

DEPOMED INC  
Form 10-Q  
August 07, 2017  
Table of Contents

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, 2017

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

DEPOMED, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Edgar Filing: DEPOMED INC - Form 10-Q

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

7999 Gateway Boulevard, Suite 300

Newark, California 94560

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

(510) 744-8000

(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, as defined 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, no par value, as of August 4, 2017 was 62,988,986.

---

Table of Contents

DEPOMED, INC

	PAGE
 <u>PART I — FINANCIAL INFORMATION</u>	
<u>Item 1.</u> <u>Condensed Consolidated Financial Statements</u> (unaudited)	
<u>Condensed Consolidated Balance Sheets at June 30, 2017 and December 31, 2016</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2017 and 2016</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2017 and 2016</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	28
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosure About Market Risk</u>	41
<u>Item 4.</u> <u>Controls and Procedures</u>	41
 <u>PART II — OTHER INFORMATION</u>	
<u>Item 1.</u> <u>Legal Proceedings</u>	42
<u>Item 1A.</u> <u>Risk Factors</u>	45
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	67
<u>Item 3.</u> <u>Defaults upon Senior Securities</u>	67
<u>Item 4.</u> <u>Mine Safety Disclosures</u>	67
<u>Item 5.</u> <u>Other Information</u>	67
<u>Item 6.</u> <u>Exhibits</u>	68
<u>Signatures</u>	69



Table of Contents

## PART I — FINANCIAL INFORMATION

## ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

DEPOMED, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	June 30, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 113,225	\$ 117,709
Short-term investments	3,574	59,711
Accounts receivable, net	78,337	102,056
Receivables from collaborative partners	371	533
Inventories	10,433	13,033
Prepaid and other current assets	13,103	13,162
Total current assets	219,043	306,204
Property and equipment, net	14,532	15,526
Intangible assets, net	850,679	902,149
Other assets	1,346	1,458
Total assets	\$ 1,085,600	\$ 1,225,337
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 12,407	\$ 14,855
Accrued rebates, returns and discounts	140,006	131,536
Accrued liabilities	53,052	59,398
Income taxes payable	—	59
Current portion of Senior Notes	57,500	—
Contingent consideration liability, current portion	1,851	4,578
Interest payable	13,208	15,924
Other current liabilities	917	892
Total current liabilities	278,941	227,242
Contingent consideration liability, long-term portion	5,505	10,247
Senior Notes	311,112	466,051
Convertible Notes	260,938	252,725

Edgar Filing: DEPOMED INC - Form 10-Q

Other long-term liabilities	17,708	18,284
Commitments		
Shareholders' equity:		
Preferred stock	—	—
Common stock	306,103	291,634
Additional paid-in capital	75,707	75,917
Accumulated deficit	(170,412)	(116,744)
Accumulated other comprehensive loss, net of tax	(2)	(19)
Total shareholders' equity	211,396	250,788
Total liabilities and shareholders' equity	\$ 1,085,600	\$ 1,225,337

---

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

Table of Contents

DEPOMED, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	\$ 100,232	\$ 116,517	\$ 190,517	\$ 221,088
Royalties	225	165	387	374
Total revenues	100,457	116,682	190,904	221,462
Costs and expenses:				
Cost of sales (excluding amortization of intangible assets)	19,725	20,965	37,499	44,514
Research and development expenses	5,614	7,116	10,698	13,065
Selling, general and administrative expenses	50,010	51,903	98,529	104,462
Amortization of intangible assets	25,735	27,037	51,470	54,074
Restructuring charges	3,441	—	3,441	—
Total costs and expenses	104,525	107,021	201,637	216,115
(Loss) Income from operations	(4,068)	9,661	(10,733)	5,347
Other (expense) income:				
Interest and other income	282	67	532	197
Loss on prepayment of Senior Notes	(5,364)	(5,777)	(5,364)	(5,777)
Interest expense	(17,758)	(20,148)	(37,882)	(42,875)
Total other expense	(22,840)	(25,858)	(42,714)	(48,455)
Net loss before income taxes	(26,908)	(16,197)	(53,447)	(43,108)
Benefit from income taxes	249	5,656	47	11,650
Net loss	\$ (26,659)	\$ (10,541)	\$ (53,400)	\$ (31,458)
Basic and diluted net loss per share	\$ (0.43)	\$ (0.17)	\$ (0.86)	\$ (0.52)
Shares used in computing basic and diluted net loss per share	62,531,696	61,166,044	62,331,471	61,032,155

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



Table of Contents

DEPOMED, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	\$ (26,659)	\$ (10,541)	\$ (53,400)	\$ (31,458)
Unrealized gains on available-for-sale securities, net of tax	2	(1)	17	35
Comprehensive loss	\$ (26,657)	\$ (10,542)	\$ (53,383)	\$ (31,423)

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

Table of Contents

DEPOMED, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Operating Activities		
Net loss	\$ (53,400)	\$ (31,458)
Adjustments for non-cash items:		
Depreciation and amortization	52,691	55,336
Accretion of debt discount and debt issuance costs	9,411	8,624
Loss on prepayment of Senior Notes	5,364	5,777
Provision for inventory obsolescence	2,110	403
Gain on disposal of property and equipment	(275)	—
Stock-based compensation	6,959	8,238
Change in fair value of contingent consideration	(6,176)	527
Deferred income taxes	—	(12,232)
Other	264	472
Changes in assets and liabilities:		
Accounts receivable	23,719	(8,354)
Receivables from collaborative partners	162	67
Inventories	490	(346)
Prepaid and other assets	173	(4,912)
Accounts payable and other accrued liabilities	(9,135)	(3,060)
Accrued rebates, returns and discounts	8,470	(3,251)
Interest payable	(2,716)	(2,889)
Net cash provided by operating activities	38,111	12,942
Investing Activities		
Purchases of property and equipment	(504)	(2,538)
Proceeds from disposal of property and equipment	280	—
Purchases of marketable securities	(2,391)	(26,570)
Maturities of marketable securities	58,281	103,707
Net cash provided by investing activities	55,666	74,599
Financing Activities		
Payment of contingent consideration liability	(1,293)	(600)
Repayment of Senior Notes	(100,000)	(100,000)
Prepayment fees for repayment of Senior Notes	(4,000)	(5,000)
Proceeds from issuance of common stock	7,242	5,163

Edgar Filing: DEPOMED INC - Form 10-Q

Shares withheld for payment of employee's withholding tax liability	(210)	(367)
Net cash used in financing activities	(98,261)	(100,804)
Net increase in cash and cash equivalents	(4,484)	(13,263)
Cash and cash equivalents at beginning of year	117,709	101,084
Cash and cash equivalents at end of period	\$ 113,225	\$ 87,821
Supplemental Disclosure of Cash Flow Information		
Net cash paid for income taxes	\$ 121	78
Cash paid for interest	\$ 30,187	35,823
Capital expenditures incurred but not yet paid	\$ 130	124

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

Table of Contents

DEPOMED, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Depomed, Inc. (Depomed or the Company) is a specialty pharmaceutical company focused on pain and other central nervous system (CNS) conditions. The products that comprise the Company's current specialty pharmaceutical business are (i) NUCYNTA® ER (tapentadol extended release tablets), a product for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults, and for which alternative treatment options are inadequate, and NUCYNTA® IR (NUCYNTA) (tapentadol), a product for the management of moderate to severe acute pain in adults, each of which the Company acquired the U.S. rights to in April 2015, (ii) Gralise® (gabapentin), a once-daily product for the management of postherpetic neuralgia (PHN) that the Company launched in October 2011, (iii) CAMBIA® (diclofenac potassium for oral solution), a product for the acute treatment of migraine attacks that the Company acquired in December 2013, (iv) Zipsor® (diclofenac potassium) liquid filled capsules, a product for the treatment of mild to moderate acute pain that the Company acquired in June 2012, and (v) Lazanda® (fentanyl) nasal spray, a product for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain that the Company acquired in July 2013.

As of June 30, 2017, the Company has one product candidate, cebranopadol initially for the treatment of chronic lower back pain and potentially for chronic nociceptive and neuropathic pain. The Company is currently evaluating the development plan for cebranopadol, including the timing of potential Phase 3 trials.

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, 2017 are not necessarily indicative of results to be expected for the entire year ending December 31, 2017 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, 2016 included in the Company's Annual Report on Form 10-K filed with the SEC (the 2016 Form 10-K). The balance sheet as of December 31, 2016 has been derived from the audited financial statements at that date, as filed in the Company's 2016 Form 10-K.

See Note 14 herein for information regarding impact of an out of period adjustment related to the Branded Prescription Drug fee ("BPD") on our consolidated financial statements.

#### Principles of Consolidation

The condensed 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 on consolidation.

On November 17, 2015, the Company entered into a definitive agreement to acquire the U.S. and Canadian rights to cebranopadol and its related follow-on compound from Grünenthal GmbH (Grünenthal). The acquisition of these rights closed on December 30, 2015 at which point the Company assigned its rights under the agreement to Depo Bermuda, a Company which was formed in Bermuda on December 22, 2015.

Table of Contents

Depo NF Sub was formed on March 26, 2015, in connection with a Note Purchase Agreement dated March 12, 2015 (Note Purchase Agreement) governing the Company's issuance of \$575.0 million aggregate principal amount of Senior Notes on April 2, 2015, for aggregate gross proceeds of approximately \$562.0 million. On April 2, 2015, the Company and Depo NF Sub entered into a Pledge and Security Agreement with the Collateral Agent pursuant to which the Company and Depo NF Sub each granted the Collateral Agent (on behalf of the Purchasers) a security interest in substantially all of their assets, other than specifically excluded assets.

Depo DR Sub was formed in October 2013 for the sole purpose of facilitating the license of certain rights to PDL Biopharma (the PDL Transaction). The Company contributed to Depo DR Sub all of its rights, title and interests in certain license agreements to receive royalty and milestone payments. Immediately following the transaction, Depo DR Sub sold to PDL, among other things, such rights to receive royalty and milestone payments, for an upfront cash purchase price of \$240.5 million.

The Company and Depo DR Sub continue to retain certain administrative duties and obligations under the specified license agreements. These include the collection of the royalty and milestone amounts due and enforcement of related provisions under the specified license agreements, among others. In addition, the Company and Depo DR Sub must prepare a quarterly distribution report relating to the specified license agreements, containing, among other items, the amount of royalty payments received by the Company and reimbursable expenses. The Company and Depo DR Sub must also provide PDL with notice of certain communications, events or actions with respect to the specified license agreements and infringement of any underlying intellectual property.

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, but not limited to, sales discounts and returns, depreciable and amortizable lives, share-based compensation assumptions, fair value of contingent consideration and taxes on income. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of the Company's business and operations, actual results could differ materially from these estimates.

Change in estimate – During the three months ended March 31, 2017, the Company established a reserve with respect to a dispute with a PBM over rebates relating to NUCYNTA ER, NUCYNTA and Gralise. The dispute relates to rebate claims submitted with respect to the year ended December 31, 2015 and the first half of 2016. As of December 31, 2016, the Company established a reserve for \$1.0 million with respect to these claims, and had determined the likely amount payable on settlement would not be material to the consolidated financial statements. However, as a

result of further communication with the PBM during the three months ended March 31, 2017, it became clear that the Company's failure to pay the disputed amount would adversely impact the Company's ability to maintain a favorable position on the PBM's formulary. Accordingly, despite the Company's belief that the claims in dispute are invalid, the Company increased the reserve against this matter by \$4.7 million which is an offset to net sales for the three months ended March 31, 2017. The Company will adjust net sales in the future if it resolves this matter for an amount different than currently reserved.

#### Measuring the Fair Value of Assets and Liabilities associated with Business Combinations

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

Significant judgments are used in determining the estimated fair values assigned to the assets acquired, liabilities assumed, contingent consideration 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 calculate present value of expected future net cash flows, the assessment

## Table of Contents

of each asset's life cycle, 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 are recognized in operating expenses until the contingent consideration arrangement is settled. Changes in the fair value of contingent consideration resulting from the passage of time are recorded within interest expense until the contingent consideration is settled.

## Revenue Recognition

The Company recognizes revenue from the sale of its products, royalties and milestones earned under its contractual arrangements.

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable and the Company is reasonably assured of collecting the resulting receivable. Revenue arrangements with multiple elements are evaluated to determine whether the multiple elements meet certain criteria for dividing the arrangement into separate units of accounting, including whether the delivered element(s) have stand-alone value to the Company's customer or licensee. Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period that the Company remains obligated to perform services.

- Product Sales—The Company sells commercial products to wholesale distributors and retail pharmacies. Products 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.
- Product Sales Allowances—The Company 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 amounts owed or to be claimed 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 or expected to be 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. 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 product that is within six months before and up to 12 months after its product expiration date. The Company estimates product returns on NUCYNTA ER and NUCYNTA, Gralise, CAMBIA, Zipsor and Lazanda. Under the terms of the Zipsor asset purchase agreement, the Company assumed financial responsibility for returns of Zipsor product previously sold by Xanodyne Pharmaceuticals, Inc. (Xanodyne). Under the terms of the CAMBIA asset purchase agreement, the Company also assumed financial responsibility for returns of CAMBIA product previously sold by Nautilus. 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. See Note 12 for further information on the acquisition of NUCYNTA ER and NUCYNTA, CAMBIA, Lazanda and Zipsor.

The shelf life of NUCYNTA ER is 24 to 36 months and NUCYNTA is 36 months from the date of tablet manufacture, respectively. The shelf life of Gralise is 24 to 36 months from the date of tablet manufacture. The shelf life of CAMBIA is 24 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. 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 product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels and consideration of the introduction of competitive products.

Table of Contents

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**—Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectability is reasonably assured.

- **License and Collaborative Arrangements**—Revenue from license and collaborative arrangements is recognized when the Company has substantially completed its obligations under the terms of the arrangement and the Company's remaining involvement is inconsequential and perfunctory. If the Company has significant continuing involvement under such an arrangement, license and collaborative fees are recognized over the estimated performance period. The Company recognizes milestone payments for its research and development collaborations upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) consideration earned relates to past performance and (3) the milestone payment is nonrefundable. A milestone is considered substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone or consistent with the increase in value to the collaboration resulting from the Company's performance; the consideration earned relates solely to past performance; and the consideration earned is reasonable relative to all of the other deliverables and payments within the arrangement. License, milestones and collaborative fee payments received in excess of amounts earned are classified as deferred revenue until earned.

Table of Contents

Recently Issued Accounting Standards

In July 2015, the FASB issued ASU 2015-11 Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 requires an entity to measure inventory, other than inventory accounted for under last-in, first-out method or retail inventory method, at the lower of cost or net realizable value. ASU 2015-11 is effective for annual and interim periods beginning after December 15, 2016 on a prospective basis. The Company adopted this guidance on January 1, 2017, and the adoption of this guidance did not materially affect our consolidated financial statements.

In March 2016, the FASB issued ASU No 2016-09 “Improvements to Employee Share-Based Payment Accounting”. This guidance simplifies the accounting for the taxes related to stock based compensation, requiring excess tax benefits and deficiencies to be recognized as a component of income tax expense rather than equity. This guidance also requires excess tax benefits and deficiencies to be presented as an operating activity on the statement of cash flows and allows an entity to make an accounting policy election to either estimate expected forfeitures or to account for them as they occur. The inclusion of excess tax benefits and deficiencies as a component of our income tax expense will increase volatility within our provision for income taxes as the amount of excess tax benefits or deficiencies from stock-based compensation awards are dependent on our stock price at the date the awards vest. The magnitude of such impacts will depend upon future movements in the Company’s share price as well as the timing of stock award exercises, which are both difficult to estimate. The Company adopted this ASU as of January 1, 2017.

As a result of adopting this standard, the Company has made an accounting policy election to account for forfeitures as they occur, rather than estimate expected forfeitures. This change has been applied on a modified retrospective basis, resulting in a cumulative-effect adjustment to increase accumulated deficit by \$0.3 million as of January 1, 2017; the date of adoption. The adoption of this guidance also requires excess tax benefits and tax deficiencies be recorded in the income statement as opposed to additional paid-in capital when the awards vest or are settled.

Additionally, the Company has applied the provisions of this ASU on a retrospective basis in our condensed consolidated statements of cash flows, which includes presenting: (i) excess tax benefits as an operating activity, which were previously presented as a financing activity; and (ii) cash payments to tax authorities for employee taxes when shares are withheld to meet statutory withholding requirements as a financing activity, which were previously presented as an operating activity.

The adoption requires recognition through opening retained earnings of any pre-adoption date net operating loss (NOL) carryforwards from non-qualified stock options and other employee share- based payments. As a result, the Company determined the impact of the adoption to be a \$5.8 million increase to deferred tax assets related to share-based compensation incurred as of December 31, 2016 with a corresponding increase to the Company's valuation allowance for financial statement purposes since the Company is in a full valuation allowance position.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU or Update) No. 2014-09, "Revenue from Contracts with Customers". This guidance outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On July 9, 2015, the FASB deferred the effective date of this Update to fiscal years beginning after December 15, 2017, with early adoption permitted on the original effective date of fiscal years beginning after December 15, 2016. This guidance can be adopted on a full retrospective basis or on a modified retrospective basis. The Company plans to adopt this guidance on January 1, 2018, using the modified retrospective transition method applied to those contracts which were not completed as of that date. Upon adoption, the Company will recognize the cumulative effect of adopting this guidance as an adjustment to its opening balance of accumulated deficit. Prior periods will not be retrospectively adjusted. The Company has substantially completed an analysis of existing contracts with its customers and has assessed the differences in accounting for such contracts under this guidance compared with current revenue accounting standards. Based on its review of current customer contracts, the Company does not expect the implementation of this guidance to have a material impact on its consolidated financial statements as the timing of revenue recognition for product sales is not expected to significantly change.

Table of Contents

In February 2016, the FASB issued ASU No. 2016-02, "Leases". This guidance requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. If the available accounting election is made, leases with a term of twelve months or less can be accounted for similar to existing guidance for operating leases. For a public entity, the amendments in this guidance are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application of the amendments in this guidance is permitted for all entities. The Company is currently evaluating and has not yet determined the impact implementation will have on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15 "Classification of Certain Cash Receipts and Cash Payments". ASU 2016-15 provides guidance on the classification of certain cash receipts and cash payments in the statement of cash flows. The guidance is effective for the Company in the first quarter of fiscal 2018 and will be applied on a retrospective basis. Early adoption is permitted. The Company early adopted this guidance on January 1, 2017, and the adoption of this guidance did not materially affect the Company's consolidated financial statements.

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

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

Securities classified as cash and cash equivalents and short-term investments as of June 30, 2017 and December 31, 2016 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2017				
Cash and cash equivalents:				

Edgar Filing: DEPOMED INC - Form 10-Q

Cash	\$ 91,971	\$ —	\$ —	\$ 91,971
Money market funds	63	—	—	63
Commercial paper	21,191	—	—	21,191
Total cash and cash equivalents	\$ 113,225	\$ —	\$ —	\$ 113,225
Short-term investments				
Corporate debt securities and commercial paper with maturities less than 1 year	\$ 3,576	\$ —	\$ (2)	\$ 3,574
Total short-term investments	\$ 3,576	\$ —	\$ (2)	\$ 3,574
Total	\$ 116,801	\$ —	\$ (2)	\$ 116,799

Table of Contents

December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 87,845	\$ —	\$ —	\$ 87,845
Money market funds	532	—	—	532
Corporate debt securities and commercial paper	29,334	—	(2)	29,332
Total cash and cash equivalents	\$ 117,711	\$ —	\$ (2)	\$ 117,709
Short-term investments				
Corporate debt securities and commercial paper with maturities less than 1 year	\$ 59,728	\$ —	\$ (17)	\$ 59,711
Total short-term investments	\$ 59,728	\$ —	\$ (17)	\$ 59,711
Total	\$ 177,439	\$ —	\$ (19)	\$ 177,420

The Company considers all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks, money market instruments and corporate debt securities. The Company invests its cash in marketable securities, U.S. Treasury and government agency securities, and high quality securities of financial and commercial institutions. To date, the Company has not experienced material losses on any of its balances. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in “accumulated other comprehensive loss” within shareholders’ equity on the Condensed Consolidated Balance Sheets. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in “interest and other income” in the Condensed Consolidated Statement of Operations. As of June 30, 2017, commercial paper includes \$1.6 million of fair value of securities issued by Federal Home Loan Banks. As of December 31, 2016, the Company did not have any securities issued by Federal Home Loan Banks.

As of June 30, 2017, the Company had 1 security in an unrealized loss position. The following table shows the gross unrealized losses and fair value of the Company’s investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at June 30, 2017 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Corporate debt securities	\$ 1,178	\$ (2)	\$ —	\$ —	\$ 1,178	\$ (2)

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



the Company. Based on the Company's review of these securities, including the assessment of the duration and severity of the unrealized losses and the Company's ability and intent to hold the investments until the recovery or maturity of such investments, there were no material other-than-temporary impairments for these securities at June 30, 2017. For debt securities, the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of the amortized cost.

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.

The Company utilizes the following fair value hierarchy based on three levels of 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.

Table of Contents

- 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, 2017 and December 31, 2016 (in thousands):

June 30, 2017	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$ 63	\$ —	\$ —	\$ 63
Commercial paper	—	23,587	—	23,587
Corporate debt securities	—	1,178	—	1,178
Total	\$ 63	\$ 24,765	\$ —	\$ 24,828
Liabilities:				
Contingent consideration—Zipsor	\$ —	\$ —	\$ 579	\$ 579
Contingent consideration—Lazanda	—	—	5,857	5,857
Contingent consideration—CAMBIA	—	—	920	920
	\$ —	\$ —	\$ 7,356	\$ 7,356

December 31, 2016	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$ 532	\$ —	\$ —	\$ 532
Commercial paper	—	52,192	—	52,192
Corporate debt securities	—	36,850	—	36,850
Total	\$ 532	\$ 89,042	\$ —	\$ 89,574
Liabilities:				
Contingent consideration—Zipsor	\$ —	\$ —	\$ 1,489	\$ 1,489
Contingent consideration—Lazanda	—	—	11,742	11,742
Contingent consideration—CAMBIA	—	—	1,594	1,594
	\$ —	\$ —	\$ 14,825	\$ 14,825

The fair value measurement of the contingent consideration obligations arises from the Zipsor, CAMBIA and Lazanda acquisitions and relates to fair value of the potential future 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 revenue forecast, discount rate and the probability assigned to the potential milestones and royalties being achieved. At each reporting date, the Company re-measures the contingent consideration obligation arising from the above acquisitions to their estimated fair values. Any changes in the fair value of contingent consideration resulting from a change in the underlying inputs are recognized in operating expenses until the contingent consideration arrangement is settled. Changes in the fair value of contingent consideration resulting from the passage of time are

recorded within interest expense until the contingent consideration is settled. The table below provides a summary of the changes in fair value recorded in interest expense and selling, general and administrative expenses for the three and six months ended June 30, 2017 and June 30, 2016:

	Three Months Ended		Six Months Ended June	
	June 30, 2017	2016	30, 2017	2016
Fair value, beginning of the period	\$ 8,611	\$ 14,864	\$ 14,825	\$ 14,971
Changes in fair value recorded in interest expense	265	600	796	1,194
Changes in fair value recorded in selling, general and administrative expenses	(1,128)	(110)	(6,128)	(287)
Royalties and milestone paid	(392)	(456)	(2,137)	(980)
Total	7,356	14,898	7,356	14,898

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, based on quoted market prices of the Company's debt, was approximately \$305.0 million and \$390.0 million (par value \$345.0 million) as of June 30, 2017 and December 31, 2016, respectively, and represents a Level 2 valuation. The principal amount of the Senior Notes approximates their fair value as of June 30, 2017 and represents a Level 2 valuation. When determining the estimated

Table of Contents

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, 2017 and June 30, 2016.

## NOTE 3. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, plus potentially dilutive common shares, related to unexercised stock options, unvested restricted stock awards, outstanding shares under the employee stock purchase plan and convertible debt. As the Company had net losses for the three and six months ended June 30, 2017 and June 30, 2016, all potentially dilutive common shares were determined to be anti-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,	
	2017	2016	2017	2016
Basic and diluted net loss per share				
Net loss	\$ (26,659)	\$ (10,541)	\$ (53,400)	\$ (31,458)
Denominator	62,532	61,166	62,331	61,032
Basic and diluted net loss per share	\$ (0.43)	\$ (0.17)	\$ (0.86)	\$ (0.52)

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

(in thousands)	June 30, 2017	June 30, 2016
Convertible debt	17,931	17,931
Stock options and equivalents	8,215	9,645
Total potentially dilutive common shares	26,146	27,576

#### NOTE 4. LICENSE ARRANGEMENTS

Janssen Pharmaceuticals, Inc.

In August 2012, the Company entered into a license agreement with Janssen Pharma that granted Janssen Pharma a non-exclusive license to certain patents and other intellectual property rights to its Acuform® drug delivery technology for the development and commercialization of tapentadol extended release products, including NUCYNTA ER (tapentadol extended-release tablets). The Company receives low single digit royalties on net sales of NUCYNTA ER in Canada and Japan through December 31, 2021. The Company was also previously receiving royalties on sales of NUCYNTA ER in the U.S. until its acquisition of the U.S. rights to NUCYNTA ER from Janssen Pharma on April 2, 2015.

Table of Contents

## NOTE 5. STOCK-BASED COMPENSATION

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of sales	\$ 39	\$ 8	\$ 75	\$ 16
Research and development expense	260	131	607	208
Selling, general and administrative expense	3,104	4,189	6,277	8,014
Total	\$ 3,403	\$ 4,328	\$ 6,959	\$ 8,238

At June 30, 2017, the Company had \$34.0 million of total unrecognized compensation expense related to stock option grants and restricted stock units that will be recognized over an average vesting period of 2.62 years.

## NOTE 6. INVENTORIES

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

	June 30, 2017	December 31, 2016
Raw materials	\$ 1,750	\$ 2,362
Work-in-process	1,152	869
Finished goods	7,531	9,802
Total	\$ 10,433	\$ 13,033

## NOTE 7. ACCRUED LIABILITIES

Accrued liabilities consist of the following (in thousands):

	June 30, 2017	December 31, 2016
Accrued compensation	\$ 10,604	\$ 11,730
Accrued royalties	18,486	21,703
Other accrued liabilities	23,962	25,965
Total accrued liabilities	\$ 53,052	\$ 59,398

## NOTE 8. 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) between 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 during 2015.

The Senior Notes will mature on April 2, 2022 (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)

Table of Contents

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 March 31, 2017 was 10.75% and the interest rate for the three months ended June 30, 2017 was 10.90%.

Pursuant to the repayment terms specified in the Note Purchase Agreement, in April 2016, the Company prepaid and retired \$100.0 million of the Senior Notes and paid a \$5.0 million prepayment fee. The Company recorded a net loss on prepayment of the Senior Notes of \$5.8 million which represented the prepayment fee of \$5.0 million and the immediate recognition of unamortized balances of debt discount and debt issuance costs of \$0.8 million in April 2016.

In April 2017, the Company prepaid and retired \$100.0 million of the Senior Notes and paid a \$4.0 million prepayment fee. The Company recorded a net loss on prepayment of the Senior Notes of \$5.4 million which represented the prepayment fee of \$4.0 million and the immediate recognition of unamortized balances of debt discount and debt issuance costs of \$1.4 million in April 2017.

The remaining \$375.0 million of Senior Notes can be repaid prior to maturity, at the Company's option. The Company is required to repay the outstanding Senior Notes in full if the principal amount outstanding on its existing 2.50% Convertible Senior Notes due 2021 as of March 31, 2021, is greater than \$100.0 million. In addition, if the successor entity in a Major Transaction, as defined in the Note Purchase Agreement, does not satisfy specified qualification criteria, the Purchasers may require the Company to prepay the Senior Notes upon consummation of the Major Transaction in an amount equal to the principal amount of outstanding Senior Notes, accrued and unpaid interest and a prepayment premium in an amount equal to what the Company would have otherwise paid in an optional prepayment described in the following paragraph. The Company is required to make mandatory prepayments on the Senior Notes in an amount equal to the proceeds it receives in connection with asset dispositions in excess of \$10.0 million, together with accrued and unpaid interest on the principal amount prepaid.

The Company paid a prepayment premium of \$5.0 million in connection with the April 2016 prepayment of Senior Notes and a prepayment premium of \$4.0 million with the April 2017 prepayment of Senior Notes. The Company is required to pay a prepayment premium equal to (i) 4% of the principal amount of the Notes to be prepaid, if such prepayment occurs after the second anniversary of the Purchase Date but on or prior to the third anniversary of the Purchase Date; (ii) 3% of the principal amount of the Notes to be prepaid, if such prepayment occurs after the third anniversary of the Purchase Date but on or prior to the fourth anniversary of the Purchase Date; (iii) 2% of the principal amount of the Notes to be prepaid, if such prepayment occurs after the fourth anniversary of the Purchase Date but on or prior to the fifth anniversary of the Purchase Date; (iv) 1% of the principal amount of the Notes to be prepaid, if such prepayment occurs after the fifth anniversary of the Purchase Date but on or prior to the sixth anniversary of the Purchase Date; and (v) zero, if such prepayment occurs after the sixth anniversary of the Purchase Date.



The Senior Notes and related indentures 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.

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

Table of Contents

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

April 2, 2018	\$ 57,500
April 2, 2019	115,000
April 2, 2020	115,000
April 2, 2021	87,500
	\$ 375,000

The following is a summary of the carrying value of the Senior Notes as of June 30, 2017 and December 31, 2016 (in thousands):

	June 30, 2017	December 31, 2016
Principal amount of the Senior Notes	\$ 375,000	\$ 475,000
Unamortized debt discount balance	(6,142)	(8,605)
Unamortized debt issuance costs	(246)	(344)
	\$ 368,612	\$ 466,051

The debt discount and debt issuance costs are being amortized as interest expense through April 2022 using the effective interest method. The following is a summary of interest expense for the three and six months ended June 30, 2017 and June 30, 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Contractual interest expense	\$ 10,393	\$ 12,997	\$ 23,159	\$ 28,622
Amortization of debt discount and debt issuance costs	595	564	1,197	1,082
Total interest expense	\$ 10,988	\$ 13,561	\$ 24,356	\$ 29,704

## Convertible Notes

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

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

Prior to March 1, 2021, holders of the Convertible Notes can convert their securities, at their option: (i) during any calendar quarter commencing after December 31, 2014, if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to \$25.01 (130% of the \$19.24 conversion price) on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; and (iii) at any time upon the occurrence of specified corporate transactions, to include a change of control (as defined in the Notes Indenture). On or after March 1, 2021 to the close of business on the second scheduled trading day immediately preceding the maturity date, the holders of the Convertible Notes may convert all or any portion of their notes, in multiples of \$1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. The initial conversion rate of 51.9852 shares of common stock per \$1,000 principal amount of Convertible Notes is equivalent to a conversion price of approximately \$19.24 per share of common stock.

Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. As more fully described in the prospectus supplement relating to the issuance of the Convertible Notes filed with the SEC on

Table of Contents

September 5, 2014, if the conversion obligation is satisfied solely in cash or through payment and delivery of a combination of cash and shares, the amount of cash and shares, if any, due upon conversion will be based on a daily conversion value calculated on a proportionate basis for each trading day in a 40 trading day observation period.

The closing price of the Company's common stock did not exceed 130% of the \$19.24 conversion price, for the required period during the three months ended June 30, 2017. As a result, the Convertible Notes were not convertible as of June 30, 2017.

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

The following is a summary of the liability component of the Convertible Notes as of June 30, 2017 and December 31, 2016 (in thousands):

	June 30, 2017	December 31, 2016
Principal amount of the Convertible Notes	\$ 345,000	\$ 345,000
Unamortized discount of the liability component	(79,864)	(87,570)
Unamortized debt issuance costs	(4,198)	(4,705)
	\$ 260,938	\$ 252,725

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, 2017 and June 30, 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Stated coupon interest	\$ 2,156	\$ 2,156	\$ 4,312	\$ 4,312
Amortization of debt discount and debt issuance costs	4,165	3,824	8,213	7,542
Total interest expense	\$ 6,321	\$ 5,980	\$ 12,525	\$ 11,854

## NOTE 9. SHAREHOLDERS' EQUITY

### Option Exercises

For the three and six months ended June 30, 2017, employees exercised options to purchase 529,555 and 813,352 shares of the Company's common stock with net proceeds to the Company of approximately \$3.4 million and \$6.0 million, respectively. For the three and six months ended June 30, 2016, employees exercised options to purchase 203,494 and 414,499 shares of the Company's common stock with net proceeds to the Company of approximately \$2.0 million and \$3.4 million, respectively.

Table of Contents

Restricted Stock Units

For the three and six months ended June 30, 2017, the Company issued 42,068 shares of the Company's common stock due to vesting of restricted stock units. For the three and six months ended June 30, 2016, the Company issued 42,697 shares of the Company's common stock due to vesting of restricted stock units.

NOTE 10. INCOME TAXES

As of June 30, 2017, our 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, we provided a full valuation allowance against our net deferred assets in December of 2016. We reassess 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.

For the three and six months ended June 30, 2017, the difference between the recorded benefit for income taxes and the tax benefit based on the federal statutory rate of 35%, was primarily attributable to the impact of the valuation allowance. For the three and six months ended June 30, 2016, the difference between the recorded benefit for income taxes and the tax benefit based on the federal statutory rate of 35%, was primarily attributable to the impact of net non-deductible expenses and minor discrete adjustments.

As of June 30, 2017 and December 31, 2016, the Company had \$14.9 million and \$14.7 million of unrecognized tax benefits, respectively. Tax years 2013-2017 remain open to examination by the Internal Revenue Service and tax years 2012-2017 remain open in certain state taxing jurisdictions in which the Company operates. The Company's net operating losses and credits from earlier tax years may remain open to adjustment by taxing authorities until the statute of limitation tolls on the year all carryovers are utilized in full. Interest and penalties, if any, related to unrecognized tax benefits, would be recognized as income tax expense by the Company. The Company has approximately \$0.9 million of accrued interest and penalties associated with unrecognized tax benefits.

NOTE 11. COMMITMENTS AND CONTINGENCIES

Leases

We have a non-cancelable operating lease for our office building and we are obligated to make payments under non-cancelable operating leases for automobiles used by our sales force. Future minimum lease payments under our non-cancelable operating leases at June 30, 2017 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2017 (remainder)	\$ 2,268
2018	3,747
2019	2,579
2020	2,005
2021	1,673
Thereafter	1,572
Total	\$ 13,844

In April 2012, the Company entered into an office and laboratory lease agreement to lease approximately 52,500 rentable square feet in Newark, California commencing on December 1, 2012. The Company occupied approximately 8,000 additional rentable square feet commencing in July 2015. The lease will expire on November 30, 2022. However, the Company has the right to renew the lease for one additional five year term, provided that written notice is made to the landlord no later than 12 months prior to the lease expiration.

The Company was allowed to control physical access to the premises upon signing the lease. Therefore, in accordance with the applicable accounting guidance, the lease term was deemed to have commenced in April 2012. Accordingly, the rent free periods and the escalating rent payments contained within the lease are being recognized on a straight-line basis from April 2012. The Company will pay approximately \$8.7 million in aggregate rent over the

## Table of Contents

remaining term of the lease for the above premises. Deferred rent was approximately \$1.5 million as of June 30, 2017 and \$1.6 million as of December 31, 2016. Rent expense relating to the office and laboratory lease agreement for the three months ended June 30, 2017 and June 30, 2016, was \$0.1 million and \$0.1 million, respectively, and \$0.3 million and \$0.3 million for the six months ended June 30, 2017 and June 30, 2016, respectively.

The Company has an operating lease agreement with Enterprise FM Trust (Enterprise) for the lease of vehicles to be used by the Company's sales force, with the lease terms ranging from 18 to 48 months. The Company will pay approximately \$5.1 million in aggregate rent over the remaining term of the lease for the vehicles. Rent expense relating to the lease of cars for the three months ended June 30, 2017 and June 30, 2016 was \$0.8 million and \$0.8 million, respectively, and \$1.6 million and \$1.6 million for the six months ended June 30, 2017 and June 30, 2016, respectively.

## Legal Matters

### Depomed v. NUCYNTA and NUCYNTA ER ANDA Filers

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

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



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

In each of the foregoing actions, the ANDA filers counterclaimed for declaratory relief of noninfringement 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 the NUCYNTA ER and NUCYNTA from Janssen Pharma. As part of the acquisition, the Company became the exclusive U.S. licensee of the patents referred to above. The Company was added as a plaintiff to the pending cases and is actively litigating them.

In September 2015, the Company filed an additional complaint in the D.N.J. asserting the '130 Patent against Actavis. The '130 Patent issued in September 2013 and was timely listed in the Orange Book for NUCYNTA ER, but Actavis did not file a Paragraph IV Notice with respect to this patent. In its new lawsuit, the Company claimed that Actavis would infringe or induce infringement of the '130 Patent if its proposed generic products were approved. In response, Actavis counterclaimed for declaratory relief of noninfringement 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. A two-week bench trial on the validity of the three asserted patents and infringement of the '130 Patent was commenced on March 9, 2016. Closing arguments took place on April 27, 2016. On September 30, 2016, the Court issued its final decision. The Court found that the '593, '364 Patent, and '130 Patents are all valid and enforceable, that Alkem will induce infringement of the '130 Patent, and that Roxane and Actavis will not infringe the '130 Patent.

## Table of Contents

On November 3, 2016, Alkem filed an appeal in the United States Court of Appeals for the Federal Circuit appealing the Court's finding that the '364 and '130 Patents are not invalid and that Alkem infringes the '130 Patent. The Company moved to terminate Alkem's appeal on the grounds that a final judgment had not yet been entered by the Court, and the Federal Circuit deactivated Alkem's appeal on December 16, 2016. On April 11, 2017, the Court entered final judgment in favor of the Company on the validity and enforceability of all three patents, on infringement of the '593 and '364 Patents by all defendants, and on infringement of the '130 Patent against Alkem. The judgment includes an injunction enjoining all three defendants from engaging in certain activities with tapentadol (the active ingredient in NUCYNTA), and ordering the effective date of any approval of Actavis, Actavis UT, and Roxane's ANDAs, and Alkem's ANDA for NUCYNTA IR to be no earlier than the expiry of the '364 Patent (June 27, 2025), and the effective date of any approval of Alkem's ANDA for NUCYNTA ER to be no early than the expiry of the '130 Patent (September 22, 2028). The period of exclusivity with respect to all four defendants may in the future be extended with the award of pediatric exclusivity.

Notices of appeal were filed by defendants Alkem and Roxane concerning the '364 and '130 patent issues. The Company filed its own cross-appeal with regard to the Court's finding that Roxane and Actavis will not infringe the claims of the '130 Patent. The appeals have been consolidated at the Federal Circuit, and the briefing schedule is expected to continue until the first quarter of 2018, with a hearing scheduled later in 2018. The '593 patent is not the subject of any appeals.

### '364 Patent Inter Partes Review Petition

On January 15, 2016, Rosellini Scientific, LLC (with nXn Partners, LLC as an additional real party in interest) (Rosellini) filed with the Patent Trial and Appeal Board (PTAB) a petition to request an inter partes review (an IPR) of the '364 Patent. On April 27, 2016, Grünenthal, the owner of the '364 Patent, filed its Patent Owner Preliminary Response. An IPR is a proceeding that became available in September 2012 in accordance with the America Invents Act (the AIA). In an IPR, a petitioner may request that the PTAB reconsider the validity of issued patent claims on the basis of prior art in the form of printed publications and other patents. Any patent claim the PTAB determines to be unpatentable is stricken from the challenged patent. Any party may appeal final written decisions of the PTAB to the U.S. Court of Appeals for the Federal Circuit, but the PTAB's decisions denying institution of an IPR are non-appealable. Accordingly, if the PTAB finds a challenged claim patentable, or declines to institute an IPR as to a challenged claim, the IPR petitioner is estopped from asserting in a patent infringement lawsuit that these claims are invalid on any ground the petitioner raised or reasonably could have raised in the IPR. On July 18, 2016, the PTAB declined to institute the IPR petition filed by Rosellini with respect to the '364 Patent with respect to all patent claims subject of the petition.

### Depomed v. Purdue

The Company has 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 arises from Purdue's commercialization of reformulated OxyContin® (oxycodone hydrochloride controlled-release) in the U.S. and alleges infringement of U.S. Patent Nos. 6,340,475 (the '475 Patent) and 6,635,280 (the '280 Patent), which expired in September 2016.

On September 28, 2015, the district court stayed the Purdue lawsuit pending the decision of the U.S. Court of Appeals for the Federal Circuit (CAFC) in Purdue's appeal of the PTAB's Final Written Decisions described below. On June 30, 2016, the district court lifted the stay based on the CAFC's opinion and judgment affirming the PTAB's Final Written Decisions confirming the patentability of the patent claims of the '475 and '280 Patents Purdue had challenged. The parties filed opening Markman briefs on June 3, 2016 and their responsive Markman briefs in July 2016. The Markham hearing was held on November 2, 2016 and on April 6, 2017, the Court issued a Markman order which is available on the docket. On June 10, 2016, the Company filed a motion for leave to file a second amended Complaint to plead willful infringement and remove claims of infringement related to U.S. Patent No. 6,723,340 (the '340 Patent) and 8,329,215 (the '215 Patent). On June 21, 2016, Purdue filed an opposition to the Company's motion for leave to plead willful infringement, but did not oppose removing claims related to the '340 and '215 Patents. On June 28, 2016, the Company filed a reply brief to its motion for leave. On January 31, 2017, the Court granted the Company's motion for leave to plead willful infringement.

On June 1, 2016, Purdue filed a motion for leave to amend its invalidity contentions to add allegations of indefiniteness and confirm that certain invalidity defenses remained in the case post-IPR proceedings. On June 21, 2016 the Company filed an opposition to Purdue's motion for leave and a cross-motion to strike Purdue's invalidity

## Table of Contents

contentions. On November 4, 2016, the Court granted Purdue's motion for leave to amend its invalidity contentions, and denied the Company's cross-motion to strike. On October 28, 2016, Purdue moved for leave to amend its answer to add a counterclaim of unenforceability and affirmative defenses of inequitable conduct and unclean hands. On November 7, 2016, Depomed filed its opposition to Purdue's motion for leave to amend its Answer. On November 14, 2016, Purdue filed a reply to its motion for leave to amend its Answer.

On February 1, 2017, Depomed filed a Second Amended Complaint pleading willful infringement. On February 15, 2017, Purdue answered Depomed's Second Amended Complaint asserting counterclaims of non-infringement, invalidity and unenforceability. On March 6, 2017, Depomed moved to dismiss Purdue's counterclaim of inequitable conduct and moved to strike affirmative defenses of inequitable conduct, unclean hands, and patent misuse. On March 20, 2017, Purdue filed an opposition to Depomed's motion, and on March 27, 2017, Depomed filed a reply brief. On April 17, 2017, the Court issued an order finding Purdue's motion to amend its Answer was moot. On June 28, 2017, the Court issued an order granting Depomed's motion to dismiss Purdue's affirmative defense of patent misuse and theory of inequitable conduct related to interrogatory responses, and the order denied the remainder of Depomed's motion. On July 10, 2017, the case was reassigned to Judge Wolfson. On July 11, 2017, the Court scheduled fact discovery regarding inequitable conduct to close on August 2, 2017, expert discovery to close on November 16, 2017, the deadline for dispositive motions as December 19, 2017, and a pretrial conference on January 25, 2018. The Court also scheduled a teleconference for October 12, 2017. No trial date has been set by the Court, though the Company expects a trial may be scheduled in early 2018.

In response to petitions filed by Purdue, the PTAB instituted IPRs of certain of the claims asserted in the Company's lawsuit against Purdue. In the IPRs initiated by Purdue, in July 2014, the PTAB declined to institute an IPR as to two claims of the '475 patent and two claims of the '280 Patent. The PTAB instituted an IPR as to the other 15 claims of the '475 Patent and as to the other ten claims of the '280 Patent asserted against Purdue. In July 2015, the PTAB issued Final Written Decisions confirming the patentability of all claims at issue. In March 2016, following Purdue's appeal of the PTAB's decisions, the CAFC affirmed the PTAB's Final Written Decisions.

### Depomed v. Strides Pharma Inc. and Strides Pharma Global Pte Limited

On May 5, 2017, the Company filed suit in the U.S. District Court for the District of New Jersey against Strides Pharma Inc. and Strides Pharma Global Pte Limited (collectively, Strides) based on Strides' filing of an ANDA to market a generic version of ZIPSOR prior to the expiration of U.S. Patent Nos. 7,662,858; 7,884,095; 7,939,518; 8,110,606; 8,623,920; and 9,561,200 (the patents-in-suit). By letter dated March 27, 2017, Strides informed the Company that it had filed an ANDA for a generic version of ZIPSOR with Paragraph IV certifications against each of the patents-in-suit. The Company's filing of the complaint against Strides resulted in an automatic 30-month stay of FDA approval of Strides' ANDA, lasting until September 2019.

Previously, in July 2013, the Company filed suit against Banner Pharmacaps Inc. (Banner) and Watson Laboratories, Inc. (Watson) based on Banner's filing of an ANDA for a generic version of ZIPSOR. The Company and the

defendants reached a settlement of the case that permits Watson to begin selling their generic version of ZIPSOR on March 24, 2022, or earlier under certain circumstances. The Company believes that Banner and Watson may be entitled to 180-day exclusivity with respect to generic ZIPSOR.

#### Opioid-Related Request and Subpoenas

The Company and a number of other pharmaceutical companies recently received a request for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs related to the promotion of opioids. The Company has voluntarily furnished information responsive to such request.

The Company and a number of other pharmaceutical companies recently received subpoenas related to opioid sales and marketing from the Office of the Attorney General of Maryland and the United States Department of Justice. The Company is currently cooperating with the State of Maryland and the Department of Justice in their respective investigations.

## Table of Contents

### General

The Company cannot reasonably predict the outcome of the pending legal proceedings or other matters 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 we prevail in litigation involving a claim for damages. As such, the Company is not currently able to estimate the impact of the above matters 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. 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 it believes may have a material adverse effect on its business, results of operations or financial condition. However, regardless of the outcome, litigation, actions, claims, suits, investigations and proceedings can have an adverse impact on the Company because of associated cost and diversion of management time.

### NOTE 12. ACQUISITIONS

#### The Cebranopadol Acquisition

On November 17, 2015, the Company entered into a definitive agreement to acquire the U.S. and Canadian rights to cebranopadol and its related follow-on compound from Grünenthal. Cebranopadol is a novel, first-in-class analgesic in development for the treatment of moderate to severe chronic nociceptive and neuropathic pain. The Company is currently evaluating the development plan for cebranopadol, including the timing of potential Phase 3 trials. The acquisition was completed on December 30, 2015.

Under the terms of the acquisition agreement, the Company entered into a settlement agreement with Endo Pharmaceuticals, Inc., a subsidiary of Endo International Plc (Endo), to resolve Depomed's ongoing patent litigation against Endo for alleged infringement of three of the Company's patents by Endo's OPANA ER product (the Settlement). As the formulator of OPANA ER, Grünenthal indemnified Endo for certain intellectual property matters, including the Company's ongoing patent infringement lawsuit against Endo. The settlement agreement granted Endo a non-exclusive patent license in the United States, and a covenant not to sue outside the United States, for the currently marketed form of OPANA ER. In addition, the Company provided Grünenthal with a limited covenant not to sue under certain of the Company's Acuform® drug delivery patents with specific drug substances as well as \$25.0 million in cash. The Company will also pay Grünenthal royalties on net sales and one-time net sales milestones. There are no clinical, regulatory or approval milestone payments.

The cebranopadol acquisition was treated as an asset acquisition under the applicable guidance contained within U.S. GAAP. The total purchase consideration of \$54.9 million consisting of \$25 million paid in cash upon the closing of the acquisition and \$29.9 million reflecting the fair value of each of the elements of the Settlement, was recorded as in-process research and development expense in the fourth quarter of 2015. Significant judgments were used in determining the estimated fair values assigned to the elements of the Settlement, such as but not limited to, the probability of the Company succeeding in its litigation against Endo had the litigation not been resolved, estimates of royalty rates and any damages that may have been awarded by the court, the timing of such an award and estimates of appropriate discount rates used to present value these expected future net cash flows. An actual judgment awarded by the court may have differed materially from the amounts recorded.

#### The NUCYNTA Acquisition

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

The NUCYNTA franchise includes NUCYNTA ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, NUCYNTA (tapentadol), an immediate release version of

Table of Contents

tapentadol, for management of moderate to severe acute pain in adults, and NUCYNTA (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized (collectively, the Products).

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

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

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

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

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

(Amounts in thousands)	
Cash Paid	\$ 1,050,000
Rebates payable by Seller	(9,977)



Total Purchase Consideration      \$ 1,040,023

The rebates payable by Janssen Pharma represent a reduction to the total purchase consideration. The fair value of the rebates payable by Janssen Pharma was determined based on estimates that take into consideration the terms of agreements with customers, historical rebates taken, and the estimated amount of time it takes the product to flow through the distribution channel.

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

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

#### NUCYNTA U.S. Product Rights

The valuation of the NUCYNTA US Product Rights was based on management's estimates, information and reasonable and supportable assumptions. This estimated fair value was determined using the income approach under the

Table of Contents

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

## NOTE 13. INTANGIBLE ASSETS

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

	June 30, 2017				December 31, 2016		
Amounts in thousands	Remaining Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
NUCYNTA product rights	8.5	\$ 1,019,978	\$ (219,440)	\$ 800,538	\$ 1,019,978	\$ (172,288)	\$ 847,690
AMBIA product rights	6.5	51,360	(18,187)	33,173	51,360	(15,619)	35,741
azanda product rights	5.1	10,480	(4,561)	5,919	10,480	(3,979)	6,501
ipsor product rights	4.8	27,250	(16,201)	11,049	27,250	(15,033)	12,217
		\$ 1,109,068	\$ (258,389)	\$ 850,679	\$ 1,109,068	\$ (206,919)	\$ 902,149

In September 2016, the United States District Court for the District of New Jersey ruled in favor of the Company in the Company's patent litigation against all three ANDA filers for the Company's NUCYNTA franchise. Based upon the Court's ruling, the Company expects market exclusivity until December 2025 for NUCYNTA ER, NUCYNTA and NUCYNTA oral solution (an unmarketed form of NUCYNTA). Based upon the Court's ruling in 2016, the Company reviewed the useful life of the NUCYNTA product rights and extended that from the previous estimate of June 2025 to December 2025.

Based on finite-lived intangible assets recorded as of June 30, 2017, and assuming the underlying assets will not be impaired and that we 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
2017 (remainder)	\$ 51,469
2018	102,939
2019	102,939
2020	102,939
2021	102,939
Thereafter	387,454
Total	\$ 850,679

Table of Contents

NOTE 14. OUT OF PERIOD ADJUSTMENT

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

NOTE 15. RESTRUCTURING CHARGES

The Company announced a reduction-in-force during the three months ended June 30, 2017 in order to streamline operations and achieve operating efficiencies. The Company recorded \$3.4 million in severance and benefits charges during the period. Restructuring and related liabilities payable as of June 30, 2017 is \$1.9 million. The restructuring activities were substantially completed by July 31, 2017.



Table of Contents

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

FORWARD-LOOKING INFORMATION

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

- the commercial success and market acceptance of our products;
- the current and future market conditions for short-acting and long-acting opioids;
- 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, proceeding or government investigation that may be instituted related to any of our products, product candidate or products we may acquire;
- legal and regulatory developments in the United States affecting our industry;
- our ability to generate sufficient cash flow from our business to make payments on our indebtedness and our compliance with the terms and conditions of the agreements governing our indebtedness;
- our and our collaborative partners' compliance or non-compliance with legal and regulatory requirements related to the promotion of pharmaceutical products in the U.S.;
- our plans to acquire, in-license or co-promote other products;
- the results of our research and development efforts including clinical studies relating to our product candidate;
- submission, acceptance and approval of regulatory filings;
- our ability to raise additional capital, if necessary;
- our collaborative partners' compliance or non-compliance with obligations under our collaboration agreements; and
- the outcome of our ongoing patent infringement litigation against Purdue Pharma L.P. (Purdue).

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.

## ABOUT DEPOMED

Depomed is a specialty pharmaceutical company focused on pain and other central nervous system (CNS) conditions. Our current specialty pharmaceutical business includes the following six products marketed in the United States for various pain states:

- The NUCYNTA® franchise of pain products we acquired in April 2015 (the Nucynta Acquisition), which includes two products currently marketed in the U.S.:
- NUCYNTA® ER (tapentadol extended release tablets), a product for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults, and for which alternate treatment options are inadequate; and

## Table of Contents

- NUCYNTA® IR (NUCYNTA) (tapentadol), an immediate release version of tapentadol for the management of moderate to severe acute pain in adults.
- Gralise® (gabapentin), a once-daily product for the management of postherpetic neuralgia (PHN) we launched in October 2011.
- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks we acquired in December 2013.
- Lazanda® (fentanyl) nasal spray, a product for the management of breakthrough cancer pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain we acquired in July 2013.
- Zipsor® (diclofenac potassium) liquid filled capsules, a non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain we acquired in June 2012.

We actively seek to expand our product portfolio through acquiring or in-licensing commercially available products or late-stage product candidates that may be marketed and sold effectively with our existing products through our sales and marketing capability, which currently includes approximately 300 full-time sales representatives.

We currently have one product candidate, cebranopadol initially for treatment of chronic lower back pain and potentially for chronic nociceptive and neuropathic pain. We licensed the U.S. and Canadian rights to cebranopadol from Grünenthal GmbH (Grünenthal) in December 2015. We are currently evaluating the development plan for cebranopadol, including the timing of potential Phase 3 trials.

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

## Commercialized Products and Product Candidate Development Pipeline

The following table summarizes our products and product candidate development pipeline:

### Depomed Commercialized Products and Development Pipeline

Product	Indication	Status
NUCYNTA ER	Pain severe enough to require daily, around-the-clock, long term opioid treatment, including neuropathic pain associated with DPN in adults,	Currently sold in the U.S.



and for which alternate treatment options are inadequate

Acquired in  
April 2015

NUCYNTA

Management of acute pain severe enough to require an opioid analgesic  
and for which alternative treatments are inadequate.

Currently sold in  
the U.S.  
Acquired in  
April 2015

Gralise

Management of PHN

Currently sold in  
the U.S.  
Launched in  
October 2011

CAMBIA

Acute treatment of migraine attacks in adults 18 years of age or older

Currently sold in  
the U.S.  
Acquired in  
December 2013

Table of Contents

Zipsor	Mild to moderate acute pain	Currently sold in the U.S. Acquired in June 2012
Lazanda	Breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to continuous opioid therapy for their underlying persistent cancer pain	Currently sold in the U.S. Acquired in July 2013
Cebranopadol	Initially for chronic lower back pain and potentially for chronic nociceptive and neuropathic pain	In development Licensed in December 2015

OUR BUSINESS OPERATIONS

As of June 30, 2017, our revenues are generated primarily from commercialized products.

Commercialized Products

NUCYNTA ER (Tapentadol Extended Release Tablets)

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

NUCYNTA (Tapentadol)

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

Combined NUCYNTA ER and NUCYNTA product sales were \$63.9 million and \$124.6 million for the three and six months ended June 30, 2017, respectively.

#### 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. The FDA has granted Orphan Drug exclusivity for PHN. Gralise product sales were \$18.1 million and \$36.7 million for the three and six months ended June 30, 2017, respectively.

#### CAMBIA (Diclofenac Potassium for Oral Solution)

CAMBIA is a non-steroidal anti-inflammatory drug (NSAID) indicated for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older. We acquired CAMBIA in December 2013 from Nautilus Neurosciences, Inc. (Nautilus). We began shipping and recognizing product sales on CAMBIA in December 2013. CAMBIA product sales were \$8.5 million and \$15.7 million for the three and six months ended June 30, 2017, respectively.

#### Zipsor (Diclofenac Potassium) Liquid-Filled Capsules

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

Table of Contents

June 21, 2012 from Xanodyne Pharmaceuticals, Inc. (Xanodyne). Zipsor product sales were \$4.4 million and \$9.1 million for the three and six months ended June 30, 2017, respectively.

Lazanda (Fentanyl) Nasal Spray

Lazanda nasal spray is an intranasal fentanyl drug used to manage breakthrough pain in adults (18 years of age and older) who are already routinely taking other opioid pain medicines around-the-clock for cancer pain. We acquired Lazanda in July 2013 from Archimedes Pharma US Inc. and its affiliated companies (collectively, Archimedes). Lazanda product sales were \$5.3 million and \$9.2 million for the three and six months ended June 30, 2017, respectively.

Segment and Customer Information

The Company operates in one operating segment and has operations solely in the United States. To date, all of the Company's revenues from product sales are related to sales in the United States. The Company has recognized license and royalty revenue from license agreements in the territories of the United States, Canada and Korea.

OUR DRUG DELIVERY TECHNOLOGY AND RELATED LICENSE AND DEVELOPMENT  
ARRANGEMENTS AND PATENT LITIGATION

Our Acuform drug delivery technology is based on our proprietary oral drug delivery technologies and is designed to include formulations of drug-containing polymeric tablets that allow multi-hour delivery of an incorporated drug when taken with a meal. Of our marketed products, Gralise and NUCYNTA ER utilize this technology.

We have also licensed our drug delivery technology to several other pharmaceutical companies, and have asserted the U.S. patents comprising our Acuform technology in patent infringement litigation.

Ironwood Pharmaceuticals, Inc.—IW-3718 for Refractory GERD

In July 2011, we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for

IW-3718, an Ironwood product candidate under evaluation for refractory GERD. We have received \$3.4 million under the agreement, including a milestone payment of \$1.0 million in March 2014 as a result of the initiation of clinical trials relating to IW-3718 by Ironwood.

#### Janssen Pharmaceuticals, Inc.—NUCYNTA ER

In August 2012, the Company entered into a license agreement with Janssen Pharma that grants Janssen Pharma a non-exclusive license to certain patents and other intellectual property rights to the Company's Acuform drug delivery technology for the development and commercialization of tapentadol extended release products, including NUCYNTA ER. The Company received a \$10.0 million upfront license fee. The Company also received low single digit royalties on sales of NUCYNTA ER in the U.S. for sales from July 2, 2012 until the Company's acquisition of the U.S. rights to NUCYNTA ER from Janssen Pharma on April 2, 2015, and will continue to receive low single digit royalties on net sales of NUCYNTA ER in Canada and Japan through December 31, 2021.

#### 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, 2016 filed with the SEC on February 24, 2017 (the 2016 Form 10-K). The description of our critical accounting policies is incorporated herein by reference to our 2016 Form 10-K.

Table of Contents

## RESULTS OF OPERATIONS

Three and Six Months Ended June 30, 2017 and 2016.

## Revenue

Total revenues by products are summarized in the following table (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Product sales:				
NUCYNTA products	\$ 63,938	\$ 71,917	\$ 124,634	\$ 141,281
Gralise	18,122	23,788	36,674	42,811
CAMBIA	8,495	7,618	15,698	13,790
Lazanda	5,274	6,352	9,199	10,912
Zipsor	4,403	6,842	9,054	12,294
Pharmacy benefit manager dispute reserve	—	—	(4,742)	—
Total product sales	100,232	116,517	190,517	221,088
Royalties:				
Total royalty revenue	225	165	387	374
Total revenues	\$ 100,457	\$ 116,682	\$ 190,904	\$ 221,462

## Product Sales

NUCYNTA. We completed the acquisition of the NUCYNTA franchise on April 2, 2015 and began shipments on April 6, 2015. From closing until June 2015, we retained the contract sales force that had been promoting NUCYNTA for Janssen Pharma, and we re-launched NUCYNTA with our increased sales force in mid-June 2015. The decrease in NUCYNTA product sales in the three and six months ended June 30, 2017 as compared to the same periods in 2016 is primarily the result of lower unit demand for NUCYNTA attributable to declines in both the long-acting and short-acting opioid prescription markets. While we expect NUCYNTA franchise product sales to increase in the second half of 2017 over first half of 2017, prescriptions in the opioid market have declined in recent quarters as a result of, among other things, regulatory actions, government investigations and heightened public attention on opioid abuse, and we expect prescriptions in the opioid market to continue to decline at least in the short term.

Gralise. In October 2011, we announced the commercial availability of Gralise and began distributing Gralise to wholesalers and retail pharmacies. The decrease in Gralise product sales for the three and six months ended June 30, 2017 as compared to the same periods in 2016 was primarily due to lower unit demand resulting, in part, from a decline in the number of sales representatives promoting Gralise. We currently plan on expanding the sales force promoting Gralise in the third quarter of 2017, and expect Gralise product sales to be consistent with current levels for the remainder of 2017.

CAMBIA. We began shipping and recognizing product sales on CAMBIA in December 2013. We began commercial promotion of CAMBIA in February 2014. The increase in CAMBIA product sales for the three and six months ended June 30, 2017 as compared to the same periods in 2016, is primarily a result of lower managed care rebates and lower co-pay assistance programs, offset by lower prescription demand. We currently plan on expanding the sales force promoting CAMBIA in the third quarter of 2017, and expect CAMBIA product sales to be consistent with current levels for the remainder of 2017.

Lazanda. We began shipping and recognizing product sales on Lazanda in August 2013. We began commercial promotion of Lazanda in October 2013. The decrease in Lazanda product sales in the three and six months ended June 30, 2017, as compared to the same periods in 2016 is primarily a result of lower unit demand attributable to decline in the Transmucosal Immediate Release Fentanyl (TIRF) prescription market offset, in part, by price increases. We expect Lazanda product sales to decline modestly from current levels for the remainder of 2017 as a result of continued deterioration of the TIRF market and the cessation of promotion of Lazanda by our salesforce in May 2017.

## Table of Contents

Zipsor. We began shipping and recognizing product sales on Zipsor at the end of June 2012. We began commercial promotion of Zipsor in July 2012. The decrease in Zipsor product sales in the three and six months ended June 30, 2017 as compared to the same periods in 2016, is a result of reduced unit demand offset, in part, by price increases.

Pharmacy Benefit Manager (“PBM”). During the three months ended March 31, 2017, the Company established a reserve with respect to a dispute with a PBM over rebates relating to NUCYNTA ER, NUCYNTA and Gralise. The dispute relates to rebate claims submitted with respect to the year ended December 31, 2015 and the first half of 2016. As of December 31, 2016, the Company established a reserve for \$1.0 million with respect to these claims, and had determined the likely amount payable on settlement would not be material to the consolidated financial statements. However, as a result of further communication with the PBM during the three months ended March 31, 2017, it became clear that the Company’s failure to pay the disputed amount would adversely impact the Company’s ability to maintain a favorable position on the PBM’s formulary. Accordingly, despite the Company’s belief that the claims in dispute are invalid, the Company increased the reserve against this matter by \$4.7 million which is an offset to net sales for the three months ended March 31, 2017. The Company will adjust net sales in the future if the dispute is resolved for an amount that is different than that currently reserved.

## Commercial Initiatives

We believe the key drivers of our financial results for the three and six months ended June 30, 2017 include the significant decline in the opioid market and a highly disruptive salesforce realignment implemented in February 2017. On May 9, 2017, we announced a series of initiatives aimed at driving the growth of our products and increasing our business efficiencies.

- Our pain salesforce, which was recently increased from 190 to 258, will continue to carry NUCYNTA ER and NUCYNTA IR as their primary focus. Gralise has been reassigned to our neurology salesforce, where we believe it will receive enhanced promotional focus. In addition, we will further optimize our sales targeting to ensure health care providers focused on treating pain are sufficiently covered.
- We reinvested in Gralise and CAMBIA as well as our neurology salesforce that promotes these products. The neurology salesforce will be increased from 40 to 90 and will now promote both Gralise and CAMBIA.
- Due to the significant deterioration within the TIRF market, we ceased promoting Lazanda through our salesforce and instead are utilizing non-salesforce promotional efforts to support this product. The headcount associated with the 20 person salesforce promoting Lazanda were reassigned to our neurology salesforce to further support the promotion of Gralise and CAMBIA.

## Royalties

Royalties for the three and six months ended June 30, 2017 are primarily comprised of royalties from Tribute Pharmaceuticals, Inc. on net sales of CAMBIA in Canada and royalties from Janssen Pharma on net sales of



NUCYNTA ER in Canada and Japan. Mallinckrodt ceased commercial promotion of XARTEMIS™ XR in 2015.

## Cost of Sales

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, royalty payments, inventory write-downs, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales. Cost of sales excludes the amortization of intangible assets described separately below under “Amortization of Intangible Assets”. Total cost of sales for the three and six months ended June 30, 2017, as compared to the corresponding period in the prior year, was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of Sales	\$ 19,725	\$ 20,965	\$ 37,499	\$ 44,514
Dollar change from prior year	(1,240)	(1,900)	(7,015)	18,537
Percentage change from prior year	(5.9) %	(8.3) %	(15.8) %	71.4 %

## Table of Contents

The decrease in cost of sales for the three and six months ended June 30, 2017 as compared to the same periods in 2016 was primarily due to lower product sales and no milestone payments for the three and six months ended June 30, 2017 as compared to the same periods in 2016.

We acquired and began selling CAMBIA in December 2013. In connection with the acquisition, the Company assumed a liability to make certain milestone payments to third parties that were unrelated to the Seller. The milestones are based on cumulative net sales of CAMBIA in a consecutive twelve month period. A post-acquisition milestone of \$3 million was triggered during the three months ended March 31, 2016 and is included in cost of sales for the six months ended June 30, 2016.

Cost of sales for NUCYNTA includes a royalty on net sales payable to Grünenthal. NUCYNTA cost of sales for the three and six months ended June 30, 2017 was approximately 25%.

The cost of sales for Gralise, CAMBIA, Lazanda and Zipsor, combined was approximately 10% for the three and six months ended June 30, 2017.

We expect cost of sales for the remainder of 2017 for NUCYNTA to be approximately 25% of net sales reflecting the manufacturing transfer price and a royalty on net sales payable to Grünenthal, the developer of the product. Cost of sales for our other products varies significantly, but we expect cost of sales as a percentage of net sales for the remainder of 2017 will continue at approximately the levels incurred in the first half of 2017.

## Research and Development Expenses

Our research and development expenses currently include salaries, clinical trial costs, and consultant fees, supplies, manufacturing costs for research and development programs and allocations of corporate costs. It is extremely difficult to predict the scope and magnitude of future research and development expenses for our product candidate in development, as it is extremely difficult to determine the nature, timing and extent of clinical trials and studies and the FDA's requirements for a particular drug. As potential products proceed through the development process, each step is typically more extensive, and therefore more expensive, than the previous step. Therefore, success in development generally results in increasing expenditures until actual product approval. Total research and development expenses for the three and six months ended June 30, 2017 and 2016 were as follows (in thousands):

Three Months Ended June 30,	Six Months Ended June 30,
--------------------------------	------------------------------

Edgar Filing: DEPOMED INC - Form 10-Q

	2017	2016	2017	2016
Research and development expenses	\$ 5,614	\$ 7,116	\$ 10,698	13,065
Dollar change from prior year	(1,502)	2,402	(2,367)	6,493
Percentage change from prior year	(21.1) %	51.0 %	(18.1) %	98.8 %

Research and development expenses for the three and six months ended June 30, 2017 decreased as compared to the same periods in 2016 primarily as a result of lower costs associated with pediatric studies for NUCYNTA. In light of the changing opioid landscape, we are exploring ways to improve cebranopadol's differentiated profile and potential modifications to the development program prior to its entry into Phase 3 trials. Therefore, we do not expect to incur significant expenses associated with cebranopadol in 2017.

We expect research and development costs for the remainder of 2017 to approximate the levels incurred in the first half of 2017.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses primarily consist of personnel, marketing and promotion expenses associated with our commercial products, personnel expenses to support our administrative and operating activities,

Table of Contents

facility costs and professional expenses, such as legal fees. Total selling, general and administrative expenses for the three and six months ended June 30, 2017, as compared to the same periods in 2016, were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Selling, general and administrative expenses	\$ 50,010	\$ 51,903	\$ 98,529	\$ 104,462
Dollar change from prior year	(1,893)	(5,505)	(5,933)	12,512
Percentage change from prior year	(3.6) %	(9.6) %	(5.7) %	13.6 %

The decrease in selling, general and administrative expenses for the six months ended June 30, 2017, as compared to the same period in 2016, was primarily due to lower legal expenses in 2017 and a \$6.1 million reduction in the fair value of contingent consideration relating to our Lazanda, CAMBIA and Zipsor acquisitions. The decrease in the fair value of contingent consideration resulted from a reduction in the Company's estimate of future sales of these products in light of the lower than expected results since March 2017. Selling, general and administrative expenses for the three months ended March 31, 2017 includes a \$3.4 million adjustment related to an increase in estimates associated with the branded prescription drug fee of which \$1.4 million and \$2.0 million related to the years ended December 31, 2015 and 2016, respectively. We expect selling, general and administrative expenses to increase from our current levels for the remainder of 2017 in part, due to an expected increase in legal expenses associated with new government inquiries and subpoenas directed to opioid manufacturers as well as higher expenses associated with the increase in our neurology salesforce.

## Amortization of Intangible Assets

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Amortization of intangible assets—NUCYNTA	\$ 23,576	24,877	\$ 47,152	\$ 49,755
Amortization of intangible assets—Zipsor	584	585	1,168	1,169
Amortization of intangible assets—Lazanda	291	291	582	582
Amortization of intangible assets—CAMBIA	1,284	1,284	2,568	2,568
	\$ 25,735	\$ 27,037	\$ 51,470	\$ 54,074

The NUCYNTA product rights of approximately \$1.0 billion that we acquired on April 2, 2015, have been recorded as intangible assets in the accompanying Condensed Consolidated Balance Sheets and are being amortized using the straight line method over the estimated useful life of approximately ten years. Amortization commenced on the acquisition date. In September 2016, the United States District Court for the District of New Jersey ruled in favor of the Company in the Company's patent litigation against all three filers of Abbreviated New Drug Applications (ANDAs) for the Company's NUCYNTA franchise. Based upon the Court's ruling, the Company expects market

exclusivity until December 2025 for NUCYNTA ER, NUCYNTA and NUCYNTA oral solution (an unmarketed form of NUCYNTA). Based also upon the Court's ruling, the Company reviewed the useful life of the NUCYNTA product rights and in 2016 extended that from the previous estimate of June 2025 to December 2025. The estimated amortization expense for the remainder of 2017 is expected to be \$47.2 million.

The Zipsor product rights of \$27.2 million have been recorded as intangible assets on the accompanying Condensed Consolidated Balance Sheets and are amortized over the estimated useful life of the asset on a straight-line basis through March 2022. The estimated amortization expense for the remainder of 2017 is expected to be \$1.2 million.

The CAMBIA product rights of \$51.4 million have been recorded as intangible assets on the accompanying Condensed Consolidated Balance Sheets and are being amortized over the estimated useful life of the asset on a straight-line basis through December 2023. Amortization commenced on December 17, 2013, the date on which we acquired CAMBIA. The estimated amortization expense for the remainder of 2017 is expected to be \$2.6 million.

The Lazanda product rights of \$10.5 million have been recorded as intangible assets on the accompanying Condensed Consolidated Balance Sheets and are being amortized over the estimated useful life of the asset on a straight-line basis through August 2022. Amortization commenced on July 29, 2013, the date on which we acquired Lazanda. The estimated amortization expense for the remainder of 2017 is expected to be \$0.6 million.

Table of Contents

## Restructuring Charges

The Company announced a reduction-in-force during the three months ended June 30, 2017 in order to streamline operations and achieve operating efficiencies. The Company recorded \$3.4 million in severance and benefits charges during the period. Restructuring and related liabilities payable as of June 30, 2017 is \$1.9 million.

## Interest Income and Expense

The decrease in net interest expense for the three and six months ended June 30, 2017, as compared to the corresponding periods in the prior year, is primarily due to prepayment of \$100.0 million of the Senior Notes in April 2016 and April 2017 resulting in lower interest expense for the three and six months ended June 30, 2017. The net interest expense is comprised of:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Interest and other income	\$ 282	\$ 67	\$ 532	\$ 197
Interest expense	(17,758)	(20,148)	(37,882)	(42,875)
Net interest expense	\$ (17,476)	\$ (20,081)	\$ (37,350)	\$ (42,678)

The interest expense is comprised of:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Interest payable on Senior Notes	\$ 10,393	\$ 12,997	\$ 23,159	28,622
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	4,760	4,388	9,410	8,624
Changes in fair value of contingent consideration	265	600	796	1,194
Other	184	7	205	123
Total interest expense	\$ 17,758	\$ 20,148	\$ 37,882	\$ 42,875

## The Senior Notes

On April 2, 2015, the Company issued \$575.0 million aggregate principal amount of 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) between 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.

The Senior Notes will mature in seven years after issuance (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 Senior Notes can be prepaid, at the Company's option, (i) after the first anniversary of the purchase date but prior to the second anniversary, up to \$100.0 million, (ii) before the second anniversary, under certain conditions and (iii) after the second anniversary, at the Company's discretion.

In April 2016, the Company prepaid and retired \$100.0 million of the Senior Notes and paid a \$5.0 million prepayment fee. The Company recorded a net loss on prepayment of the Senior Notes of \$5.8 million which represented

## Table of Contents

the prepayment fee of \$5.0 million and unamortized balances of debt discount and debt issuance costs of \$0.8 million. This loss was recorded as a loss on prepayment of Senior Notes in the consolidated statements of operations for the three months ended June 30, 2016. In April 2017, the Company prepaid and retired \$100.0 million of the Senior Notes and paid a \$4.0 million prepayment fee. The Company recorded a loss on prepayment of the Senior Notes of \$5.4 million which represented the prepayment fee of \$4.0 million and unamortized balances of debt discount and debt issuance costs of \$1.4 million in the Consolidated Statement of Operations during the three months ended June 30, 2017. As a result of the prepayment of \$100.0 million of Senior Notes in April 2017, the Company expects the interest expense relating to the Senior Notes to decrease in the remainder of 2017.

## Convertible Notes

In September, 2014, the Company issued the Convertible Debt resulting in net proceeds of \$334.2 million after deducting the underwriting discount and offering expenses of \$10.4 million and \$0.4 million, respectively. The interest rate for the Convertible Notes is fixed at 2.50% per annum and is payable semi-annually in arrears on March 1 and September 1 of each year.

In accordance with accounting guidance on embedded conversion features, we valued and bifurcated the conversion option associated with the Convertible Notes from the respective host debt instrument and recorded the conversion option of \$111.9 million for the Convertible Notes in "Shareholders' Equity" on our Condensed Consolidated Balance Sheets. The resulting debt discounts on the Convertible Notes are being amortized to interest expense at an effective interest rate of 9.34% over the contractual term of the Convertible Notes.

## Income Tax Provision

We recorded a benefit from income taxes of \$0.2 million and \$0.1 million for the three and six months ended June 30, 2017, compared to a benefit from income taxes of \$5.7 million and \$11.7 million, for the three and six months ended June 30, 2016, respectively. The benefit for income taxes in the three and six months ended June 30, 2017 as compared to the benefit from income taxes for the same period in 2016 is primarily attributable to a full valuation allowance in 2017. We paid approximately \$0.1 million in income taxes in the three and six months ended June 30, 2017. We paid approximately \$0.1 million in income taxes in the three and six months ended June 30, 2016.

## Non-GAAP Financial Measures

To supplement our financial results presented on a U.S. generally accepted accounting principles, or GAAP, basis, we have included information about non GAAP adjusted earnings, non GAAP adjusted earnings per share and non-GAAP



adjusted EBITDA, non GAAP financial measures, as useful operating metrics for the three and six months periods ended June 30, 2017 and 2016.

We believe that the presentation of these non GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information to analysts, investors, lenders, and our management in assessing the Company's performance and results from period to period. We use these non GAAP measures internally to understand, manage and evaluate the Company's performance, and in part, in the determination of bonuses for executive officers and employees.

These non GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

Non GAAP adjusted earnings and non GAAP adjusted earnings per share are not based on any standardized methodology prescribed by GAAP and represent GAAP net income (loss) and GAAP earnings (loss) per share adjusted to exclude amortization, IPR&D and non cash adjustments related to product acquisitions, stock based compensation expense, non cash interest expense related to debt, the special meeting requests made by an activist investor and CEO transition, restructuring costs, adjustments associated with non-recurring legal settlements and disputes, and to adjust for the tax effect related to each of the non-GAAP adjustments. Non GAAP adjusted EBITDA is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) adjusted to exclude interest income, interest expense, amortization, IPR&D and non cash adjustments related to product acquisitions, stock based

Table of Contents

compensation expense, depreciation, taxes, restructuring costs, adjustments related to non-recurring legal settlements and disputes, the special meeting requests made by an activist investor, and CEO transition.

Non GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, non GAAP measures used by other companies.

The following table reconciles the Company's GAAP net loss to non-GAAP adjusted earnings for the three and six months ended June 30, 2017 and June 30, 2016, respectively (in thousands, except per share amount):

## RECONCILIATION OF GAAP NET LOSS TO NON-GAAP ADJUSTED EARNINGS

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
GAAP net loss	\$ (26,659)	\$ (10,541)	\$ (53,400)	\$ (31,458)
Non-cash interest expense on debt	6,124	5,166	10,774	9,401
Managed care dispute reserve	—	—	4,742	—
Intangible amortization related to product acquisitions	25,735	27,037	51,470	54,074
Inventory step-up related to product acquisitions	—	5	—	16
Contingent consideration related to product acquisitions	(863)	490	(5,332)	907
Stock based compensation	3,403	4,328	6,959	8,238
Other costs (1)	253	743	2,529	927
Restructuring charges	3,441	—	3,441	—
Valuation allowance on deferred tax assets	7,534	—	15,102	—
Income tax effect of non-GAAP adjustments (3)	(13,519)	(13,190)	(26,403)	(25,733)
Non-GAAP adjusted earnings	\$ 5,449	\$ 14,038	\$ 9,882	\$ 16,372
Add interest expense of convertible debt, net of tax (2)	1,348	1,348	2,695	2,695
Numerator	\$ 6,797	\$ 15,386	\$ 12,577	\$ 19,067
Shares used in calculation (2)	81,400	81,356	81,719	81,044
Non-GAAP adjusted earnings per share	\$ 0.08	\$ 0.19	\$ 0.15	\$ 0.24

(1) Other costs represents non-recurring costs associated with the special meeting requests of an activist investor, CEO transition and costs associated with the Company's defense of Horizon Pharma's hostile takeover attempt.

- (2) The Company uses the if-converted method to compute diluted earnings per share with respect to its convertible debt.
- (3) Calculated by taking the pre-tax non-GAAP adjustments and applying the statutory tax rate. Expected cash taxes were zero for the three months ended June 30, 2017 and \$1,791 for the three months ended June 30, 2016. Expected cash taxes were \$202 for the six months ended June 30, 2017 and \$2,811 for the six months ended June 30, 2016.

Table of Contents

The following table reconciles the Company's GAAP net loss to non-GAAP adjusted EBITDA for the three and six months ended June 30, 2017 and 2016 (in thousands):

## RECONCILIATION OF GAAP NET LOSS TO NON-GAAP ADJUSTED EBITDA

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
GAAP net loss	\$ (26,659)	\$ (10,541)	\$ (53,400)	\$ (31,458)
Pharmacy benefit manager dispute reserve	—	—	4,742	—
Intangible amortization related to product acquisitions	25,735	27,037	51,470	54,074
Inventory step-up related to product acquisitions	—	5	—	16
Contingent consideration related to product acquisitions	(863)	490	(5,332)	907
Stock based compensation	3,403	4,328	6,959	8,238
Interest income	(56)	(67)	(260)	(197)
Interest expense	22,673	25,320	42,245	47,336
Depreciation	608	632	1,234	1,262
Benefit from income taxes	(249)	(5,656)	(47)	(11,650)
Other costs (1)	253	743	2,529	927
Restructuring charges	3,441	—	3,441	—
Transaction costs	—	1	—	44
Non-GAAP adjusted EBITDA	\$ 28,286	\$ 42,292	\$ 53,581	\$ 69,499

(1) Other costs represents non-recurring costs associated with the special meeting requests of an activist investor, CEO transition and costs associated with the Company's defense of Horizon Pharma's hostile takeover attempt.

## LIQUIDITY AND CAPITAL RESOURCES

(In thousands)	June 30, 2017	December 31, 2016
Cash, cash equivalents and short-term investments	\$ 116,799	\$ 177,420

The decrease in cash, cash equivalents and short-term investments during the six months ended June 30, 2017 is primarily attributable to the prepayment of \$100.0 million of secured indebtedness in April 2017 along with a \$4.0 million related prepayment fee. These payments were partially off-set by the cash generated from operations during the six months ended June 30, 2017.

We may incur operating losses in future years. We believe that our existing cash 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 Convertible Notes and the Senior Notes. We base this expectation on our current operating plan and the anticipated impact of the NUCYNTA acquisition, which may change as a result of many factors.

Our cash needs may vary materially from our current expectations because of numerous factors, including:

- acquisitions or licenses of complementary businesses, products, technologies or companies;
- sales of our marketed products;
- expenditures related to our commercialization of NUCYNTA ER, NUCYNTA, Gralise, CAMBIA and Zipsor;
- the timing and cost of our cebranopadol clinical trials;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements;
- expenses associated with any litigation, action, claim, suit, investigation or proceeding instituted by or against us;
- interest and principal payments on our current and future indebtedness;
- financial terms of definitive license agreements or other commercial agreements we may enter into;
- changes in the focus and direction of our business strategy and/or research and development programs; and

Table of Contents

- results of clinical testing requirements of the FDA and comparable foreign regulatory agencies.

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

(In thousands)	Six Months Ended June 30,	
	2017	2016
Cash provided by operating activities	\$ 38,111	\$ 12,942
Cash provided by investing activities	55,666	74,599
Cash used in financing activities	(98,261)	(100,804)

Cash Flows from Operating Activities

Cash provided by operating activities was higher during the six months ended June 30, 2017 as compared to the same period in 2016 due to a reduction in our accounts receivable balance as a result of lower sales in the six months ended June 30, 2017.

Cash Flows from Investing Activities

The reduction in cash provided by investing activities during the six months ended June 30, 2017 primarily relates to the timing of maturity of marketable securities for the prepayment of debt in April 2017. Cash provided by investing activities during the six months ended June 30, 2017 primarily relates to the maturities of marketable securities.

Cash Flows from Financing Activities

The reduction in cash used in financing activities during the six months ended June 30, 2017 as compared to the same period in 2016 primarily relates to higher proceeds from stock option exercises during the six months ended June 30, 2017.

Contractual Obligations

Edgar Filing: DEPOMED INC - Form 10-Q

As of June 30, 2017, our aggregate contractual obligations as shown in the following table were as follows (in thousands):

	1 Year	2 3 Years	4 5 Years	More than 5 Years	Total
Senior Notes—principal	\$ 57,500	230,000	87,500	—	\$ 375,000
Senior Notes—interest	41,503	57,529	9,670	—	108,702
Convertible Debt—principal	—	—	345,000	—	345,000
Convertible Debt—interest	8,625	17,250	12,938	—	38,813
Operating leases(1)	4,555	5,177	3,397	714	13,843
Purchase commitments	34,662	1,100	—	—	35,762
	\$ 146,845	\$ 311,056	\$ 458,505	\$ 714	\$ 917,120

(1) Amounts represent payments under a non-cancelable office and laboratory lease and under an operating lease for vehicles used by our sales force.

As of June 30, 2017, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$35.8 million under our manufacturing agreements related to NUCYNTA, Gralise, Zipsor, Lazanda and CAMBIA. The amounts disclosed only represent minimum purchase requirements. Actual purchases are expected to exceed these amounts.

In April 2012, we entered into an office and laboratory lease agreement to lease approximately 52,500 rentable square feet in Newark, California commencing on December 1, 2012. We leased an additional 8,000 rentable square feet commencing in July 2015. The Newark lease included free rent for the first five months of the lease. Lease payments began in May 2013.

Table of Contents

Off-Balance Sheet Arrangements

None.

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 2016 Form 10-K.

**Interest Rate Risk.** We are subject to interest rate fluctuation exposure through our borrowings under the Senior Secured Credit Facility and our investments in money market funds 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. Since current LIBOR rates are below the 1.0% LIBOR floor, the interest rate on our borrowings under the Senior Secured Credit Facility has been 10.75% per annum. An increase in LIBOR of 100 basis points above the current three-month LIBOR rates would increase our interest expense by \$3.8 million per year on the remaining principal of \$375 million of Senior Notes.

The goals of our investment policy are associated with 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. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in interest rates would have any material negative impact on the fair value of our cash equivalents.

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, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Legal Matters

Depomed v. NUCYNTA and NUCYNTA ER ANDA Filers

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

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

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

In each of the foregoing actions, the ANDA filers counterclaimed for declaratory relief of noninfringement 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 the NUCYNTA ER and

NUCYNTA from Janssen Pharma. As part of the acquisition, the Company became the exclusive U.S. licensee of the patents referred to above. The Company was added as a plaintiff to the pending cases and is actively litigating them.

In September 2015, the Company filed an additional complaint in the D.N.J. asserting the '130 Patent against Actavis. The '130 Patent issued in September 2013 and was timely listed in the Orange Book for NUCYNTA ER, but Actavis did not file a Paragraph IV Notice with respect to this patent. In its new lawsuit, the Company claimed that Actavis would infringe or induce infringement of the '130 Patent if its proposed generic products were approved. In response, Actavis counterclaimed for declaratory relief of noninfringement 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. A two-week bench trial on the validity of the three asserted patents and infringement of the '130 Patent was commenced on March 9, 2016. Closing arguments took place on April 27, 2016. On September 30, 2016, the Court issued its final decision. The Court found that the '593, '364 Patent, and '130 Patents are all valid and enforceable, that Alkem will induce infringement of the '130 patent, and that Roxane and Actavis will not infringe the '130 Patent.

On November 3, 2016, Alkem filed an appeal in the United States Court of Appeals for the Federal Circuit appealing the Court's finding that the '364 and '130 Patents are not invalid and that Alkem infringes the '130 Patent. The Company moved to terminate Alkem's appeal on the grounds that a final judgment had not yet been entered by the Court, and the Federal Circuit deactivated Alkem's appeal on December 16, 2016. On April 11, 2017, the Court entered final judgment in favor of the Company on the validity and enforceability of all three patents, on infringement of the '593 and '364 Patents by all defendants, and on infringement of the '130 Patent against Alkem. The judgment includes

## Table of Contents

an injunction enjoining all three defendants from engaging in certain activities with tapentadol (the active ingredient in NUCYNTA), and ordering the effective date of any approval of Actavis, Actavis UT, and Roxane's ANDAs, and Alkem's ANDA for NUCYNTA IR to be no earlier than the expiry of the '364 Patent (June 27, 2025), and the effective date of any approval of Alkem's ANDA for NUCYNTA ER to be no early than the expiry of the '130 Patent (September 22, 2028). The period of exclusivity with respect to all four defendants may in the future be extended with the award of pediatric exclusivity.

Notices of appeal were filed by defendants Alkem and Roxane concerning the '364 and '130 patent issues. The Company filed its own cross-appeal with regard to the Court's finding that Roxane and Actavis will not infringe the claims of the '130 Patent. The appeals have been consolidated at the Federal Circuit, and the briefing schedule is expected to continue until the first quarter of 2018, with a hearing scheduled later in 2018. The '593 patent is not the subject of any appeals.

### '364 Patent Inter Partes Review Petition

On January 15, 2016, Rosellini Scientific, LLC (with nXn Partners, LLC as an additional real party in interest) (Rosellini) filed with the Patent Trial and Appeal Board (PTAB) a petition to request an inter partes review (an IPR) of the '364 Patent. On April 27, 2016, Grünenthal, the owner of the '364 Patent, filed its Patent Owner Preliminary Response. An IPR is a proceeding that became available in September 2012 in accordance with the America Invents Act (the AIA). In an IPR, a petitioner may request that the PTAB reconsider the validity of issued patent claims on the basis of prior art in the form of printed publications and other patents. Any patent claim the PTAB determines to be unpatentable is stricken from the challenged patent. Any party may appeal final written decisions of the PTAB to the U.S. Court of Appeals for the Federal Circuit, but the PTAB's decisions denying institution of an IPR are non-appealable. Accordingly, if the PTAB finds a challenged claim patentable, or declines to institute an IPR as to a challenged claim, the IPR petitioner is estopped from asserting in a patent infringement lawsuit that these claims are invalid on any ground the petitioner raised or reasonably could have raised in the IPR. On July 18, 2016, the PTAB declined to institute the IPR petition filed by Rosellini with respect to the '364 Patent with respect to all patent claims subject of the petition.

### Depomed v. Purdue

The Company has 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 arises from Purdue's commercialization of reformulated OxyContin® (oxycodone hydrochloride controlled-release) in the U.S. and alleges infringement of U.S. Patent Nos. 6,340,475 (the '475 Patent) and 6,635,280 (the '280 Patent), which expired in September 2016.

On September 28, 2015, the district court stayed the Purdue lawsuit pending the decision of the U.S. Court of Appeals for the Federal Circuit (CAFC) in Purdue's appeal of the PTAB's Final Written Decisions described below. On June 30, 2016, the district court lifted the stay based on the CAFC's opinion and judgment affirming the PTAB's Final Written Decisions confirming the patentability of the patent claims of the '475 and '280 Patents Purdue had challenged. The parties filed opening Markman briefs on June 3, 2016 and their responsive Markman briefs in July 2016. The Markham hearing was held on November 2, 2016 and on April 6, 2017, the Court issued a Markman order which is available on the docket. On June 10, 2016, the Company filed a motion for leave to file a second amended Complaint to plead willful infringement and remove claims of infringement related to U.S. Patent No. 6,723,340 (the '340 Patent) and 8,329,215 (the '215 Patent). On June 21, 2016, Purdue filed an opposition to the Company's motion for leave to plead willful infringement, but did not oppose removing claims related to the '340 and '215 Patents. On June 28, 2016, the Company filed a reply brief to its motion for leave. On January 31, 2017, the Court granted the Company's motion for leave to plead willful infringement.

On June 1, 2016, Purdue filed a motion for leave to amend its invalidity contentions to add allegations of indefiniteness and confirm that certain invalidity defenses remained in the case post-IPR proceedings. On June 21, 2016 the Company filed an opposition to Purdue's motion for leave and a cross-motion to strike Purdue's invalidity contentions. On November 4, 2016, the Court granted Purdue's motion for leave to amend its invalidity contentions, and denied the Company's cross-motion to strike. On October 28, 2016, Purdue moved for leave to amend its answer to add a counterclaim of unenforceability and affirmative defenses of inequitable conduct and unclean hands. On November 7, 2016, Depomed filed its opposition to Purdue's motion for leave to amend its Answer. On November 14, 2016, Purdue filed a reply to its motion for leave to amend its Answer.

## Table of Contents

On February 1, 2017, Depomed filed a Second Amended Complaint pleading willful infringement. On February 15, 2017, Purdue answered Depomed's Second Amended Complaint asserting counterclaims of non-infringement, invalidity and unenforceability. On March 6, 2017, Depomed moved to dismiss Purdue's counterclaim of inequitable conduct and moved to strike affirmative defenses of inequitable conduct, unclean hands, and patent misuse. On March 20, 2017, Purdue filed an opposition to Depomed's motion, and on March 27, 2017, Depomed filed a reply brief. On April 17, 2017, the Court issued an order finding Purdue's motion to amend its Answer was moot. On June 28, 2017, the Court issued an order granting Depomed's motion to dismiss Purdue's affirmative defense of patent misuse and theory of inequitable conduct related to interrogatory responses, and the order denied the remainder of Depomed's motion. On July 10, 2017, the case was reassigned to Judge Wolfson. On July 11, 2017, the Court scheduled fact discovery regarding inequitable conduct to close on August 2, 2017, expert discovery to close on November 16, 2017, the deadline for dispositive motions as December 19, 2017, and a pretrial conference on January 25, 2018. The Court also scheduled a teleconference for October 12, 2017. No trial date has been set by the Court, though the Company expects a trial may be scheduled in early 2018.

In response to petitions filed by Purdue, the PTAB instituted IPRs of certain of the claims asserted in the Company's lawsuit against Purdue. In the IPRs initiated by Purdue, in July 2014, the PTAB declined to institute an IPR as to two claims of the '475 patent and two claims of the '280 Patent. The PTAB instituted an IPR as to the other 15 claims of the '475 Patent and as to the other ten claims of the '280 Patent asserted against Purdue. In July 2015, the PTAB issued Final Written Decisions confirming the patentability of all claims at issue. In March 2016, following Purdue's appeal of the PTAB's decisions, the CAFC affirmed the PTAB's Final Written Decisions.

### Depomed v. Strides Pharma Inc. and Strides Pharma Global Pte Limited

On May 5, 2017, the Company filed suit in the U.S. District Court for the District of New Jersey against Strides Pharma Inc. and Strides Pharma Global Pte Limited (collectively, Strides) based on Strides' filing of an ANDA to market a generic version of ZIPSOR prior to the expiration of U.S. Patent Nos. 7,662,858; 7,884,095; 7,939,518; 8,110,606; 8,623,920; and 9,561,200 (the patents-in-suit). By letter dated March 27, 2017, Strides informed the Company that it had filed an ANDA for a generic version of ZIPSOR with Paragraph IV certifications against each of the patents-in-suit. The Company's filing of the complaint against Strides resulted in an automatic 30-month stay of FDA approval of Strides' ANDA, lasting until September 2019.

Previously, in July 2013, the Company filed suit against Banner Pharmacaps Inc. (Banner) and Watson Laboratories, Inc. (Watson) based on Banner's filing of an ANDA for a generic version of ZIPSOR. The Company and the defendants reached a settlement of the case that permits Watson to begin selling their generic version of ZIPSOR on March 24, 2022, or earlier under certain circumstances. The Company believes that Banner and Watson may be entitled to 180-day exclusivity with respect to generic ZIPSOR.

## Opioid-Related Request and Subpoenas

The Company and a number of other pharmaceutical companies recently received a request for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs related to the promotion of opioids. The Company has voluntarily furnished information responsive to such request.

The Company and a number of other pharmaceutical companies recently received subpoenas related to opioid sales and marketing from the Office of the Attorney General of Maryland and the United States Department of Justice. The Company is currently cooperating with the State of Maryland and the Department of Justice in their respective investigations.

## General

The Company cannot reasonably predict the outcome of the pending legal proceedings or other matters 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 we prevail in litigation involving a claim for damages. As such, the Company is not currently able to estimate the impact of the above matters on its financial position or results of operations.

## Table of Contents

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. 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 it believes may have a material adverse effect on its business, results of operations or financial condition. However, regardless of the outcome, litigation, actions, claims, suits, investigations and proceedings can have an adverse impact on the Company because of associated cost and diversion of management time.

## ITEM 1A. RISK FACTORS

The risk factors presented below amend and restate the risk factors previously disclosed in our 2016 Form 10-K.

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

If we do not successfully commercialize NUCYNTA® ER and NUCYNTA® IR (NUCYNTA), our largest selling products, or Gralise®, CAMBIA®, Zipsor® and Lazanda®, our business, financial condition and results of operations will be materially and adversely affected.

In April 2015, we acquired and began commercial promotion of NUCYNTA ER and NUCYNTA. 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 July 2013, we acquired Lazanda and began commercial promotion of Lazanda in October 2013. In December 2013, we acquired CAMBIA and began commercial promotion of CAMBIA in February 2014. As a Company, we have a limited history of selling and marketing pharmaceutical products. In addition to the risks discussed elsewhere in this section, our ability to successfully commercialize and generate revenues from NUCYNTA ER and NUCYNTA, our largest selling products, or Gralise, CAMBIA, Zipsor and Lazanda, 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;
- 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. Further, if we are unable to maintain or increase our revenues from NUCYNTA ER and NUCYNTA, our largest selling products which generated approximately 62% of our total product revenues in 2016, and approximately 64% of our total product revenues for the six months ended June 30, 2017, our business, financial condition and results of operations will be materially and adversely affected.

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

Under the Federal Food, Drug and Cosmetics Act (FDCA), the FDA can approve an ANDA for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary

## Table of Contents

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

We have been involved in patent litigation lawsuits against filers of ANDAs (the Filers) seeking to market generic versions of NUCYNTA and NUCYNTA ER before the expiration of the patents listed in the Patent and Exclusivity Information Addendum of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for these two products. A two-week bench trial was completed on April 27, 2016. On September 30, 2016, the Court issued its opinion finding all three of the Orange Book patents valid and enforceable. On April 11, 2017, the Court entered a final judgment, which included an injunction enjoining the Filers from engaging in certain activities with tapentadol (the active ingredient in NUCYNTA) and ordering the effective date of any approval of Actavis, Actavis UT, and Roxane's ANDAs, and Alkem's ANDA for NUCYNTA IR to be no earlier than the expiry of the '364 Patent (June 27, 2025), and the effective date of any approval of Alkem's ANDA for NUCYNTA ER to be no early than the expiry of the '130 Patent (September 22, 2028). The foregoing periods of exclusivity may in the future be extended with the award of pediatric exclusivity. The Court's final judgment remains subject to potential appeal.

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

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

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

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

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

Third-party payers frequently require pharmaceutical companies to negotiate agreements that provide discounts or rebates from list prices. We 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. If we 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

Table of Contents

their plans, our business, financial condition and results of operations will be adversely affected. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce 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 and the Health Care and Education Reconciliation Act (“ACA”), intended to curb rising healthcare costs. These cost containment measures may include: controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payers to make coverage and payment decisions. In California, voters rejected Proposition 61 in November 2016, a ballot initiative that would have prohibited the state from buying prescription drugs from a drug manufacturer at a price over the lowest price paid for such drug by U.S. Department of Veterans Affairs. Although Proposition 61 was defeated, these and other cost containment or price control measures, if adopted at the federal or state level, could significantly decrease the price that we receive for our products and any product that we may develop or acquire, which would harm our business, financial condition and results of operations.

## Table of Contents

Changes in laws and regulations applicable to and investigations of, the pharmaceutical industry, including the opioid market, may adversely affect our business, financial condition and results of operations.

The manufacture, marketing, sale, promotion and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations applicable to the pharmaceutical industry could potentially affect our business. For instance, federal, state and local governments have recently given increased attention to the public health issue of opioid abuse. The Centers for Disease Control (CDC) recently issued national, non-binding guidelines on the prescribing of opioids, providing recommended considerations for primary care providers when prescribing opioids, including specific considerations and cautionary information about opioid dosage increases and morphine milligram equivalents (MME). Certain third-party payers are, or are considering, adopting these CDC guidelines. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealth of Massachusetts and the States of New York, Ohio and New Jersey, have either recently enacted or have pending legislation or regulations designed to among other things, limit the duration and quantity of initial prescriptions of immediate release form of opiates and mandate the use by prescribers of prescription drug databases. Also, at the state and local level, a number of states and major cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. These and other similar initiatives and actions, whether taken by governmental authorities or other industry stakeholders, may result in the reduced prescribing and use of opioids, including NUCYNTA and NUCYNTA ER, which could adversely affect our business, financial condition and results of operations.

At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, the U.S. Drug Enforcement Agency (DEA) and other agencies to address this issue. The DEA 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. In addition, many state legislatures are considering various bills intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. Further, the FDA is requiring “black-box” warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose and death. In addition, during the 2016 presidential campaign, President Trump called for the DEA to restrict the amount of opioids that can be manufactured in the U.S. In March 2017, President Trump announced the creation of a commission to make recommendations to the president regarding new laws and policies to combat opioid addiction and abuse. In August 2017, the commission issued a preliminary report calling on President Trump to officially declare the crisis of opioid abuse a national emergency. These and other changes, and potential changes in laws, regulations and industry practices including those that have the effect of reducing the overall market for opioids or reducing the prescribing of opioids, could adversely affect our business, financial condition and results of operations.

Heightened attention on the problems associated with the abuse of opioids could adversely affect our business, financial condition and results of operations.

In recent years, there has been increased public attention on the problem of opioid abuse. The ability of drug abusers to discover previously unknown ways to abuse and misuse opioid products; public inquiries and 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 our products and our reputation. Such negative publicity could reduce the potential size of the market for our products and product candidate and decrease the revenues we are able to generate from their sale. Additionally, such increased scrutiny of opioids generally, whether focused on our products or otherwise, could have the effect of negatively impacting our relationships with healthcare providers and other members of the healthcare community, reducing the overall market for opioids or reducing the prescribing and use of our products.

Governmental investigations and inquiries as well as regulatory actions with respect to the commercialization and use of opioids could adversely affect our business, financial condition and results of operations.

Table of Contents

As a result of the greater public awareness of the problem 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. For example, we were named as a defendant in a case brought by the City of Chicago against a number of pharmaceutical companies marketing and selling opioid based pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. This case against the Company was dismissed. We recently received a letter from Senator Claire McCaskill, the Ranking Member on the United States Senate Committee on Homeland Security and Governmental Affairs, requesting certain information from the Company regarding its commercialization of opioid products. We have voluntarily furnished information responsive to Sen. McCaskill's requests. We recently received an Administrative Subpoena from the Office of the Attorney General of Maryland seeking documents and information regarding the sales and marketing of opioid products. We are currently cooperating with the State of Maryland in its investigation. We recently received a subpoena from the United States Department of Justice (DOJ) seeking documents and information regarding the sales and marketing of opioid products. We are currently cooperating with the DOJ in its investigation.

These and other governmental investigations or inquiries in which we may become involved may result in claims being brought against the Company by governmental agencies or private parties. It is not possible at this time to predict the outcome of any governmental investigations or inquiries of the Company or any lawsuits or regulatory responses that may result from such investigations or inquiries or otherwise. However, the initiation of any investigation, inquiry or lawsuit relating to the Company, or any assertion, claim or finding of wrongdoing by the Company, 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 to market our products;
- cause us to incur significant costs and expenses; and
- cause our senior management to be distracted from execution of our business strategy.

Furthermore, governmental regulators could take measures that could have a negative effect on the Company's business. For example, Endo Pharmaceuticals, Inc. recently voluntarily withdrew, at the FDA's request, OPANA® ER from the market due to the FDA's view that the risks associated with the use of the product outweighed the potential benefits. Any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to NUCYNTA or NUCYNTA ER would adversely affect our business, results of operations and financial condition.

We may be unable to compete successfully in the pharmaceutical industry.

Tapentadol, the active pharmaceutical ingredient in NUCYNTA ER and NUCYNTA, is a proprietary opioid analgesic that we market exclusively in the U.S. NUCYNTA ER and NUCYNTA 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 marketed by Purdue Pharma L.P., and OPANA® ER (oxymorphone hydrochloride), which is owned by Endo Pharmaceuticals, Inc. (voluntarily withdrawn from the market as of July 2017), each of which 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®, and prior to its withdrawal, OPANA® ER, achieved significant levels of market acceptance. There are also a number of branded and generic opioids, including oxymorphone, fentanyl, morphine, buprenorphine 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. Butrans® (promoted by Purdue) will lose its patent in 2017. 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 has received approval for MorphaBond ER (morphine sulfate) and RoxyBond (oxycodone HCL), with expected launch in 2H 2017. Lyrica® (pregabalin), which is marketed by Pfizer, Inc. (Pfizer), has been approved for marketing in the U.S. for the treatment of neuropathic pain associated with DPN. 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 ER and NUCYNTA.

Branded gabapentin is currently sold by Pfizer as Neurontin® for adjunctive therapy for partial onset epileptic seizures and for PHN. Pfizer's basic U.S. patents relating to Neurontin® have expired, and numerous companies have



## Table of Contents

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. Pfizer announced positive Phase 3 clinical trial results for its Lyrica® controlled release formulation for fibromyalgia and for PHN (in 2012 and 2014, respectively), though its epilepsy trial did not meet primary endpoint (in 2012). Arbor Pharmaceuticals, LLC's Horizant™ (gabapentin enacarbil extended-release tablets) is approved for the management of PHN and Restless Leg Syndrome. There are other products prescribed for or under development for PHN which are now or may become competitive with Gralise.

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

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

Transmucosal immediate-release fentanyl (TIRF), an opioid analgesic, is currently sold by a number of companies for the treatment of breakthrough pain in opioid-tolerant cancer patients. Branded TIRF products against which Lazanda currently competes include Subsys®, which is sold by Insys Therapeutics, Inc., Fentora® and Actiq®, which are sold by Teva, Abstral®, which is sold by Sentynt Therapeutics Inc., and Onsolis®, which Collegium Pharmaceutical, Inc. plans to relaunch in 2017. Generic TIRF products against which Lazanda currently competes are sold by Mallinckrodt, Teva and Endo.

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 do.

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

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

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

## Table of Contents

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

We sell a significant amount of our products to a limited number of independent wholesale drug distributors. Three of our wholesale distributors represented 36%, 27% and 25% of our product shipments for the year ended December 31, 2016 and 34%, 28% and 27% of our product shipments for the six months ended June 30, 2017. If we 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 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.

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

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

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 Department of Health and Human Services (OIG), the FDA, and the Department of Justice (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. 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.

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 U.S. rights to NUCYNTA ER and NUCYNTA, 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.

Table of Contents

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 ER and NUCYNTA, whether as a result of identified or unidentified risks, integration difficulties, regulatory setbacks, governmental investigations, litigation or other events, could adversely affect our business, results of operations and financial condition.

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

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

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

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

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

We have one qualified supplier for the active pharmaceutical ingredient in each of NUCYNTA ER, NUCYNTA, CAMBIA, Zipsor, Lazanda and Gralise. An affiliate of Janssen Pharma is currently our sole supplier of NUCYNTA ER and NUCYNTA pursuant to a manufacturing supply agreement we entered into with such entity in April 2015. Patheon Puerto Rico Inc. (Patheon) is our sole supplier for Gralise pursuant to a manufacturing and supply agreement we entered into with Patheon in September 2011. Accucaps Industries Limited is our sole supplier for Zipsor pursuant to a manufacturing agreement we assumed in connection with our acquisition of Zipsor in June 2012. Renaissance Lakewood, LLC (formerly DPT Lakewood Inc.) is our sole supplier for Lazanda pursuant to a manufacturing and supply agreement that we assumed in connection with our acquisition of Lazanda in July 2013. 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 ER, NUCYNTA, Gralise, CAMBIA, Zipsor or Lazanda, or the necessary active pharmaceutical ingredients, excipients or components from our suppliers would adversely affect our business, 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

Table of Contents

suppliers are subject to numerous regulations, including current FDA regulations governing manufacturing processes, stability testing, record keeping 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 fail 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.

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 against us. However, 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. 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 could be subject to substantial damages for past infringement or could be forced to stop or delay our activities with respect to any infringing product, unless we can obtain a license, or we may have to redesign our product 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 ER, NUCYNTA and NUCYNTA oral solution as well as Gralise. It is possible our issued or licensed patents may not be held valid by a court of competent jurisdiction or the PTAB. Whether or not the outcome of litigation or the PTAB proceeding is favorable to us, the litigation and the proceedings may take significant time, may be expensive and may divert management's attention from other business concerns. We may also be required to participate in derivation proceedings or other post-grant proceedings declared by the U.S. Patent and Trademark Office for the purposes of,



Table of Contents

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

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

We have incurred significant indebtedness in the aggregate principal amount of \$720.0 million 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. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on commercially reasonable or acceptable terms, which could result in a default on our obligations, including the Convertible Notes and the Senior Notes.

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

- make it more difficult for us to meet our payment and other obligations under the Convertible Notes, the Senior Secured Notes or our other indebtedness;
- result in an event of default if we fail to comply with the financial and other covenants contained in the Note Purchase Agreement, which event of default could result in all of our debt becoming immediately due and payable;
- make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- subject us to the risk of increased sensitivity to interest rate increases on our indebtedness with variable interest rates, including the Senior Notes;
- require the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including working capital, clinical trials, research and development, capital expenditures and other general corporate purposes;
- prevent us from raising funds necessary to repurchase the Convertible Notes in the event we are required to do so following a “fundamental change,” as specified in the indenture governing the Convertible Notes, to repurchase the Senior Notes in the event we are required to do so following a “major transaction” or as required in the event that the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than \$100.0 million, as specified in the Note Purchase Agreement or to settle conversions of the Convertible Notes in cash ;

- result in dilution to our existing shareholders as a result of the conversion of the Convertible Notes into shares of common stock;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- put us at a disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including funding possible acquisitions of, or investments in, additional products, technologies and companies.

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

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.

Table of Contents

Since June 2012, we have acquired NUCYNTA ER, NUCYNTA, CAMBIA, Zipsor and Lazanda and exclusively in-licensed the right to develop and commercialize cebranopadol. 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 products that could be sold by our sales force. 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 any acquired business, product or technology or retain any key employees. If we are unable to enhance and broaden our product offerings, our business and prospects will be limited.

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

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

- minimize the disruption and distraction of our management and other employees, including our sales force, in connection with the integration of any acquired business, product or technology;
- maintain and increase sales of our existing products;
- establish or manage the transition of the manufacture and supply of any acquired product, including the necessary active pharmaceutical ingredients, excipients and components;
- identify and add the necessary sales, marketing, manufacturing, regulatory and other related personnel, capabilities and infrastructure that are required to successfully integrate any acquired business, product or technology;
- manage the transition and migration of all commercial, financial, legal, clinical, regulatory and other pertinent information relating to any acquired business, product or technology;
- comply with legal, regulatory and contractual requirements applicable to any acquired business, product or technology;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers with respect to any acquired product; and
- maintain and extend intellectual property protection for any acquired product or technology.

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

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.

## Table of Contents

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.

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

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

Many members of Congress and President Trump have pledged to repeal the ACA. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the ACA and permits such legislation to pass with a majority vote in the Senate. President Trump also recently 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. Further, the House recently passed the American Health Care Act of 2017, which would repeal significant portions of the ACA, if it becomes law. There is still uncertainty with respect to the impact President Trump's administration and the Congress may have, if any, and any changes will likely take time to unfold. Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the

industry, could adversely affect our ability to successfully commercialize our products and product candidates. In addition, President Trump has indicated that reducing the price of prescription drugs will be a priority of his administration. The implementation of any price controls or caps on prescription drugs, whether at the federal level or state level, could adversely affect our business, operating results and financial condition.

If we are unable to obtain or maintain regulatory approval for our products 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. 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

## Table of Contents

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

Further, with respect to our approved products, once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of approved products are also subject to ongoing regulation and inspection, including compliance with FDA regulations governing current Good Manufacturing Practices (cGMP) or Quality System Regulation (QSR). The FDCA, the Controlled Substances Act of 1970 (CSA) and other federal and foreign statutes and regulations govern and influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. In addition, with respect to Lazanda®, we and our partners are also subject to ongoing DEA regulatory obligations, including annual registration renewal, security, recordkeeping, 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 Food, Drug and Cosmetic Act.

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

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as "Paragraph IV certifications," that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505(b)(2) application are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement

lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and may require us to file such submissions under Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

If a product liability claim against us is successful, our business will suffer.

Our business involves exposure to potential product liability risks that are inherent in the development, production and commercialization of pharmaceutical products. Side effects, manufacturing defects, misuse or abuse of any of our products could result in patient injury or death. For instance, Lazanda is a self-administered, opioid analgesic that contains fentanyl, a Schedule II "controlled substance" under the CSA. A patient's failure to follow instructions on the



## Table of Contents

use and administration of, or the abuse of Lazanda, could result in injury or death. In addition, patients using Lazanda have been diagnosed with cancer, an often fatal disease. Patient injury or death can result in product liability claims being brought against us, even if our products did not cause an injury or death. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others who come into contact with our products.

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

- we may be unable to maintain product liability insurance on acceptable terms;
- we may be unable to obtain product liability insurance for future trials;
- we may be unable to obtain product liability insurance for future products;
- we may be unable to secure increased coverage as the commercialization of our Acuform gastric retentive technology expands; or
- our insurance may not provide adequate protection against potential liabilities.

Our inability to obtain or maintain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. 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 claim or series of claims against us for uninsured liabilities or in excess of insured liability limits, our business, results of operations and financial condition could be adversely affected.

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

We currently have collaboration or license arrangements with a number of companies, including Grünenthal, Janssen Pharma and Ironwood. In addition, we have in the past and may in the future enter into other 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.

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 collaborative arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the 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 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 collaborative partners to abide by the terms of their respective agreements with us, including their failure to accurately calculate, report or pay any royalties payable to us, may adversely affect our results of operations.

We may be unable to enter into future collaborative arrangements on acceptable terms, 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 collaborative partner of competitive technologies or products;
- arrangements with collaborative partners that limit or preclude us from developing products or technologies;
- premature termination of a collaboration agreement; or
- failure by a collaborative partner to devote sufficient resources to the development and commercial sales of products using our current and potential future products and technologies.

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

Table of Contents

collaboration with us. Our collaborative partners may also terminate their collaborative relationships with us or otherwise decide not to proceed with development and commercialization of our products.

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

Each of NUCYNTA ER and NUCYNTA are opioid analgesics that contain tapentadol. Lazanda is an opioid analgesic that contains fentanyl. Cebranopadol is a development stage opioid analgesic. Tapentadol and fentanyl are regulated “controlled substances” under the CSA. The CSA establishes, among other things, certain registration, production quotas, security, recordkeeping, 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 those that present the highest risk of abuse. Each of tapentadol and fentanyl are listed by the DEA as a Schedule II substance under the CSA. The scheduling for cebranopadol will not be determined until after the FDA’s approval. 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, such as prescriptions for fentanyl, 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 in order to be able to obtain, handle and distribute fentanyl or to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law and could adversely affect our business, results of operations and financial condition.

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

The availability and production of all Schedule II substances, including tapentadol and fentanyl, 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 manufacturing. The DEA annually establishes an aggregate quota for total tapentadol and total fentanyl production in the U.S. based on the DEA's estimate of the quantity needed to meet commercial and scientific need. The aggregate quota of tapentadol and fentanyl that the DEA allows to be produced in the U.S. annually is allocated among applicable individual drug manufacturers, which must submit applications annually to the DEA for individual production quotas. In turn, the manufacturers of NUCYNTA ER, NUCYNTA and Lazanda have to obtain a procurement quota to source tapentadol and fentanyl for the production of NUCYNTA ER, NUCYNTA and Lazanda, respectively.

The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas for these activities. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Based on a variety of factors, including public policy considerations, the DEA may set the aggregate quota lower for tapentadol or fentanyl than the total amount requested by individual manufacturers. Although through our manufacturing partner we are permitted to ask the DEA to increase our manufacturer's procurement quota after it is initially established, we cannot be certain that the DEA would act favorably upon such a request. In addition, our manufacturers obtain a procurement quota for tapentadol or fentanyl for all tapentadol or fentanyl products manufactured at their facility, which is allocated to NUCYNTA ER, NUCYNTA and Lazanda, as applicable, at the manufacturer's discretion. If the available quota of tapentadol or fentanyl is insufficient to meet our commercial demand

Table of Contents

or clinical needs, our business, results of operations and financial condition could be adversely affected. Further, during the 2016 presidential campaign, President Trump called for the DEA to restrict the amount of opioids that can be manufactured in the U.S. Any delay or refusal by the DEA or our manufacturers in establishing the production or procurement quota or any reduction by the DEA or our manufacturer in the allocated quota for tapentadol or fentanyl could 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 Lazanda.

NUCYNTA ER and Lazanda are subject to a FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) protocol that requires enrollment and participation in the REMS program to prescribe, dispense or distribute such products for outpatient use. Lazanda is subject to a REMS protocol that is specific to Transmucosal Immediate Release Fentanyl (TIRF) medicines for outpatient use. Many physicians, health care practitioners and pharmacies are unwilling to enroll and participate in the REMS programs. As a result, there are relatively few prescribers and dispensers of products subject to REMS protocols, and in particular, TIRF products. If we are not able to successfully promote NUCYNTA ER and Lazanda to participants in the applicable REMS program, or if the FDA mandates a REMS protocol for NUCYNTA, our business, results of operations and financial condition could be adversely affected.

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

The trading price of our common stock has been, and is likely to continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. From June 30, 2015 through June 30, 2017, our stock price has ranged from \$9.38 to \$33.74 per share.

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

- the degree of commercial success and market acceptance of NUCYNTA ER, NUCYNTA, Gralise, CAMBIA, Zipsor and Lazanda;
- 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 collaborative partners;
- the reversal or any appeal of the court's favorable ruling in our patent infringement litigation against the filers of ANDAs for NUCYNTA ER and NUCYNTA;
- developments concerning proprietary rights, including patents, infringement allegations, inter party review proceedings and litigation matters;

- legal and regulatory developments in the United States;
- 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 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, including the sales force realignment we undertook in the first quarter of 2017 and the commercial initiatives we announced in May 2017;
- 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;
- our ability to successfully develop, obtain regulatory approval for and commercialize a product containing cebranopadol;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply, or other manufacture or supply difficulties;
- variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other contract revenues;
- adverse events or circumstances related to our peer companies or our industry or the markets for our products;
- adoption of new technologies by us or our competitors;
- the outcome of our patent infringement litigation against Purdue;

Table of Contents

- the outcome and impact of a proxy contest initiated by an activist shareholder;
- our compliance with the terms and conditions of the agreements governing our indebtedness;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
  - 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 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 2016 and 2015 we incurred net losses of \$88.7 million and \$75.7 million, respectively, and in 2014 we recognized net income of \$131.8 million. We expect to incur operating losses in 2017 and may continue to incur operating losses in future years. Any such losses may have an adverse impact on our total assets, shareholders' equity and working capital.

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

We fund our operations primarily through revenues from product sales and do not have any committed sources of capital. To the extent that our existing capital resources and revenues from ongoing operations are insufficient to fund our future operations, or product acquisitions and strategic transactions that we may pursue, we will have to raise additional funds through the sale of our equity securities, through additional debt financing, from development and licensing arrangements or from the sale of assets. We may be unable to raise such additional capital on favorable

terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions.

The development of drug candidates such as cebranopadol 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 was the case with the Phase 3 trial for Gralise for the management of PHN that we completed in 2007, and with the Phase 3 trials evaluating Sefelsa, our prior product candidate, for menopausal hot flashes, the last of which we completed in October 2011. 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.

Our own product candidates, including cebranopadol, and those of our collaborative partners 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



## Table of Contents

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

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

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

We are unable to predict whether any of our product candidates, including cebranopadol, or those of our collaborative partners 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 these other product candidates receive regulatory clearance, our products may not achieve or maintain market acceptance. If it is discovered that the Acuform technology could have adverse effects or other characteristics that indicate it is unlikely to be effective as a delivery system for drugs or therapeutics, our product development efforts and our business could be significantly harmed.

Even assuming our products obtain regulatory approval, successful commercialization requires:

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

Any material delay or failure in the governmental approval process and/or the successful commercialization of our potential products or those of our collaborative partners could adversely impact our financial position and liquidity.

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

We rely on third party contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise conducting our clinical trials. We do not control these third parties and, as a result, we may be unable to control the amount and timing of resources that they devote to our clinical trials.

Although we rely on third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and other applicable regulatory agencies' requirements, including good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. If we, contract research organizations or other third parties assisting us with our clinical trials fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, or other applicable regulatory agencies, may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, the FDA or other

Table of Contents

applicable regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

We also rely on clinical investigators and clinical sites to enroll patients and other third parties to manage our trials and to perform related data collection and analysis. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedule, we will be unable to complete these trials or to complete them as planned, which could delay or prevent us from obtaining regulatory approvals for our product candidates.

Our 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, our 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 our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product candidates.

We have recently experienced a significant transition in our Board of Directors and executive management.

We recently experienced significant changes in our Board of Directors and executive management team. If our newly appointed directors and Chief Executive Officer are not able to timely develop, implement and execute successful business strategies and plans to maintain and increase our product revenues, our business, financial condition and results of operations will be materially and adversely affected. Moreover, the changes to our Board of Directors and executive management team may result in disruption to the operation of our business. While our newly appointed Chief Executive Officer has significant industry-related experience, he has not previously worked together with the other members of our executive management team and it may take time for the team to become fully integrated. Any delay in the integration of our Board of Directors or 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 and results of operations.

Further, as a result of the changes to our Board of Directors and executive management, the future business strategies and plans of the Company may differ materially from those of those we previously pursued. If the implementation of our new business strategies and plans, including the strategic initiatives announced by us in May 2017, 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 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. We do not have agreements with any of our executive officers that provide for their continued employment with us. We may have difficulty filling open senior commercial, scientific and financial positions. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates.

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

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

Table of Contents

are based upon reasonable assumptions within the bounds of its knowledge of the Company's business and operations, actual results could differ materially from these estimates.

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

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

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

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

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

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

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

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

In May 2008, FASB issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options (ASC 470-20). Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital within shareholders' equity on our consolidated

## Table of Contents

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 will be 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 will require interest to include both the accretion of the debt discount and the instrument's non-convertible coupon interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock.

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

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

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

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

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

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;
- perceived uncertainties as to our future direction may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel, business partners, customers and others important to our success, any of which could negatively affect our business and our results of operations and financial condition;
- and
- .

if nominees advanced by activist shareholders are elected or appointed to our Board of Directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans or to realize long-term value from our assets, and this could in turn have an adverse effect on our business and on our results of operations and financial condition.

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.



Table of Contents

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

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

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

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

Provisions in our restated articles of incorporation, bylaws and California law might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the market price of our common stock.

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

On July 12, 2015, our Board of Directors adopted and approved an amendment and restatement to our bylaws (the Amended Bylaws). The Amended Bylaws, among other things, provide for the establishment of a measurement record date for purposes of ascertaining shareholders eligible to call for a special meeting of shareholders and establish certain other procedures relating to the calling of a special meeting of shareholders. The Amended Bylaws also supplement the advanced notice requirements and procedures for the submission by shareholders of nominations for the Board of Directors and of other proposals to be presented at shareholder meetings, and provide that the exclusive forum for any shareholder to bring any: (i) derivative action, (ii) claim asserting a breach of fiduciary duty, (iii) action under the California Corporations Code or the our organizational documents or (iv) other action relating to our internal affairs, shall in each case be the Santa Clara County Superior Court within the State of California or, if no state court located within the State of California has jurisdiction, the federal district court for the Northern District of California. The Amended Bylaws also make certain other ministerial changes.

We are also subject to the provisions of Section 1203 of the California General Corporation Law, which requires a fairness opinion to be provided to our shareholders in connection with their consideration of any proposed “interested party” reorganization transaction.

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

Table of Contents

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.

Business interruptions could limit our ability to operate our business.

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, power loss, telecommunications failures, equipment failures, intentional acts of theft, vandalism, terrorism and similar events. In particular, our corporate headquarters are located in the San Francisco Bay area, which has a history of seismic activity. 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.

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 motive (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted to target our information systems. Cyber-attacks are becoming increasingly more prevalent and much harder to detect and defend against. Our network and storage applications and those of our third party vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information, including the information of our business partners. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our third party vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

Table of Contents

ITEM 6. EXHIBITS

(a) Exhibits

3.1	(1)	Third Amended and Restated Articles of Incorporation
3.2	(2)	Certificate of Amendment to Amended and Restated Articles of Incorporation
3.3	(3)	Certificate of Amendment to Amended and Restated Articles of Incorporation
3.4	(4)	Certificate of Determination of Series RP Preferred Stock of the Company
3.5	(5)	Certificate of Amendment to Certificate of Determination of Series RP Preferred Stock of the Company
3.6	(5)	Certificate of Determination of Series B Junior Participating Preferred Stock of the Company
3.7	(6)	Certificate of Amendment to Certificate of Determination of Series A Preferred Stock
3.8	(7)	Amended and Restated Bylaws
10.1	(7)	Depomed, Inc. Amended and Restated Bonus Plan, as adopted on May 17, 2017
10.2	(*)	Waiver and Release Agreement dated June 30, 2017 by and between the Company and Srinivas G. Rao
31.1	(*)	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Arthur J. Higgins
31.2	(*)	

		Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of August J. Moretti
32.1	(**)	Certification pursuant to 18 U.S.C. Section 1350 of Arthur J. Higgins
32.2	(**)	Certification pursuant to 18 U.S.C. Section 1350 of August J. Moretti
101	(*)	Interactive Data Files pursuant to Rule 405 of Regulation S-T

---

(1) Incorporated by reference to the Company's registration statement on Form SB-2 (File No. 333-25445)

(2) Incorporated by reference to the Company's Form 10-K filed on March 31, 2003 (File No. 001-13111)

(3) Incorporated by reference to the Company's Form 8-K filed on May 19, 2015 (File No. 001-13111)

(4) Incorporated by reference to the Company's Form 10-Q filed on May 10, 2005 (File No. 001-13111)

(5) Incorporated by reference to the Company's Form 8-K filed on July 13, 2015 (File No. 001-13111)

(6) Incorporated by reference to the Company's Form 8-K filed on July 29, 2015 (File No. 001-13111)

(7) Incorporated by reference to the Company's Form 8-K filed on May 22, 2017 (File No. 001-13111)

(\*) Filed herewith

(\*\*) Furnished herewith

Table of Contents

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 7, 2017 DEPOMED, INC.

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

/s/ August J. Moretti  
August J. Moretti  
Chief Financial Officer