company on a systematic basis in proportion to the underlying net product sales and are included as gross-to-net adjustments in the related revenue line in the Company's Statements of Operations.

Product Sales

The Company sells commercial products to wholesale distributors and retail pharmacies. Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which typically occurs on delivery to the customer. The Company's performance obligation is to deliver product to the customer, and the performance obligation is completed upon delivery. The transaction price consists of a fixed invoice price and variable product sales allowances, which include rebates, discounts and returns. Product sales revenues are recorded net of applicable reserves for these product sales allowances. Receivables related to product sales are typically collected one to two months after delivery.

Product Sales Allowances—The Company considers products sales allowances to be variable consideration and estimates and recognizes product sales allowances as a reduction of product sales in the same period the related

revenue is recognized. Product sales allowances are based on actual or estimated amounts owed on the related sales. These estimates take into consideration the terms of the Company's agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. The Company uses the most likely method in estimating product sales allowances. If actual future results vary from the Company's estimates, the Company may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company's sales allowances include:

Product Returns—The Company allows customers to return product for credit with respect to that product within six months before and up to 12 months after its product expiration date. The Company estimates product returns and associated credit on NUCYNTA ER and NUCYNTA, Gralise, CAMBIA, Zipsor and Lazanda. Estimates for returns are based on historical return trends by product or by return trends of similar products, taking into consideration the shelf life of the product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels and consideration of the

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introduction of competitive products. The Company did not assume financial responsibility for returns of NUCYNTA ER and NUCYNTA previously sold by Janssen Pharma or Lazanda product previously sold by Archimedes Pharma US Inc. Under the Commercialization Agreement with Collegium for NUCYNTA ER and NUCYNTA and the divestiture of Lazanda to Slán, the Company is only financially responsible for product returns for product that were sold by the Company, which are identified by specific lot numbers.

The shelf life of NUCYNTA ER and NUCYNTA is 24 months to 36 months from the date of tablet manufacture. The shelf life of Gralise is 24 months to 36 months from the date of tablet manufacture. The shelf life of CAMBIA is 24 months to 48 months from the manufacture date. The shelf life of Zipsor is 36 months from the date of tablet manufacture. The shelf life of Lazanda is 24 to 36 months from the manufacture date. Because of the shelf life of the Company's products and its return policy of issuing credits with respect to product that is returned within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when the Company issues credit on a returned product. Accordingly, the Company may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments.

Wholesaler and Retail Pharmacy Discounts — The Company offers contractually determined discounts to certain wholesale distributors and retail pharmacies that purchase directly from it. These discounts are either taken off invoice at the time of shipment or paid to the customer on a quarterly basis one to two months after the quarter in which product was shipped to the customer.

Prompt Pay Discounts—The Company offers cash discounts to its customers (generally 2% of the sales price) as an incentive for prompt payment. Based on the Company's experience, the Company expects its customers to comply with the payment terms to earn the cash discount.

Patient Discount Programs—The Company offers patient discount co-pay assistance programs in which patients receive certain discounts off their prescriptions at participating retail pharmacies. The discounts are reimbursed by the Company approximately one month after the prescriptions subject to the discount are filled.

Medicaid Rebates—The Company participates in Medicaid rebate programs, which provide assistance to certain low income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three months after the quarter in which prescriptions subject to the rebate are filled.

Chargebacks—The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product.

Managed Care Rebates—The Company offers discounts under contracts with certain managed care providers. The Company generally pays managed care rebates one to three months after the quarter in which prescriptions subject to the rebate are filled.

Medicare Part D Coverage Gap Rebates—The Company participates in the Medicare Part D Coverage Gap Discount Program under which it provides rebates on prescriptions that fall within the "donut hole" coverage gap. The Company generally pays Medicare Part D Coverage Gap rebates two to three months after the quarter in which prescriptions subject to the rebate are filled.

Royalties

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue at the later of (1) when the related sales occur, or (2) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company currently receives royalties based on sales of CAMBIA in Canada and sales of NUCYNTA ER in Canada and Japan, which are recognized as revenue when the related sales occur as there are no continuing performance obligations by the Company under those agreements.

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Stock Based Compensation

The Company uses the Black Scholes option valuation model to determine the fair value of stock options and employee stock purchase plan (ESPP) shares. The determination of the fair value of stock based payment awards on the date of grant using an option valuation model is affected by the Company's stock price as well as assumptions, which include the Company's expected term of the award, the expected stock price volatility, risk free interest rate and expected dividends over the expected term of the award.

The Company uses historical option exercise data to estimate the expected term of the options. The Company estimates the volatility of its common stock price by using the historical volatility over the expected term of the options. The Company bases the risk free interest rate on U.S. Treasury zero coupon issues with terms similar to the expected term of the options as of the date of grant. The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation models. As a result of adopting ASU 2016-9 Improvements to Employee Share-Based Payment Accounting, the Company made an accounting policy election to account for forfeitures as they occur, rather than estimating expected forfeitures at the time of the grant.

The fair value of each restricted stock unit (RSU) that does not contain a market condition is equal to the market value of our common stock as of the date of the grant. The Company's performance stock units (PSUs) vest over a three year period based on the Relative Total Shareholder Return (TSR) of the Company's common stock against the Russell 3000 Pharmaceuticals Total Return Index over the period. The grant-date fair value of the PSUs is determined using the Monte Carlo simulation method.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-9, Revenue from Contracts with Customers. This guidance outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model requires revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services.

The Company adopted ASC 606 using the modified retrospective method as of January 1, 2018. The Company determined that there was no cumulative effect of applying the new guidance to all contracts with customers that were not completed as of January 1, 2018, therefore no adjustment was required to the accumulated deficit as of the adoption date. Furthermore, upon adoption of the new guidance no adjustments to any prior year periods would have been reportable to present the condensed consolidated balance sheets, statements of operations, or statements of cash flows on a comparable basis to any current year reported balances or amounts.

In January 2017, the FASB issued ASU No. 2017-1, Business Combinations (Topic 805): Clarifying the Definition of a Business, which provides clarification on the definition of a business and adds guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard was effective for the Company beginning January 1, 2018. The future impact of ASU No. 2017-1 will be dependent upon the nature of the Company's future acquisition or disposition transactions, if any.

In May 2017, the FASB issued accounting guidance to clarify which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was required to be applied prospectively. The guidance was effective for the Company beginning January 1, 2018. The adoption of this

guidance did not have a material impact on the Company's consolidated financial statements.

In March 2018, the FASB issued ASU No. 2018-5, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, which provides clarification and guidance on the income tax accounting implications of the Tax Cuts and Jobs Act. The standard was effective for the Company beginning January 1, 2018. The adoption of this guidance did not materially affect the Company's consolidated financial statements.

In January of 2016, the FASB issued ASU No. 2016-1, Financial Instruments – Overall (Subtopic 405-20), Recognition and Measurement of Financial Assets and Financial Liabilities. ASU 2016-1 changed accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, it clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The guidance became effective for the Company on

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January 1, 2018 and required adoption using a modified retrospective approach, with certain exceptions. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40). It requires implementation costs incurred by customers in cloud computing arrangements to be deferred and recognized over the term of the arrangement, if those costs would be capitalized by the customer in a software licensing arrangement under the internal-use software guidance (Subtopic 350-40). This guidance is effective for interim and annual periods beginning after December 15, 2019. Early adoption is permitted. The Company is currently assessing the impact of this guidance on its consolidated financial statements and does not expect this guidance to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). It removes disclosure requirements on fair value measurements including the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. It also amends and clarifies certain disclosures and adds new disclosure requirements including the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements, and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This guidance is effective for interim and annual periods beginning after December 15, 2019. An entity is permitted to early adopt any removed or modified disclosures and delay adoption of the additional disclosures until the effective date. The Company is currently evaluating this guidance and does not expect this guidance to have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-2, Leases. This guidance requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. If the available accounting election is made, leases with a term of twelve months or less can be accounted for similar to existing guidance for operating leases. Additionally, the FASB issued ASU 2018-1, ASU 2018-10 and ASU 2018-11, Leases, (Topic 842); which allow a Land Easement Practical Expedient for Transition to Topic 842, some narrow scope exceptions and relief from the costs of implementing certain aspects of the standard, respectively. The new standard will be adopted using the modified retrospective approach and will be effective for the Company starting with the first quarter of 2019, with early adoption permitted. The Company will adopt the standard effective in the first quarter of 2019 and is currently assessing the impact of adopting this guidance on its consolidated financial statements and related disclosures. The Company does not expect the adoption to have a material impact on its consolidated statement of earnings. However, the new standard will require the Company to establish liabilities and corresponding right-of-use assets on its consolidated balance sheet for operating leases that exist as of the January 1, 2019 adoption date.

In June 2016, the FASB issued ASU 2016-13 (ASU 2016-13), Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. ASU 2016-13 is effective for annual reporting periods, and interim periods within those years beginning after December 15, 2019. The Company is currently in the process of evaluating the impact of the adoption of ASU 2016-13 on the Company's consolidated financial statements.

In February 2018, the FASB issued ASU 2018-2, Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, that provides companies with an option to reclassify stranded tax effects resulting from enactment of the Tax Cuts and Jobs Act (TCJA) from accumulated other comprehensive income to retained earnings. The guidance will be effective for the Company beginning in the first quarter of 2019 with early adoption permitted, and would be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the tax rate as a result of TCJA is recognized. The Company has not made a determination as to which alternative methods it will use when it adopts this standard, but does not expect the adoption of this ASU to have a material impact on its results of operations, financial position and cash flows.

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NOTE 2. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Securities classified as cash and cash equivalents and short-term investments as of September 30, 2018 and December 31, 2017 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

September 30, 2018	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents				
Cash	$106,702	$ —	$ —	$106,702
Money market funds	13	—	—	13
Commercial paper	15,189	—	—	15,189
Total cash and cash equivalents	$121,904	$ —	$ —	$121,904

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents				
Cash	$103,119	$ —	$ —	$103,119
Money market funds	95	—	—	95
Commercial paper	23,670	—	—	23,670
Total cash and cash equivalents	126,884	—	—	126,884
Short-term investments				
Corporate debt securities and commercial paper with maturities less than 1 year	1,210	—	(5)	1,205
Total short-term investments	1,210	—	(5)	1,205
Total	$128,094	$ —	$ (5)	$128,089

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash and cash equivalents generally consist of cash on deposit with banks, money market instruments, U.S. Agency discount notes, commercial paper and corporate debt securities.

The Company invests its cash in money market funds and marketable securities including U.S. Treasury and government agency securities, commercial paper, and high quality debt securities of financial and commercial institutions. To date, the Company has not experienced material losses on any of its balances. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in “accumulated other comprehensive loss” within shareholders’ equity on the consolidated balance sheets. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in “interest and other income” in the consolidated statement of operations.

As of September 30, 2018, the Company held zero securities in an unrealized loss position or that have been in a continuous loss position. The following table shows the gross unrealized losses and fair value of the Company’s investments with unrealized losses that were not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2017 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Gross Unrealized		Gross Unrealized		Gross Unrealized	

December 31, 2017	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses
Corporate Debt Securities	$1,205	$ (5)	$ —	$ —	$1,205	$ (5)

The gross unrealized losses above were caused by interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of the securities held by the

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Company. Based on the Company's review of these securities, including the assessment of the duration and severity of the unrealized losses and the Company's ability and intent to hold the investments until maturity, there were no material other than temporary impairments for these securities at September 30, 2018 or December 31, 2017. Gross realized gains and losses on marketable securities were not material for the three and nine months ended September 30, 2018 or 2017.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017:

(in thousands)

September 30, 2018	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 13	$—	$ —	$13
Commercial paper	—	15,189	—	15,189
Total	$ 13	$15,189	$ —	$15,202
Liabilities:				
Contingent consideration—Zipsor	$ —	$—	$ 367	$367
Contingent consideration—CAMBIA	—	—	510	510
Total	$ —	$—	$ 877	$877

(in thousands)

December 31, 2017	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 95	$—	$—	$95
Commercial paper	—	23,670	—	23,670
Corporate debt securities	—	1,205	—	1,205
Total	$ 95	$24,875	$—	$24,970
Liabilities:				
Contingent consideration—Zipsor	$ —	$—	$464	$464
Contingent consideration—Lazanda	—	—	156	156
Contingent consideration—CAMBIA	—	—	993	993
Total	$ —	$—	$1,613	$1,613

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The fair value measurement of the contingent consideration obligations arises from the Zipsor, CAMBIA and Lazanda acquisitions and relates to fair value of the potential future contingent milestone payments and royalties payable under the respective agreements which are determined using Level 3 inputs. The remaining contingent consideration liability following the divestiture of Lazanda in November 2017 was $0.2 million. This liability was settled in the first quarter of 2018. The key assumptions in determining the fair value are the discount rate and the probability assigned to the potential milestones and royalties being achieved. At each reporting date, the Company re-measures the contingent consideration obligation arising from the above acquisitions to their estimated fair values. Any changes in the fair value of contingent consideration resulting from a change in the underlying inputs are recognized in operating expenses until the contingent consideration arrangement is settled. Changes in the fair value of contingent consideration resulting from the passage of time are recorded within interest expense until the contingent consideration is settled. The table below provides a summary of the changes in fair value recorded in interest expense and selling, general and administrative expenses for the three and nine months ended September 30, 2018 and 2017:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Fair value, beginning of the period	$967	$7,356	$1,613	$14,825
Changes in fair value recorded in interest expense	27	221	106	1,017
Changes in fair value recorded in selling, general and administrative expenses	(117)	(1,415)	(658)	(7,542)
Royalties and milestone paid	—	(526)	(184)	(2,664)
Total	$877	$5,636	$877	$5,636

The estimated fair value of the 2.50% Convertible Senior Notes Due 2021, which the Company issued on September 9, 2014 is based on a market approach. The estimated fair value was approximately $276.9 million and $295.4 million (par value $345.0 million) as of September 30, 2018 and December 31, 2017, respectively, and represents a Level 2 valuation. The principal amount of the Senior Notes approximates their fair value as of September 30, 2018 and December 31, 2017, respectively and represents a Level 2 valuation. When determining the estimated fair value of the Company’s debt, the Company uses a commonly accepted valuation methodology and market-based risk measurements that are indirectly observable, such as credit risk.

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy during the three and nine months ended September 30, 2018 and 2017.

NOTE 3. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period, plus potentially dilutive common shares, consisting of stock options, RSUs, PSUs, ESPP and convertible debt. The Company uses the treasury-stock method to compute diluted earnings per share with respect to its stock options and equivalents. The Company uses the if-converted method to compute diluted earnings per share with respect to its convertible debt. For purposes of this calculation, options to purchase stock, including stock options, RSUs, PSUs and ESPP, are considered to be potential common shares and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive. Basic and diluted earnings per common share are calculated as follows:

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(in thousands, except for per share amounts)	Three Months Ended September 30, 2018	2017	Nine Months Ended September 30, 2018	2017
Basic net income (loss) per share				
Net income (loss)	$48,270	$(15,992)	$61,046	$(69,392)
Denominator	63,917	62,997	63,714	62,556
Basic net income (loss) per share	$0.76	$(0.25)	$0.96	$(1.11)
Diluted net income (loss) per share				
Numerator:				
Net income (loss)	$48,270	$(15,992)	$61,046	$(69,392)
Add: Interest Expense on convertible debt, net of tax	5,340	—	15,815	—
Denominator:				
Denominator for basic income (loss) per share	63,917	62,997	63,714	62,556
Add effect of diluted securities:				
Stock options and equivalents and convertible debt	18,773	—	18,568	—
Denominator for diluted income (loss) per share	82,690	62,997	82,282	62,556
Diluted net income (loss) per share	$0.65	$(0.25)	$0.93	$(1.11)

The following table sets forth outstanding potentially dilutive common shares that are not included in the computation of diluted net income (loss) per share because to do so would be anti-dilutive:

(in thousands)	September 30, 2018	September 30, 2017
Convertible debt	—	17,931
Stock options and equivalents	3,359	7,393
Total potentially dilutive common shares	3,359	25,324

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NOTE 4. REVENUE

Disaggregated Revenue

The following table summarizes revenue from contracts with customers for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product sales, net				
Gralise	$14,630	$21,103	$43,272	$57,777
CAMBIA	10,365	8,164	24,870	23,862
Zipsor	4,441	3,232	13,175	12,286
Total neurology product sales, net	29,436	32,499	81,317	93,925
NUCYNTA products	11	58,665	18,782	183,299
Lazanda	(12)	4,040	528	13,239
Pharmacy benefit manager dispute reserve	—	—	—	(4,742)
Total product sales, net	29,435	95,204	100,627	285,721
Commercialization agreement:				
Commercialization rights and facilitation services, net	27,781	—	87,055	—
Revenue from transfer of inventory	—	—	55,705	—
Royalties and milestone revenue	20,277	209	25,784	596
Total revenues	$77,493	$95,413	$269,171	$286,317

NUCYNTA product sales for the nine months ended September 30, 2018 reflect the Company's sales of NUCYNTA between January 1 and January 8, 2018. During the three and nine months ended September 30, 2018 the Company recognized an insignificant amount of sales reserve estimate adjustments related to sales recognized for NUCYNTA and Lazanda in prior periods. During the first quarter of 2018, in connection with the Collegium transaction, the Company recognized revenue of $12.5 million related to the release of NUCYNTA sales reserves which were primarily recorded in the fourth quarter of 2017, as financial responsibility for those reserves transferred to Collegium upon closing of the Commercialization Agreement.

Commercialization Agreement with Collegium

In January 2018, the Company entered into a Commercialization Agreement with Collegium (Commercialization Agreement), pursuant to which the Company granted Collegium the right to commercialize the NUCYNTA pain products in the U.S. Under the Commercialization Agreement, Collegium assumed all commercialization responsibilities for NUCYNTA effective January 9, 2018, including sales and marketing. The Company will receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of $132 million for the year ended December 31, 2018. Pursuant to the Amendment to the Commercialization Agreement described in Note 17, royalties for fiscal years beginning 2019 will be based on certain annual NUCYNTA net sales thresholds for future years. The Company received an upfront payment of $10.0 million as well as $6.2 million with respect to the inventory of finished goods which was transferred to Collegium on closing of the transaction in January 2018.
The Company identified the following three performance obligations under the Commercialization Agreement:

1. License to commercialize the NUCYNTA pain products,
2. Services to arrange for supplies of NUCYNTA pain products using the Company’s existing contract manufacturing contracts with third parties; and

3. Transfer of control of all NUCYNTA finished goods held at closing.

In January 2018, the Company determined the total transaction price to be $553.2 million, which consists of $537.0 million in total annual minimum royalty payments, the $10.0 million upfront fee, and a $6.2 million payment for NUCYNTA finished goods inventory at cost. In accordance with the relevant Accounting Standard, the Company determined that the

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duration of the Commercialization Agreement begins on the effective date of January 9, 2018 and lasts through December 31, 2021, which is consistent with the contractual period in which the Company and Collegium have enforceable rights and obligations which include the minimum royalty period and the period in which Collegium would incur a $25.0 million termination penalty on terminating the agreement. See Note 17, for information regarding the Amendment to the Commercialization Agreement which impacts certain of these provisions in the fourth quarter of 2018.

The transaction price was allocated to the performance obligations noted above in proportion to their standalone selling prices and will be recognized as these performance obligations are satisfied by the Company. The transaction price allocated to the inventory transferred to Collegium on closing was $55.7 million and was recognized on the closing date as the control of such inventory was transferred to Collegium. The transaction price allocated to the other remaining performance obligations of the license to commercialize NUCYNTA and the related services to arrange for supplies was $497.5 million. This amount will be recognized ratably over time through December 31, 2021, which represents the period over which enforceable rights and obligations exist after considering the various termination rights for either parties that exist in the contract. For the three and nine months ended September 30, 2018, the Company recognized $27.8 million and $87.1 million, respectively, related to the right to commercialize NUCYNTA and related facilitation services. Total revenue recognized for the three and nine months ended September 30, 2018 were $27.8 million and $142.8 million, respectively, which includes the portion of the transaction price allocated to inventory. The commercialization revenues were reduced by anticipated additional royalties payable to Grünenthal by the Company. See "Collegium" below for additional discussion.

The annual minimum royalty amounts are payable by Collegium in equal quarterly installments of $33.8 million, and are initially received through a lockbox sweep mechanism. Remittances from customers on product sales of NUCYNTA made by Collegium are deposited to a designated lockbox account, separate from Collegium's other receivables. On a daily basis, 35% of the cash receipts in this lockbox account are swept to Assertio's bank accounts up to the minimum cash royalty amounts which are $30.8 million for the three months ended March 31, 2018 and $33.8 million per quarter, thereafter. If the cash receipts received by Assertio in a quarter are lower than the minimum quarterly royalty, or if the royalty receivable to Assertio is above the minimum quarterly amount, Collegium is responsible to remit the remaining royalty payment within 45 days after the end of the each quarter. For the nine months ended September 30, 2018, $98.3 million was received by Assertio. See Note 17 for information regarding the Amendment to the Commercialization Agreement.

Contract Assets and Liabilities

The following table presents changes in the Company's contract assets and liabilities for the nine months ended September 30, 2018 (in thousands):

	Balance as of December 31, 2017	Additions	Deductions	Balance as of September 30, 2018
Contract assets:				
Contract asset, net - Collegium	$ —	$ 55,705	$ (23,654)	$ 32,051
Contract asset - Ironwood	—	5,000	(5,000)	—
	—	60,705	(28,654)	32,051

Collegium

The Company receives payments from Collegium based on the above described schedule as established in the Company's contracts. Contract asset relates to conditional right to consideration for completed performance under the

Commercialization Agreement. This contract asset relates to the revenue recognized by the company from the transfer of inventory to Collegium on the date of closing of the agreement in January 2018 net of the contract liability of $10.0 million resulting from the upfront payment received. Accounts receivable are recorded when the right to consideration becomes unconditional. As of September 30, 2018, $9.9 million and $22.1 million of the contract asset has been recorded within “Prepaid and other current assets” and “Other long-term assets,” respectively.

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The Company acquired the U.S. rights to NUCYNTA from Janssen Pharmaceuticals, Inc. (Janssen) in April 2015. As part of that transaction, the Company also acquired the related royalty obligations for NUCYNTA to Grünenthal, the originator of tapentadol. Pursuant to the terms of the Commercialization Agreement, Collegium will now remit payment on behalf of the Company to satisfy this royalty obligation In addition, as a condition of giving its consent to the Commercialization Agreement with Collegium, Grünenthal amended the terms of the original royalty agreement to require payment of a minimum royalty of $34.0 million per year on net sales of NUCYNTA greater than $180.0 million and equal to, or less than, $243.0 million for each of the years ended December 31, 2018 through 2021. In return for this agreement to pay minimum royalties, the Company received the right to share royalties with Grünenthal on annual net sales of NUCYNTA above $243.0 million during the same period. The Company is obligated to cover any shortfall between the minimum royalty amount of $34.0 million and the amounts paid to Grünenthal by Collegium for each of the years ended December 31, 2018 through 2021, as a result of which the Company could be obligated to pay up to $8.8 million per year for each of the years ended December 31, 2018 through 2021.

In the three months ended September 30, 2018, the Company recorded a royalty payable to Grünenthal of $3.7 million in anticipation of the Collegium payments to Grünenthal falling below the minimum of royalty amount of $34.0 million for the full 2018 fiscal year. Grünenthal royalties related to NUCYNTA sales for the three and nine months ended September 30, 2018 were $10.8 million and $25.2 million, respectively, of which approximately $7.1 million and $21.5 million, respectively, were paid directly by Collegium to Grünenthal. These royalties were recorded as a gross-to-net adjustment in the Revenue from Commercialization Agreement, net line in the Company’s Statement of Operations. Pursuant to the Amendment, Collegium will reimburse the Company for the amount of any minimum annual royalties paid by the Company to Grünenthal on net sales of NUCYNTA from 2019 to 2021 related to this Commercialization Agreement.

Collaboration and License Agreements

Ironwood Pharmaceuticals, Inc. In July 2011, the Company entered into a collaboration and license agreement with Ironwood (Ironwood Agreement) granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to the Company’s Acuform drug delivery technology for IW 3718, an Ironwood product candidate under development for refractory GERD. The Company has received $3.4 million under the agreement, including a contingent milestone payment of $1.0 million in March 2014 as a result of the initiation of clinical trials relating to IW 3718 by Ironwood. The Company is entitled to receive additional contingent milestone payments upon the occurrence of certain development milestones and royalties on net sales of the product if approved.

The Company identified the following two performance obligations under the Ironwood Agreement: (1) the license to the Acuform technology and (2) formulation work associated with IW-3718. The license was granted in 2011 and the formulation work was completed in 2012. The Company has no ongoing performance obligations and has recognized all proceeds received to date as revenue.

The future contingent milestones under the Ironwood Agreement are considered variable consideration and are estimated using the most likely method. As part of implementation of ASC 606, the Company evaluated whether the future milestones under the Ironwood Agreement should have been included as part of the transaction price in periods before January 1, 2018. The Company concluded that because of development and regulatory risks at the time, it was probable that a significant revenue reversal could have occurred. Accordingly, the associated future contingent milestone values were not included in the transaction price for periods before January 1, 2018. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

During the nine months ended September 30, 2018, the Company recognized and collected a $5.0 million milestone payment related to the dosing of the first patient in a Phase 3 trial. There was no revenue recognized under this agreement for the three and nine months ended September 30, 2017.

PDL BioPharma, Inc. In October 2013, the Company sold its interests in royalty and milestone payments under its license agreements relating to our Acuform technology in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for $240.5 million. On August 2, 2018 the Company sold its remaining interest in such payments to PDL for $20.0 million. The $20 million of revenue was recognized as royalty revenue in the three months ended September 30, 2018.

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NOTE 5. STOCK-BASED COMPENSATION

The following table presents stock-based compensation expense recognized for stock options, stock awards, restricted stock units, performance-based restricted stock units and the Company's Employee Stock Purchase Program (ESPP) in the Company's Condensed Consolidated Statements of Operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of sales	$—	$9	$30	$84
Research and development expense	270	45	337	652
Selling, general and administrative expense	2,674	2,857	7,523	9,134
Restructuring	(173)	52	2,385	52
Total	$2,771	$2,963	$10,275	$9,922

At September 30, 2018, the Company had $16.3 million of total unrecognized compensation expense related to stock option grants and restricted stock units that will be recognized over an average vesting period of 2.2 years.

The reduction of stock based compensation expense related to restructuring is due to forfeitures of stock based compensation awards by employees who were terminated in conjunction with the Company's restructuring plan, see Note 15—Restructuring for additional discussion.

Performance-based Restricted Stock Units

During the nine months ended September 30, 2018, the Company granted Performance Stock Units (PSUs) with an aggregate target award of 523,187 units and a weighted-average grant-date fair value of $10.18 per unit. The PSUs vest in annual cliffs over a three year period based on the Relative Total Shareholder Return (TSR) of the Company's common stock against the Russell 3000 Pharmaceuticals Total Return Index over the period. The ultimate award, which is determined at the end of the three-year cycle, can range from zero to 200% of the target. The recipients of the PSU awards will have voting rights and the right to receive a dividend once the underlying shares have been issued. The grant-date fair value is based upon the Monte Carlo simulation method.

The following table summarizes the PSU activity for the nine months ended September 30, 2018 under the 2014 Plan (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in 000s)
Non-vested performance-based restricted stock units at December 31, 2017	—	$ —		
Granted	523,187	10.18		
Vested	—	—		
Forfeited	(36,800)	10.04		
Non-vested performance-based restricted stock units at September 30, 2018	486,387	$ 10.19	2.36	$ 2,860

As of September 30, 2018, total unrecognized compensation cost related to PSUs was $3.7 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.36 years.

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NOTE 6. INVENTORIES, NET

Inventories, net, consist of raw materials, work in process and finished goods and are stated at the lower of cost or market and consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 1,625	$ 3,008
Work-in-process	802	204
Finished goods	1,828	9,830
Total	$ 4,255	$ 13,042

NOTE 7. ACCOUNTS RECEIVABLES, NET

Accounts receivables, net, consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Product sales, net	$ 30,479	$ 71,919
Receivables from collaborative partners	13,433	563
Total accounts receivable, net	$ 43,912	$ 72,482

NOTE 8. ACCRUED LIABILITIES

Accrued liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued compensation	$ 4,205	$ 7,345
Accrued royalties	4,715	17,370
Accrued restructuring and one-time termination costs	1,835	9,483
Other accrued liabilities	15,320	26,298
Total accrued liabilities	$ 26,075	$ 60,496

NOTE 9. DEBT

Senior Notes

On April 2, 2015, the Company issued $575.0 million aggregate principal amount of senior secured notes (the Senior Notes) for aggregate gross proceeds of approximately $562.0 million pursuant to a Note Purchase Agreement dated March 12, 2015, among the Company and Deerfield Private Design Fund III, L.P., Deerfield Partners, L.P., Deerfield International Master Fund, L.P., Deerfield Special Situations Fund, L.P., Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., BioPharma Secured Investments III Holdings Cayman LP, Inteligo Bank Ltd. and Phemus Corporation (collectively, the Purchasers) and Deerfield Private Design Fund III, L.P., as collateral agent. The Company used $550.0 million of the net proceeds received upon the sale of the Senior Notes to fund a portion of the Purchase Price paid to Janssen Pharma in connection with the NUCYNTA acquisition. The Company incurred debt issuance costs of $0.5 million for 2015.

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The Senior Notes will mature on April 14, 2021 (unless earlier prepaid or repurchased), are secured by substantially all of the assets of the Company and any subsidiary guarantors, and bear interest at the rate equal to the lesser of (i) 9.75% over the three month London Inter-Bank Offer Rate (LIBOR), subject to a floor of 1.0% and (ii) 11.95% (through the third anniversary of the purchase date) and 12.95% (thereafter). The interest rate is determined at the first business day of each fiscal quarter, commencing with the first such date following April 2, 2015. The interest rate for the three months ended September 30, 2018 and 2017 was 12.15% and 11.05%, respectively.

In April 2017, the Company prepaid and retired $100.0 million of the Senior Notes and paid a $4.0 million prepayment fee; and in November 2017, the Company prepaid and retired an additional $10 million of the Senior Notes and paid a $0.4 million prepayment fee. The Company recorded a net loss on prepayment of the Senior Notes of $5.9 million which represented the prepayment fees of $4.4 million and the immediate recognition of unamortized balances of debt discount and debt issuance costs of $1.5 million in 2017. This loss is recorded as a loss on prepayment of Senior Notes in the consolidated statements of operations for 2017.

The remaining $307.5 million of Senior Notes can be prepaid, at the Company's option. The Company is required to repay the outstanding Senior Notes in full if the principal amount outstanding on its existing 2.50% Convertible Senior Notes due 2021 as of March 31, 2021, is greater than $100.0 million. In addition, if the successor entity in a Major Transaction, as defined in the Note Purchase Agreement, does not satisfy specified qualification criteria, the Purchasers may require the Company to prepay the Senior Notes upon consummation of the Major Transaction in an amount equal to the principal amount of outstanding Senior Notes, accrued and unpaid interest and a prepayment premium in an amount equal to what the Company would have otherwise paid in an optional prepayment described in the following paragraph. The Company is required to make mandatory prepayments on the Senior Notes in an amount equal to the proceeds it receives in connection with asset dispositions in excess of $10.0 million, together with accrued and unpaid interest on the principal amount prepaid.

Pursuant to the Note Purchase Agreement, upon the consummation of the sale of the Senior Notes on April 2, 2015, the Company and Depo NF Sub, LLC entered into a Pledge and Security Agreement with the Deerfield Private Design Fund III, L.P. (the Collateral Agent), pursuant to which the Company and Depo NF Sub each granted the Collateral Agent (on behalf of the Purchasers) a security interest in substantially all of their assets, other than specifically excluded assets.

On December 4, 2017, the Company and the Purchasers entered into an Amendment to the existing Note Purchase Agreement. The Amendment facilitated the Company's entry into a Commercialization Agreement, by and between the Company and Collegium and Collegium NF, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium, on December 4, 2017, pursuant to which the Company, or one of its subsidiaries, granted the right to Collegium and its sub licensees to commercialize NUCYNTA® in the United States of America, the District of Columbia and Puerto Rico.

In connection with its entry into the Commercialization Agreement, the Purchasers (i) waived the requirement that some or all of the Asset Disposition Proceeds realized from the granting of the Exclusive License be used to prepay the outstanding principal amount of the Notes pursuant to Section 2.7(b) of the Note Purchase Agreement and (ii) agreed to (a) replace the minimum net sales covenant in Section 6.7 of the Note Purchase Agreement with a minimum EBITDA covenant, and (b) made certain other amendments related to the amortization of the Notes. In addition, the prepayment premiums were amended to 4% of the principal amount of the Notes to be prepaid, if such prepayment occurs after the second anniversary of the Purchase Date but on or prior to the fifth anniversary of the Purchase Date; and (iii) zero, if such prepayment occurs after the fifth anniversary of the Purchase Date. The minimum EBITDA covenants stipulate that the Company's EBITDA, measured as of the last day of the twelve month measurement period be (i) for the twelve month period from October 1, 2017 through to September 30, 2018 be at least $90 million and (ii) $125 million, thereafter. The amendment also modified the repayment schedule; and required the Company to prepay

and retire $10.0 million of the Senior Notes and pay a $0.4 million prepayment fee. The Company paid a $3.0 million upfront non-refundable amendment fee which, pursuant to the terms of the modification, can be off-set dollar for dollar against any future prepayment fees. The Purchasers have also consented to terms and conditions of the Amendment to the Commercialization Agreement with Collegium described in Note 17.

The Company accounted for the amendment as a debt modification in accordance with the applicable accounting standards. Accordingly, the $3.0 million amendment fee paid to the Purchasers on the fourth quarter of 2017 was capitalized and is being amortized over the remaining term of the Senior Notes.

The Senior Notes and related indenture contain customary covenants, including, among other things, and subject to certain qualifications and exceptions, covenants that restrict the Company’s ability and the ability of its subsidiaries to: incur or guarantee additional indebtedness; create or permit liens on assets; pay dividends on capital stock or redeem, repurchase or retire capital stock or subordinated indebtedness; make certain investments and other restricted payments; engage in mergers, acquisitions, consolidations and amalgamations; transfer and sell certain assets; and engage in transactions with affiliates.

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The principal amount of the Senior Notes is repayable as of September 30, 2018 is as follows (amounts in thousands):

2018 (remainder)	$25,000
2019	120,000
2020	80,000
2021	82,500
Total	$307,500

The principal payment due in the remainder of 2018 was paid by the Company in October 2018. The Company is scheduled to make the Senior Notes principal payments of $125.0 million prior to September 30, 2019 and has classified this portion of the Senior Notes within the current liabilities section of the condensed consolidated balance sheet.

The following is a summary of the carrying value of the Senior Notes as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Principal amount of the Senior Notes	$ 307,500	$ 365,000
Unamortized debt discount balance	(3,053)	(4,717)
Unamortized debt issuance costs	(1,981)	(3,063)
Total Senior Notes	$ 302,466	$ 357,220

The debt discount and debt issuance costs are being amortized as interest expense through April 2021 using the effective interest method. The following is a summary of interest expense for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Contractual interest expense	$9,517	$10,589	$29,383	$33,748
Amortization of debt discount and debt issuance costs	886	614	2,747	1,811
Total interest expense Senior Notes	$10,403	$11,203	$32,130	$35,559

Convertible Debt

On September 9, 2014, the Company issued $345.0 million aggregate principal amount of 2.50% Convertible Senior Notes Due 2021 (the Convertible Notes) resulting in net proceeds to the Company of $334.2 million after deducting the underwriting discount and offering expenses of $10.4 million and $0.4 million, respectively.

The Convertible Notes were issued pursuant to an indenture, as supplemented by a supplemental indenture dated September 9, 2014, between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (the Trustee), and mature on September 1, 2021, unless earlier converted, redeemed or repurchased. The Convertible Notes bear interest at the rate of 2.50% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning March 1, 2015.

Prior to March 1, 2021, holders of the 2021 Convertible Notes can convert their securities, at their option: (i) during any calendar quarter commencing after December 31, 2015, if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last

trading day of the immediately preceding calendar quarter is greater than or equal to $25.01 (130% of the $19.24 conversion price) on each applicable trading day; (ii) during the five business day period after any five consecutive trading day 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 our common stock and the conversion rate on each such trading day; and (iii) at any time upon the occurrence of specified corporate transactions, to include a change of control (as defined in the Notes Indenture). On or after March 1, 2021 to the close of business on the second scheduled trading day immediately preceding the maturity date, the holders of the 2021 Convertible Notes may convert all or any portion of their notes, in multiples of $1,000 principal

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amount, at the option of the holder regardless of the foregoing circumstances. The initial conversion rate of 51.9852 shares of common stock per $1,000 principal amount of Convertible Notes is equivalent to a conversion price of approximately $19.24 per share of common stock.

Upon conversion, the Company will pay or deliver, as the case may be, 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. If the conversion obligation is satisfied solely in cash or through payment and delivery of a combination of cash and shares, the amount of cash and shares, if any, due upon conversion will be based on a daily conversion value calculated on a proportionate basis for each trading day in a 40 trading day observation period.

The closing price of the Company’s common stock did not exceed 130% of the $19.24 conversion price for the required period during the quarter or the nine month period ended September 30, 2018. As a result, the Convertible Notes are not convertible as of September 30, 2018.

The Convertible Notes were accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Pursuant to ASC Subtopic 470-20, since the Convertible Notes can be settled in cash, shares of common stock or a combination of cash and shares of common stock at the Company’s option, the Company is required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The effective interest rate used in determining the liability component of the Convertible Notes was 9.34%. This resulted in the initial recognition of $226.0 million as the liability component net of a $119.0 million debt discount with a corresponding net of tax increase to paid-in capital of $73.3 million, representing the equity component of the Convertible Notes. The underwriting discount of $10.4 million and offering expenses of $0.4 million were allocated between debt issuance costs and equity issuance costs in proportion to the allocation of the proceeds. Equity issuance costs of $3.7 million related to the convertible notes were recorded as an offset to additional paid-in capital.

The following is a summary of the liability component of the Convertible Notes as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Principal amount of the Convertible Notes	$ 345,000	$ 345,000
Unamortized discount of the liability component	(59,006)	(71,799)
Unamortized debt issuance costs	(2,933)	(3,691)
Total Convertible Notes	$ 283,061	$ 269,510

The debt discount and debt issuance costs are being amortized as interest expense through September 2021. The following is a summary of interest expense for the three and six months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stated coupon interest	$2,156	$2,156	$6,468	$6,468
Amortization of debt discount and debt issuance costs	4,604	4,225	13,551	12,438
Total interest expense Convertible Notes	$6,760	$6,381	$20,019	$18,906

NOTE 10. SHAREHOLDERS’ EQUITY

Reclassification

On August 14, 2018, Depomed reincorporated from California to Delaware (the Reincorporation) and changed its name to Assertio Therapeutics, Inc. To effectuate the Reincorporation, Depomed merged with and into Assertio Therapeutics, Inc., a Delaware corporation and wholly owned subsidiary of Depomed prior to the effective time of the merger, with Assertio continuing as the surviving corporation. Pursuant to the merger, each share of Depomed common stock, no par value, was converted into one share of Assertio common stock, $0.0001 par value, and all outstanding Depomed equity awards were assumed by Assertio. As a result of the Reincorporation and the related conversion of each share of Depomed-California
common stock, no par value, into one share of Assertio-Delaware common stock, $0.0001 par value, the Company has separated the par value of stock within Common Stock from additional-paid-in-capital on the Company's Consolidated Balance Sheets. The Company has elected to present this change in disclosure retrospectively. Accordingly, to conform to current year presentation, the Company reclassified $313.9 million from common stock to additional paid-in capital as of December 31, 2017 on the Company's Consolidated Balance Sheets.

Option Exercises

For the three and nine months ended September 30, 2018, employees exercised options to purchase 34,551 shares and 262,443 shares, respectively, of the Company’s common stock with net proceeds to the Company of approximately $0.2 million and $1.5 million, respectively. For the three and nine months ended September 30, 2017, employees exercised options to purchase 50,159 shares and 863,511 shares, respectively, of the Company’s common stock with net proceeds to the Company of approximately $0.3 million and $6.3 million, respectively.

Restricted Stock Units

For the three and nine months ended September 30, 2018, the Company issued 2,597 shares and 204,142 shares of the Company’s common stock, respectively, due to vesting of restricted stock units. For the three and nine months ended September 30, 2017, the Company issued zero and 42,068 shares of the Company’s common stock due to vesting of restricted stock units, respectively.

NOTE 11. INCOME TAXES

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act (the Tax Act). The Tax Act includes significant changes to the U.S. corporate income tax system including, but not limited to, a federal corporate rate reduction from 35% to 21% and limitations on the deductibility of interest expense and executive compensation. In order to calculate the effects of the new corporate tax rate on our deferred tax balances, ASC 740 Income Taxes (ASC 740) required the re-measurement of our deferred tax balances as of the enactment date of the Tax Act, based on the rates at which the balances were expected to reverse in the future. Due to the Company’s full valuation allowance position, there was no change to the presentation of the deferred tax balances on the financial statements, except for the re-measurement of these deferred tax balances in the income tax footnote. The re-measurement resulted in a one-time reduction in federal & state deferred tax assets as of December 31, 2017 of approximately $25.5 million, which was fully offset by a corresponding change to the Company's valuation allowance.

As of September 30, 2018, our net deferred tax assets are fully offset by a valuation allowance. The valuation allowance is determined in accordance with the provisions of ASC 740, Income taxes, which require an assessment of both negative and positive evidence when measuring the need for a valuation allowance. Based on the weight of available evidence, the Company recorded a full valuation allowance against our net deferred assets beginning in the fourth quarter of 2016. The Company continued to provide a full valuation allowance against our net deferred assets in subsequent quarters. The Company reassesses the need for a valuation allowance on a quarterly basis. If it is determined that a portion or all of the valuation allowance is not required, it will generally be a benefit to the income

tax provision in the period such determination is made.

In the nine months ended September 30, 2018, the Company recorded an expense from income taxes of approximately $6.4 million that represents an effective tax rate of 9.5%. The difference between the income tax expense of $6.4 million and the tax at the statutory rate of 21% on current year operations is principally due to the change in valuation allowance in connection with the utilization of net operating losses in 2018. For the nine months ended September 30, 2017, the difference between the recorded provision for income taxes and the tax benefit based on the federal statutory rate of 35%, was primarily attributable to the impact of the valuation allowance.

The Company files income tax returns in the United States federal jurisdiction and in various states, and the tax returns filed for the years 1997 through 2016 and the applicable statutes of limitation have not expired with respect to those returns. Because of net operating losses and unutilized R&D credits, substantially all of the Company's tax years remain open to examination. Interest and penalties, if any, related to unrecognized tax benefits, would be recognized as income tax expense by the Company. At September 30, 2018 the Company had approximately $1.2 million of accrued interest and penalties associated with unrecognized tax benefits.

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NOTE 12. COMMITMENTS AND CONTINGENCIES

Leases

The Company has non-cancelable operating leases for our office buildings and is obligated to make payments under non-cancelable operating leases for automobiles used by our sales force. Future minimum lease payments under our non-cancelable operating leases at September 30, 2018 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2018 (remainder)	$ 667
2019	2,637
2020	2,509
2021	2,356
2022	2,188
Thereafter	632
Total	$ 10,989

In April 2012, the Company entered into an office and laboratory lease agreement to lease approximately 52,500 rentable square feet in Newark, California (Newark Lease) commencing on December 1, 2012. The Company occupied approximately 8,000 additional rentable square feet commencing in July 2015. The lease is due to expire on November 30, 2022.

The Company relocated its corporate headquarters from Newark, California to Lake Forest, Illinois in the third quarter of 2018. The Company has entered into a sublease for approximately 60% of the Newark facility and anticipates being able to sublease the remaining office space. The anticipated value of these subleases is in excess of the Company's remaining costs under the Newark lease and therefore no cease use cost has been recognized as of September 30, 2018.

Effective February 28, 2018, the Company entered into an Office Lease, in Lake Forest, Illinois (Lake Forest Lease) for its new corporate headquarters, where the Company leases approximately 31,000 rentable square feet of space. The initial tenant improvements in the space were completed in August 2018 and the Company began occupying the space at that time. The Lake Forest Lease term is for five years and six months. The Company has the right to renew the term of the Lease for one period of five years, provided that written notice is made to the Landlord no later than twelve months prior to the expiration of the initial term of the Lease.

The Lake Forest Lease initial annual base rent is $18.00 per rentable square foot and will increase annually by $0.50 per rentable square foot. The lease is a triple net lease, with the Company required to pay its pro rata share of real estate taxes and operating expenses. The Landlord will make available to the Company a tenant improvement allowance of $28.00 per square rentable square foot, which the Company may use towards the initial build-out or apply to the payment of rent.

As of September 30, 2018, the aggregate rent payable over the remaining term of the lease agreements was approximately $6.8 million on the Newark Lease and $3.1 million on the Lake Forest Lease, including the Company’s option to renew. Deferred rent was approximately $1.4 million as of September 30, 2018 and $1.4 million as of December 31, 2017. As of September 30, 2018 the Company had a liability of $3.2 million related to the deferred recognition of tenant improvement allowances.

Rent expense relating to the office lease agreements for the three and nine months ended September 30, 2018, was $0.2 million and $1.2 million, respectively. These amounts exclude the out of period adjustment related to the Newark, California tenant improvement allowance. See Note 16 for further discussion. Rent expense relating to the office lease agreements for the three and nine months ended September 30, 2017, was $0.1 million and $0.4 million, respectively.

The Company has an operating lease agreement with Enterprise FM Trust (Enterprise) for the lease of vehicles to be used by the Company's sales force, with the lease terms ranging from 24 to 48 months. As of September 30, 2018, the aggregate rent payable over the remaining lease term of the vehicle lease agreement was approximately $1.0 million. Rent expense relating to the lease of cars for the three and nine months ended September 30, 2018 was $0.1 million and $0.8 million, respectively. Rent expense relating to the lease of cars for the three and nine months ended September 30, 2017 was $0.8 million and $2.4 million, respectively.

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Legal Matters

Company v. NUCYNTA and NUCYNTA ER ANDA Filers

Actavis & Alkem: In July 2013, Janssen Pharma filed patent infringement lawsuits in the U.S. District Court for the District of New Jersey (D.N.J.) against Actavis Elizabeth LLC, Actavis Inc. and Actavis LLC (collectively, Actavis), as well as Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively, Alkem). The patent infringement claims against Actavis and Alkem relate to their respective ANDAs seeking approval to market generic versions of NUCYNTA and NUCYNTA ER before the expiration of U.S. Reissue Patent No. 39,593 (the ’593 Patent), U.S. Patent No. 7,994,364 (the ’364 Patent) and, as to Actavis only, U.S. Patent No. 8,309,060 (the ’60 Patent). In December 2013, Janssen Pharma filed an additional complaint in the D.N.J. against Alkem asserting that newly issued U.S. Patent No. 8,536,130 (the ’130 Patent) was also infringed by Alkem’s ANDA seeking approval to market a generic version of NUCYNTA ER. In August 2014, Janssen Pharma amended the complaint against Alkem to add additional dosage strengths.

Sandoz & Roxane: In October 2013, Janssen Pharma received a Paragraph IV Notice from Sandoz, Inc. (Sandoz) with respect to NUCYNTA related to the ’364 Patent, and a Paragraph IV Notice from Roxane Laboratories, Inc. (Roxane) with respect to NUCYNTA related to the ’364 and ’593 Patents. In response to those notices, Janssen Pharma filed an additional complaint in the D.N.J. against Roxane and Sandoz asserting the ’364 Patent against Sandoz and the ’364 and ’593 Patents against Roxane. In April 2014, Janssen Pharma and Sandoz entered into a joint stipulation of dismissal of the case against Sandoz, based on Sandoz's agreement not to market a generic version of NUCYNTA products prior to the expiration of the asserted patents. In June 2014, in response to a new Paragraph IV Notice from Roxane with respect to NUCYNTA ER, Janssen Pharma filed an additional complaint in the D.N.J. asserting the ’364, ’593, and ’130 Patents against Roxane.

Watson: In July 2014, in response to a Paragraph IV Notice from Watson Laboratories, Inc. (Watson) with respect to the NUCYNTA oral solution product and the ’364 and ’593 Patents, Janssen Pharma filed a lawsuit in the D.N.J. asserting the ’364 and ’593 Patents against Watson.

In each of the foregoing actions, the ANDA filers counterclaimed for declaratory relief of non-infringement and patent invalidity. At the time that the actions were commenced, Janssen Pharma was the exclusive U.S. licensee of the patents referred to above. On April 2, 2015, the Company acquired the U.S. rights to NUCYNTA ER and NUCYNTA from Janssen Pharma. As part of the acquisition, the Company became the exclusive U.S. licensee of the patents referred to above. The Company was added as a plaintiff to the pending cases and is actively litigating them.

In September 2015, the Company filed an additional complaint in the D.N.J. asserting the ’130 Patent against Actavis. The ’130 Patent issued in September 2013 and was timely listed in the Orange Book for NUCYNTA ER, but Actavis did not file a Paragraph IV Notice with respect to this patent. In its new lawsuit, the Company claimed that Actavis would infringe or induce infringement of the ’130 Patent if its proposed generic products were approved. In response, Actavis counterclaimed for declaratory relief of non-infringement and patent invalidity, as well as an order requiring the Company to change the corrected use code listed in the Orange Book for the ’130 Patent.

In February 2016, Actavis, Actavis UT, Roxane and Alkem each stipulated to infringement of the ’593 and ’364 patents. On March 9, 2016, a two-week bench trial on the validity of the three asserted patents and infringement of the ’130 patent commenced. Closing arguments took place on April 27, 2016. On September 30, 2016, the Court issued its final decision. The Court found that the ’593, ’364 patent, and ’130 patents are all valid and enforceable, that Alkem will induce infringement of the ’130 patent, but that Roxane and Actavis will not infringe the ’130 patent.

On April 11, 2017, the Court entered final judgment in favor of the Company on the validity and enforceability of all three patents, on infringement of the ’593 and ’364 Patents by all defendants, and on infringement of the ’130 Patent against Alkem. The judgment includes an injunction enjoining all three defendants from engaging in certain activities with regard to tapentadol (the active ingredient in NUCYNTA), and ordering the effective date of any approval of Actavis, Actavis UT, and Roxane’s ANDAs, and Alkem’s ANDA for NUCYNTA IR to be no earlier than the expiry of the ’364 Patent (June 27, 2025), and the effective date of any approval of Alkem’s ANDA for NUCYNTA ER to be no

early than the expiry of the ’130 Patent (September 22, 2028). The period of exclusivity with respect to all four defendants may in the future be extended with the award of pediatric exclusivity.

Notices of appeal were filed by defendants Alkem and Roxane concerning the validity of the ’364 and ’130 patents. The Company filed its own cross-appeal with regard to the Court’s finding that Roxane and Actavis will not infringe the claims of the ’130 Patent. The appeals have been consolidated at the Federal Circuit. Briefing concluded in March 2018 and oral arguments occurred on September 4, 2018. It is estimated that the Federal Circuit will issue a written decision in late 2018 or in the first quarter of 2019. The ‘593 patent is not the subject of any appeals.

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Company v. Purdue

The Company sued Purdue Pharma L.P (Purdue) for patent infringement in a lawsuit filed in January 2013 in the U.S. District Court for the District of New Jersey. The lawsuit arose from Purdue's commercialization of reformulated OxyContin® (oxycodone hydrochloride controlled-release) in the U.S. and alleges infringement of U.S. Patent Nos. 6,340,475 (the '475 Patent) and 6,635,280 (the '280 Patent), which expired in September 2016.

On September 28, 2015, the district court stayed the Purdue lawsuit pending the decision of the U.S. Court of Appeals for the Federal Circuit (CAFC) in Purdue's appeal of the PTAB's Final Written Decisions described below. On June 30, 2016, the district court lifted the stay based on the CAFC's opinion and judgment affirming the PTAB's Final Written Decisions confirming the patentability of the patent claims of the '475 and '280 Patents Purdue had challenged. On June 10, 2016, the Company filed a motion for leave to file a second amended Complaint to plead willful infringement. On June 21, 2016, Purdue filed an opposition to the Company's motion for leave to plead willful infringement. On January 31, 2017, the Court granted the Company's motion for leave to plead willful infringement.

On February 1, 2017, the Company filed a Second Amended Complaint pleading willful infringement. On July 10, 2017, the case was reassigned to Judge Wolfson. On February 15, 2017, Purdue answered the Company's Second Amended Complaint and pled counterclaims of non-infringement, invalidity, unenforceability and certain affirmative defenses. On September 26, 2017, the case was reassigned to Judge Martinotti. On December 22, 2017, the Court set the close of expert discovery for March 30, 2018. On January 5, 2018, the Court vacated the January 25, 2018 pretrial conference.

On July 9, 2018, the Court issued an order administratively terminating the case pending the outcome of settlement discussions between the parties. On August 28, 2018, the Company and each of Purdue, The P.F. Laboratories, Inc. a New Jersey corporation, and Purdue Pharmaceuticals L.P., a Delaware limited partnership (collectively, Purdue Companies), entered into a Settlement Agreement. Pursuant to the Settlement Agreement: (i) Purdue Companies paid the Company $30 million on August 28, 2018 and will pay the Company an additional $32 million on February 1, 2019; (ii) each party covenanted not to the sue the other with regard to any alleged infringement of such party's patents or patent rights as a result of the commercialization of the other party's current product portfolio; (iii) each party covenanted not to challenge the other party's patents or patent rights covering such other party's current product portfolio; and (iv) each party agreed to a mutual release of claims relating to any claim or potential claim relating to the other party's current product portfolio.

Securities Class Action Lawsuit

On August 23, 2017, the Company, its current chief executive officer and president, its former chief executive officer and president, and its former chief financial officer were named as defendants in a purported federal securities law class action filed in the United States District Court for the Northern District of California (Huang v. Depomed et al., No. 3:17-cv-4830-JST, N.D. Cal.). The action alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 relating to certain prior disclosures of the Company about its business, compliance, and operational policies and practices concerning the sales and marketing of its opioid products and contends that the conduct supporting the alleged violations affected the value of Company common stock and is seeking damages and other relief. In an amended complaint filed on February 6, 2018, the lead plaintiff (referred to in its pleadings as the Depomed Investor Group), which seeks to represent a class consisting of all purchasers of Company common stock between July 29, 2015 and August 6, 2017, asserted the same claims arising out of the same and similar disclosures against the Company and the same individuals as were involved in the original complaint. The Company and the individuals filed a motion to dismiss the amended complaint on April 9, 2018. The lead plaintiff filed an opposition to the motion on June 8, 2018. The Company and the individuals filed a reply in support of their motion to dismiss on July 23, 2018. Oral arguments are scheduled for November 29, 2018. The Company believes that the action is without merit and intends to contest it vigorously.

In addition, three shareholder derivative actions were filed on behalf of the Company and purport to assert claims by the Company against its officers and directors for breach of fiduciary duty, arising out of the same factual allegations as the class action. Two of these actions were filed in the Northern District of California, the first on November 10,

2017 (Solak v. Higgins et al., No. 3:17-cv-6546-JST) and the second on November 15, 2017 (Ross v. Fogarty et al., No. 3:17-cv-6592- JST). The third derivative action was filed in the Superior Court of California, Alameda County (Singh v. Higgins, et al., RG17877280) on September 29, 2017. On December 7, 2017, the plaintiffs in Solak v. Higgins, et al. voluntarily dismissed the first federal derivative action. And, on January 18, 2018 and January 23, 2018, respectively, the remaining federal and state derivative actions were stayed pending the resolution of the motion to dismiss in the securities class action. The Company believes that these actions are without merit and intends to contest them vigorously.

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Opioid-Related Requests and Subpoenas

As a result of the greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers generally by federal, state, and local regulatory and governmental agencies. The Company received a letter from Senator Claire McCaskill (D-MO), the Ranking Member on the U.S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information from the Company regarding its prior commercialization of opioid products. The Company voluntarily furnished information responsive to Sen. McCaskill's request. The Company has also received subpoenas or civil investigative demands focused on historical promotion and sales of Lazanda, NUCYNTA, and NUCYNTA ER from various State Attorneys General seeking documents and information regarding our prior sales and marketing of opioid products. In addition, the State of California Department of Insurance (CDI) has issued a subpoena to the Company seeking information relating to our prior sales and marketing of Lazanda. The CDI subpoena also seeks information on Gralise, a non-opioid product in our portfolio. The Company has received subpoenas from the U.S. Department of Justice (DOJ) seeking documents and information regarding our prior sales and marketing of opioid products. The Company also from time to time receives and complies with subpoenas from governmental authorities related to investigations primarily directed at third parties, including health care practitioners, pursuant to which our records related to agreements with and payments made to those third parties, among other items, are produced. As a general matter, the Company is cooperating with all of the requests from and investigations by regulators described above.

Multidistrict Opioid Litigation

A number of pharmaceutical manufacturers, distributors and other industry participants have been named in numerous lawsuits around the country brought by various groups of plaintiffs, including city and county governments, hospitals and others. In general, the lawsuits assert claims arising from defendants' manufacturing, distributing, marketing and promoting of FDA-approved opioid drugs. The specific legal theories asserted vary from case to case, but most of the lawsuits include federal and state statutory claims as well as claims arising under state common law. Plaintiffs seek various forms of damages, injunctive and other relief and attorneys' fees and costs.

For such cases filed in or removed to federal court, the Judicial Panel on Multi-District Litigation issued an order in December 2017, establishing a Multi-District Litigation court (MDL Court) in the Northern District of Ohio (In re National Prescription Opiate Litigation, Case No. 1:17-MD-2804). Since that time, more than 600 such cases that were originally filed in U.S. District Courts, or removed to federal court from state court, have been transferred to the MDL Court. The Company is currently involved in 16 lawsuits that have been transferred to the MDL Court and two additional federal lawsuits, one each in the Northern District of Georgia and the District of Arizona. The Arizona lawsuit was originally filed in state court and was removed to federal court. A motion to remand, which is being contested, is pending in that case. Plaintiffs may file additional lawsuits in which the Company may be named. Plaintiffs in the federal cases include county and municipal governmental entities, employee benefit plans, health clinics and health insurance providers who assert federal and state statutory claims and state common law claims, such as conspiracy, nuisance, fraud, negligence or deceptive trade practices. In these cases, plaintiffs seek a variety of forms of relief, including actual damages to compensate for alleged past and future costs such as to provide care and services to persons with opioid-related addiction or related conditions, injunctive relief to prohibit alleged deceptive marketing practices and abate an alleged nuisance, establishment of a compensation fund, disgorgement of profits, punitive and statutory treble damages, and attorneys' fees and costs. These lawsuits are in the earliest stages of proceedings, and the Company intends to defend itself vigorously in these matters.

State Opioid Litigation

Related to the cases in the MDL Court noted above, there have been more than 200 similar lawsuits filed in state courts around the country, in which various groups of plaintiffs assert opioid-drug related claims against similar groups of defendants. The Company is currently named in 13 such cases -- three filed in Texas, three in Pennsylvania, three in Utah, two in Nevada and one each in Arkansas and Missouri. Plaintiffs may file additional lawsuits in which the Company may be named. In these cases, plaintiffs are asserting state common law and statutory claims against the

defendants similar in nature to the claims asserted in the MDL cases. Plaintiffs are seeking past and future damages, disgorgement of profits, injunctive relief, punitive and statutory treble damages, and attorneys' fees and costs. These lawsuits are likewise in their earliest stages, and the Company intends to defend itself vigorously in these matters.

General

The Company cannot reasonably predict the outcome of the legal proceedings described above, nor can the Company estimate the amount of loss, range of loss or other adverse consequence, if any, that may result from these proceedings or the amount of any gain in the event the Company prevails in litigation involving a claim for damages. As such the Company is not currently able to estimate the impact of the above litigation on its financial position or results of operations.

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The Company may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims and other matters. The Company may also become party to further litigation in federal and state courts relating to opioid drugs. Although actions, claims, suits, investigations and proceedings are inherently uncertain and their results cannot be predicted with certainty, other than the matters set forth above, the Company is not currently involved in any matters that the Company believes may have a material adverse effect on its business, results of operations or financial condition. However, regardless of the outcome, litigation can have an adverse impact on the Company because of associated cost and diversion of management time.

NOTE 13. ACQUISITIONS

Asset Purchase Agreement with Slán

On November 7, 2017, the Company entered into an Asset Purchase Agreement (the Asset Purchase Agreement) with Slán Medicinal Holdings Limited (Slán) under which the Company acquired a license to market the specialty drug, cosyntropin depot in the United States and Canada. The term of the License Agreement runs from November 7, 2017, through the end of the 10-year period following the first commercial sale of an approved product (Licensed Product), but the Company may terminate the License Agreement if the U.S. Food and Drug Administration (FDA) determines that a Licensed Product is not approvable in the U.S. Under the terms of the Agreement, Slán is responsible for clinical and regulatory expenses associated with cosyntropin depot prior to its first approval by the FDA. Upon approval, the Company will be responsible for marketing and selling cosyntropin depot for the first seven years following the first commercial sale of a Licensed Product in the U.S., and Slán will be responsible for selling the Licensed Product during the remaining three years of the 10-year period.

The acquisition of cosyntropin depot was treated as an asset acquisition under the applicable guidance contained with U.S. GAAP. The fair value of the license to market cosyntropin depot was estimated to be approximately $24.9 million which, in accordance with the applicable accounting rules, was expensed as “acquired in process research and development” during the fourth quarter of 2017, as cosyntropin depot is still under development and the rights the Company acquired were deemed to have no alternative future use.

As consideration for this acquisition, the Company provided the seller all of the rights and obligations, as defined under the arrangement, associated with Lazanda and together with $5.0 million in cash to Slán. The divestiture of Lazanda was treated as a disposition of a business for accounting purposes and resulted in a gain of approximately $17.1 million which was recorded as “gain on divestiture of Lazanda” in the Company’s 2017 consolidated statements of operations. The Company determined that the divestiture of Lazanda does not qualify for reporting as discontinued operations as the divestiture does not constitute on its own a strategic shift that will have a significant effect on the Company’s operations and financial results.

The Cebranopadol Acquisition

On November 17, 2015, the Company entered into a definitive agreement to acquire the U.S. and Canadian rights to cebranopadol and its related follow-on compound from Grünenthal. The acquisition was completed on December 30, 2015.

Under the terms of the acquisition agreement, the Company entered into a settlement agreement with Endo Pharmaceuticals, Inc., a subsidiary of Endo International Plc (Endo) to resolve the Company's ongoing patent litigation against Endo for alleged infringement of three of the Company’s patents by Endo's OPANA® ER product (the Settlement). As the formulator of OPANA® ER, Grünenthal indemnified Endo for certain intellectual property matters, including the Company’s ongoing patent infringement lawsuit against Endo. The settlement agreement granted

Endo a non-exclusive patent license in the United States, and a covenant not to sue outside the United States, for the currently marketed form of OPANA® ER. In addition, the Company provided Grünenthal with a limited covenant not to sue under certain of the Company's Acuform® drug delivery patents with specific drug substances as well as $25.0 million in cash. The Company also agreed to pay Grünenthal royalties on net sales and one-time net sales milestones. There are no clinical, regulatory or approval contingent milestone payments.

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The cebranopadol acquisition was treated as an asset acquisition under the applicable guidance contained with U.S. GAAP. Accordingly, the total purchase consideration of $54.9 million was expensed to research and development expenses. The total expense of $54.9 million consists of $25.0 million paid in cash upon the closing of the acquisition and $29.9 million reflecting a one-time accounting adjustment to recognize the total non-cash fair value of each of the elements of the Settlement reached with Endo. The $29.9 million was recorded as income within “Non-cash gain on settlement agreement” and as an additional expense within “acquired in-process research and development” in the Company’s 2015 consolidated statements of operations. Significant judgments were used in determining the estimated fair values assigned to the elements of the Settlement, such as but not limited to, the probability of the Company succeeding in its litigation against Endo had the litigation not been resolved, estimates of royalty rates and any damages that may have been awarded by the court, the timing of such an award and estimates of appropriate discount rates used to present value these expected future net cash flows. An actual judgment awarded by the court may have differed materially from the amounts recorded.

In January 2018, the Company gave 120 days’ written notice of termination to Grünenthal of the cebranopadol license agreement.

The NUCYNTA Acquisition

On January 15, 2015, the Company, entered into an asset purchase agreement pursuant to which the Company acquired from Janssen and its affiliates the U.S. rights to the NUCYNTA franchise of pharmaceutical products (the NUCYNTA U.S. Product Rights) as well as certain related assets for $1.05 billion in cash (the Purchase Price).

The NUCYNTA franchise includes NUCYNTA ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, NUCYNTA (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and NUCYNTA (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized (collectively, the Products).

Upon the consummation of the transaction on April 2, 2015, the Company acquired (i) rights to commercialize the Products in the United States, and (ii) certain other assets relating to the Products, including finished goods product inventory and certain manufacturing equipment. In addition, Janssen Pharma assigned to the Company all of its rights and obligations under the License Agreement (U.S.) (the License Agreement) by and among Janssen Pharma, Janssen Research & Development, LLC and Grünenthal GmbH (Grünenthal) pursuant to which Janssen has a royalty-bearing license to certain Grünenthal patents and other intellectual property rights covering the commercialization of the Products in the United States.

In connection with the transaction, the Company assumed responsibility for the ongoing legal proceedings relating to certain of the Grünenthal patents licensed under the License Agreement and Janssen Pharma’s clinical obligations relating to the Products and will be responsible for the associated post acquisition costs. Other than as set forth in the Asset Purchase Agreement, Janssen Pharma retained all liabilities relating to the Products associated with Janssen Pharma’s commercialization of the Products prior to the consummation of the transaction.

In connection with the Transaction, the Company, Janssen Pharma and certain affiliates of Janssen also entered into (i) supply agreements pursuant to which Janssen Pharma will manufacture and supply the Products to the Company until the Company, or its contract manufacturer, begins commercial production of the Products, following which the Company will manufacture and supply Janssen Pharma for its requirements for NUCYNTA outside of the United States and (ii) a supply agreement pursuant to which an affiliate of Janssen will manufacture and supply the Company with the active pharmaceutical ingredient contained in the Products.

In connection with the consummation of the transaction, on April 2, 2015, the Company sold an aggregate of $575.0 million principal amount of the Senior Notes for gross proceeds of approximately $562.0 million. The Company used $550.0 million of the net proceeds received upon the sale of the Senior Notes to fund a portion of the Purchase Price paid to Janssen Pharma.

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Pursuant to ASC Topic 805, Business Combinations, the Transaction was determined to be a business combination and was accounted for using the acquisition method of accounting. The following table presents a summary of the purchase price consideration for the Transaction:

(in thousands)	
Cash Paid	$1,050,000
Rebates payable by Seller	(9,977)
Total Purchase Consideration	$1,040,023

The rebates payable by Janssen Pharma represent a reduction to the total purchase consideration. The fair value of the rebates payable by Janssen Pharma was determined based on estimates that take into consideration the terms of agreements with customers, historical rebates taken, and the estimated amount of time it takes the product to flow through the distribution channel. The actual amount of rebates paid by Janssen Pharma, determined in the fourth quarter of 2015, was approximately $0.5 million lower than the Company's estimate of $10.5 million recorded as of the acquisition date. Consequently, the total purchase consideration and the fair value of the NUCYNTA U.S. Product Rights was increased by $0.5 million.

Under the acquisition method of accounting, the Company has recognized net tangible and intangible assets acquired based upon their respective estimated fair values as of the acquisition date. The table below shows the fair values assigned to the assets acquired:

(in thousands)	
NUCYNTA U.S. Product Rights	$1,019,978
Inventories	11,590
Manufacturing Equipment	8,455
	$1,040,023

The fair value of inventories acquired included a step-up in the value of NUCYNTA inventories of $5.9 million that was fully amortized to cost of sales in 2015 as the acquired inventories were sold. The Company incurred non-recurring transaction costs of $12.3 million in 2015 with respect to the NUCYNTA Acquisition which were recorded in "Selling, general and administrative expenses" within the Company's Condensed Consolidated Statement of Operations.

NUCYNTA U.S. Product Rights

The valuation of the NUCYNTA U.S. Product Rights was based on management's estimates, information and reasonable and supportable assumptions. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the NUCYNTA U.S. Product Rights included revenue projections based on assumptions relating to pricing and reimbursement rates, market size and market penetration rates, general and administrative expenses, sales and marketing expenses, research and development expenses for clinical and regulatory support and developing an appropriate discount rate. If the Company's assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense. The NUCYNTA U.S. Product Rights intangible asset is amortized using the straight-line method over an estimated useful life of approximately ten years. The estimated useful life was determined based on the period of time over which the NUCYNTA U.S. Product Rights are expected to contribute to the Company's future cash flows.

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NOTE 14. INTANGIBLE ASSETS

The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	September 30, 2018				December 31, 2017		
Product rights	Remaining Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
NUCYNTA	7.2	$1,019,978	$ (337,316)	$682,662	$1,019,978	$ (266,590)	$753,388
CAMBIA	5.2	51,360	(24,607)	26,753	51,360	(20,755)	30,605
Zipsor	3.5	27,250	(19,123)	8,127	27,250	(17,370)	9,880
Total		$1,098,588	$ (381,046)	$717,542	$1,098,588	$ (304,715)	$793,873

Based on finite-lived intangible assets recorded as of September 30, 2018, and assuming the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2018 (remainder)	$ 25,443
2019	101,774
2020	101,774
2021	101,774
2022	99,969
Thereafter	286,808
Total	$ 717,542

NOTE 15. RESTRUCTURING CHARGES

In June 2017, the Company announced a limited reduction-in-force in order to streamline operations and achieve operating efficiencies. The activities related to that reduction-in-force were completed during the third quarter of 2017. In December 2017, the Company initiated a company-wide restructuring plan following the entry into the Commercialization Agreement with Collegium. This plan focused on a reduction of the Company's pain sales force during the first quarter of 2018, a reduction of the staff at its headquarters office during the second quarter of 2018 and a move from its headquarters facility in Newark, California to Lake Forest, Illinois in the third quarter of 2018.

The following table summarizes the total expenses recorded related to the 2017 restructuring and one-time termination cost activities by type of activity and the locations recognized within the consolidated statements of operations as restructuring costs (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Employee compensation costs	$400	$434	$14,993	$3,875
Fixed Asset disposals and accelerated depreciation of leasehold improvements	3,511	—	3,511	—
Other exit costs	—	—	238	—

Total restructuring costs	$3,911	$434	$18,742	$3,875

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Selected information relating to accrued restructuring, severance costs and one-time termination costs is as follows (in thousands):

	Employee compensation costs	Fixed Asset and Other exit costs	Total
Balance at December 31, 2017	$ 9,483	$ —	$9,483
Net accruals	8,779	238	9,017
Non-cash adjustments	(258)	—	(258)
Cash paid	(11,184)	(238)	(11,422)
Balance at March 31, 2018	$ 6,820	$ —	$6,820
Net accruals	5,814	—	5,814
Non-cash adjustments	(2,300)	—	(2,300)
Cash paid	(4,834)	—	(4,834)
Balance at June 30, 2018	5,500	—	5,500
Net accruals	400	3,511	3,911
Non-cash adjustments	173	(3,511)	(3,338)
Cash paid	(4,238)	—	(4,238)
Balance at September 30, 2018	$ 1,835	$ —	$1,835

As of September 30, 2018, the full $1.8 million accrued restructuring liability balance was classified as a current liability in the Condensed Consolidated Balance Sheet. The Company has incurred $31.9 million in related restructuring costs since the announcement of the plan in December 2017 through September 30, 2018. The Company expects to incur additional related restructuring costs of $1.5 million to $3.0 million through June 30, 2019.

NOTE 16. OUT OF PERIOD ADJUSTMENTS

During the three months ended September 30, 2018, the Company identified that it had understated restructuring costs by incorrectly derecognizing its deferred landlord incentives related to the Newark, California headquarters office lease since the plan to exit the facility had been established in December 2017. Accordingly, the Company recorded an adjustment during the three months ended September 30, 2017 to increase restructuring costs by $2.1 million, of which $0.3 million related to the year ended December 31, 2017, and its accrued liabilities as of September 30, 2018. This adjustment resulted in a decrease to EPS of $0.03 in the three months ended September 30, 2018.

During the three months ended March 31, 2017, the Company identified that it had understated the amount payable for the Branded Prescription Drug fee (BPD) relating to net sales of the NUCYNTA franchise since its acquisition in the second quarter of 2015. Accordingly, the Company recorded an adjustment during the three months ended March 31, 2017 to increase its BPD accrual relating to the net sales of the NUCYNTA franchise in the cumulative amount of $3.4 million of which $1.4 million and $2.0 million related to the years ended December 31, 2015 and 2016, respectively. This adjustment resulted in an increase in loss per share by $0.05 in the three months ended March 31, 2017.

In accordance with the relevant guidance, management evaluated the materiality of the errors from a qualitative and quantitative perspective. Based on such evaluation, the Company concluded that correcting the cumulative errors would not be material to the expected full year results for 2017 or to the third quarter of 2018, and correcting the

errors would not have had a material impact on any individual prior period financial statements or affect the trend of financial results.

NOTE 17. SUBSEQUENT EVENTS

Amendment to Collegium Commercialization Agreement

On November 8, 2018, the Company, Collegium and Collegium NF, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium (Newco) entered into an amendment (Amendment) to the Commercialization Agreement. Pursuant to the Amendment, Collegium may only terminate the Commercialization Agreement after December 31, 2020, with 12-months' notice. In the event any such termination notice has an effective date of termination prior to December 31, 2022, then Collegium shall pay a $5,000,000 termination fee to the Company concurrent with the delivery of such notice.

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The Amendment also provides that Collegium shall reimburse the Company for the amount of any minimum annual royalties paid by the Company to Grünenthal GmbH (Grünenthal) on net sales of the NUCYNTA franchise during the first four years of the Commercialization Agreement as provided in the Consent Agreement, dated as of November 30, 2017 (the Grünenthal Consent Agreement), by and among the Company, Grünenthal and Newco.

In connection with the Amendment, Collegium issued the Company a warrant to purchase up to 1,041,667 shares of Collegium common stock at an exercise price of $19.20 per share. The warrant is exercisable for a period of four years and contains customary terms, including with regard to net exercise.

Pursuant to the Amendment, the royalties payable by Collegium to the Company in connection with Collegium's commercialization of NUCYNTA are amended such that effective as of January 1, 2019 through December 31, 2021, the Company will receive: (i) 65% of net sales of NUCYNTA up to $180,000,000, plus (ii) 14% of annual net sales of NUCYNTA between $180,000,000 and up to $210,000,000, plus (iii) 58% of annual net sales of NUCYNTA between $210,000,000 and $233,000,000, plus (iv) 20% of annual net sales of NUCYNTA between $233,000,000 and up to $258,000,000, plus (v) 15% of annual net sales of NUCYNTA above $258,000,000. Payments described in clauses (i), (ii) and (iii) hereof will be swept daily from a lock-box account of Newco where revenues from gross sales of NUCYNTA will be deposited. Payments described in clauses (iv) and (v) hereof will be paid annually within 60 days of the end of the calendar year. In connection with the Amendment, Collegium's obligation to maintain a standby letter of credit with respect to royalties due to the Company on net sales of NUCYNTA occurring in 2018 will expire on the first to occur of February 28, 2019 or one business day after the date Collegium pays the Company its royalties owed for the quarter ended December 31, 2018. For the year ending December 31, 2018, the Company will receive total royalties from Collegium of $132 million.

The Amendment does not change the royalties the Company will receive on annual net sales of NUCYNTA by Collegium for the period beginning January 1, 2022 and for each year of the Commercialization Agreement term thereafter, which are: (i) 58% of net sales of NUCYNTA up to $233,000,000, payable quarterly within 45 days of the end of each calendar quarter, plus (ii) 25% of annual net sales of NUCYNTA between $233,000,000 and $258,000,000, plus (iii) 17.5% of annual net sales of NUCYNTA above $258,000,000. Payments described in clauses (ii) and (iii) hereof will be paid annually within 60 days of the end of the calendar year.

The Amendment provides that the Company may terminate the Commercialization Agreement upon 60 days' prior written notice to Collegium in the event that (i) the net sales of NUCYNTA by Collegium during any period of 12 consecutive calendar months ending on or before December 31, 2021 are less than $180,000,000, or (ii) the net sales of NUCYNTA by Collegium during any period of 12 consecutive calendar months commencing on or after January 1, 2022 are less than $170,000,000.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FORWARD-LOOKING INFORMATION

Statements made in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q that are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

- the commercial success and market acceptance of our products;
- the success of Collegium Pharmaceutical, Inc. (Collegium) in commercializing NUCYNTA® ER and NUCYNTA®;
- the reversal or any successful appeal of the court's favorable ruling in our patent infringement litigation against the filers of Abbreviated New Drug Applications (each, an ANDA) to market generic versions of NUCYNTA ER and NUCYNTA in the United States (U.S.);
- any additional patent infringement or other litigation, investigation or proceeding that may be instituted related to us or any of our products, product candidates or products we may acquire;
- our ability to generate sufficient cash flow from our business to make payments on our indebtedness and our compliance with the terms and conditions of the agreements governing our indebtedness;
- our and our collaborative partners' compliance or non-compliance with legal and regulatory requirements related to the development or promotion of pharmaceutical products in the U.S.;
- our plans to acquire, in-license or co-promote other products;
- the results of our research and development efforts including clinical studies relating to our product candidates, including cosyntropin depot;
- submission, acceptance and approval of regulatory filings, including cosyntropin depot;
- our ability to raise additional capital, if necessary;
- our ability to successfully develop and execute our sales and marketing strategies;
- variations in revenues obtained from commercialization and collaborative agreements, including contingent milestone payments, royalties, license fees and other contract revenues, including non-recurring revenues, and the accounting treatment with respect thereto;
- our collaborative partners' compliance or non-compliance with obligations under our collaboration agreements;
- the outcome of both our opioid-related investigations and our opioid-related litigation brought by state and local governmental entities and private parties, and the costs and expenses associated therewith;
- the regulatory strategy for cosyntropin depot and our and our collaborative partner's ability to successfully develop and execute such strategy; and
- our ability to attract and retain key executive leadership following our restructuring and office relocation.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the "RISK FACTORS" section and elsewhere in this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update any forward-looking statement publicly, or to revise any forward-looking statement to reflect events or developments occurring after the date of this Quarterly Report on Form 10-Q, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

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COMPANY OVERVIEW

Assertio is a specialty pharmaceutical company focused on neurology, orphan and specialty medicines. Our current specialty pharmaceutical business includes the following three products which we market in the United States (U.S.):

- Gralise® (gabapentin), a once daily product for the management of postherpetic neuralgia (PHN), that we launched in October 2011.

- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, that we acquired in December 2013.

- Zipsor® (diclofenac potassium) liquid filled capsules, a non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain, that we acquired in June 2012.

Assertio was formerly known as Depomed, Inc., a California corporation (Depomed). On August 14, 2018, Depomed reincorporated from California to Delaware and changed its name to Assertio Therapeutics, Inc. The use of the term “Company” in this filing refers to Depomed any time prior to the Effective Time and to Assertio any time after the Effective Time.

In January 2018, pursuant to the terms of a Commercialization Agreement we entered into with Collegium Pharmaceutical, Inc. (Collegium) in December 2017, we granted Collegium the right to commercialize the NUCYNTA® franchise of pain products in the U.S. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We will receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of $132.0 million for the year ended December 31, 2018. The parties amended the Commercialization Agreement in November 2018 (Amendment) as described in Note 17, "Subsequent Events" of the Notes to the unaudited condensed Consolidated Financial Statements. We expect to receive royalties from Collegium of $132 million for 2018 and royalties based on certain annual NUCYNTA net sales thresholds for future years. Both we and Collegium may terminate the Commercialization Agreement under certain circumstances, provided that Collegium may not terminate the agreement prior to the end of 2021. Additionally, we retained certain rights to co-promote NUCYNTA products, subject to providing advanced notice to Collegium. The NUCYNTA franchise includes two products currently marketed in the U.S. by Collegium:

- NUCYNTA® ER (tapentadol extended release tablets), a product for the management of pain severe enough to require daily, around the clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults, and for which alternate treatment options are inadequate; and

- NUCYNTA® IR (NUCYNTA) (tapentadol), an immediate release version of tapentadol for the management of moderate to severe acute pain in adults.

In November 2017, we entered into definitive agreements with Slán Medicinal Holdings Limited and certain of its affiliates (Slán) pursuant to which we acquired Slán’s rights to market the specialty drug cosyntropin depot (synthetic ACTH Depot) in the U.S. and Canada, and Slán acquired our rights to Lazanda® (fentanyl) nasal spray. We believe cosyntropin depot can be second-to-market behind Mallinckrodt plc's marketed product, H-P Acthar gel. We expect Slán to file a New Drug Application (NDA) for cosyntropin depot by the end of 2018.

We actively seek to expand our product portfolio through acquiring or in licensing commercially available products or late stage product candidates that may be marketed and sold effectively through our sales and marketing capability.

We also have royalty and milestone producing license arrangements based on our proprietary Acuform® gastroretentive drug delivery technology, including with Ironwood Pharmaceuticals, Inc. (Ironwood).

In October 2013, we sold our interests in royalty and milestone payments under our license agreements relating to our Acuform technology in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for $240.5 million. On August 2, 2018, we sold our remaining interest in such payments to PDL for $20.0 million.

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Strategy

Our commercial strategy is based on three pillars: Maintain, Grow and Build.

We intend to “Maintain” our NUCYNTA franchise of pain products through our Commercialization Agreement with Collegium. In January 2018, pursuant to the terms of a Commercialization Agreement we entered into with Collegium in December 2017, we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the U.S. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We will receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of $132 million for the year ending December 31, 2018. Pursuant to the Amendment to the Commercialization Agreement described in Note 17, "Subsequent Events" of the Notes to the unaudited condensed Consolidated Financial Statements, we expect to receive royalties from Collegium of $132 million for 2018 and royalties based on certain annual NUCYNTA net sales thresholds for future years. Both we and Collegium may terminate the Commercialization Agreement under certain circumstances, provided that Collegium may not terminate the agreement prior to the end of 2021.

We intend to “Grow” our neurology, orphan and specialty medicine business through organic and inorganic growth. We intend to “Build” a portfolio of high-value products positioned to address the needs of patients, physicians and payers. In November 2017 we acquired the exclusive rights to market cosyntropin depot (synthetic ACTH Depot) in the U.S. and Canada. Cosyntropin depot is a long-acting alcohol-free synthetic ACTH analogue. We expect that a New Drug Application will be filed with the U.S. Food and Drug Administration for cosyntropin depot by year end. We intend to file for a 505(b)(2) application for a diagnostic indication for suspected adrenocortical insufficiency. As previously announced, Assertio and our development partner began enrolling and dosing pediatric patients in a new clinical trial evaluating cosyntropin depot for the treatment of infantile spasms, a specific seizure type present in infantile epilepsy syndrome, a rare pediatric disorder. We are also seeking to bring additional specialty and orphan products into this portfolio.

In connection with our entry into the Commercialization Agreement with Collegium, we eliminated our pain sales force, relocated our headquarters and reduced our headquarters’ staff. Excluding restructuring charges we expect these actions will significantly reduce our operating expenses in future periods, further enabling us to implement our strategy.

OUR BUSINESS OPERATIONS

As of September 30, 2018, our revenues were generated primarily from the following commercialized products.

Gralise (Gabapentin)

Gralise is our proprietary, once daily formulation of gabapentin indicated for management of PHN, a persistent pain condition caused by nerve damage during a shingles, or herpes zoster, viral infection. We made Gralise commercially available in October 2011, following its U.S. Food and Drug Administration (FDA) approval in January 2011. The FDA has granted Orphan Drug exclusivity for PHN. Gralise product sales were $14.6 million and $21.1 million for the three months ended September 30, 2018 and 2017, respectively. Gralise product sales were $43.3 million and $57.8 million for the nine months ended September 30, 2018 and 2017, respectively.

CAMBIA (Diclofenac Potassium for Oral Solution)

CAMBIA is a non-steroidal anti-inflammatory drug (NSAID) indicated for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older. We acquired CAMBIA in December 2013 from Nautilus

Neurosciences, Inc.

We began shipping and recognizing product sales on CAMBIA in December 2013. Our CAMBIA product sales were $10.4 million and $8.2 million for the three months ended September 30, 2018 and 2017, respectively. CAMBIA product sales were $24.9 million and $23.9 million for the nine months ended September 30, 2018 and 2017, respectively.

Zipsor (Diclofenac Potassium) Liquid Filled Capsules

Zipsor is an NSAID indicated for relief of mild to moderate acute pain in adults. Zipsor uses proprietary ProSorb® delivery technology to deliver a finely dispersed, rapidly absorbed formulation of diclofenac. We acquired Zipsor in June 2012 from Xanodyne Pharmaceuticals, Inc.

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Our Zipsor® product sales were $4.4 million and $3.2 million for the three months ended September 30, 2018 and 2017, respectively, and Zipsor® product sales were $13.2 million and $12.3 million for the nine months ended September 30, 2018 and 2017, respectively.

NUCYNTA ER (Tapentadol Extended Release Tablets)

NUCYNTA ER is an extended release version of tapentadol that is indicated for the management of pain severe enough to require daily, around the clock, long term opioid treatment, including neuropathic pain associated with DPN in adults, and for which alternate treatment options are inadequate. We acquired the U.S. rights to NUCYNTA ER from Janssen Pharmaceuticals, Inc. (Janssen Pharma) and began shipping and recognizing product sales on NUCYNTA ER in April 2015. We began commercial promotion of NUCYNTA ER in June 2015.

NUCYNTA (Tapentadol)

NUCYNTA is an immediate release version of tapentadol that is indicated for the management of moderate to severe acute pain in adults. We acquired the U.S. rights to NUCYNTA from Janssen Pharma and began shipping and recognizing product sales on NUCYNTA in April 2015. We began commercial promotion of NUCYNTA in June 2015.

In January 2018, pursuant to the terms of a Commercialization Agreement we entered into with Collegium in December 2017, we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the U.S. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We will receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of $132.0 million for the year ended December 31, 2018. Pursuant to the Amendment to the Commercialization Agreement described in Note 17, "Subsequent Events" of the Notes to the unaudited condensed Consolidated Financial Statements, we expect to receive royalties from Collegium of $132 million for 2018 and royalties based on certain annual NUCYNTA net sales thresholds for future years. Both we and Collegium may terminate the Commercialization Agreement under certain circumstances, provided that Collegium may not terminate the agreement prior to the end of 2021.

Lazanda (Fentanyl) Nasal Spray

Lazanda nasal spray is an intranasal fentanyl drug used to manage breakthrough pain in adults (18 years of age and older) who are already routinely taking other opioid pain medicines around the clock for cancer pain. We acquired Lazanda in July 2013 from Archimedes Pharma US Inc. and its affiliated companies (collectively, Archimedes). In November 2017, we entered into agreements with Slán pursuant to which Slán acquired our rights to Lazanda. Lazanda product sales for the three and nine months ended September 30, 2017 were $4.0 million and $13.2 million, respectively.

Product Candidates

In November 2017, we entered into agreements with Slán pursuant to which we obtained the marketing rights to cosyntropin depot. We believe cosyntropin depot can be second-to-market behind Mallinckrodt plc's marketed product, H-P Acthar gel. We expect Slán to file an NDA for cosyntropin depot by the end of 2018.

In December 2015, we entered into a license agreement with Grünenthal GmbH (Grünenthal) pursuant to which we acquired the U.S. and Canadian rights to cebranopadol, a product candidate for the treatment of moderate to severe chronic nociceptive and neuropathic pain. In January 2018, we gave Grünenthal 120 days’ written notice of termination of the cebranopadol license agreement.

Segment and Customer Information

We operate in one operating segment and have operations solely in the United States. To date, all of our revenues from product sales are related to sales in the United States. We have recognized license and royalty revenue from license agreements in the territories of the United States, Canada, and South Korea.

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Collaboration and License Agreement with Ironwood Pharmaceuticals, Inc.

In July 2011, we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for IW 3718, an Ironwood product candidate under evaluation for refractory GERD. We have received $3.4 million under the agreement, including a contingent milestone payment of $1.0 million in March 2014 as a result of the initiation of clinical trials relating to IW 3718 by Ironwood. During the three months ended June 30, 2018, we recognized a $5.0 million milestone payment related to the dosing of the first patient in a Phase 3 trial. We will receive additional contingent milestone payments upon the occurrence of certain development milestones and royalties on net sales of the product, if approved.

PDL Royalty Sale

In October 2013, pursuant to the terms and conditions of a Royalty Purchase and Sale Agreement with PDL (Royalty Purchase Agreement), we sold to PDL our right to receive royalty, milestone and other specified payments arising on and after October 2013 under each of the following license agreements relating to our Acuform technology in the Type 2 diabetes therapeutic area: (i) the License and Services Agreement, effective as of March 4, 2011, with Boehringer Ingelheim International GMBH (BI) relating to potential future development milestones and sales of BI's investigational fixed-dose combinations of drugs and extended-release metformin worldwide; (ii) the License Agreement, effective as of August 5, 2010, with Janssen Pharmaceutica N.V. (Janssen) relating to potential future development milestones and sales of Janssen's investigational fixed-dose combination of Invokana® (canagliflozin) and extended-release metformin worldwide; (iii) the Non-Exclusive License, Covenant Not to Sue and Right of Reference Agreement, effective as of July 21, 2009, with Merck & Co., Inc. relating to sales of Janumet XR® (sitagliptin and metformin HCL extended-release) worldwide; (iv) the Commercialization Agreement, effective as of August 22, 2011, with Santarus, Inc. relating to sales of Glumetza® (metformin HCL extended-release tablets) in the United States; (v) the Amended License Agreement, effective as of January 9, 2007, with LG Life Sciences Ltd. relating to sales of extended-release metformin in Korea; and (vi) the Amended and Restated License Agreement (Extended Release Metformin Formulations — Canada), dated as of December 13, 2005, with Biovail Laboratories International SRL relating to sales of extended-release metformin in Canada.

Under the Royalty Purchase Agreement, PDL is entitled to receive all payments due under such license agreements until PDL received $481 million, after which all net payments received are shared evenly between we and PDL. In August 2018, pursuant to the terms and conditions of an amendment to the Royalty Purchase Agreement, we sold our remaining interest in such payments to PDL for $20.0 million.

RESTRUCTURING

In June 2017, we announced a limited reduction-in-force in order to streamline operations and achieve operating efficiencies. In December 2017, we continued our restructuring plans by initiating a company-wide restructuring designed to help position the Company for sustainable, long-term growth that we believe will align our staff and office locations to fit our commercial strategy. Pursuant to our restructuring plans, in February 2018 we eliminated our pain sales force, consisting of approximately 230 sales representative and 25 manager positions. We reduced the staff at our headquarters office during the second quarter of 2018. In the third quarter of 2018, we relocated our corporate headquarters from Newark, California to Lake Forest, Illinois and reduced our headquarters office space by 50%. For further information about our restructuring costs, see Note 15, "Restructuring Charges" of the Notes to unaudited condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

CRITICAL ACCOUNTING POLICIES

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, accrued liabilities and use of estimates to be critical policies. These estimates form the basis for making judgments about the carrying value of assets and liabilities. There have been no changes to our critical accounting policies, other than those listed below, since we filed our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 1, 2018 (the 2017 Form 10-K). The description of our critical accounting policies is incorporated herein by reference to our 2017 Form 10-K.

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Recently Adopted Accounting Pronouncements - Revenue Recognition

We account for revenue arising from contracts and customers in accordance with Accounting Standards Update (ASU or Update) No. 2014-09, Revenue from Contracts with Customers (ASC 606), which was adopted on January 1, 2018 using the modified retrospective transition method. There was no adjustment to our opening balance of accumulated deficit resulting from the adoption of this guidance.

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five step model: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We derive revenue from the sale of our products, royalties and license fees under our Commercialization Agreement with Collegium, and from license fees, milestones and royalties earned on license and collaborative arrangements. Royalty payments made on products that the Company is not actively commercializing, which are remitted to the licensor on a pass through basis, are recorded by the Company on a systematic basis in proportion to the underlying net product sales and are included as gross-to-net adjustments in the related revenue line in the Company’s Condensed Consolidated Statements of Operations.

For further information about our accounting policies, see Note 1, "Organization and Summary of Significant Accounting Policies" of the Notes to unaudited condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2018 and 2017 .

Revenue

Total revenues by products are summarized in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product sales, net				
Gralise	$14,630	$21,103	$43,272	$57,777
CAMBIA	10,365	8,164	24,870	23,862
Zipsor	4,441	3,232	13,175	12,286
Total neurology product sales, net	29,436	32,499	81,317	93,925
NUCYNTA products [1]	11	58,665	18,782	183,299
Lazanda [2]	(12)	4,040	528	13,239

Pharmacy benefit manager dispute reserve	—	—	—	(4,742)
Total product sales, net	29,435	95,204	100,627	285,721
Commercialization agreement:	—	—	—	—
Commercialization rights and facilitation services, net	27,781	—	87,055	—
Revenue from transfer of inventory	—	—	55,705	—
Royalties and Milestone Revenue	20,277	209	25,784	596
Total revenues	$77,493	$95,413	$269,171	$286,317

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(1) NUCYNTA product sales for the nine months ended September 30, 2018 reflect our sales of NUCYNTA between January 1 and January 8, 2018. During the three and nine months ended September 30, 2018 we recognized an insignificant amount of sales reserve estimate adjustments related to sales recognized for NUCYNTA and Lazanda in prior periods. During the first quarter of 2018, in connection with the Collegium transaction, we recognized revenue of $12.5 million related to the release of NUCYNTA sales reserves which were primarily recorded in the fourth quarter of 2017, as financial responsibility for those reserves transferred to Collegium upon closing of the Commercialization Agreement.

(2) We divested Lazanda in November 2017. Product sales for the three and nine months ended September 30, 2018 relate to sales reserve estimate adjustments.

Product Sales

Gralise. The decrease in Gralise product sales during the three and nine months ended September 30, 2018 as compared to 2017 was primarily due to lower prescription demand and higher managed care rebates.

CAMBIA. The increase in CAMBIA product sales during the three and nine months ended September 30, 2018 as compared to 2017 was primarily the result of a price increase.

Zipsor. The increase in Zipsor product sales during the three and nine months ended September 30, 2018 as compared to 2017 was primarily the result of a price increase.

NUCYNTA. Net sales in the nine months ended September 30, 2018 reflect solely the period of January 1st to January 8th prior to closing of the Collegium Commercialization Agreement and the release of approximately $12.5 million of rebate reserves in the nine-month period ended September 30, 2018 that Collegium assumed pursuant to the terms of the Commercialization Agreement. Release of reserves in the three month period ended September 30, 2018 were insignificant. We will not record NUCYNTA product net sales during the remainder of the term of the Commercialization Agreement.

During the three months ended March 31, 2017, we identified that we had understated the amount payable for the Branded Prescription Drug fee (BPD) relating to net sales of the NUCYNTA franchise since its acquisition in the second quarter of 2015. Accordingly, we recorded an adjustment during the three months ended March 31, 2017 to increase the BPD accrual relating to the net sales of the NUCYNTA franchise in the cumulative amount of $3.4 million of which $1.4 million and $2.0 million related to the years ended December 31, 2015 and 2016, respectively. This adjustment resulted in an increase in loss per share of $0.05 in the three months ended March 31, 2017. In accordance with the relevant guidance, management evaluated the materiality of the error from a qualitative and quantitative perspective. Based on such evaluation, we concluded that correcting the cumulative error would not be material to the expected full year results for 2017, and correcting the error would not have had a material impact on any individual prior period financial statements or affect the trend of financial results.

Lazanda. In November 2017, we entered into definitive agreements with Slán pursuant to which we acquired Slán's rights to market cosyntropin depot in the U.S. and Canada, and Slán acquired our rights to Lazanda nasal spray CII. We ceased recording revenues and related costs associated with Lazanda after November 7, 2017. Product sales for the nine months ended September 30, 2018 reflect adjustments made for previously recorded sales reserve estimates.

Commercialization Agreement Revenues. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We will receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of $132.0 million for the year ended December 31, 2018. Pursuant to the Amendment to the

Commercialization Agreement described in Note 17, "Subsequent Events" of the Notes to the unaudited condensed Consolidated Financial Statements, we expect to receive royalties from Collegium of $132 million for 2018 and royalties based on certain annual NUCYNTA net sales thresholds for future years. Both we and Collegium may terminate the Commercialization Agreement under certain circumstances, provided that Collegium may not terminate the agreement prior to the end of 2021.

We determined the total transaction price to be $553.2 million, which consists of $537.0 million in total annual minimum royalty payments, the $10.0 million upfront fee, and a $6.2 million payment for NUCYNTA finished goods inventory at cost. In accordance with the relevant Accounting Standard, we allocated the total transaction price to the performance obligations under the Commercialization Agreement over the deemed contract term of four years which begins on the effective date of January 9, 2018 and lasts through December 31, 2021.

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We acquired the U.S. rights to NUCYNTA from Janssen Pharmaceuticals, Inc. (Janssen) in April 2015. As part of that transaction, the Company also acquired the related royalty obligations for NUCYNTA to Grünenthal, the originator of tapentadol. Pursuant to the terms of the Commercialization Agreement, Collegium will now remit payment on behalf of the Company to satisfy this royalty obligation In addition, as a condition of giving its consent to the Commercialization Agreement with Collegium, Grünenthal amended the terms of the original royalty agreement to require payment of a minimum royalty of $34.0 million per year on net sales of NUCYNTA greater than $180.0 million and equal to, or less than, $243.0 million for each of the years ended December 31, 2018 through 2021. In return for this agreement to pay minimum royalties, the Company received the right to share royalties with Grünenthal on annual net sales of NUCYNTA above $243.0 million during the same period. We are obligated to cover any shortfall between the minimum royalty amount of $34.0 million and the amounts paid to Grünenthal by Collegium for each of the years ended December 31, 2018 through 2021, as a result of which we could be obligated to pay up to $8.8 million per year for each of the years ended December 31, 2018 through 2021. Pursuant to the Amendment, Collegium will reimburse us for the amount of any minimum annual royalties paid by us to Grünenthal on net sales of NUCYNTA from 2019 to 2021 related to this Commercialization Agreement.

Revenue in the three and nine months ended September 30, 2018 reflects $27.8 million and $87.1 million, respectively, attributable to royalty income and the allocation of $55.7 million of total transaction price to the one-time sale of inventory to Collegium at closing, which was recorded in the first quarter of 2018. Included within this revenue, we recorded an incremental royalty payable to Grünenthal of $3.7 million in anticipation of the Collegium payments to Grünenthal falling below the minimum of $34.0 million for 2018. Grünenthal royalties related to NUCYNTA sales for the three and nine months ended September 30, 2018 were $10.8 million and $25.2 million, respectively, of which approximately $7.1 million and $21.5 million, respectively, were paid directly by Collegium to Grünenthal. These royalties were recorded as a gross-to-net adjustment in the Revenue from Commercialization Agreement, net line in the Company’s Statement of Operations.

Pharmacy Benefit Manager. During the three months ended March 31, 2017, we established a reserve with respect to a dispute with a pharmacy benefit manager (PBM) over rebates relating to NUCYNTA ER, NUCYNTA and Gralise. The dispute relates to rebate claims submitted with respect to the year ended December 31, 2015 and the first half of 2016. As of December 31, 2016, we established a reserve for $1.0 million with respect to these claims, and had determined the likely amount payable on settlement would not be material to the consolidated financial statements. However, as a result of further communication with the PBM during the three months ended March 31, 2017, it became clear that our failure to pay the disputed amount would adversely impact our ability to maintain a favorable position on the PBM’s formulary. Accordingly, despite our belief that the claims in dispute were invalid, we increased the reserve against this matter by $4.7 million which was an offset to net sales for the three months ended March 31, 2017. We paid this amount in the fourth quarter of 2017.

Royalties

Royalties are primarily comprised of royalties from Aralez Pharmaceuticals, Inc. on net sales of CAMBIA in Canada and royalties from Janssen Pharma on net sales of NUCYNTA ER in Canada and Japan.

PDL BioPharma, Inc. In October 2013, we sold our interests in royalty and milestone payments under our license agreements relating to our Acuform technology in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for $240.5 million. On August 2, 2018 we sold our remaining interest in such payments to PDL for $20.0 million. The $20 million of revenue was recognized as royalty revenue in the three months ended September 30, 2018.

License and other revenue

Janssen Pharmaceuticals, Inc. In August 2012, we entered into a license agreement with Janssen Pharma that granted Janssen Pharma a non-exclusive license to certain patents and other intellectual property rights to our Acuform drug delivery technology for the development and commercialization of tapentadol extended release products, including NUCYNTA ER (tapentadol extended release tablets).We receive low single digit royalties on net sales of NUCYNTA ER in Canada and Japan.

Ironwood Pharmaceuticals, Inc. In July 2011, we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for IW 3718, an Ironwood product candidate under evaluation for refractory GERD. During the nine months ended September 30, 2018, we recognized and collected a $5.0 million contingent milestone payment related to the dosing of the first patient in a Phase 3 trial for IW 3718. The dosing of the patient was considered probable at the commencement of the trial. There was no revenue under this agreement for the three and six months ended June 30, 2017.

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Cost of Sales

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, royalties payable to third parties, inventory write downs, amortization of inventory write-ups associated with business acquisitions, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales. Cost of sales excludes the amortization of intangible assets described separately below under "Amortization of Intangible Assets." Total cost of sales for the three and nine months ended September 30, 2018 and 2017, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Cost of Sales	$2,975	$17,396	$17,772	$54,895
Dollar change from prior year	(14,421)	(2,847)	(37,123)	(9,862)
Percentage change from prior year	(82.9)%	(14.1)%	(67.6)%	(15.2)%

Cost of sales decreased during the three and nine months ended September 30, 2018 as compared to 2017 primarily due to the reduction in NUCYNTA and Lazanda net product sales. Pursuant to the terms of our Commercialization Agreement with Collegium, effective January 9, 2018, we no longer record product sales of NUCYNTA and NUCYNTA ER and, as a result, no longer incur or record the cost of sales of such products. The cost of sales during the nine months ended September 30, 2018 includes $6.2 million, which we recorded in the first quarter of 2018, related to the cost of inventory transferred to Collegium on closing of the Commercialization Agreement. Following the divestiture of Lazanda in November 2017, we no longer record Lazanda product sales or related cost of sales.

We review the net sales of NUCYNTA by Collegium and recognize an estimated liability for the amount we believe is likely to be paid for the year. As this estimation process requires a significant amount of judgment and is based on expected net sales of NUCYNTA by Collegium, the liability recorded as of a reporting period may not necessarily be reflective of the amount ultimately due to Grünenthal for the year.

The cost of sales as a percentage of sales for Gralise, CAMBIA and Zipsor, combined for both the three and nine months ended September 30, 2018 was approximately 9% and 8%, respectively.

Research and Development Expenses

Our research and development expenses currently include salaries, clinical trial costs, consultant fees, supplies, manufacturing costs for research and development programs and allocations of corporate costs. It is extremely difficult to predict the scope and magnitude of future research and development expenses for our product candidates in research and development, as it is extremely difficult to determine the nature, timing and extent of clinical trials and studies and the FDA's requirements for a particular drug. As potential products proceed through the development process, each step is typically more extensive, and therefore more expensive, than the previous step. Therefore, success in development generally results in increasing expenditures until actual product approval. Total research and development expenses for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Research and development expenses	$2,127	$1,761	$5,835	$12,459
Dollar change from prior year	366	(8,651)	(6,624)	(11,018)
Percentage change from prior year	20.8%	(83.1)%	(53.2)%	(46.9)%

Research and development expenses during the three months ended September 30, 2018 increased compared to the prior year period, primarily due to a low level of research and development expenses in the three months ended September 30, 2017 due to delays experienced in the third quarter of 2017 related to pediatric trials of NUCYNTA.

Research and development expenses during the nine months ended September 30, 2018 decreased compared to the nine months ended as a result of a reduction in the development costs associated with cebranopadol. In January 2018, we gave to Grünenthal 120 days' written notice of termination of the cebranopadol license agreement and, consequently, our research and development costs relating to cebranopadol in 2018 will be insignificant. During the nine months ended September 30,

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2018 we recognized $1.25 million of research and development expenses related to our amended licensing agreement with Applied Pharma Research for the development of a new product presentation of CAMBIA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses primarily consist of personnel, contract personnel, marketing and promotion expenses associated with our commercial products, personnel expenses to support our administrative and operating activities, facility costs, and professional expenses, such as legal fees. Total selling, general and administrative expenses were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Selling, general and administrative expenses	$33,409	$48,850	$93,750	$147,379
Dollar change from prior year	(15,441)	(2,724)	(53,629)	(8,657)
Percentage change from prior year	(31.6)%	(5.3)%	(36.4)%	(5.5)%

The decrease in selling, general and administrative expense during the three and nine months ended September 30, 2018 as compared to 2017 was primarily due to the reduction in our sales force following the restructuring plan announced in December 2017 and the elimination of all commercialization efforts relating to NUCYNTA following the Commercialization Agreement with Collegium. In December 2017, in connection with the signing of the Commercialization Agreement with Collegium we announced the termination of our pain sales force which occurred during the first quarter of 2018, consisting of approximately 255 sales representative and sales manager positions, and our plan to significantly reduce our office staff and reduce our headquarters office space by approximately 50%.

Selling, general and administrative expenses in 2017 include a $3.4 million adjustment booked in the three months ended March 31, 2017 related to an increase in estimates associated with the branded prescription drug fee of which $1.4 million and $2.0 million related to the years ended December 31, 2015 and 2016, respectively.

In connection with the Multidistrict Opioid Litigation, the State Opioid Litigation and the Opioid-Related Requests and Subpoenas described in Note 12, “Commitments and Contingencies - Legal Matters” of the Notes to unaudited condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we expect to incur additional costs and expenses related to our ongoing opioid-related litigation and investigations, which may be significant.

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Amortization of Intangible Assets

(in thousands)	Three Months Ended September 30, 2018	2017	Nine Months Ended September 30, 2018	2017
Amortization of intangible assets - NUCYNTA	$23,576	$23,575	$70,726	$70,727
Amortization of intangible assets - CAMBIA	1,284	584	3,852	1,752
Amortization of intangible assets - Lazanda	—	291	—	873
Amortization of intangible assets - Zipsor	583	1,284	1,753	3,852
Total	$25,443	$25,734	$76,331	$77,204

The reduction in amortization expense during the three and nine months ended September 30, 2018 as compared to 2017 was due to the divestiture of Lazanda to Slán in November 2017, where we exchanged our interest in Lazanda for exclusive distribution rights to cosyntropin depot in the United States and Canada. Consequently, no amortization expense was recorded relating to Lazanda subsequent to its divestiture.

Restructuring Charges

(in thousands)	Three Months Ended September 30, 2018	2017	Nine Months Ended September 30, 2018	2017
Employee compensation costs	$400	$434	$14,993	$3,875
Fixed Asset disposals and accelerated depreciation of leasehold improvements	3,511	—	3,511	—
Other exit costs	—	—	238	—
Total restructuring costs	$3,911	$434	$18,742	$3,875

During the first nine months of 2018 we continued to execute the restructuring plan announced in December 2017. We completed the previously announced termination of our pain sales force during the first quarter of 2018, consisting of approximately 255 sales representative and sales manager positions. We continued our restructuring plan and significantly reduced our office staff during the nine months ended 2018. We relocated our corporate headquarters from Newark, California to Lake Forest, Illinois, which reduced our headquarters office space requirement by approximately 50%. During the first quarter of 2018, we entered into an Office Lease pursuant to which we lease approximately 31,000 rentable square feet of space in Lake Forest, Illinois. Our initial tenant improvements in the space were completed in August 2018 and we began occupying the space at that time.

For the three months ended September 30, 2018 and 2017, restructuring expenses and one-time termination costs were $3.9 million, and $0.4 million, respectively. For the nine months ended September 30, 2018 and 2017, restructuring expenses and one-time termination costs were $18.7 million, and $3.9 million, respectively. To date we have incurred $31.9 million in related restructuring costs since the announcement of the plan in December 2017 through September 30, 2018. We expect to incur additional related restructuring costs of $1.5 million to $3.0 million through June 30, 2019.

Other Income and Expense

Other income and expense for the three and nine months ended September 30, 2018 and 2017 was comprised of:

	Three Months Ended September	Nine Months Ended September 30,

(in thousands)	30, 2018	2017	2018	2017
Litigation settlement	62,000	—	62,000	—
Interest and other income	$677	$72	$973	$604
Loss on prepayment of Senior Notes	—	—	—	(5,364)
Interest expense	(17,190)	(17,815)	(52,268)	(55,697)
Total other income (expense)	$45,487	$(17,743)	$10,705	$(60,457)

For the three and nine months ended September 30, 2018, other income includes the present value of the Settlement Agreement with the Purdue Companies, as further described in Note 12, “Commitments and Contingencies - Legal Matters” of the Notes to unaudited condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on

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Form 10-Q. The total settlement amount was $62.0 million of which $30.0 million was paid during the three months ended September 30, 2018 and the remaining $32.0 million will be paid in the first quarter of 2019.

The interest expense was comprised of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Interest payable on Senior Notes	$9,517	$10,589	$29,383	$33,748
Interest payable on Convertible Notes	2,156	2,156	6,468	6,468
Amortization of debt discounts and issuance costs relating to Senior Notes and Convertible Notes	5,490	4,839	16,298	14,249
Changes in fair value of contingent consideration	27	221	106	1,017
Other	—	10	13	215
Total interest expense	$17,190	$17,815	$52,268	$55,697

We prepaid and retired $100.0 million of principal of the Senior Notes in April 2017 and $10.0 million of principal of the Senior Notes in November 2017. The decrease in interest expense in 2018 as compared to 2017 is due to these principal prepayments, offset in part by the impact of increasing interest rates in 2018. The increase in amortization of debt discounts and issuance costs was primarily due to the modification of the prepayment schedule for our Senior Notes.

On April 2, 2015, we issued $575.0 million aggregate principal amount of senior secured notes (the Senior Notes) for aggregate gross proceeds of approximately $562.0 million pursuant to a Note Purchase Agreement dated March 12, 2015, among us and Deerfield Private Design Fund III, L.P., Deerfield Partners, L.P., Deerfield International Master Fund, L.P., Deerfield Special Situations Fund, L.P., Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., BioPharma Secured Investments III Holdings Cayman LP, Inteligo Bank Ltd. and Phemus Corporation (collectively, the Purchasers) and Deerfield Private Design Fund III, L.P., as collateral agent. We used $550.0 million of the net proceeds received upon the sale of the Senior Notes to fund a portion of the Purchase Price paid to Janssen Pharma in connection with the NUCYNTA acquisition. We incurred debt issuance costs of $0.5 million during 2015. In November 2017, the Company prepaid and retired $10.0 million of the Senior Notes and paid a $0.4 million prepayment fee. In April 2017, the Company prepaid and retired $100.0 million of the Senior Notes and paid a $4.0 million prepayment fee.

In December 2017 we amended our Note Purchase Agreement for our Senior Notes, modifying the repayment schedule, paying a $3.0 million amendment fee which will offset future prepayment fees, replaced the net sales covenant with an EBITDA covenant, and received a waiver to allow the Commercialization Agreement with Collegium to proceed. We are required to make a scheduled principal repayment of secured indebtedness of $25.0 million in October 2018 pursuant to the terms of the original and the amended Note Purchase Agreement.

We monitor our compliance with each of the financial and other covenants contained in the Note Purchase Agreement. While we are currently in compliance, and anticipate continued compliance with such covenants, if our anticipated results of operations indicated a potential for noncompliance, we would seek to prevent such potential noncompliance by taking one or more actions, including refinancing our debt, significantly reducing expenses, renegotiating our debt covenants, restructuring our debt, selling assets or obtaining additional capital, each of which may be on terms that may be onerous, highly dilutive or disruptive to our business. Any prepayment of the Senior Notes will be subject to a prepayment fee of 4% of the principal amount of the Senior Notes prepaid. In addition, in connection with any refinancing of our debt, we would also accelerate the recognition of the balance of the unamortized debt discount and

the debt issuance costs as of the date of any refinancing. RF Language

On September 9, 2014, we issued and sold $345.0 million aggregate principal amount of convertible senior notes in a public offering (the Convertible Notes). The convertible debt offering resulted in net proceeds of $334.2 million after deducting the underwriting discount and offering expenses of $10.4 million and $0.4 million, respectively.

Income Tax Provision

In the three and nine months ended September 30, 2018, we recorded an expense from income taxes of approximately $6.8 million and $6.4 million respectively, that represents an effective tax rate of 12.4% and 9.5%, respectively. The difference for the three and nine months ended September 30, 2018 between the income tax benefit of $6.8 million and $6.4 million,

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respectively, and the tax at the statutory rate of 21% on current year operations is principally due to the change in valuation allowance. In the three and nine months ended September 30, 2017, we recorded a benefit from income taxes of approximately $0.5 million and $0.6 million respectively, that represents an effective tax rate of (3.1 %) and (.80%), respectively. For the three and nine months ended September 30, 2017, the difference between the recorded provision for income taxes and the tax benefit based on the federal statutory rate of 35%, was primarily attributable to the impact of the valuation allowance. The difference between our 2018 and 2017 tax expense is attributable primarily to taxable income created in 2018 by our litigation settlement.

LIQUIDITY AND CAPITAL RESOURCES

(in thousands)	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$121,904	$128,089

The decrease in cash, cash equivalents and short-term investments during the nine months ended September 30, 2018 is primarily attributable to the payment of $57.5 million of principal on our Senior Notes in April 2018. This payment was partially off-set by the cash generated from operations during the nine months ended September 30, 2018, the receipt of $20.0 million from the PDL royalty and milestone monetization and $30.0 million from the Purdue settlement.

We may incur operating losses in future years. We believe that our existing cash and investment balances and cash we expect to generate from operations will be sufficient to fund our operations, and to meet our existing obligations for the foreseeable future, including our obligations under the Senior Notes and the Convertible Notes. We base this expectation on our current operating plan and the anticipated impact of the cash expected to be received from Collegium pursuant to the Commercialization Agreement, which may change as a result of many factors, including:

- payments from Collegium pursuant to our Commercialization Agreement;
- acquisitions or licenses of complementary businesses, products, technologies or companies;
- sales of our marketed products;
- expenditures related to our commercialization of Gralise, CAMBIA, and Zipsor;
- expenditures related to our product candidates;
- the timing of our NUCYNTA pediatric clinical trials;
- milestone and royalty revenue we receive under our collaborative development arrangements;
- interest and principal payments on our current and future indebtedness;
- our ability to refinance the Convertible Notes in 2021;
- financial terms of definitive license agreements or other commercial agreements we may enter into; and
- changes in the focus and direction of our business strategy and/or research and development programs.

The inability to raise any additional capital that may be required to fund our future operations or product acquisitions and strategic transactions which we may pursue could have a material adverse effect on our company.

The following table summarizes our cash flow activities (in thousands):

	Nine Months Ended September 30,	
(in thousands)	2018	2017
Cash (used in) provided by operating activities	$56,735	$34,905
Cash provided by investing activities	(5,562)	53,325
Cash provided by financing activities	(56,153)	(98,354)
Net (decrease) increase in cash and cash equivalents	$(4,980)	$(10,124)

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Cash Flows from Operating Activities

Cash provided by operating activities increased during the nine months ended September 30, 2018 as compared to the same period in 2017 primarily due to the receipt of $20.0 million from the PDL royalty and milestone monetization and $30.0 million from the Purdue settlement.

Cash Flows from Investing Activities

The reduction in cash provided by investing activities during the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, primarily relates to the maturities of marketable securities in 2017 which did not recur in 2018. Cash used in investing activities in the nine months ended September 30, 2018 includes a $3.0 million investment in a company engaged in medical research.

Cash Flows from Financing Activities

The reduction in cash used in financing activities during the nine months ended September 30, 2018 as compared to the same period in 2017 primarily relates to lower principal payments on our Senior Notes as we made a payment of $57.5 million in April 2018 compared to a payment of $100.0 million in April 2017.

Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements during the quarter ended September 30, 2018.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in the sources and effects of our market risk compared to the disclosures in Item 7A of our Annual Report on the 2017 Form 10-K.

Interest Rate Risk. We are subject to interest rate fluctuation exposure through our borrowings under the Senior Secured Credit Facility and our investment in money market accounts which bear a variable interest rate. Borrowings under the Senior Secured Credit Facility bear interest at a rate equal to the three month LIBOR plus 9.75% per annum, subject to a 1.0% LIBOR floor and certain thresholds. Current LIBOR rates are above the 1.0% LIBOR floor, and the interest rate on our borrowings under the Senior Secured Credit Facility is currently 12.15% per annum. An increase in the three month LIBOR of 100 basis points above the current three month LIBOR rates would increase our interest expense by approximately $3.2 million for 2018, assuming we timely make the scheduled principal payments. As of September 30, 2018, we had $345 million aggregate principal amount of convertible senior notes outstanding, which are fixed rate instruments.

The goals of our investment policy are the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds and short term corporate debt securities. Because of the short term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

Foreign Currency Risk. We have not had any significant transactions in foreign currencies, nor did we have any significant balances that were due or payable in foreign currencies at December 31, 2017. Accordingly, significant changes in foreign currency rates would not have a material impact on our financial position and results of operations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this quarterly report. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were effective.

We review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. Our goal is to ensure that our senior management has timely access to all material financial and non-financial information concerning our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

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Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the three months ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For a description of our material pending legal proceedings, see Note 12 “Commitments and Contingencies - Legal Matters” of the Notes to unaudited condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

The risk factors presented below amend and restate the risk factors previously disclosed in our 2017 Form 10-K, our Quarterly Report on Form 10-Q for the three months ended March 31, 2018 filed with the SEC on May 10, 2018 and our Quarterly Report on Form 10-Q for the three months ended June 30, 2018 filed with the SEC on August 8, 2018.

The following factors, along with those described above under “MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS — LIQUIDITY AND CAPITAL RESOURCES” should be reviewed carefully, in conjunction with the other information contained in this Form 10-Q and our financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-Q and presented elsewhere by our management from time to time. See “Part I, Item 2—Forward-Looking Information.”

We rely on Collegium Pharmaceutical Inc. to commercialize NUCYNTA and NUCYNTA ER and their failure to successfully commercialize these products could have a material adverse effect on our business, financial condition and results of operations.

In December 2017, we entered into a commercialization agreement with Collegium pursuant to which Collegium assumed, effective as of January 9, 2018, responsibility for the sales and marketing of NUCYNTA and NUCYNTA ER. Collegium will pay us royalties based on net sales of NUCYNTA and NUCYNTA ER. Although we have retained certain rights to promote NUCYNTA and NUCYNTA ER to physicians that Collegium does not call on, we do not have any immediate plans to exercise such rights. As a result, the commercial success of NUCYNTA and NUCYNTA ER will depend almost entirely on Collegium’s commercialization efforts.

As a company, Collegium has a limited history of selling and marketing pharmaceutical products. Collegium’s ability to successfully commercialize and generate revenues from NUCYNTA and NUCYNTA ER, our largest selling product, depends on a number of factors, including, but not limited to, Collegium’s ability to:

- develop and execute its sales and marketing strategies for NUCYNTA and NUCYNTA ER;
- achieve, maintain and grow market acceptance of, and demand for, NUCYNTA and NUCYNTA ER;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;
- maintain and manage the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize NUCYNTA and NUCYNTA ER;
- obtain adequate supply of NUCYNTA and NUCYNTA ER; and
- comply with applicable legal and regulatory requirements.

Additional factors that may affect the success of our commercialization arrangement with Collegium include the following:

- Collegium may prioritize the commercialization of their other products, including Xtampza, over NUCYNTA and NUCYNTA ER;
- Collegium may pursue higher-priority programs, or change the focus of its marketing programs;
- Collegium may acquire or develop alternative products;
- Collegium may in the future choose to devote fewer resources to NUCYNTA and NUCYNTA ER;
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changes in laws and regulations applicable to, and scrutiny of, the pharmaceutical industry, including the opioid market;

- market acceptance of NUCYNTA and NUCYNTA ER may fail to increase or may decrease;

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- the outcome of the appeal of the court's ruling in our litigation against the ANDA filers seeking to prevent such ANDA filers from marketing a generic version of NUCYNTA and NUCYNTA ER in the U.S.;
- Collegium may experience financial difficulties;
- Collegium may fail to comply with its obligations under our commercialization and related agreements; or
- Collegium's involvement in governmental investigations and inquires or lawsuits and the disposition of such proceedings.

Any of the preceding factors could affect Collegium's commitment to, and ability to perform, its obligations under the commercialization agreement, which, in turn, could adversely affect the commercial success of NUCYNTA and NUCYNTA ER. Any failure by Collegium to successfully commercialize NUCYNTA and NUCYNTA ER could have a material adverse effect on our business, financial condition and results of operations.

If our commercialization agreement with Collegium terminates, we may not succeed in commercializing NUCYNTA and NUCYNTA ER on our own or through an alternative commercialization partner.

Our agreement with Collegium grants each party specified termination rights. See Note 17, "Subsequent Events" of the Notes to the unaudited condensed Consolidated Financial Statements for a description of these termination events. If the agreement is terminated, we may either perform commercialization activities relating to NUCYNTA and NUCYNTA ER on our own or search for another commercialization partner. Both alternatives would result in us incurring greater expenses and could cause a disruption in the commercialization of the products while we expand our commercial operations or seek an alternative commercialization partner, which disruption could lead to a loss of market share and decreased demand for the products. If we elect to increase our expenditures to fund commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements. If we elect to seek another commercialization partner, we may be unsuccessful in identifying a satisfactory partner or, if we do successfully identify a partner, we may be unable to negotiate a new commercialization agreement on acceptable terms, or at all.

If we do not successfully commercialize Gralise, CAMBIA, and Zipsor, our business, financial condition and results of operations will be materially and adversely affected.

In October 2011, we began commercial sales of Gralise. In June 2012, we acquired Zipsor and began commercial promotion of Zipsor in July 2012. In December 2013, we acquired CAMBIA and began commercial promotion of CAMBIA in February 2014. In addition to the risks discussed elsewhere in this section, our ability to successfully commercialize and generate revenues from Gralise, CAMBIA and Zipsor, depends on a number of factors, including, but not limited to, our ability to:

- develop and execute our sales and marketing strategies for our products;
- achieve, maintain and grow market acceptance of, and demand for, our products;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;
- maintain, manage or scale the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize our products;
- obtain adequate supply of our products;
- maintain and extend intellectual property protection for our products; and
- comply with applicable legal and regulatory requirements.

If we are unable to successfully achieve or perform these functions, we will not be able to maintain or increase our product revenues and our business, financial condition and results of operations will be materially and adversely affected.

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We depend on third parties that are single source suppliers to manufacture our products. If these suppliers are unable to manufacture and supply our products, or if there is insufficient availability of our products or the raw materials necessary to manufacture our products, our business will suffer.

We have one qualified supplier for the active pharmaceutical ingredient in each of NUCYNTA ER, NUCYNTA, CAMBIA, Zipsor and Gralise. An affiliate of Janssen Pharma is currently the sole supplier of NUCYNTA ER pursuant to a manufacturing supply agreement we entered into with such entity in April 2015. Halo Pharmaceutical, Inc. (Halo) is the sole supplier of NUCYNTA pursuant to a manufacturing supply agreement we entered into with Halo in June 2017. Patheon Puerto Rico Inc. (Patheon) is our sole supplier for Gralise pursuant to a manufacturing and supply agreement we entered into with Patheon in September 2011. Catalent Ontario Limited (Catalent) is our sole supplier for Zipsor pursuant to a manufacturing agreement we entered into with Catalent effective June 30, 2018. MiPharm, S.p.A is our sole supplier for CAMBIA pursuant to a manufacturing and supply agreement that we assumed in connection with our acquisition of CAMBIA in December 2013. We do not have, and we do not intend to establish in the foreseeable future, internal commercial scale manufacturing capabilities. Rather, we intend to use the facilities of third parties to manufacture products for commercialization and clinical trials. Our dependence on third parties for the manufacture of our products and our product candidates may adversely affect our ability to obtain such products on a timely or competitive basis, if at all. Any stock out, or failure to obtain sufficient supplies of NUCYNTA or NUCYNTA ER, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture NUCYNTA or NUCYNTA ER, would adversely affect Collegium's ability to commercialize such products, which would adversely affect our results of operations and financial condition. Any stock out, or failure to obtain sufficient supplies of Gralise, CAMBIA, or Zipsor, or the necessary active pharmaceutical ingredients, excipients or components from our suppliers would adversely affect our business, results of operations and financial condition.

Hurricanes Irma and Maria caused significant devastation and damage throughout Puerto Rico in 2017, including widespread flooding and power loss. As a result, we experienced delays in the manufacture, packaging and delivery of certain dosage strengths of NUCYNTA ER in fourth quarter of 2017 and the first quarter of 2018. We and Collegium may experience further outages in the future. Any delay in the manufacture, packaging or delivery of NUCYNTA and NUCYNTA ER, whether due to the manufacturing facility at which NUCYNTA and NUCYNTA ER are produced not being fully operational for an extended period of time or otherwise, could adversely affect the ability of Collegium to commercialize such products, which could adversely affect our results of operations and financial condition. In addition, if our contract manufacturer is unable to deliver a certain percentage of ordered quantities of NUCYNTA ER for a period of two months or longer in calendar year 2018, then we may be required to make a payment to Collegium to ensure that it receives a minimum level of gross profit for 2018, in which case we would not be ensured a minimum amount of royalties from Collegium for 2018.

The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third-party manufacturers and our suppliers are subject to numerous regulations, including current FDA regulations governing manufacturing processes, stability testing, record keeping, product serialization and quality standards. Similar regulations are in effect in other countries. Our third-party manufacturers and suppliers are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any third-party manufacturer or supplier fails to perform as required or fails to comply with the regulations of the FDA and other applicable governmental authorities, our ability to deliver adequate supplies of our products to our customers on a timely basis, or to continue our clinical trials could be adversely affected. The manufacturing processes of our third party manufacturers and suppliers may also be found to violate the proprietary rights of others. To the extent these risks materialize and adversely affect such third-party manufacturers' performance obligations to us, and we are unable to contract for a sufficient supply of required products on acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers or suppliers, our business, results of operation and financial condition could be adversely affected.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our products, our business will be materially and adversely affected.

Under the Federal Food, Drug and Cosmetics Act (FDCA), the FDA can approve an ANDA for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage, form, inactive ingredients or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The FDCA requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to

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notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the company seeking approval of a product covered by one of our patents. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. Such litigation is often time-consuming and quite costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe such patents. If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs.

We have been involved in patent litigation lawsuits against filers of ANDAs (the Filers) seeking to market generic versions of NUCYNTA and NUCYNTA ER before the expiration of the patents listed in the Patent and Exclusivity Information Addendum of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for these two products. Such patent litigation against the Filers is described in Note 12 "Commitments and Contingencies - Legal Matters" of the Notes to unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Any introduction of one or more products generic to NUCYNTA ER, NUCYNTA, Gralise, CAMBIA, or Zipsor, whether as a result of an ANDA or otherwise, would harm our business, financial condition and results of operations. The filing of the ANDAs described above, or any other ANDA or similar application in respect to any of our products, could have an adverse impact on our stock price. Moreover, if the patents covering our products are not upheld in litigation or if a generic competitor is found not to infringe these patents, the resulting generic competition would have a material adverse effect on our business, financial condition and results of operations.

If we or our commercialization partner are unable to negotiate acceptable pricing or obtain adequate reimbursement for our products from third-party payers, our business will suffer.

Sales of our products depend significantly on the availability of acceptable pricing and adequate reimbursement from third-party payers such as:

- government health administration authorities;
- private health insurers;
- health maintenance organizations;
- managed care organizations;
- pharmacy benefit management companies; and
- other healthcare-related organizations.

If reimbursement is not available for our products or product candidates, demand for our products may be limited. Further, any delay in receiving approval for reimbursement from third party payers could have an adverse effect on our future revenues.

Third-party payers frequently require pharmaceutical companies to negotiate agreements that provide discounts or rebates from list prices and that protect the payers from price increases above a specified annual limit. We and our commercialization partner have agreed to provide such discounts and rebates to certain third-party payers. We expect increasing pressure to offer larger discounts and rebates or discounts and rebates to a greater number of third-party payers to maintain acceptable reimbursement levels for and access to our products for patients at co-pay levels that are reasonable and customary. Consolidation among large third party payers may increase their leverage in negotiations with pharmaceutical companies. If we or our commercialization partner are forced to provide additional discounts and rebates to third party payers to maintain acceptable access to our products for patients, our results of operations and financial condition could be adversely affected. If third-party payers do not accurately and timely report the eligibility and utilization of our products under their plans, our reserves for rebates or other amounts payable to third party

payers may be lower than the amount we are invoiced and we may be required to dispute the amount payable, which would adversely affect our business, financial condition and results of operations. For example, we have had, and continue to have, disputes with managed care providers over rebates related to our products. Even when rebate claims made by such managed care providers are without merit, we may be forced to pay such disputed amounts to the extent our failure to do so could otherwise adversely impact our business, such as our ability to maintain a favorable position on such provider's formulary. In addition, if competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce sales of our products and harm our results of operations. The process for determining whether a third-party payer will provide coverage for a product may be separate from

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the process for setting the price or reimbursement rate that such third-party payer will pay for the product once coverage is approved. Third-party payers may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, including one or more of our products. Any third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursement of, our products, including by reducing, limiting or denying reimbursement for new products or excluding products that were previously eligible for reimbursement, would limit the market acceptance and commercial prospects of our products and harm our business, financial condition and results of operations. In addition, any third-party payer decision to impose restrictions, limitations or conditions on prescribing or reimbursement of our products, including on the dosing or duration of prescriptions for our products, would harm our business, financial condition and results of operations.

There have been, and there will continue to be, legislative, regulatory and third-party payer proposals to change the healthcare system in ways that could impact our ability to commercialize our products profitably. We anticipate that the federal and state legislatures and the private sector will continue to consider and may adopt and implement healthcare policies, such as the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the ACA), intended to curb rising healthcare costs. These cost containment measures may include: controls on government- funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payers to make coverage and payment decisions. In California, voters rejected Proposition 61 in November 2016, a ballot initiative that would have prohibited the state from buying prescription drugs from a drug manufacturer at a price over the lowest price paid for such drug by U.S. Department of Veterans Affairs. Although Proposition 61 was defeated, these and other cost containment or price control measures, if adopted at the federal or state level, could significantly decrease the price that we or our commercialization partner receive for our products and any product that we may develop or acquire, which would harm our business, financial condition and results of operations.
Changes in laws and regulations applicable to, and investigations of, the pharmaceutical industry, including the opioid market, may adversely affect our business, financial condition and results of operations.
The manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations applicable to, and the investigations of, the pharmaceutical industry could adversely affect our business and our ability to commercialize Gralise, CAMBIA and Zipsor as well as Collegium's ability to commercialize NUCYNTA and NUCYNTA ER, thereby adversely affecting our financial condition and results of operations.

For instance, federal, state, and local governments have for the last several years given significant attention to the public health issue of opioid abuse. In 2016, the Centers for Disease Control and Prevention (CDC) issued national, non-binding guidelines on the prescribing of opioids, providing recommended considerations for primary care providers when prescribing opioids, including specific considerations and cautionary information about opioid dosage increases and morphine milligram equivalents (MME). A number of third-party payers have adopted or are considering adopting some or all of these CDC guidelines to limit access to higher doses of opioids. Industry associations and trade groups are also changing or considering changes to guidelines relevant to opioid prescriptions along similar lines. In addition, a number of state legislatures across the country have enacted legislation with some type of limit, guidance, or requirement related to opioid prescribing, including to limit the duration and quantity of initial prescriptions of opioids and to mandate the use by prescribers of prescription drug databases. At the federal level, the White House Office of National Drug Control Policy (ONDCP) and the National Institutes of Health (NIH) are coordinating efforts between the FDA, the U.S. Drug Enforcement Agency (DEA), the U.S. Department of Health and Human Services, and pharmaceutical industry groups to research and develop effective non-opioid pain relievers. In July 2018, the DEA issued a final rule, "Controlled Substances Quotas," to strengthen the process for setting controls

over diversion of controlled substances and to make other improvements in the quota management regulatory system for production, manufacturing, and procurement of controlled substances. The DEA also continues to increase its efforts to hold manufacturers, distributors, prescribers, and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances. The DEA also recently proposed reducing the quota for controlled substances to be manufactured in the U.S. in 2018. Further, the FDA is requiring “black-box” warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose, and death as well as implementing a Risk Evaluation and Mitigation Strategies (REMS) for immediate release opioids. In October 2018 Congress approved H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, and President Trump signed such legislation into law. The SUPPORT Act and other similar legislation or policy initiatives may adversely impact the commercialization of opioids generally, including NUCYNTA and NUCYNTA ER.

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In addition, various federal and state governmental entities, including the DOJ and a number of state attorneys general, have launched investigations into the marketing and sales practices of pharmaceutical companies that market opioid and non-opioid pain medications, including us. For instance, we have received subpoenas or civil investigative demands from the DOJ and several state attorneys general and other state regulators seeking documentation and information in connection with our prior sales and marketing of opioid products. We also received a subpoena from the State of California Department of Insurance seeking information relating to our prior sales and marketing of Gralise. There has been recent regulatory attention focused on gabapentin as a result of a perceived risk of the compound being used as a potentiator for opioid abuse. Although gabapentin is neither an opioid nor classified as a controlled substance by the DEA, as a result, several states have scheduled gabapentin as a controlled substance. Continued changes in regulations and legislation applicable to gabapentin could have a material adverse impact the commercial prospects of Gralise which could, in turn, have a material adverse affect on our business, financial condition and results of operations.

The foregoing and other similar initiatives and actions, whether taken by governmental authorities or other industry stakeholders, may result in the reduced availability, prescribing and use of our products, which could adversely affect our ability to commercialize Gralise, CAMBIA and Zipsor, as well as Collegium's ability to commercialize NUCYNTA and NUCYNTA ER, thereby adversely affecting our business, financial condition and results of operations.

Heightened attention on the problems associated with the abuse of opioids could adversely affect Collegium's ability to commercialize NUCYNTA and NUCYNTA ER, which would adversely affect our financial condition and results of operations.

In recent years, there has been increased public attention on the public health issue of opioid abuse. The ability of drug abusers to discover previously unknown ways to abuse and misuse opioid products; public inquiries and governmental investigations into prescription drug abuse; litigation and heightened regulatory activity regarding the sales, marketing, distribution or storage of opioid products, among other things, could cause additional unfavorable publicity regarding the use and misuse of opioids, which could have a material adverse effect on opioid products, the reputation of the opioid manufacturers and the ability of our commercialization partner to successfully commercialize NUCYNTA and NUCYNTA ER. Such negative publicity could reduce the potential size of the market for NUCYNTA and NUCYNTA ER, and decrease the revenues Collegium is able to generate from their sale, which in turn would adversely affect our financial condition and results of operations. Additionally, such increased scrutiny of opioids generally, whether focused on NUCYNTA and NUCYNTA ER or otherwise, could have the effect of negatively impacting relationships with healthcare providers and other members of the healthcare community, reducing the overall market for opioids or reducing the prescribing and use of NUCYNTA and NUCYNTA ER. Governmental investigations and inquiries, regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our historical commercialization of opioids could adversely affect our business, financial condition and results of operations.

As a result of the greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers generally by federal, state and local regulatory and governmental agencies, as well as increased legal action brought by state and local governmental entities and private parties. For example, we are currently named as a defendant, along with numerous other manufacturers and distributors of opioid drugs, in multiple lawsuits alleging common-law and statutory causes of action for alleged misleading or otherwise improper marketing and promotion of opioid drugs. Such litigation and related matters are described in Note 12 "Commitments and Contingencies - Legal Matters" of the Notes to unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We received a letter from Senator Claire McCaskill, the Ranking Member on the U.S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information from the Company regarding its prior commercialization of opioid products. We voluntarily furnished information responsive to Sen. McCaskill's request.

The Company has also received subpoenas or civil investigative demands focused on historical promotion and sales of Lazanda, NUCYNTA, and NUCYNTA ER from various State Attorneys General seeking documents and information regarding our prior sales and marketing of opioid products. In addition, the State of California Department of Insurance (CDI) has issued a subpoena to us seeking information relating to our prior sales and marketing of Lazanda. The CDI subpoena also seeks information on Gralise, a non-opioid product in our portfolio. We are cooperating with each of the foregoing states and the CDI in their investigations. We have received subpoenas from the U.S. Department of Justice (DOJ) seeking documents and information regarding our prior sales and marketing of opioid products. We are cooperating with the DOJ in its investigations. We also from time to time receive and comply with subpoenas from governmental authorities related to investigations primarily directed at third parties, including health care practitioners, pursuant to which our records related to agreements with and

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payments made to those third parties, among other items, are produced. These matters are described in Note 12 “Commitments and Contingencies - Legal Matters” of the Notes to unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

These and other governmental investigations or inquiries, as well as lawsuits, in which we are and may become involved may result in additional claims and lawsuits being brought against us by governmental agencies or private parties. It is not possible at this time to predict the outcome of the opioid-related lawsuits mentioned above or any governmental investigations or inquiries of us or any lawsuits or regulatory responses that may result from such investigations or inquiries or otherwise. It is also not possible at this time to predict the additional expenses related to related to such ongoing opioid-related litigation and investigations, which may be significant. The initiation of any additional investigation, inquiry or lawsuit relating to us, the costs and expenses associated therewith, or any assertion, claim or finding of wrongdoing by us, could:

- adversely affect our business, financial condition and results of operations;
- result in reputational harm and reduced market acceptance and demand for our products;
- harm our and our commercial partner’s ability to market our products;
- cause us to incur significant liabilities, costs and expenses; and
- cause our senior management to be distracted from execution of our business strategy.

To the extent governmental investigations and inquiries or lawsuits similar to those matters described above are, or may be, initiated against Collegium, such proceedings, and any assertion, claim or finding of wrongdoing by Collegium, could adversely affect Collegium’s ability to commercialize NUCYNTA or NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition.

Furthermore, governmental regulators could take measures that could have a negative effect on our business and our products. For example, in 2017 Endo Pharmaceuticals, Inc. voluntarily withdrew, at the FDA’s request, OPANA ER from the market due to the FDA’s view that the risks associated with the use of the product outweighed the potential benefits. Any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to NUCYNTA or NUCYNTA ER would adversely affect Collegium’s ability to commercialize NUCYNTA and NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition. Further, the FDA is in the process of issuing guidance to encourage the development of nonaddictive alternatives to opioid pain medications. Such efforts intended to spur the development of non-opioid medications for chronic pain could negatively impact the commercialization of opioids generally, including NUCYNTA and NUCYNTA ER. Likewise, any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to our other products could adversely affect our business, results of operations, and financial condition.

We may incur significant liability if it is determined that we are promoting or have in the past promoted the “off-label” use of drugs.

Companies may not promote drugs for “off-label” use—that is, uses that are not described in the product’s labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the Food, Drug, and Cosmetics Act (FDCA) and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the U.S. Department of Health and Human Services (OIG), the FDA, and the DOJ all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If any of the investigations of the DOJ, the Attorneys General identified above, and the CDI, as well as the actions filed by state and municipalities against us, result in a finding that we engaged in wrongdoing, including sales and marketing practices for our current and future products that violate applicable laws and regulations, we would incur significant liabilities. Such liabilities would harm our business,

financial condition and results of operations as well as divert management's attention from our business operations and damage our reputation.

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We and our commercial partner may be unable to compete successfully in the pharmaceutical industry.

Tapentadol, the active pharmaceutical ingredient in NUCYNTA and NUCYNTA ER, is a proprietary opioid analgesic that is marketed in the U.S. by our commercialization partner Collegium. NUCYNTA and NUCYNTA ER compete with a number of branded and generic products that are widely used to treat moderate to severe pain, including neuropathic pain associated with DPN, and acute pain, respectively. These products include OxyContin® (oxycodone hydrochloride extended-release tables), which is owned by Purdue, is approved for marketing in the U.S. for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin® has achieved significant levels of market acceptance. Unlike NUCYNTA ER, a number of long- acting opioids have product labelling related to their abuse deterrent properties, which may put NUCYNTA ER at a competitive disadvantage. There are also a number of branded and generic short and long acting opioids, including oxycodone, oxymorphone, fentanyl patch, morphine, buprenorphine patch, tramadol, hydrocodone and hydromorphone, which have received approval and are marketed in the U.S. for the treatment of moderate to severe pain, including chronic and acute pain. More opioid development and launches of both generics and brands are expected to continue. For example, Butrans (promoted by Purdue) has been facing generic entrants since June 2017. In addition, Pfizer’s new opioid Troxyca ER was approved in 2016, but has not yet launched. Teva’s Vantrela ER was approved in 2017, but has not yet launched. Inspirion received approval for MorphaBond™ ER (morphine sulfate) and RoxyBond (oxycodone HCL). MorphaBond launched in the fourth quarter of 2017 and RoxyBond is expected to launch in the first quarter of 2018. Lyrica (pregabalin), which is marketed by Pfizer, is approved for marketing in the U.S. for the treatment of neuropathic pain associated with DPN. Pfizer also received approval on October 13, 2017 to market Lyrica CR (pregabalin extended-release tablets), a once-daily treatment for the management of DPN and PHN. Branded and generic versions of duloxetine and lidocaine have also been approved for marketing in the U.S. for the treatment of neuropathic pain associated with DPN. There are a number of other products and treatments prescribed for, or under development for, the management of chronic and acute pain, including neuropathic pain associated with DPN, which are now or may become competitive with NUCYNTA and NUCYNTA ER. Further, in light of the FDA's efforts to spur the development of non-opioid medications for chronic pain, we expect that additional other competitive products and treatments may be developed and commercialized.

Branded gabapentin is currently sold by Pfizer as Neurontin for adjunctive therapy for partial onset epileptic seizures and for PHN. Pfizer’s basic U.S. patents relating to Neurontin have expired, and numerous companies have received approval to market generic versions of the immediate release product. In addition to receiving approval for marketing to treat neuropathic pain associated with DPN, Lyrica (pregabalin) has also been approved for marketing in the U.S. for the treatment of post herpetic pain, fibromyalgia, adjunctive therapy for partial onset epileptic seizures, and nerve pain associated with spinal cord injury and has captured a significant portion of the market. Moreover, generic versions of Lyrica (pregabalin) are expected to be available as early as 2019. Pfizer received approval on October 13, 2017 to market Lyrica CR (pregabalin extended-release tablets), a once-daily treatment for the management of DPN and PHN. Arbor Pharmaceuticals, LLC’s Horizant (gabapentin enacarbil extended-release tablets) is approved for the management of PHN and Restless Leg Syndrome. There are other products prescribed for or under development for PHN which are now or may become competitive with Gralise.

Diclofenac, the active pharmaceutical ingredient in Zipsor, is an NSAID that is approved in the U.S. for the treatment of mild to moderate pain in adults, including the symptoms of arthritis. Both branded and generic versions of diclofenac are marketed in the U.S. Zipsor competes against other drugs that are widely used to treat mild to moderate pain in the acute setting. In addition, a number of other companies are developing NSAIDs in a variety of dosage forms for the treatment of mild to moderate pain and related indications. Other drugs are in clinical development to treat acute pain.

An alternate formulation of diclofenac is the active ingredient in CAMBIA that is approved in the U.S. for the acute treatment of migraines in adults. CAMBIA competes with a number of triptans that are used to treat migraines and certain other headaches. Pfizer's Relpax patent expired in December 2016, and generic entrants began in July 2017. Currently, seven triptans are available and sold in the U.S. (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan). Branded competitors include Zomig nasal, Onzetra, Xsail Zembrace, SymTouch™ and Treximet, which is a fixed-dose combination product containing sumatriptan plus naproxen. There are other products prescribed for or under development for the treatment or prevention of migraines that are now or may become competitive with CAMBIA, including calcitonin gene-related peptide (CGRP) inhibitor products.

Competition in the pharmaceutical industry is intense and we expect competition to increase. Competing products currently under development or developed in the future may prove superior to our products and may achieve greater commercial acceptance. Most of our principal competitors have substantially greater financial, sales, marketing, personnel and research and development resources than we or Collegium do.

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Pharmaceutical marketing is subject to substantial regulation in the U.S. and any failure by us or our commercial and collaborative partners to comply with applicable statutes or regulations could adversely affect our business.

All marketing activities of Collegium associated with NUCYNTA and NUCYNTA ER, and of us associated with Gralise, CAMBIA, and Zipsor, as well as marketing activities related to any other products that we may acquire, or for which we or our collaborative partners obtain regulatory approval, are and will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products. The FDA regulates post-approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. For example, the federal healthcare program anti-kickback statute prohibits giving things of value to induce the prescribing or purchase of products that are reimbursed by federal healthcare programs, such as Medicare and Medicaid. In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Under this law, in recent years, the federal government has brought claims against drug manufacturers alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, and, in some states, such statutes or regulations apply regardless of the payer.

Governmental authorities may also seek to hold us responsible for any failure of our commercialization or collaborative partners to comply with applicable statutes or regulations. If we, or our commercial or collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunctions and exclusion of our products from reimbursement under government programs, as well as other regulatory or investigatory actions against our product candidates, our commercial or collaborative partners or us.

If we engage in strategic transactions that fail to achieve the anticipated results and synergies, our business will suffer.

We may seek to engage in strategic transactions with third parties, such as product or company acquisitions, strategic partnerships, joint ventures, divestitures or business combinations. We may face significant competition in seeking potential strategic partners and transactions, and the negotiation process for acquiring any product or engaging in strategic transactions can be time-consuming and complex. Engaging in strategic transactions, such as our acquisition in 2015 of the rights to NUCYNTA and NUCYNTA ER, our completion in 2018 of the commercialization arrangement covering NUCYNTA and NUCYNTA ER with Collegium, and our acquisition of the right to market the specialty drug cosyntropin depot in the U.S. and Canada may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, pose integration challenges and fail to achieve the anticipated results or synergies or distract our management and business, which may harm our business.

As part of an effort to acquire a product or company or to enter into other strategic transactions, we conduct business, legal and financial due diligence with the goal of identifying, evaluating and assessing material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining, evaluating and accurately assessing all such risks and, as a result, might not realize the intended advantages of the transaction. We may also assume liabilities and legal risks in connection with a transaction, including those relating to activities of the seller prior to the consummation of the transaction and contracts that we assume. Failure to realize the expected benefits from acquisitions or strategic transactions that we may consummate, or that we have completed, such as the acquisition in 2015 of the U.S. rights to NUCYNTA and NUCYNTA ER, and the recently completed commercialization arrangement covering NUCYNTA and NUCYNTA ER with Collegium, whether as a result of identified or unidentified risks, integration difficulties, regulatory setbacks, governmental investigations, litigation or other events, could adversely affect our business, results of operations and financial condition.

Our failure to generate sufficient cash flow from our business to make payments on our debt would adversely affect our business, financial condition and results of operations.

We have incurred significant indebtedness in the aggregate principal amount of $652.5 million at September 30, 2018 under the senior secured notes we issued in April 2015 (the Senior Notes) and the convertible notes we issued in September 2014 (the Convertible Notes). Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Convertible Notes, the Senior Notes and any additional debt obligations we may incur depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and to make necessary capital expenditures. Further, our results of operations may cause us to fail to comply with the financial covenants contained in the Note Purchase Agreement, such as the minimum EBITDA covenant contained therein and further described in Note 9 “Debt Senior Notes” of

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the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which event of default could result in all of our debt becoming immediately due and payable. If we are unable to generate sufficient cash flow or if our results of operations cause us to fail to comply with our financial covenants, we may be required to take one or more actions, including refinancing our debt, significantly reducing expenses, renegotiating our debt covenants, restructuring our debt, selling assets or obtaining additional capital, each of which may be on terms that may be onerous, highly dilutive or disruptive to our business. 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 commercially reasonable or acceptable terms, which could result in a default on our obligations, including the Convertible Notes and the Senior Notes.

In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences to our business. For example, it could:

- make it more difficult for us to meet our payment and other obligations under the Convertible Notes, the Senior Secured Notes or our other indebtedness;
- result in other events of default under our Convertible Notes, Senior Secured Notes or our other indebtedness, which events of default could result in all of our debt becoming immediately due and payable;
- make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- subject us to the risk of increased sensitivity to interest rate increases on our indebtedness with variable interest rates, including the Senior Notes;
- require the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including working capital, clinical trials, research and development, business development activities, capital expenditures and other general corporate purposes;
- prevent us from raising funds necessary to repurchase the Convertible Notes in the event we are required to do so following a “fundamental change,” as specified in the indenture governing the Convertible Notes, to repurchase the Senior Notes in the event we are required to do so following a “major transaction” or as required in the event that the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than $100.0 million, as specified in the Note Purchase Agreement or to settle conversions of the Convertible Notes in cash;
- result in dilution to our existing shareholders as a result of the conversion of the Convertible Notes into shares of common stock;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- put us at a disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including funding possible acquisitions of, or investments in, additional products, technologies and companies.

Any of these factors could adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash, to repurchase the Convertible Notes upon a fundamental change or to repurchase the Senior Notes upon a major transaction put or as required in the event that the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than $100.0 million.

Holders of the Convertible Notes will have the right to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of certain events, including events deemed to be a “fundamental change,” at a repurchase price equal to 100% of the principal amount of the outstanding Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. Upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be

required to make cash payments in respect of the Convertible Notes being converted.

Furthermore, holders of the Senior Notes will have the right to require us to repurchase all of their Senior Notes (i) if the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than $100.0 million, at a repurchase price equal to 100% of the principal amount of the outstanding Senior Notes to be repurchased, plus accrued and unpaid interest, if any, or (ii) upon the occurrence of certain events deemed to be a “major transaction” at a repurchase price

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equal to: (a) 100% of the principal amount of the outstanding Senior Notes to be repurchased, plus (b) accrued and unpaid interest, if any, plus (c) a prepayment premium, which may be substantial.

However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes or Senior Notes or pay cash with respect to Convertible Notes being converted. In addition, our ability to repurchase or to pay cash upon conversion of the Convertible Notes may be limited by law, regulatory authority or agreements governing our future indebtedness. An event of default under the indenture governing the Convertible Notes, including our failure to repurchase Convertible Notes when required by the indenture governing the Convertible Notes, would constitute a default under the Note Purchase Agreement. In addition, an event of default under the Note Purchase Agreement, including our failure to repurchase Senior Notes when the repurchase is required by the Note Purchase Agreement, would constitute a default under the indenture governing the Convertible Notes. Moreover, the occurrence of a fundamental change under the indenture governing the Convertible Notes or a major transaction under the Note Purchase Agreement could constitute an event of default under either the indenture governing the Convertible Notes or the Note Purchase Agreement, as applicable and any agreements that may govern any future indebtedness. Following an event of default, if the payment of our outstanding indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay such indebtedness.

Acquisition of new and complementary businesses, products and technologies is a key element of our corporate strategy. If we are unable to successfully identify and acquire such businesses, products or technologies, our business growth and prospects will be limited.

Since June 2012, we have acquired NUCYNTA, NUCYNTA ER, CAMBIA, and Zipsor, exclusively in-licensed the right to develop and commercialize cebranopadol, and in-licensed the right to market cosyntropin depot. An important element of our business strategy is to actively seek to acquire products or companies and to in-license or seek co-promotion rights to additional products. We cannot be certain that we will be able to successfully identify, pursue and complete any further acquisitions or whether we would be able to successfully integrate or develop any acquired business, product or technology or retain any key employees. If we are unable to enhance and broaden our product offerings, our business and prospects will be limited.

If we are unable to successfully integrate any business, product or technology we may acquire, our business, financial condition and operating results will suffer.

Integrating any business, product or technology we acquire is expensive, time consuming and can disrupt and adversely affect our ongoing business, including product sales, and distract our management. Our ability to successfully integrate any business, product or technology we acquire depends on a number of factors, including, but not limited to, our ability to:

- minimize the disruption and distraction of our management and other employees, including our sales force, in connection with the integration of any acquired business, product or technology;
- maintain and increase sales of our existing products;
- establish or manage the transition of the manufacture and supply of any acquired product, including the necessary active pharmaceutical ingredients, excipients and components;
- identify and add the necessary sales, marketing, manufacturing, regulatory and other related personnel, capabilities and infrastructure that are required to successfully integrate any acquired business, product or technology;
- manage the transition and migration of all commercial, financial, legal, clinical, regulatory and other pertinent information relating to any acquired business, product or technology;
- comply with legal, regulatory and contractual requirements applicable to any acquired business, product or technology;

- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers with respect to any acquired product; and
- maintain and extend intellectual property protection for any acquired product or technology.

If we are unable to perform the above functions or otherwise effectively integrate any acquired businesses, products or technologies, our business, financial condition and operating results will suffer.

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Health care reform could increase our expenses and adversely affect the commercial success of our products.

The ACA includes numerous provisions that affect pharmaceutical companies. For example, the ACA seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The ACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in the U.S. The ACA also requires increased disclosure obligations and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost-containment measures that could reduce reimbursement levels for pharmaceutical products. The ACA also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties. These and other aspects of the ACA, including regulations that may be imposed in connection with the implementation of the ACA, such as the 340B Program, could increase our expenses and adversely affect our ability to successfully commercialize our products and product candidates.

Many members of Congress and President Trump have pledged to repeal the ACA. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the ACA and permits such legislation to pass with a majority vote in the Senate. President Trump also issued an executive order in which he stated that it is his administration’s policy to seek the prompt repeal of the ACA and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of burdensome provisions of the ACA to the maximum extent permitted by law. Although several attempts to repeal and replace the ACA failed to pass both houses of Congress, there is still uncertainty with respect to the impact President Trump’s administration and the Congress may have, if any, and any changes will likely take time to unfold. Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our products and product candidates. In addition, President Trump has indicated that reducing the price of prescription drugs will be a priority of his administration. The implementation of any price controls, caps on prescription drugs or price transparency requirements, whether at the federal level or state level, could adversely affect our business, operating results and financial condition.

If we or our collaborative partners are unable to obtain or maintain regulatory approval for our products, our raw materials or product candidates, we will be limited in our ability to commercialize our products, and our business will suffer.

The regulatory process is expensive and time consuming. Even after investing significant time and expenditures on clinical trials, we may not obtain regulatory approval of our product candidates. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval, and the FDA may not agree with our methods of clinical data analysis or our conclusions regarding safety and/or efficacy. For example, the FDA may determine that data regarding our product candidate, cosyntropin depot, is not sufficiently compelling to warrant regulatory approval, and the FDA may require us to engage in additional clinical trials or provide further analysis, which may be costly and time-consuming. Significant clinical trial delays could impair our ability to commercialize our products and could allow our competitors to bring products to market before we do. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections. Even if we receive regulatory approval, this

approval may entail limitations on the indicated uses for which we can market a product.

Further, with respect to our approved products, once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of approved products are also subject to ongoing regulation and inspection, including compliance with FDA regulations governing current Good Manufacturing Practices (cGMP) or Quality System Regulation (QSR). The FDCA, the Controlled Substances Act of 1970 (CSA) and other federal and foreign statutes and regulations govern and influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. In addition, we and our partners are also subject to ongoing DEA regulatory obligations, including annual registration renewal, security, record keeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The failure to comply with these regulations could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of

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production, non-renewal of marketing applications or authorizations or criminal prosecution, which could adversely affect our business, results of operations and financial condition.

We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns could result in labeling changes, recalls, market withdrawals or other regulatory actions. Recalls may be issued at our discretion or at the discretion of the FDA or other empowered regulatory agencies. For example, in June 2010, we instituted a voluntary class 2 recall of 52 lots of our 500mg Glumetza product after chemical traces of 2,4,6-tribromoanisole (TBA) were found in the product bottle.

We may incur product liability losses and other litigation liability.

We are or may be involved in various legal proceedings, lawsuits and certain government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability, personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, opioid-related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. For example, we, along with other opioid manufacturers and, often, distributors, have been named in lawsuits related to the manufacturing, distribution, marketing and promotion of opioids. In addition, we have also received various subpoenas and requests for information related to the distribution, marketing and sale of our opioid products. Such litigation and related matters are described in Note 12 “Commitments and Contingencies - Legal Matters” of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We have obtained product liability insurance for sales of our products and clinical trials currently underway, but:

- we may be unable to maintain product liability insurance on acceptable terms;
- we may be unable to obtain product liability insurance for future trials;
- we may be unable to obtain product liability insurance for future products; or
- our insurance may not provide adequate protection against potential liabilities (including pending and future claims relating to opioid litigation), or may provide no protection at all.

Our inability to obtain or maintain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Collegium’s inability to obtain or maintain adequate insurance coverage with regard to its commercialization of NUCYNTA and NUCYNTA ER could prevent or inhibit Collegium’s commercialization of NUCYNTA and NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition. Defending a lawsuit could be costly and significantly divert management’s attention from conducting our business. If third parties were to bring a successful product liability or other claims, or series of claims, against us, or Collegium relating to NUCYNTA and NUCYNTA ER, for uninsured liabilities or in excess of our insured liability limits, or Collegium’s insured liability limits with respect to NUCYNTA and NUCYNTA ER, respectively, our business, results of operations and financial condition could be adversely affected.

Any failure by us or our commercialization or collaborative partners to comply with applicable statutes or regulations relating to controlled substances could adversely affect our business.

Each of NUCYNTA and NUCYNTA ER are opioid analgesics that contain tapentadol. Tapentadol is a regulated “controlled substance” under the Controlled Substances Act (CSA). The CSA establishes, among other things, certain registration, production quotas, security, record keeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with

Schedule II substances being the pharmaceutical products that present the highest risk of abuse. Tapentadol is listed by the DEA as a Schedule II substance under the CSA. The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation. For example, generally all Schedule II substance prescriptions must be written and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The DEA also conducts periodic inspections of certain registered establishments that handle controlled substances. Facilities that conduct research, manufacture, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory

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action that could adversely affect our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations and in certain circumstances, violations could lead to criminal proceedings against us or our manufacturing and distribution partners, and our respective employees, officers and directors.

In addition to federal regulations, many individual states also have controlled substances laws. Although state controlled substances laws generally mirror federal law, because the states are separate jurisdictions they may separately schedule our products. Any failure by us or our partners to obtain separate state registrations, permits or licenses in order to be able to obtain, handle and distribute tapentadol or to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law and could adversely affect our business, results of operations and financial condition.

Limitations on the production of Schedule II substances in the U.S. could limit the ability of Collegium to successfully commercialize NUCYNTA and NUCYNTA ER.

The availability and production of all Schedule II substances, including tapentadol, is limited by the DEA through a quota system that includes a national aggregate quota, production quotas for individual manufacturers and procurement quotas that authorize the procurement of specific quantities of Schedule II controlled substances for use in drug product manufacturing. The DEA annually establishes an aggregate quota for total tapentadol production in the U.S. based on the DEA's estimate of the quantity needed to meet commercial and scientific need. The aggregate quota of tapentadol that the DEA allows to be produced in the U.S. annually is allocated among applicable individual drug manufacturers, which must submit applications at least annually to the DEA for individual production quotas. In turn, our third party manufacturers of NUCYNTA and NUCYNTA ER have to obtain a procurement quota to source tapentadol for the production of NUCYNTA and NUCYNTA ER.

The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas for these activities. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Based on a variety of factors, including public policy considerations, the DEA may set the aggregate quota lower for tapentadol than the total amount requested by individual manufacturers. Although through our manufacturing partner we are permitted to ask the DEA to increase our manufacturer's procurement quota after it is initially established, we cannot be certain that the DEA would act favorably upon such a request. In addition, our manufacturers obtain a procurement quota for tapentadol for all tapentadol products manufactured at their facility, which is allocated to NUCYNTA and NUCYNTA ER, as applicable, at the manufacturer's discretion. If the available quota of tapentadol is insufficient to meet commercial demand or clinical needs, our business, results of operations and financial condition could be adversely affected. Further, during the 2016 presidential campaign, President Trump called for the DEA to restrict the amount of opioids that can be manufactured in the U.S. The DEA also recently proposed reducing the quota for controlled substances to be manufactured in the U.S. in 2018, although no changes to the 2018 quotas for tapentadol were recommended. Additionally, the DEA has proposed various changes to its process for setting production and procurement quota. Any delay or refusal by the DEA or our manufacturers in establishing the production or procurement quota or granting sufficient production or procurement quota to meet commercial demand, or any reduction by the DEA or our manufacturer in the allocated quota for tapentadol, could adversely affect the ability of Collegium to commercialize NUCYNTA and NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition.

The FDA-mandated Risk Evaluation and Mitigation Strategy program may limit the commercial success of NUCYNTA ER and NUCYNTA.

NUCYNTA ER and NUCYNTA are subject to a FDA-mandated Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) protocol. This REMS protocol requires opioid manufacturers to make training available to health care practitioners (and their patients) who practice pain management and prescribe immediate and extended release opioids concerning the safe use of opioid analgesics. The FDA-mandated REMS protocol may reduce the number of physicians, health care practitioners and pharmacies that are willing to prescribe opioid products including NUCYNTA ER and/or NUCYNTA, as well as the number of patients who are willing to use these products. Because of these factors, if Collegium is not able to successfully promote NUCYNTA ER and NUCYNTA, our business, results of operations and financial condition could be adversely affected.

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The market price of our common stock historically has been volatile. Our results of operations may fluctuate and affect our stock price.

The trading price of our common stock has been, and is likely to continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. From December 31, 2015 through September 30, 2018, our stock price has ranged from $4.31 to $27.02 per share.

Factors affecting our operating results and that could adversely affect our stock price include:

- the degree of commercial success and market acceptance of NUCYNTA and NUCYNTA ER achieved by Collegium;
- the degree of commercial success and market acceptance of Gralise, CAMBIA and Zipsor achieved;
- the current and future market conditions for short-acting and long-acting opioids;
- filings and other regulatory or governmental actions, investigations or proceedings related to our products and product candidate and those of our commercialization and collaborative partners;
- the outcome of the appeal of the court's favorable ruling in our patent infringement litigation against the filers of ANDAs for NUCYNTA and NUCYNTA ER;
- developments concerning proprietary rights, including patents, infringement allegations, inter party review proceedings and litigation matters;
- legal and regulatory developments in the U.S.;
- actions taken by industry stakeholders affecting the market for our products;
- our ability to generate sufficient cash flow from our business to make payments on our indebtedness;
- our and our commercialization and collaborative partners' compliance or non-compliance with legal and regulatory requirements and with obligations under our collaborative agreements;
- our ability to successfully develop and execute our sales and marketing strategies;
- our plans to acquire, in-license or co-promote other products, compounds or acquire or combine with other companies, and our degree of success in realizing the intended advantages of, and mitigating any risks associated with, any such transaction;
- the regulatory strategy for cosyntropin depot and our and our collaborative partner's ability to successfully develop and execute such strategy;
- our ability to successfully commercialize cosyntropin depot if regulatory approval is obtained;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply, or other manufacture or supply difficulties;
- variations in revenues obtained from commercialization and collaborative agreements, including contingent milestone payments, royalties, license fees and other contract revenues, including non-recurring revenues, and the accounting treatment with respect thereto;
- adverse events or circumstances related to our peer companies or our industry or the markets for our products;
- adoption of new technologies by us or our competitors;
- the outcome of our opioid-related investigations and litigation;
- the outcome and impact of a proxy contest initiated by an activist shareholder;
- our compliance with the terms and conditions of the agreements governing our indebtedness;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- our ability to generate additional revenues from our intellectual property rights;
- sales of large blocks of our common stock or the dilutive effect of our Convertible Notes; and
- variations in our operating results, earnings per share, cash flows from operating activities, deferred revenue, and other financial metrics and non-financial metrics, and how those results are measured, presented and compare to analyst expectations.

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As a result of these and other such factors, our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Any significant drops in our stock price could give rise to shareholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved in our favor.

In addition, if the market for pharmaceutical stocks or the stock market in general experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. For example, if one or more securities or industry analysts downgrades our stock or publishes an inaccurate research report about our company, the market price for our common stock would likely decline. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us.

We have incurred operating losses in the past and may incur operating losses in the future.

To date, we have recorded revenues from product sales, license fees, royalties, collaborative research and development arrangements and feasibility studies. In 2017, 2016 and 2015 we incurred net losses of $102.5 million. $88.7 million and $75.7 million, respectively. We expect to incur operating losses in 2018 and may continue to incur operating losses in future years. Any such losses may have an adverse impact on our total assets, shareholders' equity and working capital.

Our existing capital resources may not be sufficient to fund our future operations or product acquisitions and strategic transactions that we may pursue.

We fund our operations primarily through revenues from product sales and do not have any committed sources of capital. To the extent that our existing capital resources and revenues from ongoing operations are insufficient to fund our future operations, or product acquisitions and strategic transactions that we may pursue, we will have to raise additional funds through the sale of our equity securities, through additional debt financing, from development and licensing arrangements or from the sale of assets. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions.

We have significant amounts of intangible assets which depend upon future positive cash flows to support the values recorded in our balance sheet. We may have an increased risk of future impairment charges should actual financial results differ materially from our projections.

Our consolidated balance sheet contains significant amounts of intangible assets representing the product rights which we have acquired over the last few years. We review the carrying value of our intangible assets when indicators of impairment are present. Conditions that could indicate impairment of intangible assets include, but are not limited to, a significant adverse change in market conditions, significant competing product launches by our competitors and the legal or regulatory environment.

In performing our impairment tests, we utilize our future projections of cash flows. Projections of future cash flows are inherently subjective and reflect assumptions that may or may not ultimately be realized. Significant assumptions utilized in our projections include, but are not limited to, our evaluation of the market opportunity for our products, the current and future competitive landscape and resulting impacts to product pricing, future regulatory actions, planned strategic initiatives and the realization of benefits associated with our existing patents. Given the inherent subjectivity and uncertainty in projections, we could experience significant unfavorable variances in future periods or revise our projections downward. This would result in an increased risk that our intangible assets may be impaired. If an impairment were recognized, this could have a material adverse effect on our financial condition and results of

operations.

Our customer concentration may materially adversely affect our financial condition and results of operations.

We and our commercialization partners sell a significant amount of our products to a limited number of independent wholesale drug distributors. Three of our wholesale distributors represented 30%, 28% and 23% for the nine months ended September 30, 2018 and 36%, 27% and 26% for the year ended December 31, 2017, of our product shipments. If we, or our commercialization partners, were to lose the business of one or more of these distributors, if any of these distributors failed to fulfill their obligations, if any of these distributors experienced difficulty in paying us or our commercialization partners on a timely basis, or if any of these distributors negotiated lower pricing terms, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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Our product revenues have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year, which may cause our stock price to decline.

Our product revenues have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year. We believe this arises primarily as a result of wholesalers' reductions of inventory of our products in the first quarter and annual changes in health insurance plans that occur at the beginning of the calendar year.

In 2013, 2014, 2015, and 2016, our wholesalers ended the calendar year with higher levels of inventory of our products than at the end of the first quarter of the following year. As a result, in the first quarters of 2014, 2015, 2016 and 2017, net sales were lower than would otherwise have been the case as a result of the reduction of product inventory at our wholesalers. Any material reduction by our wholesalers of their inventory of our products in the first quarter of any calendar year as compared to the fourth quarter of the preceding calendar year, could adversely affect our operating results and may cause our stock price to decline.

Many health insurance plans and government programs reset annual limits on deductibles and out-of-pocket costs at the beginning of each calendar year and require participants to pay for substantially all of the costs of medical services and prescription drug products until such deductibles and annual out-of-pocket cost limits are met. In addition, enrollment in high-deductible health insurance plans has increased significantly in recent years. As a result of these factors, patients may delay filling or refilling prescriptions for our products or substitute less expensive generic products until such deductibles and annual out-of-pocket cost limits are met. Any reduction in the demand for our products, including those marketed by our commercialization partners as a result of the foregoing factors or otherwise, could adversely affect our business, operating results and financial condition.

Our commercialization and collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership or protection of our intellectual property and may adversely affect the commercial success of our products.

We currently have a commercialization agreement with Collegium. We currently have collaboration or license arrangements with a number of companies, including Grünenthal, Janssen Pharma, Ironwood and Slán. In addition, we have in the past and may in the future enter into other commercialization or collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements.

Commercialization and collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of such arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the commercialization or collaborative partners under these arrangements might breach the terms of their respective agreements or fail to maintain, protect or prevent infringement of the licensed patents or our other intellectual property rights by third parties. Moreover, negotiating commercialization and collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs. Any failure by our commercialization or collaborative partners to abide by the terms of their respective agreements with us, including their failure to accurately calculate, report or pay any royalties payable to us or a third party, may adversely affect our results of operations.

We may be unable to enter into future commercialization or collaborative arrangements on acceptable terms, and we may be unable to maintain our current commercialization arrangement with Collegium on acceptable terms, either of which could harm our ability to develop and commercialize our current and potential future products and technologies. If either we or Collegium seek to renegotiate the terms of the commercialization agreement, we may not be able to reach agreement on terms that are as favorable to us as the current terms, or at all. Other factors relating to collaborations that may adversely affect the commercial success of our products include:

- any parallel development by a commercialization or collaborative partner of competitive technologies or products;
- arrangements with commercialization or collaborative partners that limit or preclude us from developing products or technologies;

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- premature termination of a commercialization or collaboration agreement or the inability to renegotiate existing agreements on favorable terms; or
- failure by a commercialization or collaborative partner to devote sufficient resources to the development and commercial sales of products using our current and potential future products and technologies.

Our commercialization or collaborative arrangements do not necessarily restrict our commercialization or collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future commercialization or collaborative partners may pursue existing or other development-stage products or alternative technologies in preference to those being commercialized or developed in collaboration with us. Our commercialization or collaborative partners may also terminate their relationships with us or otherwise decide not to proceed with development or commercialization of our products.

We may be unable to protect our intellectual property and may be liable for infringing the intellectual property of others.

Our success will depend in part on our ability to obtain and maintain patent protection for our products and technologies, and to preserve our trade secrets. Our policy is to seek to protect our proprietary rights by, among other methods, filing patent applications in the U.S. and foreign jurisdictions to cover certain aspects of our technology. We hold issued U.S. patents and have patent applications pending in the U.S. In addition, we are pursuing patent applications relating to our technologies in the U.S. and abroad. We have also applied for patents in numerous foreign countries. Some of those countries have granted our applications and other applications are still pending. Our pending patent applications may lack priority over other applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or may not provide us with competitive advantages against competing products. We also rely on trade secrets and proprietary know-how, which are difficult to protect. We seek to protect such information, in part, by entering into confidentiality agreements with employees, consultants, collaborative partners and others before such persons or entities have access to our proprietary trade secrets and know-how. These confidentiality agreements may not be effective in certain cases, due to, among other things, the lack of an adequate remedy for breach of an agreement or a finding that an agreement is unenforceable. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

Our ability to develop our technologies and to make commercial sales of products using our technologies also depends on not infringing other patents or intellectual property rights. We are not aware of any such intellectual property claims directly against us. The pharmaceutical industry has experienced extensive litigation regarding patents and other intellectual property rights. Patents issued to third parties relating to sustained release drug formulations or particular pharmaceutical compounds could in the future be asserted against us, although we believe that we do not infringe any valid claim of any patents. For example, in February 2018 Purdue sued Collegium for infringement of three patents owned by Purdue that were issued in January 2018 and expire in 2022 arising from Collegium’s commercialization of the NUCYNTA franchise of products. If claims concerning any of our products were to arise and it was determined that these products infringe a third party’s proprietary rights, we or our commercial partners could be subject to substantial damages for past infringement or could be forced to stop or delay activities with respect to any infringing product, unless we or our commercial partner, as applicable, can obtain a license, or our product may need to be redesigned so that it does not infringe upon such third party’s patent rights, which may not be possible or could require substantial funds or time. Such a license may not be available on acceptable terms, or at all. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which could give our competitors access to the same intellectual property. In addition, any public announcements related to litigation or interference proceedings initiated or threatened against us, even if such claims are without merit, could cause our stock price to decline.

From time to time, we may become aware of activities by third parties that may infringe our patents. Infringement of our patents by others may reduce our market shares (if a related product is approved) and, consequently, our potential future revenues and adversely affect our patent rights if we do not take appropriate enforcement action. We may need to engage in litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third-party proprietary rights. For instance, we have previously been engaged in ANDA litigation involving NUCYNTA, NUCYNTA ER and NUCYNTA oral solution as well as Gralise and Zipsor. It is possible our issued or licensed patents may not be held valid by a court of competent jurisdiction or the PTAB. Whether or not the outcome of litigation or the PTAB proceeding is favorable to us, the litigation and the proceedings may take significant time, may be expensive and may divert management's attention from other business concerns. We may also be required to participate in derivation proceedings or other post-grant proceedings declared by the U.S. Patent and Trademark Office for the purposes of, respectively, determining the priority of inventions in connection with our patent applications or determining validity of claims in our issued patents. Adverse determinations in litigation or

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proceedings at the U.S. Patent and Trademark Office could adversely affect our business, results of operations and financial condition and could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities to third parties. If we need but cannot obtain a license, we may be prevented from marketing the affected product.

We are subject to risks associated with NDAs submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act.

The products we develop or acquire generally are or will be submitted for approval under Section 505(b)(2) of the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For instance, the NDA for Gralise relies on the FDA's prior approval of Neurontin, the immediate release formulation of gabapentin initially approved by the FDA.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch- Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as "Paragraph IV certifications," that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505(b)(2) application are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and may require us to file such submissions under Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming.

The development of drug candidates such as cosyntropin depot, is inherently difficult and uncertain, and we cannot be certain that any of our product candidates or those of our collaborative partners will be approved for marketing or, if approved, will achieve market acceptance.

Clinical development is a long, expensive and uncertain process and is subject to delays and failures. As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. Positive or encouraging results of prior clinical trials are not necessarily indicative of the results obtained in later clinical trials, as has occurred in the past in certain of our Phase 3 trials. Further, product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed in development. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

In November 2017 we acquired the exclusive rights to market cosyntropin depot (synthetic ACTH Depot) in the U.S. and Canada. Cosyntropin depot is a long-acting alcohol-free synthetic ACTH analogue. We expect that a New Drug Application (NDA) will be filed with the FDA for cosyntropin depot by year end. The Company intends to file for a 505(b)(2) application for a diagnostic indication for suspected adrenocortical insufficiency. As previously announced,

the Company and its development partner began enrolling and dosing pediatric patients in a new clinical trial evaluating cosyntropin depot for the treatment of infantile spasms, a specific seizure type present in the infantile epilepsy spectrum, a rare pediatric disorder. The expected timing of the NDA filing and related approvals, the successful execution of the clinical trial and our overall strategy with regard to its application may not achieve the Company's intended results. Our overall strategy to bring cosyntropin depot to market in the U.S. and Canada is subject to certain risks and uncertainties. The FDA may not accept our application for filing and, even if our application is accepted, it may not be successful. Further, if our product manufacturing processes or facilities do not satisfy regulatory requirements, FDA approval may not be granted. Even if we receive FDA approval for our intended diagnostic indication, the ability to commercialize the product for diagnostic use may not generate significant market share. In addition, despite our intentions to file an NDA by year end, potential modifications in our strategy intended to augment our chances at success may result in delaying such filing.

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Product candidates, such as cosyntropin depot, are subject to the risk that any or all of them may be found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. The FDA or other applicable regulatory agencies may determine that our data is not sufficiently compelling to warrant marketing approval and require us to engage in additional clinical trials or provide further analysis, which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in preclinical studies or earlier clinical trials. If our current or future product candidates fail at any stage of development, they will not receive regulatory approval, we will not be able to commercialize them and we will not receive any return on our investment in those product candidates.

Other factors could delay or result in the termination of our current and future clinical trials and related development programs, including:

- negative or inconclusive results;
- patient enrollment rates;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- FDA inspections of our clinical operations;
- failure to meet FDA preferred or recommended clinical trial design, end points or statistical power;
- failure to comply with good clinical practices;
- failure of our third party clinical trial vendors to comply with applicable regulatory laws and regulations;
- compliance with applicable laws and regulations;
- inability of our third party clinical trial vendors to satisfactorily perform their contractual obligations, comply with applicable laws and regulations or meet deadlines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in our clinical trials
- delays or failures in recruiting qualified patients to participate in our clinical trials; and
- actual or perceived lack of efficacy or safety of the product candidate.

We are unable to predict whether any product candidates, including cosyntropin depot, will receive regulatory clearances or be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frame for commercializing a product is long and uncertain. Even if cosyntropin depot and any other product candidates receive regulatory clearance, these products may not achieve or maintain market acceptance. If it is discovered that our or our collaborators' products or technologies could have adverse effects or other characteristics that indicate they may be ineffective as therapeutics, our product development efforts and our business could be significantly harmed.

Even assuming our or our collaborative partners' products obtain regulatory approval, successful commercialization requires:

- market acceptance;
- a cost-effective commercial scale production; and
- reimbursement under private or governmental health plans.

Any material delay or failure in the governmental approval process and/or the successful commercialization of our potential products or those of our collaborative partners could adversely impact our business, financial condition and results of operations.

We and our collaborative partners customarily depend on third party contract research organizations, clinical investigators and clinical sites to conduct clinical trials with regard to product candidates, and if they do not perform their regulatory, legal and contractual obligations, or successfully enroll patients in and manage our clinical trials, we and our collaborative partners may not be able to obtain regulatory approvals for product candidates, including cosyntropin depot.

We and our collaborative partners customarily rely on third party contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise conducting clinical trials. We and our collaborative

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partners do not control these third parties and, as a result, we and our collaborative partners may be unable to control the amount and timing of resources that they devote to our or our collaborative partners' clinical trials.

Although we and our collaborative partners rely on third parties to conduct clinical trials, we and our collaborative partners are responsible for confirming that each clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and other applicable regulatory agencies' requirements, including good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. If we, contract research organizations or other third parties assisting us or our collaborative partners with clinical trials fail to comply with applicable good clinical practices, the clinical data generated in such clinical trials may be deemed unreliable and the FDA, or other applicable regulatory agencies, may require us or our collaborative partners to perform additional clinical trials before approving any marketing applications with regard to product candidates. We cannot be certain that, upon inspection, the FDA or other applicable regulatory agencies will determine that any of our clinical trials or our collaborative partners comply with good clinical practices. In addition, clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our or our collaborative partners' failure, or the failure of our product manufacturers, to comply with these regulations may require the repeat or redesign of clinical trials, which would delay the regulatory approval process.

We and our collaborative partners also customarily rely on clinical investigators and clinical sites to enroll patients and other third parties to manage clinical trials and to perform related data collection and analysis. If clinical investigators and clinical sites fail to enroll a sufficient number of patients in such clinical trials or fail to enroll them on the planned schedule, these trials may not be completed or completed as planned, which could delay or prevent us or our collaborative partners from obtaining regulatory approvals for product candidates.

Agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, clinical trials if these parties fail to perform as expected. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to clinical protocols or for other reasons, clinical trials may be extended, delayed or terminated, and we and our collaborative partners may be unable to obtain regulatory approval for, or successfully commercialize, product candidates.

We have recently experienced a significant transition in our executive management team.

We recently experienced changes in our executive management team as we transitioned our corporate headquarters to Lake Forest, Illinois. If our newly appointed executive team is not able to timely develop, implement and execute successful business strategies and plans to maintain and increase our product revenues, our business, financial condition and results of operations will be materially and adversely affected. Moreover, the changes to our executive management team may result in disruption to the operation of our business. While our Chief Executive Officer and newly appointed executive officers have significant industry-related experience, it may take time for the team to become fully integrated. Any delay in the integration of our executive management team could affect our ability to develop, implement and execute our business strategies and plans, which could have a material adverse effect on our business, financial condition and results of operations.

Further, with our new executive team, the future business strategies and plans of the Company may differ materially, or may continue to evolve, from those we previously pursued. If our business strategies and plans, including our commercialization arrangement with Collegium, cause disruption in our business or operations or do not achieve the level of success or results we anticipate, our business, financial condition and results of operations will be materially and adversely affected.

Our ability to successfully manage our business following our headquarters relocation depends on our ability to successfully transition institutional knowledge and to successfully attract and retain qualified personnel at our new location.

We relocated our corporate headquarters from Newark, California to Lake Forest, Illinois in the third quarter of 2018 and have reduced our staff throughout 2018. Although our relocation and transition is substantially complete, there may be continued costs and delays associated with relocation and such costs may exceed our projections. Further, with our transition, we may face challenges in maintaining the continuity of our operations and historical knowledge. Management may be required to devote substantial time to transitioning institutional knowledge, which time could otherwise be devoted to focusing on ongoing business operations and other initiatives and opportunities. Our business could also be materially adversely affected if we are unable to retain key employees or recruit qualified personnel in a timely fashion, or if we are required to incur

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unexpected compensation costs to retain key employees. Any such difficulties could have an adverse effect on our business, results of operations or financial condition.

Our success is dependent in large part upon the continued services of our executive management with whom we do not have employment agreements.

Our success is dependent in large part upon the continued services of members of our executive management team, and on our ability to attract and retain key management and operating personnel, especially in light of our headquarters relocation. We do not have agreements with any of our executive officers that provide for their continued employment with us. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates.

Our financial results are impacted by management's assumptions and use of estimates.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as sales discounts and returns, depreciable and amortizable lives, share-based compensation assumptions, fair value of contingent consideration and taxes on income. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of the Company's business and operations, actual results could differ materially from these estimates.

If we are unable to satisfy regulatory requirements relating to internal controls, our stock price could suffer.

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of the effectiveness of their internal control over financial reporting. At the end of each fiscal year, we must perform an evaluation of our internal control over financial reporting, include in our annual report the results of the evaluation and have our external auditors also publicly attest to the effectiveness of our internal control over financial reporting.

Our ability to produce accurate financial statements and comply with applicable laws, rules and regulations is largely dependent on our maintenance of internal control and reporting systems, as well as on our ability to attract and retain qualified management and accounting personnel to further develop our internal accounting function and control policies. If we fail to effectively establish and maintain such reporting and accounting systems or fail to attract and retain personnel who are capable of designing and operating such systems, these failures will increase the likelihood that we may be required to restate our financial results to correct errors or that we will become subject to legal and regulatory infractions, which may entail civil litigation and investigations by regulatory agencies including the SEC. In addition, if material weaknesses are found in our internal controls in the future, if we fail to complete future evaluations on time or if our external auditors cannot attest to the effectiveness of our internal control over financial reporting, we could fail to meet our regulatory reporting requirements and be subject to regulatory scrutiny and a loss of public confidence in our internal controls, which could have an adverse effect on our stock price or expose us to litigation or regulatory proceedings, which may be costly or divert management attention.

Changes in fair value of contingent consideration assumed as part of our acquisitions could adversely affect our results of operations.

Contingent consideration obligations arise from the Zipsor and CAMBIA acquisitions and relate to the potential future contingent milestone payments and royalties payable under the respective agreements. The contingent consideration is initially recognized at its fair value on the acquisition date and is re-measured to fair value at each reporting date until the contingency is resolved with changes in fair value recognized in earnings. The estimates of fair values for the contingent consideration contain uncertainties as it involves assumptions about the probability assigned to the potential milestones and royalties being achieved and the discount rate. Significant judgment is employed in determining these assumptions as of the acquisition date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period.

The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

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In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert the Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes could have a material effect on our reported financial results.

In May 2008, FASB issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options (ASC 470-20). Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital within shareholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we have been required to record a greater amount of non-cash interest expense as a result of the accretion of the discounted carrying value of the Convertible Notes to their face amount over the term of the notes. We will report lower net income (or larger net losses) in our financial results because ASC 470-20 requires interest to include both the accretion of the debt discount and the instrument's non-convertible coupon interest rate, which adversely affects our reported or future financial results and may adversely affect the trading price of our common stock.

In addition, if the Convertible Notes become convertible, we are required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than a long-term liability, which would result in a material reduction of our net working capital. Finally, we use the if-converted method to compute diluted earnings per share with respect to our convertible debt, which could be more dilutive than assuming the debt would be settled in cash.

Any of these factors could cause a decrease in the market price of our common stock.

Our business could be negatively affected as a result of any future proxy fight or the actions of activist shareholders.

On October 17, 2016, we and Starboard Value LP (Starboard) entered into a settlement agreement pursuant to which, among other things, (i) three independent directors appointed by Starboard joined our Board of Directors, (ii) we amended our bylaws to move the window for shareholders director nominations and other shareholder proposals for consideration at the 2017 annual meeting of shareholders to March 15, 2017 through April 15, 2017 and (iii) Starboard agreed to withdraw its request for the Special Meeting scheduled to be held on November 15, 2016. On March 28, 2017, we and Starboard entered into a cooperation and support agreement pursuant to which, among other things, two additional independent directors appointed by Starboard joined our Board of Directors and the parties agreed to certain standstill commitments.

Another proxy contest or related activities with Starboard or other activist shareholders, could adversely affect our business for a number of reasons, including, but not limited to the following:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;
- perceived uncertainties as to our future direction may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel, business partners, customers and others important to our success, any of which could negatively affect our business and our results of operations and financial condition; and
- if nominees advanced by activist shareholders are elected or appointed to our Board of Directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans or to realize long-term value from our assets, and this could in turn have an adverse effect on our business and on our results of operations and financial condition.

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A proxy contest could also cause our stock price to experience periods of volatility. Further, if a proxy contest results in a change in control of our Board of Directors, such an event could give third parties certain rights under our existing contractual obligations, which could adversely affect our business.

We may be subject to disruptive unsolicited takeover attempts in the future.

We have in the past and may in the future be subject to unsolicited attempts to gain control of our company. Responding to any such attempt would distract management attention away from our business and would require us to incur significant costs. Moreover, any unsolicited takeover attempt may disrupt our business by causing uncertainty among current and potential employees, producers, suppliers, customers and other constituencies important to our success, which could negatively impact our financial results and business initiatives. Other disruptions to our business include potential volatility in our stock price and potential adverse impacts on the timing of, and our ability to consummate, acquisitions of products and companies.

Certain provisions applicable to the Convertible Notes and the Senior Notes could delay or prevent an otherwise beneficial takeover or takeover attempt.

Certain provisions applicable to the Convertible Notes and the indenture governing the Convertible Notes, the Senior Notes and the Note Purchase Agreement, could make it more difficult or more expensive for a third party to acquire us. For example, if an acquisition event constitutes a fundamental change under the indenture for the Convertible Notes or a major transaction under the Note Purchase Agreement, holders of the Convertible Notes or the Senior Notes, as applicable, will have the right to require us to repurchase their notes in cash. In addition, if an acquisition event constitutes a “make-whole fundamental change” under the indenture, we may be required to increase the conversion rate for holders who convert their Convertible Notes in connection with such make-whole fundamental change. In any of these cases, and in other cases, our obligations under the Convertible Notes and the indenture, the Senior Notes and the Note Purchase Agreement, as well as provisions of our organizational documents and other agreements, could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

Provisions in our Certificate of Incorporation and Bylaws might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the market price of our common stock.

Certain provisions of our governing documents could discourage a third party from acquiring, or make it more difficult for a third party to acquire, control of our company without the approval of our Board of Directors. These provisions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain provisions allow the Board of Directors to authorize the issuance of preferred stock with rights superior to those of the common stock.

Our Bylaws provide that, under specified circumstances, stockholders can call a special meeting of stockholders. The Bylaws also supplement the advanced notice requirements and procedures for the submission by stockholders of nominations for the Board of Directors and of other proposals to be presented at stockholder meetings, and provide that the exclusive forum for any stockholder to bring any internal corporate claims (such as derivative actions and claims asserting a breach of fiduciary duty) shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the Superior Court of the State of Delaware, or if such court does not have jurisdiction, another state court or a federal court located within the State of Delaware).

We do not intend to pay dividends on our common stock so any returns on shares of our common stock will be limited to changes in the value of our common stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our common stock may be prohibited or limited by the terms of any future debt financing arrangement. Any return to shareholders will therefore be limited to the increase, if any, of our stock price.

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Business interruptions could limit our ability to operate our business and may also effect the success of our commercialization partners.

Our operations and infrastructure, and those of our partners, third party suppliers and vendors are vulnerable to damage or interruption from cyber-attacks and security breaches, human error, natural disasters, fire, flood, the effects of climate change, power loss, telecommunications failures, equipment failures, intentional acts of theft, vandalism, terrorism and similar events. We have not established a formal disaster recovery plan, and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses that occur. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

For example, Hurricanes Irma and Maria caused significant devastation and damage throughout Puerto Rico in 2017, including widespread flooding and power loss. As a result, we experienced delays in the manufacture, packaging and delivery of certain dosage strengths of NUCYNTA ER in fourth quarter of 2017 and the first quarter of 2018. We and Collegium may continue to experience further outages in the future. Any delay in the manufacture, packaging or delivery of NUCYNTA ER and NUCYNTA could adversely affect the success of our commercialization partner Collegium, which in turn could adversely affect our business, financial condition and results of operations.

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage to our business.

In the ordinary course of our business, we collect, maintain and transmit sensitive data on our computer networks and information technology systems, including our intellectual property and proprietary or confidential business information. The secure maintenance of this information is critical to our business. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack and motives (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted to target our information systems. Cyber-attacks are becoming increasingly more prevalent and much harder to detect and defend against. Our network and storage applications and those of our third party vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions.

It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information, including the information of our business partners. Cyber- attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our third party vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our business.

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ITEM 6. EXHIBITS

2.1	Agreement and Plan of Merger, dated August 10, 2018, by and between Depomed Inc., a California corporation and Assertio Therapeutics, Inc., a Delaware corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
3.1	Certificate of Merger effective August 14, 2018 at 11:59 p.m. Eastern (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
3.2	Certificate of Incorporation of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
3.3	Bylaws of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
3.4	Specimen Common Stock Certificate of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
4.1	Second Supplemental Indenture, dated August 14, 2018, by and between Assertio Therapeutics, Inc., a Delaware corporation, and the Bank of New York Melon Trust Company, N.A. as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
10.1	Waiver, Consent and Third Amendment to Note Purchase Agreement and Partial Release of Security Interest, dated August 2, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 2, 2018)
10.2	Consent to Note Purchase Agreement and Assumption Agreement dated August 14, 2018. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
10.3	Form of Indemnification Agreement of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
10.4	Form of Amended and Restated Management Continuity Agreement of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
10.5	Amended and Restated 2004 Employee Stock Purchase Plan
10.6	Second Amended and Restated 2004 Equity Incentive Plan
10.7	Amended and Restated 2014 Omnibus Incentive Plan
10.8	Form of Equity Award Documents under Amended and Restated 2014 Omnibus Incentive Plan
10.9	Form of Equity Award Documents for Inducement Grants
10.10	Settlement Agreement, dated as of August 28, 2018, by and among the Company, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc.
10.11	Amendment No. 2, to Commercialization Agreement, dated as of August 29, 2018, by and among the Company, Collegium Pharmaceutical, Inc. and Collegium NF, LLC
10.12	Amendment No. 3 to Commercialization Agreement, dated November 8, 2018, by and among Assertio Therapeutics, Inc., Collegium Pharmaceutical, Inc., and Collegium NF, LLC. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 8, 2018)
10.13	Consent, dated November 8, 2018, by and among Assertio Therapeutics, Inc., certain purchasers and Deerfield Private Design Fund III, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 8, 2018)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350*
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350*
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T

(*) Furnished herewith

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SIGNATURES

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

Date: November 8, 2018 ASSERTIO THERAPEUTICS, INC.

/s/ Arthur J. Higgins
Arthur J. Higgins
President and Chief Executive Officer

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Senior Vice President and Chief Financial Officer