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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2019**

**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**

(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

**94-3229046**

(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)

**Securities registered pursuant to Section 12(b) of the Act:**

**Title of each class:**

Common Stock, \$0.0001 par value

**Trading Symbol(s):**

ASRT

**Name of each exchange on which registered:**

The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The number of issued and outstanding shares of the registrant's Common Stock, \$0.0001 par value, as of August 5, 2019 was 64,826,248.

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**ASSERTIO THERAPEUTICS, INC.**  
**Quarterly Report on Form 10-Q**  
**For the Quarterly Period Ended June 30, 2019**

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## PART I — FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

ASSERTIO THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(in thousands)  
(Unaudited)

	June 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 68,348	\$ 110,949
Short-term investments	7,114	—
Accounts receivable, net	34,311	37,211
Inventories, net	3,005	3,396
Prepaid and other current assets	26,231	56,551
Total current assets	139,009	208,107
Property and equipment, net	13,050	13,064
Intangible assets, net	641,212	692,099
Investments	8,589	11,784
Other long-term assets	11,014	7,812
Total assets	\$ 812,874	\$ 932,866
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,188	\$ 6,138
Accrued rebates, returns and discounts	63,808	75,759
Accrued liabilities	19,648	31,361
Current portion of Senior Notes	80,000	120,000
Interest payable	9,194	11,645
Other current liabilities	2,100	1,133
Total current liabilities	176,938	246,036
Contingent consideration liability	953	1,038
Senior Notes	117,527	158,309
Convertible Notes	297,550	287,798
Other long-term liabilities	22,467	19,350
Total liabilities	615,435	712,531
Commitments and contingencies		
Shareholders' equity:		
Common stock	6	6
Additional paid-in capital	407,944	402,934
Accumulated deficit	(210,506)	(182,600)
Accumulated other comprehensive loss	(5)	(5)
Total shareholders' equity	197,439	220,335
Total liabilities and shareholders' equity	\$ 812,874	\$ 932,866

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Revenues:</b>				
Product sales, net	\$ 25,937	\$ 26,838	\$ 52,387	\$ 71,192
Commercialization agreement, net	31,003	31,179	61,859	114,979
Royalties and milestones	263	5,257	886	5,507
<b>Total revenues</b>	<b>57,203</b>	<b>63,274</b>	<b>115,132</b>	<b>191,678</b>
<b>Costs and expenses:</b>				
Cost of sales (excluding amortization of intangible assets)	2,124	2,753	4,699	14,797
Research and development expenses	1,263	2,180	3,056	3,708
Selling, general and administrative expenses	24,755	31,308	49,800	60,341
Amortization of intangible assets	25,443	25,444	50,887	50,888
Restructuring charges	—	5,814	—	14,831
<b>Total costs and expenses</b>	<b>53,585</b>	<b>67,499</b>	<b>108,442</b>	<b>144,565</b>
<b>Income (loss) from operations</b>	<b>3,618</b>	<b>(4,225)</b>	<b>6,690</b>	<b>47,113</b>
<b>Other (expense) income:</b>				
Interest expense	(14,842)	(17,010)	(31,396)	(35,078)
Other (expense) income, net	(1,240)	67	(1,849)	296
<b>Net (loss) income before income taxes</b>	<b>(12,464)</b>	<b>(21,168)</b>	<b>(26,555)</b>	<b>12,331</b>
Income taxes (expense) benefit	(1,141)	120	(1,351)	445
<b>Net (loss) income</b>	<b>\$ (13,605)</b>	<b>\$ (21,048)</b>	<b>\$ (27,906)</b>	<b>\$ 12,776</b>
Basic net (loss) income per share	\$ (0.21)	\$ (0.33)	\$ (0.43)	\$ 0.20
Diluted net (loss) income per share	\$ (0.21)	\$ (0.33)	\$ (0.43)	\$ 0.20
Shares used in computing basic net (loss) income per share	64,480	63,719	64,405	63,611
Shares used in computing diluted net (loss) income per share	64,480	63,719	64,405	64,107

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net (loss) income	\$ (13,605)	\$ (21,048)	\$ (27,906)	\$ 12,776
Unrealized (loss) gain on available-for-sale securities, net of tax	—	(1)	—	1
Comprehensive (loss) income	\$ (13,605)	\$ (21,049)	\$ (27,906)	\$ 12,777

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

**ASSERTIO THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
(in thousands)  
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Earnings (Deficit)	Accumulated Other Comprehensive Loss	Shareholders' Equity
	Shares	Amount				
Balances at December 31, 2017	63,400	6	\$ 389,015	\$ (219,508)	\$ (5)	\$ 169,508
Issuance of common stock upon exercise of options	120	—	636	—	—	636
Issuance of common stock in conjunction with vesting of restricted stock units	33	—	—	—	—	—
Stock-based compensation	—	—	2,234	—	—	2,234
Shares withheld for payment of employee's withholding tax liability	—	—	(114)	—	—	(114)
Net income	—	—	—	33,824	—	33,824
Unrealized gain on available-for-sale securities	—	—	—	—	2	2
Balances at March 31, 2018	63,553	6	\$ 391,771	\$ (185,684)	\$ (3)	\$ 206,090
Issuance of common stock upon exercise of options	108	—	667	—	—	667
Issuance of common stock under employee stock purchase plan	72	—	381	—	—	381
Issuance of common stock in conjunction with vesting of restricted stock units	169	—	—	—	—	—
Stock-based compensation	—	—	5,270	—	—	5,270
Shares withheld for payment of employee's withholding tax liability	—	—	(153)	—	—	(153)
Net (loss)	—	—	—	(21,048)	—	(21,048)
Unrealized gain on available-for-sale securities	—	—	—	—	(1)	(1)
Balances at June 30, 2018	63,902	6	\$ 397,936	\$ (206,732)	\$ (4)	\$ 191,206
Balances at December 31, 2018	64,185	6	\$ 402,934	\$ (182,600)	\$ (5)	\$ 220,335
Issuance of common stock upon exercise of options	14	—	25	—	—	25
Issuance of common stock in conjunction with vesting of restricted stock units	132	—	—	—	—	—
Stock-based compensation	—	—	2,702	—	—	2,702
Shares withheld for payment of employee's withholding tax liability	—	—	(216)	—	—	(216)
Net (loss)	—	—	—	(14,301)	—	(14,301)
Balances at March 31, 2019	64,331	6	\$ 405,445	\$ (196,901)	\$ (5)	\$ 208,545
Issuance of common stock under employee stock purchase plan	64	—	158	—	—	158
Issuance of common stock in conjunction with vesting of restricted stock units	426	—	—	—	—	—
Stock-based compensation	—	—	2,634	—	—	2,634
Shares withheld for payment of employee's withholding tax liability	—	—	(293)	—	—	(293)
Net (loss)	—	—	—	(13,605)	—	(13,605)
Balances at June 30, 2019	64,821	6	407,944	(210,506)	(5)	197,439

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

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

	Six Months Ended June 30,	
	2019	2018
<b>Operating Activities</b>		
Net (loss) income	\$ (27,906)	\$ 12,776
Adjustments for non-cash items:		
Depreciation and amortization	51,503	53,816
Accretion of debt discount and debt issuance costs	12,220	10,808
Provision for inventory obsolescence	196	218
Gain on disposal of property and equipment	6	(134)
Stock-based compensation	5,336	7,504
Change in fair value of contingent consideration	(85)	(462)
Other	3,144	39
Changes in assets and liabilities:		
Accounts receivable	2,900	30,333
Inventories	195	7,847
Prepaid and other assets	30,492	(35,740)
Accounts payable and other accrued liabilities	(14,890)	(44,322)
Accrued rebates, returns and discounts	(11,951)	(55,656)
Interest payable	(2,451)	(938)
Income taxes payable	—	(126)
Net cash provided by (used in) operating activities	<u>48,709</u>	<u>(14,037)</u>
<b>Investing Activities</b>		
Purchases of property and equipment	(621)	(772)
Proceeds from disposal of property and equipment	—	145
Proceeds from sale of other assets	—	80
Purchases of marketable securities	(7,864)	—
Maturities of marketable securities	750	1,200
Net cash (used in) provided by investing activities	<u>(7,735)</u>	<u>653</u>
<b>Financing Activities</b>		
Payment of contingent consideration liability	—	(184)
Repayment of Senior Notes	(80,000)	(57,500)
Fees for modification of Senior Notes	(3,249)	—
Proceeds from issuance of common stock	183	1,684
Shares withheld for payment of employee's withholding tax liability	(509)	(267)
Net cash (used in) financing activities	<u>(83,575)</u>	<u>(56,267)</u>
Net (decrease) in cash and cash equivalents	(42,601)	(69,651)
Cash and cash equivalents at beginning of year	110,949	126,884
Cash and cash equivalents at end of period	<u>\$ 68,348</u>	<u>\$ 57,233</u>
<b>Supplemental Disclosure of Cash Flow Information</b>		
Net cash paid for income taxes	\$ 420	\$ 166
Cash paid for interest	\$ 21,571	\$ 25,149
Capital expenditures incurred but not yet paid	\$ 287	\$ 260

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

**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 the Company markets in the United States (U.S.):

- Gralise® (gabapentin), a once daily product for the management of postherpetic neuralgia (PHN), that was launched in October 2011.
- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, that was acquired by the Company 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 was acquired by the Company in June 2012.

The Company also has the exclusive rights to market long-acting cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the U.S. Food and Drug Administration (FDA) for our collaborative partner's 505(b)(2) New Drug Application (NDA) for the novel injectable formulation of long-acting cosyntropin. The Company, together with its collaborative partner, seeks approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

The Company maintains a Commercialization Agreement with Collegium Pharmaceutical, Inc. (Collegium) pursuant to which the Company granted Collegium the right to commercialize the NUCYNTA® franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. The Company receives a royalty on all NUCYNTA revenues based on certain net sales thresholds.

***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 six months ended June 30, 2019 are not necessarily indicative of results to be expected for the entire year ending December 31, 2019 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, 2018 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 11, 2019 (the “2018 Form 10-K”). The balance sheet as of December 31, 2018 has been derived from the audited financial statements at that date, as filed in the Company’s 2018 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). All intercompany accounts and transactions have been eliminated in consolidation.

### ***Use of Estimates***

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed 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.

### ***Segment Information***

The Company maintains one operating segment and has operations solely in the United States. To date, substantially all of the Company's revenues from product sales are related to sales in the United States.

### ***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 of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

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.

### ***Revenue Recognition***

The Company adopted ASC 606, Revenue from Contracts with Customers (ASC 606) 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 the 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

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obligation, when (or as) the performance obligation is satisfied. The Company assesses the term of the contract based upon the contractual period in which the Company has enforceable rights and obligations.

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.

### ***Commercialization Agreement***

The Company derives revenue under its Commercialization Agreement with Collegium whereby the Company granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. The Company entered into the Commercialization Agreement in December 2017, which became effective in January 2018, and amended the agreement in August 2018 and again in November 2018. The Company views its performance obligations as a series of distinct goods or services that are substantially the same and that have the same pattern of transfer. Prior to the November 2018 amendment, the consideration related to the license and facilitation services was fixed and recognized ratably over the contract term. Following the November 2018 amendment, the royalty payments owed to the Company from Collegium, pursuant to the terms of the Commercialization Agreement, represent variable compensation that is subject to the sales based royalty exception for licenses of intellectual property because the License, as defined in Note 5 "Revenue", is the predominant component of this arrangement.

The Company is responsible for royalty payments to a third party related to sales of NUCYNTA. Under the terms of the Commercialization Agreement, a portion of these payments are remitted from Collegium to the third party and a portion are the responsibility of the Company. Following the November 2018 amendment, Collegium reimburses the Company for all royalties paid to the third party. As the Company is not actively commercializing NUCYNTA, such royalties 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 within Commercialization Agreement, Net on the Company's Statements of Operations.

### ***Product Sales***

The Company sells commercial products to wholesale distributors, specialty pharmacies 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 product 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, Galise, 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 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

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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).

### ***Milestones***

For arrangements that include milestones, the Company recognizes such revenue using the most likely method. As part of adopting ASC 606, the Company evaluated whether the future milestones 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. 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, adjust its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

### ***Leases***

The Company assesses contracts for lease arrangements at inception. Operating right-of-use (ROU) assets and liabilities are recognized at the lease commencement date equal to the present value of future lease payments using the implicit, if readily available, or incremental borrowing rate based on the information readily available at the commencement date. ROU assets include any lease payments as of commencement and initial direct costs but exclude any lease incentives. Lease and non-lease components are generally accounted for separately and the Company recognizes operating lease expense straight-line over the term of the lease. Operating leases are included in other long term assets, other current liabilities, and other long term liabilities in the consolidated balance sheet.

The Company has elected to keep leases with an initial term of 12 months or less off of the balance sheet. The Company will recognize the cost of those leases in the Consolidated Statements of Operations on a straight-line basis over the lease term.

### ***Stock Based Compensation***

The Company uses the Monte Carlo simulation method to determine the fair value of performance-based restricted stock units and 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 these awards on the date of grant 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 award. The Company bases the risk free interest rate on U.S. Treasury zero coupon issues with terms similar to the expected term of the award 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 valuation models. The fair value of restricted stock units equals the market value of the underlying stock on the date of grant.

As a result of adopting ASU 2016-09 *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.

### ***Recently Adopted Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. This guidance enhances comparability and transparency among organizations by requiring the recognition of right-of-use assets and liabilities on the balance sheet for both financing and operating leases greater than 12 months. The Company adopted the standard as of January 1, 2019 using the modified retrospective approach with cumulative effect. There was no adjustment to the Company's opening balance of accumulated deficit resulting from the adoption of this guidance. In addition, the Company elected the package of practical expedients, which among other things, allowed for the carryforward of the historical lease classification. The Company did not elect the hindsight practical expedient to determine the reasonably certain lease term for existing leases.

The adoption of the new standard resulted in the recognition of additional operating lease assets and lease liabilities of \$3.7 million and \$8.9 million, respectively, as of January 1, 2019. The recognition of lease assets was offset by deferred rent and tenant improvement allowances of \$5.2 million, which were recognized by the Company as of December 31, 2018. Had the Company not adopted this new lease guidance the ROU asset and liability would not have been recorded and the deferred rent and tenant improvement allowances capitalized against the ROU asset would have remained on the balance sheet in other current liabilities and other long term liabilities. The new standard did not materially affect the Company's consolidated net income nor have a notable impact on its liquidity. The standard had no impact on the Company's debt-covenant compliance under its current agreements.

### ***Recently Issued Accounting Standards***

In June 2016, the FASB issued ASU 2016-13 *Financial Instruments-Credit Losses (Topic 326)* which changes the methodology to be used to measure the credit losses for certain financial instruments and financial assets, including trade receivables. ASU 2016-13 replaces the existing incurred loss impairment model with a current expected credit 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 the new standard on the Company's condensed consolidated financial statements.

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In June 2018, the FASB issued ASU 2018-18 Collaborative Arrangements which clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The new standard should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption of ASU 2018-18 on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13 Fair Value Measurement Disclosure Framework which is part of a broader disclosure framework project by the FASB to improve the effectiveness of disclosures by more clearly communicating the information to the user. Modifications to the required disclosures are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is currently evaluating the impact on disclosures.

In August 2018, the FASB issued ASU No. 2018-15 Accounting for Cloud Computing Arrangements (Subtopic 350-40) which provides new guidance on the accounting for implementation, set-up, and other upfront costs incurred in a hosted cloud computing arrangement. Under the new guidance, entities will apply the same criteria for capitalizing implementation costs as they would for an internal-use software license arrangement. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. This ASU can be adopted prospectively to eligible costs incurred on or after the date of adoption or retrospectively. The Company does not expect the adoption of the guidance under the new standard to materially affect its financial position or results of operations.

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

Securities classified as cash and cash equivalents and short-term investments as of June 30, 2019 and December 31, 2018 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

<b>June 30, 2019</b>	<b>Amortized Cost</b>	<b>Fair Value</b>
Cash and cash equivalents		
Cash	\$ 59,986	\$ 59,986
Commercial paper	8,239	8,239
Money market funds	123	123
Total cash and cash equivalents	68,348	68,348
Short-term investments		
Commercial paper and Corporate and Government debt securities with maturities less than 1 year	\$ 7,114	\$ 7,114
Total short-term investments	\$ 7,114	\$ 7,114
Total	\$ 75,462	\$ 75,462

<b>December 31, 2018</b>	<b>Amortized Cost</b>	<b>Fair Value</b>
Cash and cash equivalents		
Cash	\$ 95,660	\$ 95,660
Commercial paper	14,028	14,028
Agency bond	1,250	1,250
Money market funds	11	11
Total cash and cash equivalents	\$ 110,949	\$ 110,949

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. 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.

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To date, the Company has not experienced material losses on any of its balances as the fair values generally approximate amortized cost. 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 shareholder's equity on the consolidated balance sheet. As of June 30, 2019 and December 31, 2018, the Company did not have any gross unrealized gains or losses. 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 Other (expense) income, net in the consolidated statement of operations.

**NOTE 3. FAIR VALUE**

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 June 30, 2019 and December 31, 2018:

*(in thousands)*

June 30, 2019	Financial Statement Classification	Level 1	Level 2	Level 3	Total
<b>Assets:</b>					
Money market	Cash and cash equivalents	\$ 123	\$ —	\$ —	\$ 123
Commercial paper	Multiple <sup>(1)</sup>	—	13,903	—	13,903
Collegium warrants	Investments	—	5,307	—	5,307
Corporate	Short-term investments	—	749	—	749
Agency bond	Short-term investments	—	701	—	701
<b>Total</b>		<b>\$ 123</b>	<b>\$ 20,660</b>	<b>\$ —</b>	<b>\$ 20,783</b>
<b>Liabilities:</b>					
Contingent consideration—Zipsor	Contingent consideration liability	\$ —	\$ —	\$ 417	\$ 417
Contingent consideration—CAMBIA	Contingent consideration liability	—	—	536	536
<b>Total</b>		<b>\$ —</b>	<b>\$ —</b>	<b>\$ 953</b>	<b>\$ 953</b>

(1) As of June 30, 2019 \$8.2M and \$5.7M of commercial paper was classified in Short-term investments and Cash and cash equivalents on the Consolidated Balance Sheets, respectively.

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(in thousands)

December 31, 2018	Financial Statement Classification	Level 1	Level 2	Level 3	Total
<b>Assets:</b>					
Money market funds	Cash and cash equivalents	\$ 11	\$ —	\$ —	\$ 11
Commercial paper	Cash and cash equivalents	—	14,028	—	14,028
Collegium warrants	Investments	—	8,784	—	8,784
Agency bond	Cash and cash equivalents	—	1,250	—	1,250
Total		<u>\$ 11</u>	<u>\$ 24,062</u>	<u>\$ —</u>	<u>\$ 24,073</u>
<b>Liabilities:</b>					
Contingent consideration—Zipsor	Contingent consideration liability	\$ —	\$ —	\$ 531	\$ 531
Contingent consideration—CAMBIA	Contingent consideration liability	—	—	507	507
Total		<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,038</u>	<u>\$ 1,038</u>

The fair value of the warrants to purchase Collegium’s common stock is calculated using the Black-Scholes option pricing model. For the three and six months ended June 30, 2019, the Company recorded a loss of \$1.8 million and \$3.5 million, respectively, in Other (expense) income, net for the change in fair value of the Collegium warrants. There were no fair adjustments related to the Collegium warrants recognized during the three and six months ended June 30, 2018.

The fair value measurement of the contingent consideration obligations arises from the Zipsor and CAMBIA 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 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 the contingent consideration obligation 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 six months ended June 30, 2019 and 2018:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Fair value, beginning of the period	\$ 1,066	\$ 1,249	\$ 1,038	\$ 1,613
Changes in fair value recorded in interest expense	29	39	57	79
Changes in fair value recorded in selling, general and administrative expenses	(142)	(299)	(142)	(541)
Royalties and milestone paid	—	(22)	—	(184)
Fair value, end of the period	<u>\$ 953</u>	<u>\$ 967</u>	<u>\$ 953</u>	<u>\$ 967</u>

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 \$250.1 million and \$231.8 million (par value \$345.0 million) as of June 30, 2019 and December 31, 2018, respectively, and represents a Level 2 valuation. The principal amount of the Senior Notes (as defined in Note 10, “Debt”), approximates their fair value as of June 30, 2019 and December 31, 2018, 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 six months ended June 30, 2019 and 2018.

**NOTE 4. 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 shares issuable in connection with stock options, restricted stock units (RSUs), performance-based restricted stock units (PSUs), the 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 the 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:

(in thousands, except for per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Basic net income (loss) per share</b>				
Net (loss) income	\$ (13,605)	\$ (21,048)	\$ (27,906)	\$ 12,776
Denominator	64,480	63,719	64,405	63,611
Basic net (loss) income per share	\$ (0.21)	\$ (0.33)	\$ (0.43)	\$ 0.20
<b>Diluted net income (loss) per share</b>				
<b>Numerator:</b>				
Net (loss) income	\$ (13,605)	\$ (21,048)	\$ (27,906)	\$ 12,776
<b>Denominator:</b>				
Denominator for basic net income (loss) per share	64,480	63,719	64,405	63,611
<b>Add effect of diluted securities:</b>				
Stock options and equivalents and convertible debt	—	—	—	496
Denominator for diluted net income (loss) per share	64,480	63,719	64,405	64,107
Diluted net (loss) income per share	\$ (0.21)	\$ (0.33)	\$ (0.43)	\$ 0.20

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)	June 30,	June 30,
	2019	2018
Convertible debt	17,931	17,931
Stock options and equivalents	6,568	3,902
Total potentially dilutive common shares	24,499	21,833

**NOTE 5. REVENUE*****Disaggregated Revenue***

The following table summarizes revenue from contracts with customers for the three and six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product sales, net				
Gralise	\$ 17,800	\$ 13,815	\$ 31,078	\$ 28,642
CAMBIA	6,758	8,089	15,566	14,505
Zipsor	1,524	3,988	5,755	8,734
Total neurology product sales, net	26,082	25,892	52,399	51,881
NUCYNTA products	(163)	626	(101)	18,771
Lazanda	18	320	89	540
Total product sales, net	25,937	26,838	52,387	71,192
Commercialization agreement:				
Commercialization rights and facilitation services, net	31,003	31,179	61,859	59,274
Revenue from transfer of inventory	—	—	—	55,705
Royalties and milestone revenue	263	5,257	886	5,507
Total revenues	\$ 57,203	\$ 63,274	\$ 115,132	\$ 191,678

NUCYNTA product sales for the six months ended June 30, 2018 reflect our sales of NUCYNTA between January 1 and January 8, 2018. 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. During the three and six months ended June 30, 2019, the Company recognized sales reserve estimate adjustments related to sales recognized for NUCYNTA and Lazanda in prior periods.

***Original Commercialization Agreement with Collegium***

In December 2017, the Company, Collegium and Collegium NE, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium (Newco), entered into a Commercialization Agreement (Commercialization Agreement), pursuant to which the Company granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. The Company also agreed to provide services to Collegium, including to arrange for the supply of NUCYNTA products by the Company's existing contract manufacturing organizations (CMOs) (the Facilitation Services). The Company identified the following three promised goods and services under the Commercialization Agreement: (1) the license to commercialize the NUCYNTA pain products (License), (2) services to arrange for supplies of NUCYNTA pain products using the Company's existing contract manufacturing contracts with third parties (Facilitation Services); and (3) the transfer of control of all NUCYNTA finished goods held at closing (Inventory Transfer).

The Inventory Transfer was deemed to be a distinct performance obligation which was completed during the first quarter of 2018. The Company concluded that the License and the Facilitation Services are not distinct from one another as the Commercialization Agreement does not grant to Collegium a license to manufacture NUCYNTA. The Company (i) exclusively controls the intellectual property underlying the NUCYNTA products for the United States market, (ii) retains responsibility for facilitating NUCYNTA product supply through its CMOs, and (iii) exclusively maintains all CMO contractual relationships. As a result, Collegium's right to commercialize NUCYNTA is inherently dependent upon the Facilitation Services. Because (i) Collegium is contractually required to use the Facilitation Services to arrange for product supply and (ii) tapentadol, the active pharmaceutical ingredient used in NUCYNTA, is a Schedule II controlled substance for which manufacturing arrangements are not easily transferred or bypassed, there is strong interdependency between the License and the Facilitation Services. These Facilitation Services are administrative in nature but necessary for the commercialization right to have utility to Collegium.

In January 2018, the Company determined the total fixed elements of the transaction price to be \$553.2 million, which consisted of \$537.0 million in total annual minimum royalty payments for years 2018 through 2021, \$10.0 million upfront fee, and a \$6.2 million payment for NUCYNTA finished goods inventory. The Company determined that the duration of the Commercialization Agreement began on the effective date of January 9, 2018 and lasts through December 31, 2021, including the minimum royalty period and the period in which Collegium would incur a \$25.0 million termination penalty on terminating the Commercialization Agreement. Beginning January 1, 2022 and for each year of the Commercialization Agreement thereafter, royalties are: (i) 58% of net sales of NUCYNTA up to \$233.0 million, payable quarterly within 45 days of the end of each calendar quarter, plus (ii) 25% of annual net sales of NUCYNTA between \$233.0 million and \$258.0 million, plus (iii) 17.5% of annual net sales of NUCYNTA above \$258.0 million. Payments described in clauses (ii) and (iii) hereof will be paid annually within 60 days of the end of the calendar year.

The portion of the transaction price allocated to the Inventory Transfer was \$55.7 million and was recognized on the closing date as the control of such inventory was transferred to Collegium. The portion of the transaction price allocated to the License and Facilitation Services, as a combined performance obligation, was \$497.5 million and would be recognized ratably through December 31, 2021.

In addition, Collegium assumed responsibility for a portion of the royalties owed by the Company to a third party on sales of NUCYNTA. The royalties owed by Collegium to the third party are 14% of sales with the Company ensuring a minimum royalty of \$34.0 million per year on net sales of NUCYNTA greater than \$180.0 million. The Company was obligated to cover any shortfall between the minimum royalty amount of \$34.0 million and the amounts paid to the third party by Collegium for each of the years ended December 31, 2018 through 2021, as a result of which the Company could have been obligated to pay up to \$8.8 million per year for each of the years ended December 31, 2018 through 2021.

#### ***Amended Commercialization Agreement with Collegium***

On November 8, 2018, the Company, Collegium and Newco entered into a third amendment to the Commercialization Agreement (Commercialization Amendment). Pursuant to the Commercialization Amendment, the royalties payable by Collegium to the Company in connection with Collegium's commercialization of NUCYNTA were 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 \$180.0 million, plus (ii) 14% of annual net sales of NUCYNTA between \$180.0 million and up to \$210.0 million, plus (iii) 58% of annual net sales of NUCYNTA between \$210.0 million and \$233.0 million, plus (iv) 20% of annual net sales of NUCYNTA between \$233.0 million and up to \$258.0 million, plus (v) 15% of annual net sales of NUCYNTA above \$258.0 million. The Commercialization Amendment does not change the royalties that 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.

In addition, the Commercialization Amendment provides that Collegium shall reimburse the Company for the amount of any minimum annual royalties paid by the Company to the third party on net sales of NUCYNTA during the first four years of the Commercialization Agreement beginning in 2019. The Commercialization Amendment also provides for Collegium to share certain costs related to the License. The reimbursement and the cost sharing are considered variable consideration. The Commercialization Amendment is being accounted for prospectively.

In connection with the Commercialization 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 (Warrant). The Warrant is exercisable for a period of four years and contains customary terms, including with regard to net exercise. The Warrant was valued at \$8.8 million as of the date of the Commercialization Amendment and is considered to be a component of the fixed consideration associated with the Commercialization Agreement. This Warrant is included in Investments on the Company's Condensed Consolidated Balance Sheet, however, as it is non-cash it does not impact investing cash flows.

In November 2018, the Company determined the total fixed elements of the transaction price of the Commercialization Agreement to be \$157.0 million, which consisted of \$132.0 million in total annual minimum royalty payments for 2018, the \$10.0 million upfront fee, the \$6.2 million payment for NUCYNTA finished goods inventory and the \$8.8 million attributed to the Warrant. There were no new performance obligations following the modification of the Commercialization Agreement and at the time of the modification, the remaining periods in the series of services related to the single combined performance obligation to deliver the license and provide facilitation services are distinct from those prior to the modification. As a result, the modification was accounted for as a termination of the old arrangement and the entering into of a new agreement, in accordance with the guidance of ASC 606.

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Pursuant to the Commercialization 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 \$5.0 million termination fee to the Company concurrent with the delivery of such notice. The Company determined that the \$5.0 million termination fee is not substantive and therefore the duration of the Commercialization Agreement is unchanged by the Commercialization Amendment and lasts through December 31, 2021, which is consistent with the contractual period in which the Company and Collegium have enforceable rights and obligations.

The Commercialization 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 \$180.0 million, 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 \$170.0 million.

#### **Revenue from the Commercialization Agreement**

For the three and six months ended June 30, 2019, the Company recognized net revenue from the Commercialization Agreement of \$31.0 million and \$61.9 million, respectively. This included variable royalty revenue for the three and six months ended June 30, 2019 of \$31.9 million and \$64.0 million, respectively. Variable royalty revenue became effective for sales beginning January 1, 2019 as recognition of such royalties are constrained by the sales-based royalty exception related to intellectual property. Other components of net revenue from the Commercialization Agreement include the amortization of revenue from contract liabilities arising from the warrants and prepayments received, amortization of the contract asset, and variable consideration revenue for reimbursement of certain shared costs. In addition, during the three and six months ended June 30, 2019, the Company recognized \$1.0 million and \$2.1 million of net expense related to the third-party royalties which have been paid by Collegium on behalf of Assertio. It is the Company's expectation that, in accordance with the amended Commercialization Agreement, Collegium will pay the full royalty owed to the third-party in 2019, 2020 and 2021 and that such amounts, over the course of the calendar year, will have no net impact to the Company.

For the three and six months ended June 30, 2018, the Company recognized royalty revenue from the Commercialization Agreement of \$31.2 million and \$59.3 million, respectively. The Company also recognized \$55.7 million of revenue related to the transfer of inventory upon closing in January 2018.

#### **Contract Assets**

The following table presents changes in the Company's contract assets as of June 30, 2019 (in thousands):

	<b>Balance as of</b>			<b>Balance as of</b>
	<b>December 31, 2018</b>	<b>Additions</b>	<b>Deductions</b>	<b>June 30, 2019</b>
Contract assets:				
Contract asset - CAMBIA Canada	\$ —	\$ 300	\$ —	\$ 300
Contract asset - Collegium, net	2,416	375	(672)	2,119
	<u>\$ 2,416</u>	<u>\$ 675</u>	<u>\$ (672)</u>	<u>\$ 2,419</u>

The Collegium contract asset, net represents the conditional right to consideration for completed performance under the Commercialization Agreement arising 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 and the \$8.8 million of warrants received. Portion of the contract asset are reclassified to accounts receivable when the right to consideration becomes unconditional. As of June 30, 2019, \$0.8 million and \$1.3 million of the contract asset has been recorded within "Prepaid and other current assets" and "Other long-term assets," respectively.

**Collaboration and License Agreements**

*Ironwood Pharmaceuticals, Inc.* The future contingent milestones under the Ironwood Agreement are considered variable consideration and are estimated using the most likely method. As part of adopting 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.

*Slán Medicinal Holdings Limited* In November 2017, the Company entered into definitive agreements (Slán Agreements) with Slán Medicinal Holdings Limited and certain of its affiliates (Slán) pursuant to which the Company acquired Slán's rights to market long-acting cosyntropin in the U.S. and Canada. As outlined in the Slán Agreements, each party will support the development, including clinical development, of the licensed product and efforts to obtain regulatory approval of the initial NDA. The Slán Agreements also detail commercialization activities which are included in the commercialization plan. Subsequent to approval of the initial NDA, Assertio and Slán will share in the net sales of long-acting cosyntropin for a 10-year period (after which time the product will revert back to Slán). The Company has committed to invest \$15.0 million in the collaboration with Slán for the commercialization efforts of long-acting cosyntropin. As of December 31, 2018 and June 30, 2019 the Company had \$4.6 million and \$5.2 million, respectively, of development expenses reimbursable by Slán and recognized within Prepaid and Other Assets on the Company's Condensed Consolidated Balance Sheet.

**NOTE 6. STOCK-BASED COMPENSATION**

The following table presents stock-based compensation expense recognized for stock options, stock awards, RSUs, PSUs and the Company's ESPP in the Company's Condensed Consolidated Statements of Operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of sales	\$ 50	\$ 16	\$ 50	\$ 30
Research and development expense	76	14	349	67
Selling, general and administrative expense	2,508	2,940	4,937	4,849
Restructuring	—	2,300	—	2,558
Total	\$ 2,634	\$ 5,270	\$ 5,336	\$ 7,504

At June 30, 2019, the Company had \$1.8 million of total unrecognized compensation expense related to stock option grants that will be recognized over an average vesting period of 2.17 years and \$21.0 million of total unrecognized compensation expense related to RSUs and PSUs that will be recognized over an average vesting period of 2.54 years.

During the six months ended June 30, 2019 the Company granted 2.2 million RSUs at an average fair market value of \$4.36 per share and 0.6 million PSUs at an average fair market value of \$6.87 per share. The fair value of restricted stock units is determined using the closing stock price on the date of grant and the fair value of the performance RSUs is determined using a Monte Carlo simulation method.

**NOTE 7. 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):

	June 30, 2019	December 31, 2018
Raw materials	\$ 1,092	\$ 1,376
Work-in-process	788	732
Finished goods	1,125	1,288
Total	<u>\$ 3,005</u>	<u>\$ 3,396</u>

**NOTE 8. ACCOUNTS RECEIVABLES, NET**

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

	June 30, 2019	December 31, 2018
Receivables related to product sales, net	\$ 32,713	\$ 23,078
Receivables from Collegium	1,477	14,011
Other	121	122
Total accounts receivable, net	<u>\$ 34,311</u>	<u>\$ 37,211</u>

**NOTE 9. ACCRUED LIABILITIES**

Accrued liabilities consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Accrued compensation	\$ 4,377	\$ 5,475
Accrued royalties	2,765	2,773
Accrued restructuring and one-time termination costs	478	1,578
Other accrued liabilities	12,028	21,535
Total accrued liabilities	<u>\$ 19,648</u>	<u>\$ 31,361</u>

**NOTE 10. 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 (Note Purchase Agreement), 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 June 30, 2019 and 2018 was 12.35% and 12.07%, 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 \$10.0 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 \$202.5 million of Senior Notes can be prepaid, at the Company's option or following a Major Transaction or asset disposition.

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.

In January 2019, the Company entered into a Fourth Amendment to Note Purchase Agreement (the Note Amendment) with respect to the Note Purchase Agreement, dated as of March 12, 2015, among the Company, the other credit parties party thereto, the purchasers party thereto and Deerfield. Pursuant to the Note Amendment, the minimum EBITDA covenant was replaced with a senior secured debt leverage ratio covenant and a minimum net sales covenant, the prepayment premium was adjusted to be 3% of the principal amount of notes prepaid on or prior to April 14, 2020 and 1% of the principal amount of notes prepaid thereafter, flexibility to sell certain royalty assets and/or modify the terms thereof was added, certain definitions were amended and certain other amendments were made. The Company paid a \$3.2 million upfront non-refundable amendment fee to the Purchasers in the first quarter of 2019 which was capitalized and is being amortized over the remaining term of the Senior Notes using the effective interest method.

The principal amount of the Senior Notes is repayable as of June 30, 2019 is as follows (in thousands):

2019 (remainder)	\$	40,000
2020		80,000
2021		82,500
Total	\$	<u>202,500</u>

The principal payment of \$20.0 million due in July 2019 was paid by the Company in July 2019. The Company is scheduled to make the Senior Notes principal payments of \$80.0 million prior to June 30, 2020 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 June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Principal amount of the Senior Notes	\$ 202,500	\$ 282,500
Unamortized debt discount balance	(1,698)	(2,541)
Unamortized debt issuance costs	(3,275)	(1,650)
Total Senior Notes	<u>\$ 197,527</u>	<u>\$ 278,309</u>

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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 six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Contractual interest expense	\$ 6,602	\$ 9,425	\$ 14,808	\$ 19,866
Amortization of debt discount and debt issuance costs	1,111	853	2,468	1,861
Total interest expense Senior Notes	<u>\$ 7,713</u>	<u>\$ 10,278</u>	<u>\$ 17,276</u>	<u>\$ 21,727</u>

**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 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.

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 six months period ended June 30, 2019. As a result, the Convertible Notes are not convertible as of June 30, 2019.

The following is a summary of the liability component of the Convertible Notes as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Principal amount of the Convertible Notes	\$ 345,000	\$ 345,000
Unamortized discount of the liability component	(45,273)	(54,521)
Unamortized debt issuance costs	(2,177)	(2,681)
Total Convertible Notes	<u>\$ 297,550</u>	<u>\$ 287,798</u>

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 June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stated coupon interest	\$ 2,156	\$ 2,156	\$ 4,312	\$ 4,312
Amortization of debt discount and debt issuance costs	4,945	4,537	9,752	8,947
Total interest expense Convertible Notes	<u>\$ 7,101</u>	<u>\$ 6,693</u>	<u>\$ 14,064</u>	<u>\$ 13,259</u>

**NOTE 11. INCOME TAXES**

As of June 30, 2019, 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 the Company's net deferred assets beginning in the fourth quarter of 2016. The Company continued to provide a full valuation allowance against the Company's 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.

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In the six months ended June 30, 2019, the Company recorded an expense from income taxes of approximately \$1.4 million that represents an effective tax rate of (5.2)%. The difference between the income tax expense of \$1.4 million and the tax at the statutory rate of 21.0% on current year operations is principally due to the change in valuation allowance. For the six months ended June 30, 2018, the difference between the income tax benefit and the federal statutory rate of 21%, 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 2017 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 June 30, 2019 the Company had approximately \$1.7 million of accrued interest and penalties associated with unrecognized tax benefits.

**NOTE 12. LEASES**

The Company has non-cancelable operating leases for its office and laboratory facilities, automobiles used by its sales force, and certain operating leases for office equipment.

The Company relocated its corporate headquarters from Newark, California to Lake Forest, Illinois in 2018 and subsequently entered into two subleases which, together, account for the entirety of the Newark facility. Each sublease contains abated rent periods resulting in reduced operating lease cash flows through May 2019. Operating lease costs and sublease income related to the Newark facility are accounted for in Other (expense) income, net in the Condensed Consolidated Statement of Operations. The Company has the right to renew the term of the Lake Forest 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.

Lease expense during the period included the following:

(in thousands)	Financial Statement Classification	Three months ended	Six months ended
		June 30, 2019	June 30, 2019
Operating lease cost	Selling, general and administrative expenses	\$ 178	\$ 365
Operating lease cost	Other (expense) income, net	147	295
Total lease cost		\$ 325	\$ 660
Sublease Income	Other (expense) income, net	\$ 361	\$ 723

Supplemental cash flow and other information related to leases were as follows:

(in thousands)	Three months ended	Six months ended
	June 30, 2019	June 30, 2019
Cash paid for amounts included in measurement of liabilities:		
Operating cash flows from operating leases	\$ 617	\$ 1,199

Supplemental balance sheet information related to leases consisted of the following:

(in thousands)	Financial Statement Classification	June 30, 2019
Assets		
Operating lease right-of-use assets	Other long-term assets	\$ 3,226
Liabilities		
Current operating lease liabilities	Other current liabilities	\$ 2,102
Noncurrent operating lease liabilities	Other long term liabilities	5,860
Total lease liabilities		\$ 7,962

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Maturity of lease liabilities as of June 30, 2019 were as follows:

(in thousands)	Operating Leases
2019 (remainder)	\$ 1,253
2020	2,438
2021	2,325
2022	2,188
2023	632
Thereafter	—
Total lease payments	\$ 8,836
Less: Interest	874
Present value of lease liabilities	\$ 7,962

Lease term and discount rate consisted of the following:

	June 30, 2019
Weighted-average remaining lease term (years):	
Operating leases	3.6
Weighted-average discount rate:	
Operating leases	6.0%

Future minimum lease payments under the Company's non-cancelable operating leases as of December 31, 2018 were as follows:

(in thousands)	Lease Payments
2019	\$ 2,624
2020	2,526
2021	2,322
2022	2,188
2023	632
Thereafter	—
Total	\$ 10,292

### NOTE 13. COMMITMENTS AND CONTINGENCIES

#### *Purchase and Other Commitments*

As of June 30, 2019 and December 31, 2018, the Company had \$3.5 million and \$6.0 million, respectively, of non-cancelable purchase orders related to consulting services. The Company also committed to support the commercialization efforts of long-acting cosyntropin, see Note 5, "Revenue -- Collaboration and License Agreements", for further discussion. Refer to Note 12, "Leases", for the Company's non-cancelable office and laboratory leases, operating leases for vehicles used by our sales force and office equipment leases.

**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 (the District Court) 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 District Court 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 District Court 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 District Court 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 District Court 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 District Court 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 District Court issued its final decision. The District Court found that the '593 Patent, '364 Patent, and '130 Patent 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 District 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 earlier 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 District Court's finding that Roxane and Actavis will not infringe the claims of the '130 Patent. The appeals were consolidated at the United States Court of Appeals for the Federal Circuit (the Federal Circuit). Briefing concluded in March 2018 and oral arguments occurred on September 4, 2018. In March 2019, the Federal Circuit affirmed the decision of the District Court in all respects. On April 29, 2019, Alkem filed a petition for panel rehearing and rehearing en banc with the Federal Circuit, which was denied on May 31, 2019.

### ***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 alleged 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 Final Written Decisions of the Patent Trial and Appeal Board (PTAB) 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 paid the Company an additional \$32 million on January 30, 2019; (ii) each party covenanted not to 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 and Related Matters***

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 (the District Court). The action (*Huang v. Depomed et al.*, No. 3:17-cv-4830-JST, N.D. Cal.) 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 took place on December 13, 2018. On March 18, 2019, the District Court granted the Company's motion to dismiss the plaintiffs' amended complaint. The dismissal was without prejudice, and the plaintiffs filed a second amended complaint on May 2, 2019. The second amended complaint 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 second amended complaint on June 17, 2019. The lead plaintiff filed an opposition to the motion on August 1, 2019. The Company believes that the action is without merit and intends to contest it vigorously.

In addition, five shareholder derivative actions were filed on behalf of the Company against its officers and directors for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of the federal securities laws. The claims arise out of the same factual allegations as the class action. The first derivative action was filed in the Superior Court of California, Alameda County on September 29, 2017 (*Singh v. Higgins et al.*, RG17877280). The second and third actions were filed in the Northern District of California on November 10, 2017 (*Solak v. Higgins et al.*, No. 3:17-cv-6546-JST) and November 15, 2017 (*Ross v. Fogarty et al.*, No. 3:17-cv-6592-JST). The fourth action was filed in the District of Delaware on December 21, 2018 (*Lutz v. Higgins et al.*, No. 18-2044-CFC). The fifth

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derivative action was filed in the Superior Court of California, Alameda County on January 28, 2019 (*Youse v. Higgins et al*, No. HG19004409). On December 7, 2017, the plaintiffs in *Solak v. Higgins, et al.* voluntarily dismissed the first federal derivative action. The *Ross, Singh, and Lutz* actions were stayed on January 18, 2018, January 23, 2018, and January 11, 2019, respectively, pending the resolution of the motion to dismiss in the securities class action. On May 28, 2019, during a brief lift of the stay in the *Singh* and *Youse* actions while the parties' motion to consolidate was pending, after having been ordered to respond to the *Singh* and *Youse* complaints, the Company did so by filing demurrers. On July 12, 2019, the *Singh* and *Youse* actions were consolidated, and the consolidated matter was stayed pending the resolution of the motion to dismiss in the federal class action. The plaintiffs have indicated that they intend to file an amended consolidated complaint. The Company believes that these actions are without merit and intends to contest them vigorously.

### ***Opioid-Related Request 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. In March 2017, the Company received a letter from Senator Claire McCaskill (D-MO), the then-Ranking Member on the U.S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information from the Company regarding its historical 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 its historical promotion and sales of Lazanda, NUCYNTA, and NUCYNTA ER from various State Attorneys General seeking documents and information regarding the Company's historical 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 its historical sales and marketing of Lazanda. The CDI subpoena also seeks information on Gralise, a non-opioid product in the Company's portfolio. The Company has received subpoenas from the U.S. Department of Justice (DOJ) seeking documents and information regarding its historical 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 focused on third parties, including health care practitioners. The Company is cooperating with the foregoing governmental investigations and inquiries.

### ***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 2,000 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 a subset of the lawsuits that have been transferred to the MDL Court. The Company is also involved in other federal lawsuits that have not yet been transferred to the MDL Court pending a determination of whether those lawsuits should proceed in state court. Plaintiffs may file additional lawsuits in which the Company may be named. Plaintiffs in the pending federal cases involving the Company include individuals, 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, gross negligence, deceptive trade practices, and products liability claims (defective design/failure to warn). In these cases, plaintiffs seek a variety of forms of relief, including actual damages to compensate for alleged personal injuries and for alleged past and future costs such as to provide care and services to persons with opioid-related addiction or related conditions, injunctive relief, including 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 hundreds of 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 a subset of those cases, including cases in Arizona, Delaware, Missouri, Pennsylvania, South Carolina, Texas, Utah, and West Virginia. Plaintiffs may file additional lawsuits in which the Company may be named. In the pending cases, plaintiffs are asserting state common law and statutory claims against the defendants similar in nature to

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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

**Insurance Litigation**

On January 15, 2019, the Company was named as a defendant in a declaratory judgment action filed by Navigators Specialty Insurance Company (Navigators) in the United States District Court for the Northern District of California (Case No. 3:19-cv-255). Navigators is the Company's primary product liability insurer. Navigators is seeking declaratory judgment that opioid litigation claims noticed by the Company (as further described above under "Multidistrict Opioid Litigation" and "State Opioid Litigation") are not covered by the Company's policies with Navigators. The Company filed a response to the complaint on February 28, 2019. Navigators filed an answer on April 11, 2019. This litigation is ongoing.

**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.

The Company may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of its 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 14. INTANGIBLE ASSETS**

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

	June 30, 2019			December 31, 2018			
	Remaining Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Product rights							
NUCYNTA	6.5	\$ 1,019,978	\$ (408,041)	\$ 611,937	\$ 1,019,978	\$ (360,891)	\$ 659,087
CAMBIA	4.5	51,360	(28,459)	22,901	51,360	(25,891)	25,469
Zipsor	2.8	27,250	(20,876)	6,374	27,250	(19,707)	7,543
Total		\$ 1,098,588	\$ (457,376)	\$ 641,212	\$ 1,098,588	\$ (406,489)	\$ 692,099

Based on finite-lived intangible assets recorded as of June 30, 2019, 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
2019 (remainder)	\$ 50,887
2020	101,774
2021	101,774
2022	99,969
Thereafter	286,808
Total	\$ 641,212

**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 restructuring plan was substantially complete as of December 31, 2018 and therefore no charges were incurred in the three and six months ended June 30, 2019.

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Employee compensation costs	\$ —	\$ 5,814	\$ —	\$ 14,593
Other exit costs	—	—	—	238
Total restructuring costs	\$ —	\$ 5,814	\$ —	\$ 14,831

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

	Employee compensation costs
Balance at December 31, 2018	\$ 1,578
Cash paid	(758)
Balance at March 31, 2019	\$ 820
Cash paid	(342)
Balance at June 30, 2019	\$ 478

As of June 30, 2019, the full \$0.5 million accrued restructuring liability balance was classified as a current liability in the Condensed Consolidated Balance Sheet.

## NOTE 16. SUBSEQUENT EVENTS

On August 9, 2019, the Company announced it has entered into separate, privately negotiated exchange agreements (the Exchange Agreements) with a limited number of holders of the Company's Convertible Notes. Pursuant to the Exchange Agreements, the Company will exchange approximately \$200 million aggregate principal amount of the Convertible Notes for a combination of (a) its new \$120 million aggregate principal amount of 5.00% Convertible Senior Notes due August 15, 2024 (the New Convertible Notes), (b) an aggregate cash payment of approximately \$30 million, and (c) an aggregate of approximately 15.8 million shares of the Company's common stock. The Exchange Agreements are subject to customary closing conditions. The shares of the Company's common stock and the New Convertible Notes will be issued in private placements exempt from registration in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended. The Company will not receive any cash proceeds from the issuance of the New Convertible Notes or the shares of its common stock.

The Company also entered into a Fifth Amendment to the Note Purchase Agreement (the Amendment) with respect to the Senior Notes to facilitate the Exchange Agreements. Pursuant to the Amendment, the Company may use up to \$30 million to make certain investments or payments, including in connection with the exchange described above. The Amendment also modifies certain other provisions of the Note Purchase Agreement and includes a \$4.4 million exit fee due upon the earlier of the maturity date or date of full repayment of the Senior Notes.

## 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 and product candidate, long-acting cosyntropin;
- the success of 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, our ability to restructure or refinance 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 timing and the results of our and our collaborative partners' research and development efforts including clinical studies relating to our and our collaborative partners' product candidates, including long-acting cosyntropin;
- approval of regulatory filings, including filings for the novel injectable formulation of long-acting cosyntropin;
- 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, our opioid-related litigation brought by state and local governmental entities and private parties, and our insurance litigation, and the costs and expenses associated therewith;
- the regulatory strategy for long-acting cosyntropin and both 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.

## COMPANY OVERVIEW

We are 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 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.

We also have the exclusive rights to market long-acting cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the U.S. Food and Drug Administration (FDA) for our collaborative partner's 505(b)(2) New Drug Application (NDA) for the novel injectable formulation of long-acting cosyntropin. We, together with our collaborative partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

We maintain a Commercialization Agreement with Collegium pursuant to which we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We receive a royalty on all NUCYNTA revenues based on certain net sales thresholds.

### Strategy

Our business 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. 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.

## OUR BUSINESS OPERATIONS

As of June 30, 2019, our revenues were generated primarily from the commercialized products set forth below.

### *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 FDA approval in January 2011. Gralise product sales were \$17.8 million and \$13.8 million for the three months ended June 30, 2019 and 2018, respectively. Gralise product sales were \$31.1 million and \$28.6 million for the six months ended June 30, 2019 and 2018, 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. (Nautilus). We began shipping and recognizing product sales on CAMBIA in December 2013. We began shipping and recognizing product sales on CAMBIA in December 2013. CAMBIA product sales were \$6.8 million and \$8.1 million for the three months ended June 30, 2019 and 2018, respectively. CAMBIA product sales were \$15.6 million and \$14.5 million for the six months ended June 30, 2019 and 2018, 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. (Xanodyne). We began shipping and recognizing product sales on Zipsor in June 2012. Zipsor product sales were \$1.5 million and \$4.0 million for the three months ended June 30, 2019 and 2018, respectively. Zipsor product sales were \$5.8 million and \$8.7 million for the six months ended June 30, 2019 and 2018, respectively.

***NUCYNTA ER (Tapentadol Extended Release Tablets) and NUCYNTA IR (NUCYNTA) (Tapentadol)***

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 diabetic peripheral neuropathy (DPN) in adults, and for which alternate treatment options are inadequate. 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 ER and NUCYNTA from Janssen Pharmaceuticals, Inc. (Janssen Pharma) and began shipping and recognizing product sales on NUCYNTA ER and NUCYNTA in April 2015. We began commercial promotion of NUCYNTA ER and NUCYNTA in June 2015.

In December 2017, we entered into a Commercialization Agreement with Collegium, which we amended in November 2018. Pursuant to the Commercialization Agreement, we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We 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. Beginning in 2019, we will receive royalties based on certain annual NUCYNTA net sales thresholds for future years. Both we and Collegium may terminate the Commercialization Agreement under certain circumstances; however, 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. See “Item 1. Financial Statements and Supplementary Data - Note 5. Revenue” for additional information regarding the terms of the Commercialization Agreement.

***Product Candidate***

*Long-Acting Cosyntropin.* 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 long-acting cosyntropin (synthetic ACTH) in the U.S. and Canada. In February 2019, notification of acceptance for filing was received from the FDA for our collaborative partner’s 505(b)(2) NDA for the novel injectable formulation of long-acting cosyntropin. We, together with our collaborative partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

***Collaboration and License Agreement with Ironwood Pharmaceuticals, Inc. (Ironwood)***

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 second quarter of 2018, we received 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. There was no revenue recognized related to the Ironwood Agreement during the six months ended June 30, 2019 and 2018.

***PDL BioPharma, Inc. (PDL) Royalty Purchase and Sale Agreement***

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-

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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 was entitled to receive all payments due under such license agreements until PDL received \$481.0 million, after which all net payments received were to be shared evenly between us and PDL. In August 2018, we amended the Royalty Purchase Agreement and sold our remaining interest in such payments to PDL for \$20.0 million.

### **Segment Information**

We maintain one operating segment and have operations solely in the United States. To date, substantially all of our revenues from product sales are related to sales in the United States.

### **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 us 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 representatives 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 since we filed our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 11, 2019 (the 2018 Form 10-K). The description of our critical accounting policies is incorporated herein by reference to our 2018 Form 10-K.

### **RESULTS OF OPERATIONS**

*Three and Six Months Ended June 30, 2019 and 2018.*

#### **Revenue**

Total revenues by products are summarized in the following table:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product sales, net				
Gralise	\$ 17,800	\$ 13,815	\$ 31,078	\$ 28,642
CAMBIA	6,758	8,089	15,566	14,505
Zipsor	1,524	3,988	5,755	8,734
Total neurology product sales, net	26,082	25,892	52,399	51,881
NUCYNTA products <sup>(1)</sup>	(163)	626	(101)	18,771
Lazanda <sup>(2)</sup>	18	320	89	540
Total product sales, net	25,937	26,838	52,387	71,192
Commercialization agreement:				
Commercialization rights and facilitation services, net	31,003	31,179	61,859	59,274
Revenue from transfer of inventory	—	—	—	55,705
Royalties and milestone revenue	263	5,257	886	5,507
Total revenues	\$ 57,203	\$ 63,274	\$ 115,132	\$ 191,678

- (1) NUCYNTA product sales for the six months ended June 30, 2018 reflect our sales of NUCYNTA between January 1 and January 8, 2018. 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. During the three and six months ended June 30, 2019, we recognized sales reserve estimate adjustments related to sales recognized for NUCYNTA and Lazanda in prior periods.
- (2) We divested Lazanda in November 2017. Product sales for the three and six months ended June 30, 2019 and 2018 relate to sales reserve estimate adjustments.

**Product Sales**

Gralise net product sales for the three and six months ended June 30, 2019 increased by \$4.0 million and \$2.4 million, respectively, as compared to the same periods in 2018, primarily due to favorable gross to net reflecting payor mix.

CAMBIA net product sales for the three months ended June 30, 2019 decreased by \$1.3 million as compared to the same period in 2018, primarily due to unfavorable gross to net reflecting payor mix. Net product sales for the six months ended June 30, 2019 increased by \$1.1 million as compared to the same period in 2018, primarily due to increased volume.

Zipsor net product sales for the three and six months ended June 30, 2019 decreased by \$2.5 million and \$3.0 million, respectively, as compared to the same periods in 2018, primarily due to the impact of short-dated product sales returns.

We ceased recording revenues and related costs associated with Lazanda after we divested the product to Slán in November 2017. Product sales for the three and six months ended June 30, 2019 and 2018 reflect adjustments made for previously recorded sales reserve estimates.

**Commercialization Agreement Revenue**

We recognized revenue as a result of the Commercialization Agreement for the three and six months ended June 30, 2019 and 2018 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Royalty revenue	\$ 31,864	\$ 31,179	\$ 63,962	\$ 59,274
Contract liability amortization	697	—	1,385	—
Contract asset amortization	(897)	—	(1,783)	—
Third-party royalty, net	(1,036)	—	(2,080)	—
Expense reimbursement	375	—	375	—
Inventory transfer	—	—	—	55,705
Total commercialization revenue	\$ 31,003	\$ 31,179	\$ 61,859	\$ 114,979

For the three and six months ended June 30, 2019, we recognized variable royalty revenue from the Commercialization Agreement of \$31.9 million and \$64.0 million, respectively, which became effective for sales beginning January 1, 2019 as recognition of such royalties are constrained by the sales-based royalty exception related to intellectual property. Other components of revenue recognized by us from the Commercialization Agreement include the amortization of revenue from the contract liabilities arising from the warrants and prepayments received, amortization of the contract asset, and variable consideration revenue for reimbursement of certain shared costs. In addition, during the three and six months ended June 30, 2019, we recognized \$1.0 million and \$2.1 million of net expense related to the third-party royalties which have been paid by Collegium on behalf of Assertio. It is our expectation that, in accordance with the amended Commercialization Agreement, Collegium will pay the full royalty owed to the third-party in 2019, 2020 and 2021 and that such amounts, over the course of the calendar year, will have no net impact to us.

For the three and six months ended June 30, 2018, we recognized royalty revenue from the Commercialization Agreement of \$31.2 million and \$59.3 million, respectively. We also recognized \$55.7 million related to the transfer of inventory upon closing in January 2018.

### **Royalties**

During the three and six months ended June 30, 2019, we recognized \$0.3 million and \$0.9 million, respectively, of revenue related to CMBIA in Canada. During the three and six months ended June 30, 2018, we recognized \$0.3 million and \$0.5 million, respectively, of revenue related to CMBIA in Canada. The revenue recognized in 2019 also included a \$0.3 million one-time amendment fee to support the continued collaboration with our partner in Canada following their acquisition.

### **License and Other Revenue**

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 second quarter of 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.

### **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, a 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.”

Cost of sales decreased by \$0.7 million from \$2.8 million to \$2.1 million in the three months ended June 30, 2019 as compared to the same period in 2018 primarily due to the inclusion of third party royalties for NUCYNTA during the quarter in 2018. Cost of sales decreased by \$10.1 million from \$14.8 million to \$4.7 million in the six months ended June 30, 2019 as compared to the same periods in 2018 driven by the inclusion of third party royalties for NUCYNTA in 2018 and other NUCYNTA related costs incurred in the first quarter of 2018. 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 in 2018 also includes \$6.2 million 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.

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The cost of sales as a percentage of sales for Gralise, CAMBIA and Zipsor, combined for the six months ended June 30, 2019 and 2018 was approximately 8.8% and 8.1% respectively. The increase in cost of sales is primarily related to higher distribution costs.

### 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 difficult to predict the scope and magnitude of future research and development expenses for our product candidates in research and development, as it is 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.

Research and development expenses decreased by \$0.9 million from \$2.2 million to \$1.3 million in the three months ended June 30, 2019 and decreased by \$0.6 million from \$3.7 million to \$3.1 million in the six months ended June 30, 2019 as compared to the same periods in 2018, primarily due to higher clinical trial costs in 2018 offset by increased salary costs in 2019.

### 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.

Selling, general, and administrative expenses decreased by \$6.5 million from \$31.3 million to \$24.8 million in the three months ended June 30, 2019 and decreased by \$10.5 million from \$60.3 million to \$49.8 million in the six months ended June 30, 2019 as compared to the same periods in 2018, 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 representatives and sales manager positions, and our decision to significantly reduce our office staff and reduce our headquarters office space by approximately 50%.

In connection with the Multidistrict Opioid Litigation, the State Opioid Litigation and the Opioid-Related Requests and Subpoenas described in Note 13, "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 and which may increase in future periods.

### Amortization of Intangible Assets

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Amortization of intangible assets - NUCYNTA	23,575	23,575	47,150	47,150
Amortization of intangible assets - CAMBIA	1,284	1,284	2,568	2,568
Amortization of intangible assets - Zipsor	584	585	1,169	1,170
Total	\$ 25,443	\$ 25,444	\$ 50,887	\$ 50,888

The amortization expense during the three and six months ended June 30, 2019 was in-line with amortization expense as compared to the same period in 2018.

### Restructuring Charges

We did not incur any restructuring charges during the three and six months ended June 30, 2019. For the three and six months ended June 30, 2018, restructuring expenses and one-time termination costs were \$5.8 million, and \$14.8 million, respectively.

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During 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 representatives and sales manager positions. 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.

**Other (Expense) Income**

Other income and expense for the three and six months ended June 30, 2019 and 2018 was comprised of:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Interest expense	(14,842)	(17,010)	(31,396)	(35,078)
Change in fair value of Collegium warrants	(1,848)	—	(3,477)	—
Interest and other income	\$ 608	\$ 67	\$ 1,628	\$ 296
Total other (expense) income	\$ (16,082)	\$ (16,943)	\$ (33,245)	\$ (34,782)

For the three and six months ended June 30, 2019 as compared to the same periods in 2018, other (expense) income decreased primarily due to lower interest payments driven by principal payments on our Senior Notes partially offset by fair value adjustments of the Collegium warrants obtained in November 2018.

The interest expense was comprised of:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Interest payable on Senior Notes	\$ 6,602	\$ 9,425	\$ 14,808	\$ 19,866
Interest payable on Convertible Notes	2,156	2,156	4,312	4,312
Amortization of debt discounts and issuance costs relating to Senior Notes and Convertible Notes	6,056	5,390	12,220	10,808
Changes in fair value of contingent consideration	29	39	57	79
Other	(1)	—	(1)	13
Total interest expense	\$ 14,842	\$ 17,010	\$ 31,396	\$ 35,078

For the three and six months ended June 30, 2019, total interest expense decreased by \$2.2 million and \$3.7 million due to lower interest expense for our Senior Notes due to principal payments made in 2018 and 2019, offset in part by the impact of increasing interest rates in 2019. The increase in amortization of debt discounts and issuance costs was primarily due to the modification of the prepayment schedule for our Senior Notes.

In January 2019, we amended our Note Purchase Agreement. The amendment replaced our minimum EBITDA covenant with a senior secured debt leverage ratio covenant and a minimum net sales covenant. In addition, the prepayment premium was adjusted to be 3% of the principal amount of notes prepaid on or prior to April 14, 2020 and 1% of the principal amount of notes prepaid thereafter. We paid a \$3.2 million upfront non-refundable amendment fee paid to the Purchasers in the first quarter of 2019 which was capitalized and is being amortized over the remaining term of the Senior Notes.

**Income Tax Provision**

In the three and six months ended June 30, 2019, we recorded an expense from income taxes of approximately \$1.1 million and \$1.4 million, respectively, that represents an effective tax rate of (9.2)% and (5.2)%, respectively. The difference for the three and six months ended June 30, 2019 between the income tax expense of \$1.1 million and \$1.4 million, respectively, and the tax at the statutory rate of 21.0% on current year operations is principally due to the change in valuation allowance. In the three and six months ended June 30, 2018, we recorded a benefit from income taxes of approximately \$0.1 million and \$0.4 million, respectively, that represents an effective tax rate of (1.0)% and (3.6%). For the three and six months ended June 30, 2018, the difference between the recorded provision for income taxes and the tax based on the federal statutory rate of 21%, was primarily attributable to the impact of the valuation allowance.

## LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short-term investments decreased by \$35.4 million from \$110.9 million to \$75.5 million during the six months ended June 30, 2019, primarily attributable to the payment of \$25.0 million and \$55.0 million of principal on our Senior Notes in January 2019 and April 2019, partially offset by \$32.0 million received related to the Purdue settlement in January 2019.

We were in compliance with our covenants, including the Senior Secured Debt Leverage Ratio and Net Sales covenants, with respect to the Senior Notes as of June 30, 2019. While we are currently in compliance with each of the financial and other covenants contained in the Note Purchase Agreement, and anticipate continued compliance with such covenants, we may seek to refinance or restructure our debt, sell assets or obtain additional capital, each of which may be on terms that may be onerous, dilutive or disruptive to our business. Any prepayment of the Senior Notes would be subject to a prepayment fee of up to 3% 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.

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 and financing plans and the anticipated impact of the cash expected to be received from Collegium pursuant to the Commercialization Agreement, any of which which may change as a result of many factors.

The following table summarizes our cash flow activities:

(in thousands)	Six Months Ended June 30,	
	2019	2018
Cash provided by (used in) operating activities	\$ 48,709	\$ (14,037)
Cash (used in) provided by investing activities	(7,735)	653
Cash (used in) provided by financing activities	(83,575)	(56,267)
Net (decrease) increase in cash and cash equivalents	\$ (42,601)	\$ (69,651)

### Cash Flows from Operating Activities

Cash provided by operating activities increased during the six months ended June 30, 2019 compared to the same period in 2018 is primarily due to the receipt of \$32.0 million from the Purdue settlement in January 2019 and favorable operating cash flows.

### Cash Flows from Investing Activities

Cash used by investing activities increased during the six months ended June 30, 2019 compared to the same period in 2018 is primarily due to the purchase of marketable securities in 2019.

### Cash Flows from Financing Activities

The increase in cash used in financing activities during the six months ended June 30, 2019 compared to the same period in 2018 primarily relates to principal payments on our Senior Notes as we made a payments of \$80.0 million in the six months ending June 30, 2019, compared to \$57.5 million in the prior year period.

### Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements during the quarter ended June 30, 2019.

### 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 2018 Form 10-K, other than the matters described below.

*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 12.35% per annum. An increase in the three month LIBOR of 100 basis points above the current three month LIBOR rates would have an insignificant effect on our interest expense for 2019, assuming we make timely scheduled principal payments. Such increase was limited as our interest rate for our senior Secured Credit Facility is capped at 12.95%. As of June 30, 2019, we had \$345.0 million aggregate principal amount of convertible senior notes outstanding, which are fixed rate instruments. In addition, it is expected that LIBOR will be phased out by the end of 2021. The Alternative Reference Rates Committee of the Federal Reserve Board has identified the Secured Overnight Financing Rate (“SOFR”) as the preferred alternative to LIBOR. As our Senior Secured Credit Facility utilizes LIBOR as a factor in determining the applicable interest rate, the expected discontinuation and transition may require us to renegotiate certain terms of the agreement to replace LIBOR with a new reference rate, which could increase the cost of servicing our debt and have an adverse effect on our results of operations and cash flows.

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 June 30, 2019. 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.

#### *Changes in Internal Controls*

There were no changes in our internal controls over financial reporting during the three months ended June 30, 2019 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 13 “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 2018 Form 10-K and our Quarterly Report on Form 10-Q for the three months ended March 31, 2019 filed with the SEC on May 9, 2019. In addition to other information in this report, the following factors should be considered carefully in evaluating an investment in our securities. If any of the risks or uncertainties described in this Form 10-K actually occurs, our business, results of operations or financial condition would be materially and adversely affected. The risks and uncertainties described below have been grouped under general risk categories, one or more of which categories may be applicable to the risk factor described. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties of which we are unaware or that we currently deem immaterial may also become important factors that may harm our business, results of operations and financial condition.

#### Risks Related to Commercial, Regulatory and Other Business Matters

*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;
- 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 commercialization agreement with Collegium grants each party specified termination rights. If the agreement is terminated, we may either perform commercialization activities relating to NUCYNTA and NUCYNTA ER on our own or identify and collaborate with 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.

***We depend on one qualified supplier for the active pharmaceutical ingredient in each of our products, and we depend on third parties that are single source suppliers to manufacture our products. If there is insufficient availability of our products or the active pharmaceutical ingredients and other raw materials necessary to manufacture our products, or if our suppliers are unable to manufacture and supply 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

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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 Galise 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, quality concern or failure to obtain sufficient supplies of Galise, 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 the fourth quarter of 2017 and the first quarter of 2018. We and Collegium may experience product delays or 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.

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.

***Our commercialization, collaborative and other 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 either us or

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a third party or their failure to repay, in full or in part, either any outstanding receivables or any other amounts for which we are entitled to reimbursement) 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. 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;
- 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.

In addition, contract disputes with customers or other third parties may arise from time to time. Our commercialization or collaborative partners, or customers or other third parties, may also terminate their relationships with us or otherwise decide not to proceed with development, commercialization or purchase of our products.

### ***We and our commercial partners may be unable to compete successfully in the pharmaceutical industry.***

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.

Branded gabapentin is currently sold by Pfizer as Neurontin for adjunctive therapy for partial onset epileptic seizures and for the management of 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, Pfizer's patents relating to Lyrica have expired, and generic versions of Lyrica (pregabalin) launched in July 2019. In January 2018, Pfizer began to sell 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 Galise.

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. Currently, eight triptans are available generically and sold in the United States (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan). Branded competitors include Zomig Nasal Spray, Onzetra, Xsail, Sumavel, Zembrace SymTouch and Treximet, which is a fixed-dose combination product containing sumatriptan and 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 CGRP inhibitor products.

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.

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 tablets), which is owned by Purdue and 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 had a marketing start date of January 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. In January 2018, Pfizer began to sell 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.

***If we or our commercialization partner are unable to negotiate acceptable pricing or obtain adequate reimbursement from 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

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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 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 (ACA) and the Health Care and Education Reconciliation Act, 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.

***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 Cosmetic 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 notify us of their application and potential infringement of our patent rights. Upon receipt of this notice, we would 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. The filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve 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. A two-week bench trial was completed on April 27, 2016. On September 30, 2016, the District Court issued its opinion finding all three of the Orange Book patents valid and enforceable. On April 11, 2017, the District Court entered a final judgment, which included an injunction enjoining the Filers 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 earlier than the expiry of the '130 Patent (September 22, 2028). The foregoing periods of exclusivity may in the future be extended with the award of

pediatric exclusivity. In March 2019, the Federal Circuit affirmed the decision of the District Court in all respects. On April 29, 2019, Alkem filed a petition for panel rehearing and rehearing en banc with the Federal Circuit, which was denied on May 31, 2019.

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.

***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 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 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 to obtain, handle and distribute tapentadol or to meet applicable regulatory requirements could lead to enforcement and sanctions by state or federal authorities, including the DEA. Such an enforcement action or sanction 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 which, in turn, could have a material adverse impact on our business.***

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 needs. The aggregate quota of tapentadol that the DEA allows to be produced in the U.S. annually is allocated among applicable individual drug manufacturers, each of whom 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 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. Through our manufacturing partner we are permitted to ask the DEA to increase our manufacturer’s procurement quota after it is initially established. However, we cannot be certain that the DEA would act favorably upon such a request. In addition, our manufacturers obtain a procurement quota for

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tapentadol for all tapentadol products manufactured at their facility, which is allocated to NUCYNTA and NUCYNTA ER, as applicable, at the manufacturer's discretion. The DEA recently proposed reducing the quota for controlled substances to be manufactured in the U.S. in 2019, although no changes to the 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 clinical needs, 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.

***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.

Although our Board of Directors, through our Audit Committee, regularly discusses with management our policies and practices regarding information technology systems, information management systems and related infrastructure, including our information technology and information management security, risk management and back-up policies, practices and infrastructure, it is often difficult to anticipate or immediately detect such incidents and the damage that may be 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 our financial information or the information of our business partners. Cyber-attacks could cause us to incur significant remediation costs, result in product

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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.

***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 executive team is not able, in a timely manner, to 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. While our Chief Executive Officer and executive officers have significant industry-related experience, it may take time for the team to become fully integrated and such team may continue to evolve until a fully integrated team is established. 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 executive team, our future business strategies and plans 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 success is dependent in large part upon the continued services of our executive management team 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.

**Risks Related to Product Development**

***The development of drug candidates such as long-acting cosyntropin, 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 long-acting cosyntropin (synthetic ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the FDA for our collaborative partner's 505(b)(2) NDA for the novel injectable formulation of long-acting cosyntropin. We, together with our collaborative partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

An independent, investigator-led clinical trial evaluating long-acting cosyntropin for the treatment of infantile spasms (the IS Trial), a specific seizure type present in the infantile epilepsy spectrum, a rare pediatric disorder, is ongoing. As a precautionary measure, due to differences in the pharmacokinetic profiles between certain manufacturing lots of the product candidate which may be the result of manufacturing processes, the investigator paused enrollment of new subjects in the IS Trial. The pause in enrollment of new subjects in the IS Trial, other developments with regard to the IS Trial, including clinically relevant findings, or the failure by our collaborative partner to manufacture the product in accordance with applicable

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specifications or regulatory requirements, may delay or prevent FDA approval of the NDA for diagnostic use of long-acting cosyntropin, which could adversely impact our business, financial condition and results of operations.

The expected timing of NDA filings and related approvals, the successful execution of applicable clinical trials and our overall strategy with regard to the product candidate's application may not achieve our intended results. Our overall strategy to bring our injectable formulation of long-acting cosyntropin to market in the U.S. and Canada is subject to certain risks and uncertainties. The NDA may not be successful or could be voluntarily withdrawn. Further, if our product, manufacturing processes or facilities do not satisfy regulatory requirements, including as a result of issues relating to manufacturing, FDA approval may be delayed or not be granted. Even if we receive FDA approval for our intended diagnostic indication, our ability to commercialize the product for diagnostic use will be subject to the availability of saleable product, which our collaborative partner may not be able to supply. Even if we are able to procure saleable product, our sales of the product may not generate significant revenue.

Product candidates, such as long-acting cosyntropin, 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 or our collaborative partner's 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;
- any findings resulting from FDA inspections of 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 third party clinical trial vendors to comply with applicable regulatory laws and regulations;
- compliance with applicable laws and regulations;
- inability of 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 or manufacturing sufficient quantities of the product candidate for use in clinical trials;
- delays or failures in recruiting qualified patients to participate in 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 long-acting cosyntropin, 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 long-acting cosyntropin 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.

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Any material delay or failure in the governmental approval process, the successful production of commercial product or the successful commercialization of our approved product candidates, 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 long-acting cosyntropin.***

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 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 trial 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.

***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, long-acting cosyntropin, 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.

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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 cGMP or Quality System Regulation (QSR). The FDCA, the 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 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 are subject to risks associated with NDAs submitted under Section 505(b)(2) of the FDCA.***

The products we or our collaborative partners 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. If the FDA disagrees with the use of the Section 505(b)(2) regulatory pathway for product candidates, we would need to reconsider our plans and might not be able to obtain approval for product candidates in a timely or cost-efficient manner, or at all. 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.

### **Risks Related to Our Industry**

#### ***Changes in laws and regulations applicable to, and increased scrutiny 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 increased scrutiny and investigations of, the pharmaceutical industry, including the opioid market, 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-

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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 seeking 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 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 has reduced the quota for controlled substances to be manufactured in the U.S. each year for the past few years, although no changes to the 2019 quotas for tapentadol (NUCYNTA) were recommended. Further, the FDA has updated the “black-box” warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose, and death in conjunction with the implementation of a Risk Evaluation and Mitigation Strategies (REMS) for these same products. Extended release opioids have been subject to a separate REMS since July 2012. The FDA has also emphasized that it will continue to evaluate patient risk associated with exposure to opioids, and that it will work to reduce the number, dosages and the duration of opioid prescriptions, where appropriate. 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. These regulatory actions, including the SUPPORT Act and other similar legislation or policy initiatives, may adversely impact the commercialization of opioids generally, including NUCYNTA and NUCYNTA ER.

In addition, various federal and state governmental entities, including the U.S. Department of Justice (DOJ) and a number of state attorneys general, have launched investigations into the marketing and sales practices of pharmaceutical companies that market or have marketed 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 historical sales and marketing of opioid products. We also received a subpoena from the State of California Department of Insurance (CDI) seeking information relating to our historical sales and marketing of Galise. 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 of the perceived risks relating to substance abuse, several states have scheduled gabapentin as a controlled substance. We have also received notice from the FDA that it has requested that all companies that hold an NDA for gabapentanoids conduct two clinical trials to assess gabapentin’s abuse liability. One clinical trial is intended to address the abuse potential of gabapentin alone. The other clinical trial is intended to evaluate gabapentin’s abuse potential when taken in combination with an opioid drug. Depending on the results of these studies, additional safety labeling, the implementation of a REMS protocol and/or scheduling of gabapentanoids, as a class or by formulation type, could be mandated by the FDA which, in turn, could result in increased expenses or have a material adverse impact on either the commercial prospects of our products or our ability or our partner’s ability to commercialize our products. Continued changes in regulations and legislation applicable to gabapentin could have a material adverse impact on the commercial prospects of Galise which could, in turn, have a material adverse effect on our business, financial condition and results of operations.

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 similar or other negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to NUCYNTA or NUCYNTA ER, including additional label modifications, additional manufacturing restrictions or additional restrictions on sales, 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.

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The regulatory actions described above, as well as the related litigation and investigations, not only create financial and operational pressure on our company, but could also put pressure on other companies in our industry and with which we have contractual arrangements. Such pressures could negatively impact our contractual counterparties and may give rise to contract cancellations, breaches or rejections in bankruptcy. Furthermore, in the event that a contract counterparty seeks to reject a contract, we may have an unsecured claim for damages, which may not be paid in full (if at all), and we may be forced to return payments made within 90 days of the date of filing for bankruptcy protection. If any of these events should occur, it may have a material adverse effect 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, sales 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 Collegium 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.

***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 our current marketing activities 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 these laws, 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.

***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

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physician's choice of treatments, the 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 states 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 could 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. For additional information regarding potential liability, see also " - *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.*"

### ***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 (which requires pharmaceutical manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices), 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 authorized 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 or have been limited or rejected by Federal courts, 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, as will the ACA-related lawsuits that are working their way through the Federal judicial system. 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, members of Congress, and state elected officials have indicated that reducing the price of prescription drugs will be a priority. 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.

### **Risks Related to the Historical Commercialization of Opioids**

***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

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marketing and promotion of opioid drugs. Such litigation and related matters are described in “Item 1. Financial Statements - Note 13. Commitments and Contingencies.”

In March 2017, we received a letter from Senator Claire McCaskill (D-MO), the then-Ranking Member on the U.S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information regarding our historical commercialization of opioid products. We voluntarily furnished information responsive to Sen. McCaskill’s request. We have 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 historical sales and marketing of opioid products. In addition, the CDI has issued a subpoena to us seeking information relating to our historical sales and marketing of Lazanda. The CDI subpoena also seeks information on Gralise, a non-opioid product in our portfolio. We have received subpoenas from the DOJ seeking documents and information regarding our historical sales and marketing of opioid products. We also from time to time receive and comply with subpoenas from governmental authorities related to investigations primarily focused on third parties, including health care practitioners. We are cooperating with the foregoing governmental investigations and inquiries. These matters are described in “Item 1. Financial Statements - Note 13. Commitments and Contingencies.”

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 either the outcome or the potential financial impact 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 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 ability 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, these pending investigations, inquiries and lawsuits could negatively affect our ability to raise capital and impair our ability to engage in strategic transactions.

### ***We may incur product liability losses and other litigation liability for which we may be unable to maintain or obtain adequate protection.***

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. Moreover, our primary product liability insurer has sought a declaratory judgment that opioid litigation claims noticed by us are not covered by our policies with such insurer. Such litigation and related matters are described in “Item 1. Financial Statements - Note 13. Commitments and Contingencies.” 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;

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- 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.

### **Risks Related to Our Intellectual Property**

#### *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 Patent Trial and Appeal Board (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 (USPTO) 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 proceedings at the USPTO 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.

### **Risks Related to Our Financial Position**

***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 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 described in "Item 1. Financial Statements - Note 10. Debt," 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.

We may seek to refinance all or a portion of our outstanding indebtedness in the future. Any such refinancing would depend on the capital markets and business and financial conditions at the time, which could affect our ability to obtain attractive terms if or when desired or at all.

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;
- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including funding possible acquisitions of, or investments in, new and complementary businesses, products and technologies which is a key element of our corporate strategy;
- 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;

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- 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; and
- put us at a disadvantage compared to our competitors who have less debt.

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.

***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 long-acting cosyntropin. 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 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 long-acting cosyntropin 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, the commercialization arrangement covering NUCYNTA and NUCYNTA ER with Collegium, and our acquisition of the right to market long-acting cosyntropin in the U.S. and Canada, whether as a result of identified or unidentified risks, integration difficulties, regulatory setbacks, governmental investigations, independent actions of or financial position of our collaborative partners, litigation or other events, could adversely affect our business, results of operations and financial condition.

***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;

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- 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.

***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 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 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.

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

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 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. 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;
- the regulatory strategy for long-acting cosyntropin and our ability and our collaborative partner's ability to successfully develop and execute such strategy;
- our ability to successfully commercialize long-acting cosyntropin if regulatory approval is obtained;
- 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;
- adverse events related to our products, or product candidates, 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 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;

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- 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.

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 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.

### ***We have significant amounts of long-lived 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 long-lived assets, including intangible assets representing the product rights which we have acquired over the last few years and property and equipment. We review the carrying value of our long-lived assets when indicators of impairment are present. Conditions that could indicate impairment of long-lived assets include, but are not limited to, a significant adverse change in market conditions, significant competing product launches by our competitors, significant adverse change in the manner in which the long-lived asset is being used, and adverse legal or regulatory outcomes.

In performing our impairment tests, which assess the recoverability of our assets, 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 long-lived 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. 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. See also “ - *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.* ”

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***Our product revenues have typically 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 typically 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.

Our wholesalers typically end 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 such first quarters, net sales are typically 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.

***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 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.

***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.

***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 our business and operations, actual results could differ materially from these estimates.

**Risks Related to Share Ownership and Other Stockholder Matters**

***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.

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.

***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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**ITEM 6. EXHIBITS**

- 10.1 [Assertio Therapeutics, Inc. Amended and Restated 2014 Omnibus Incentive Plan \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 8, 2019\)](#)
- 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

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(\*) Furnished herewith

**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: August 9, 2019

**ASSERTIO THERAPEUTICS, INC.**

/s/ Arthur J. Higgins

Arthur J. Higgins  
President and Chief Executive Officer

/s/ Daniel A. Peisert

Daniel A. Peisert  
Senior Vice President and Chief Financial Officer

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER**

I, Arthur J. Higgins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assertio Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2019 By: /s/ Arthur J. Higgins

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Arthur J. Higgins  
President and Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER**

I, Daniel A. Peisert, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assertio Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2019 By: /s/ Daniel A. Peisert

Daniel A. Peisert  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Assertio Therapeutics, Inc. (the "Company") for the quarterly period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Arthur J. Higgins, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2019

/s/ Arthur J. Higgins

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Arthur J. Higgins

President and Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Assertio Therapeutics, Inc. (the "Company") for the quarterly period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel A. Peisert, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2019

/s/ Daniel A. Peisert

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Daniel A. Peisert

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)