

DEPOMED INC  
Form 10-Q  
November 06, 2014  
[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 September 30, 2014**

**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**  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

**94-3229046**  
(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

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 November 3, 2014 was 58,740,387.

Table of Contents

DEPOMED, INC.

	PAGE
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1. Condensed Consolidated Financial Statements:</u>	
<u>Condensed Consolidated Balance Sheets at September 30, 2014 (unaudited) and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2014 and 2013 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2014 and 2013 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013 (unaudited)</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	22
<u>Item 3. Quantitative and Qualitative Disclosure About Market Risk</u>	33
<u>Item 4. Controls and Procedures</u>	33
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	33
<u>Item 1A. Risk Factors</u>	35
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	49
<u>Item 3. Defaults upon Senior Securities</u>	49
<u>Item 4. Mine Safety Disclosures</u>	49
<u>Item 5. Other Information</u>	49
<u>Item 6. Exhibits</u>	49
<u>Signatures</u>	40

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****DEPOMED, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands, except share amounts)**

	<b>September 30, 2014 (Unaudited)</b>	<b>December 31, 2013 (1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 546,698	\$ 244,674
Marketable securities	6,774	27,263
Accounts receivable, net	19,954	11,451
Receivables from collaborative partners	23,156	10,824
Inventories	7,292	10,145
Income taxes receivable	6,246	
Deferred tax assets, net	15,531	26,860
Prepaid and other current assets	6,799	5,828
Total current assets	632,450	337,045
Marketable securities, long-term	6,140	4,080
Property and equipment, net	7,357	8,340
Intangible assets, net	74,901	82,521
Deferred tax assets, net, non-current	14,264	76,342
Other assets	7,324	325
	\$ 742,436	\$ 508,653
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 45,582	\$ 34,935
Income taxes payable		61,875
Deferred license revenue	3,041	3,041
Liability related to the sale of future royalties and milestones	66,163	56,357
Other current liabilities	1,176	649
Total current liabilities	115,962	156,857
Deferred license revenue, non-current portion	10,194	12,475
Contingent consideration liability	12,603	11,264
Liability related to the sale of future royalties and milestones, less current portion	100,248	177,624
Convertible debt	226,772	
Other long-term liabilities	13,188	13,017
Commitments		
Shareholders' equity:		
Preferred stock, no par value, 5,000,000 shares authorized; Series A convertible preferred stock, 25,000 shares designated, 18,158 shares issued and surrendered, and zero shares outstanding at September 30, 2014 and December 31, 2013		
Common stock, no par value, 100,000,000 shares authorized; 58,715,889 and 57,369,683 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	234,872	221,124

Edgar Filing: DEPOMED INC - Form 10-Q

Additional paid-in capital	75,538	347
Accumulated deficit	(46,909)	(84,048)
Accumulated other comprehensive income (loss), net of tax	(32)	(7)
Total shareholders' equity	263,469	137,416
	\$ 742,436	\$ 508,653

---

(1) Derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Revenues:</b>				
Product sales	\$ 30,584	\$ 16,278	\$ 80,335	\$ 39,513
Royalties	370	15,422	1,295	44,599
License and other revenue	760	5,760	18,280	9,484
Non-cash PDL royalty revenue	19,771		95,852	
Total revenues	51,485	37,460	195,762	93,596
<b>Costs and expenses:</b>				
Cost of sales	3,523	1,751	11,900	4,923
Research and development expense	1,644	1,339	5,083	6,049
Selling, general and administrative expense	27,078	26,374	92,166	77,705
Amortization of intangible assets	2,540	1,158	7,621	3,082
Total costs and expenses	34,785	30,622	116,770	91,759
Income from operations	16,700	6,838	78,992	1,837
<b>Other income (expense):</b>				
Interest and other income	23	27	70	142
Interest expense	(1,910)	(285)	(3,153)	(440)
Non-cash interest expense on liability related to sale of future royalties and milestones to PDL	(4,364)		(14,646)	
Total other expense	(6,251)	(258)	(17,729)	(298)
Net income before income taxes	10,449	6,580	61,263	1,539
Provision for income taxes	(3,995)	(66)	(24,124)	(27)
Net income	\$ 6,454	\$ 6,514	\$ 37,139	\$ 1,512
Basic net income per share	\$ 0.11	\$ 0.11	\$ 0.64	\$ 0.03
Diluted net income per share	\$ 0.11	\$ 0.11	\$ 0.61	\$ 0.03
Shares used in computing basic net income per share	58,567,603	56,818,883	58,076,865	56,615,359
Shares used in computing diluted net income per share	60,864,107	57,661,212	61,838,173	57,316,830

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



Table of Contents

**DEPOMED, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

**(in thousands)**

**(Unaudited)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net income	\$ 6,454	\$ 6,514	\$ 37,139	\$ 1,512
Unrealized gains (losses) on available-for-sale securities:				
Unrealized gains (losses) during period, net of taxes	(14)	15	(25)	(39)
Net unrealized gains (losses) on available-for-sale securities	(14)	15	(25)	(39)
Comprehensive income	\$ 6,440	\$ 6,529	\$ 37,114	\$ 1,473

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)

	Nine Months Ended September 30,	
	2014	2013
<b>Operating Activities</b>		
Net income	\$ 37,139	\$ 1,512
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash PDL royalty revenue	(95,852)	
Non-cash interest expense on liability related to sale of future royalties and milestones to PDL	14,646	
Depreciation and amortization	9,063	4,116
Accretion of debt discount	825	
Accretion of investment discounts and amortization of investment premiums, net	262	(352)
Allowance for inventory obsolescence		243
Loss on disposal of property and equipment	17	
Stock-based compensation	6,497	4546
Change in fair value of contingent consideration and unfavorable contract	1,784	441
Deferred income taxes	31,173	
Excess tax benefit from stock-based compensation	(2,152)	
Changes in assets and liabilities:		
Accounts receivable	(1,133)	(2,389)
Inventories	2,853	2,856
Prepaid and other assets	(972)	812
Income taxes receivable	(6,246)	
Accounts payable and other accrued liabilities	5,432	(75)
Accrued compensation	(416)	1,083
Income taxes payable	(59,722)	
Deferred revenue	(2,281)	(2,371)
Net cash used in operating activities	(59,083)	10,422
<b>Investing Activities</b>		
Purchases of property and equipment	(853)	(1,370)
Acquisition of businesses		(4,000)
Acquisition of patents		(150)
Purchases of marketable securities	(6,703)	(24,263)
Maturities of marketable securities	24,845	51,988
Sales of marketable securities		323
Net cash provided by (used in) investing activities	17,289	22,528
<b>Financing Activities</b>		
Proceeds from issuance of convertible debt	345,000	
Proceeds from issuance of common stock	7,227	2,256
Excess tax benefit from stock-based compensation	2,152	
Convertible debt issuance costs	(10,561)	
Net cash provided by financing activities	343,818	2,256

Edgar Filing: DEPOMED INC - Form 10-Q

Net decrease in cash and cash equivalents		302,024		35,206
Cash and cash equivalents at beginning of period		244,674		29,076
Cash and cash equivalents at end of period	\$	546,698	\$	64,282
Supplemental disclosure of noncash financing activities:				
Convertible debt issuance costs included in accounts payable and other accrued liabilities	\$	214	\$	

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

Table of Contents

**DEPOMED, INC.**

**NOTES TO 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 CNS conditions. The products that comprise the Company's current specialty pharmaceutical business are Gralise® (gabapentin), a once-daily product for the management of postherpetic neuralgia (PHN) that we launched in October 2011, CAMBIA® (diclofenac potassium for oral solution), a product for the acute treatment of migraine attacks that we acquired in December 2013, Zipsor® (diclofenac potassium) liquid filled capsules, a product for the treatment of mild to moderate acute pain that we acquired in June 2012, and Lazanda® (fentanyl) nasal spray, a product for the management of breakthrough pain in cancer patients that we acquired in July 2013.

The Company also has a portfolio of royalty and milestone producing license agreements based on its proprietary Acuform® gastroretentive drug delivery technology with Mallinckrodt Inc. (Mallinckrodt), Ironwood Pharmaceuticals, Inc. (Ironwood) and Janssen Pharmaceuticals, Inc. (Janssen Pharma).

On October 18, 2013, the Company sold its interests in royalty and milestone payments under its license agreements in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for \$240.5 million (PDL Transaction). The interests sold include royalty and milestone payments accruing from and after October 1, 2013: (a) from Salix Pharmaceuticals, Inc. (Salix) with respect to sales of Glumetza® (metformin HCL extended-release tablets) in the United States; (b) from Merck & Co., Inc. (Merck) with respect to sales of Janumet® XR (sitagliptin and metformin HCL extended-release); (c) from Janssen Pharmaceutica N.V. and Janssen Pharma (collectively, Janssen) with respect to potential future development milestones and sales of Janssen's investigational fixed-dose combination of Invokana® (canagliflozin) and extended-release metformin; (d) from Boehringer Ingelheim International GMBH (Boehringer Ingelheim) with respect to potential future development milestones and sales of the investigational fixed-dose combinations of drugs and extended-release metformin subject to the Company's license agreement with Boehringer Ingelheim; and (e) from LG Life Sciences Ltd. (LG) and Valeant International Bermuda SRL (Valeant SRL) for sales of extended-release metformin in Korea and Canada, respectively.

The Company has one product candidate under clinical development, DM-1992 for Parkinson's disease. DM-1992 completed a Phase 2 trial for Parkinson's disease, and the Company announced a summary of the results of that trial in November 2012. The Company continues to evaluate clinical and regulatory strategies and commercial prospects for DM-1992.

*Basis of Presentation*

## Edgar Filing: DEPOMED INC - Form 10-Q

These 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 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 (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the periods presented. The results for the quarter and nine months ended September 30, 2014 are not necessarily indicative of results to be expected for the entire year ending December 31, 2014 or future operating periods.

The accompanying 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, 2013 included in the Company's Annual Report on Form 10-K filed with the SEC (the 2013 Form 10-K). The balance sheet at December 31, 2013 has been derived from the audited financial statements at that date, as filed with the 2013 Form 10-K.

### *Reclassification*

The Company has reclassified a royalty payable to PDL of \$6.9 million from Accounts payable and accrued liabilities to the current portion of Liability related to the sale of future royalties and milestones in the accompanying condensed consolidated balance sheet as of December 31, 2013 to conform to the current period presentation.

Table of Contents

***Principles of Consolidation***

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Depo DR Sub LLC (Depo DR Sub). All intercompany accounts and transactions have been eliminated on consolidation.

Depo DR Sub was formed in October 2013 for the sole purpose of facilitating the PDL Transaction. The Company contributed to Depo DR Sub all of its right, title and interest in each of the license agreements to receive royalty and milestone payments. Immediately following the transaction, Depo DR Sub sold to PDL, among other things, such right 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 the 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, reimbursable expenses and set-offs. 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. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. 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.

***Contingent Consideration***

Increases or decreases in fair value of the contingent consideration liabilities can result from updates to assumptions such as the expected timing or probability of achieving the specified milestones, changes in projected revenues or changes in discount rates. 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 the Company's results of operations in any given period.

***Revenue Recognition***

## Edgar Filing: DEPOMED INC - Form 10-Q

The Company recognizes revenue from the sale of its products, royalties earned, and payments received and services performed under 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. Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which typically occurs on delivery to the customer.

- **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, 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:

Table of Contents

- **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 Gralise, CAMBIA, Zipsor and Lazanda. The Company also estimates returns on sales of Glumetza made by the Company through August 2011, as the Company is financially responsible for return credits on Glumetza product the Company shipped as part of its commercialization agreement with Salix in August 2011. 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 Lazanda product previously sold by Archimedes Pharma US Inc. See Note 13 for further information on the acquisition of Zipsor, CAMBIA and Lazanda.

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. The shelf life of the 500mg Glumetza is 48 months from the date of tablet manufacture and the shelf life of the 1000mg Glumetza is 24 to 36 months from the date of tablet manufacture. The Company monitors actual return history on an individual product lot basis since product launch, which provides it with a basis to reasonably estimate future product returns, 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.

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.

## Edgar Filing: DEPOMED INC - Form 10-Q

- **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.



Table of Contents

- **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.

Royalties received from Mallinckrodt on sales of XARTEMIS XR and from Janssen Pharma on sales of NUCYNTA® ER are recognized in the period earned as the royalty amounts can be estimated and collectability is reasonably assured.

Until October 1, 2013, the Company received royalties from Salix based on net sales of Glumetza and from Merck based on net sales of Janumet® XR. The royalties were recognized in the period earned as the royalty amounts could be estimated and collectability was reasonably assured.

In October 2013, the Company sold its interests in royalty and milestone payments under its license agreements in the Type 2 diabetes therapeutic area, including the Glumetza royalty and the Janumet® XR royalty, to PDL for \$240.5 million. This transaction was accounted for as a liability that will be amortized using an interest method over the life of the agreement. As a result of this liability accounting, even though the Company does not retain the related royalties and milestones under the transaction as the amounts are remitted to PDL, the Company will continue to record revenue related to these royalties and milestones.

- **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 nonrecursing. 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.

***Recently Issued Accounting Standards***

There have been no developments related to recently issued accounting standards, including the expected dates of adoption and estimated effects on the Company's consolidated financial statements, from those disclosed in the Company's 2013 Annual Report on Form 10-K, except for the following:

- In August 2014, the FASB issued guidance which requires management to assess an entity's ability to continue as a going concern and to provide related disclosures in certain circumstances. Under the new guidance, disclosures are required when conditions give rise to substantial doubt about an entity's ability to continue as a going concern within one year from the financial statement issuance date. The guidance is effective for annual periods ending after December 15, 2016, and all annual and interim periods thereafter. Early application is permitted. The adoption of this guidance will not have any impact on the Company's financial position and results of operations and, as this time, the Company

does not expect any impact on its disclosures.

- In June 2014, the FASB issued guidance which requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The Company does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements.

- In May 2014, the FASB issued guidance which 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. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements and footnote disclosures.

Table of Contents**NOTE 2. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES**

Securities classified as cash and cash equivalents and available-for-sale marketable securities as of September 30, 2014 and December 31, 2013 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

<b>September 30, 2014</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
<b>Cash and cash equivalents:</b>				
Cash	\$ 15,798	\$	\$	\$ 15,798
Money market funds	530,900			530,900
Total cash and cash equivalents	\$ 546,698	\$	\$	\$ 546,698
<b>Available-for-sale securities:</b>				
<b>Total maturing within 1 year and included in marketable securities:</b>				
Corporate debt securities	\$ 6,771	\$ 4	\$ (1)	\$ 6,774
<b>Total maturing between 1 and 2 years and included in marketable securities:</b>				
Corporate debt securities	6,154		(14)	6,140
Total available-for-sale securities	\$ 12,925	\$ 4	\$ (15)	\$ 12,914
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 559,623</b>	<b>\$ 4</b>	<b>\$ (15)</b>	<b>\$ 559,612</b>

<b>December 31, 2013</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
<b>Cash and cash equivalents:</b>				
Cash	\$ 26,728	\$	\$	\$ 26,728
Money market funds	217,946			217,946
Total cash and cash equivalents	\$ 244,674	\$	\$	\$ 244,674
<b>Available-for-sale securities:</b>				
<b>Total maturing within 1 year and included in marketable securities:</b>				
Corporate debt securities	\$ 12,440	\$ 8	\$ (2)	\$ 12,446
Government agency debt securities	14,814	3		14,817
<b>Total maturing between 1 and 2 years and included in marketable securities:</b>				
Corporate debt securities	4,075	5		4,080
Total available-for-sale securities	\$ 31,329	\$ 16	\$ (2)	\$ 31,343
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 276,003</b>	<b>\$ 16</b>	<b>\$ (2)</b>	<b>\$ 276,017</b>

## Edgar Filing: DEPOMED INC - Form 10-Q

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks and money market instruments. The Company invests its cash in marketable securities with 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 gain 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.

Table of Contents

At September 30, 2014 the Company had fourteen securities 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 September 30, 2014 (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	\$ 7,155	\$ (15)	\$	\$	\$ 7,155	\$ (15)
Total available-for-sale	\$ 7,155	\$	\$	\$	\$ 7,155	\$ (15)

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 maturity, there were no material other-than-temporary impairments for these securities at September 30, 2014.

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.
- 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.

## Edgar Filing: DEPOMED INC - Form 10-Q

### Table of Contents

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013 (in thousands):

September 30, 2014	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 530,900	\$	\$	\$ 530,900
Corporate debt securities		12,914		12,914
<b>Total</b>	<b>\$ 530,900</b>	<b>\$ 12,914</b>	<b>\$</b>	<b>\$ 543,814</b>
<b>Liabilities:</b>				
Contingent consideration- Zipsor	\$	\$	\$ 1,653	\$ 1,653
Contingent consideration- Lazanda			9,811	9,811
Contingent consideration- CAMBIA			1,139	1,139
Unfavorable contract assumed			3,985	3,985
<b>Contingent consideration</b>	<b>\$</b>	<b>\$</b>	<b>\$ 16,588</b>	<b>\$ 16,588</b>
December 31, 2013	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 217,946	\$	\$	\$ 217,946
Corporate debt securities		16,526		16,526
Government agency debt securities		14,817		14,817
<b>Total</b>	<b>\$ 217,946</b>	<b>\$ 31,343</b>	<b>\$</b>	<b>\$ 249,289</b>
<b>Liabilities:</b>				
Contingent consideration- Zipsor	\$	\$	\$ 1,638	\$ 1,638
Contingent consideration- Lazanda			8,616	8,616
Contingent consideration- CAMBIA			1,010	1,010
Unfavorable contract assumed			3,540	3,540
	\$	\$	\$ 14,804	\$ 14,804

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 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. Changes in the fair value of the contingent consideration obligations are recorded as a component of operating income in the Company's condensed consolidated statement of operations. Changes in fair value included within interest and other expense in the accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2014 was \$0.6 million and \$1.8 million, respectively. Changes in fair value included within interest and other expense in the accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2013 was \$0.3 million and \$0.4 million, respectively.

The liability for the unfavorable contract assumed represents an obligation for the Company to make certain payments to a vendor upon the achievement of certain milestones by such vendor. This contract was entered into by Nautilus Neurosciences, Inc. (Nautilus) as part of a legal settlement unrelated to the CAMBIA acquisition. The liability of \$4.0 million recorded above, as of September 30 2014, represents the fair value of the amounts by which the contract terms are unfavorable compared to the current market pricing and a probability - weighted assessment of the likelihood that the stipulated milestones will be achieved by the third party. The contract may be terminated if the third party fails to achieve these milestones, in which case the fair value of the liability as of the date of the termination will be reversed on the condensed consolidated

## Edgar Filing: DEPOMED INC - Form 10-Q

balance sheet and reflected in the condensed consolidated statement of operations as a credit within interest and other income. The Company determines the fair value of this liability at each reporting period and records any changes within Interest expense in the condensed consolidated statement of operations.

Edgar Filing: DEPOMED INC - Form 10-Q

Table of Contents

The table below provides a summary of the changes in fair value of all financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2014 (in thousands):

	Balance at December 31, 2013	Changes in fair value	Balance at September 30, 2014
<b>Liabilities:</b>			
Contingent consideration obligations- Zipsor	\$ 1,638	\$ 15	\$ 1,653
Contingent consideration obligations- Lazanda	8,616	1,195	9,811
Contingent consideration obligations- CAMBIA	1,010	129	1,139
Unfavorable contract assumed	3,540	445	3,985
Total	\$ 14,804	\$ 1,784	\$ 16,588

The estimated fair value of the 2.50% Convertible Senior Notes Due 2021, which the Company issued on September 9, 2014 (the 2021 Notes), is based on a market approach. The estimated fair value was approximately \$365.0 million (par value \$345.0 million) as of September 30, 2014 and represents a Level II valuation. When determining the estimated fair value of the Company's long-term debt, the Company used a commonly accepted valuation methodology and market-based risk measurements that are indirectly observable, such as credit risk.

**NOTE 3. NET INCOME PER SHARE**

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

(in thousands, except for per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Basic income per share</b>				
Net income	\$ 6,454	\$ 6,514	\$ 37,139	\$ 1,512
Denominator	58,568	56,819	58,077	56,615
Basic net income per share	\$ 0.11	\$ 0.11	\$ 0.64	\$ 0.03
<b>Diluted net income per share</b>				
<b>Numerator:</b>				
Net income	\$ 6,454	\$ 6,514	\$ 37,139	\$ 1,512
Add interest expense on convertible debt, net of tax			803	
	\$ 6,454	\$ 6,514	\$ 37,942	\$ 1,512
<b>Denominator:</b>				
Denominator for basic income per share	58,568	56,819	58,077	56,615
<b>Add effect of dilutive securities:</b>				
Stock options and equivalents	2,296	842	2,382	702
Convertible debt			1,379	
Denominator for diluted net income per share:	60,864	57,661	61,838	57,317



Edgar Filing: DEPOMED INC - Form 10-Q

Diluted net income per share \$ 0.11 \$ 0.11 \$ 0.61 \$ 0.03

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Convertible debt	4,093			
Stock options and equivalents	1,933	4,916	1,451	5,111
Total potentially dilutive shares	6,026	4,916	1,451	5,111

Table of Contents

**NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS**

*Mallinckrodt Inc. (formerly Covidien, Ltd.)*

In November 2008, the Company entered into a license agreement related to acetaminophen/opiate combination products with Mallinckrodt. The license agreement grants Mallinckrodt worldwide rights to utilize Depomed's Acuform technology for the exclusive development of up to four products containing acetaminophen in combination with opiates, two of which Mallinckrodt has elected to develop.

Since the inception of the contract, the Company received \$27.5 million in upfront fees and milestones under the agreement. The upfront fees included a \$4.0 million upfront license fee and a \$1.5 million advance payment for formulation work the Company performed under the agreement. The milestone payments include four \$0.5 million clinical development milestones and \$5.0 million following the FDA's July 2013 acceptance for filing of the NDA for XARTEMIS XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII), previously known as MNK-795. In March 2014, the FDA approved XARTEMIS XR for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated or would otherwise be inadequate. The approval of the NDA triggered a \$10.0 million milestone payment to the Company, which the Company received in April 2014. This \$10.0 million milestone payment was recognized as revenue during the three months ended March 31, 2014. In May 2014, the FDA accepted for filing the NDA for MNK-155, and this acceptance triggered a \$5.0 million milestone payment to the Company, which the Company received in June 2014. This \$5.0 million milestone payment was recognized as revenue during the three months ended June 30, 2014. If MNK-155 is approved by the FDA, the Company will receive a \$10.0 million milestone payment. The Company receives high single digit royalties on net sales of XARTEMIS XR, which was launched in March 2014, and will receive the same high single digit royalties on net sales of MNK-155 if that product is approved.

*Janssen Pharmaceutica N.V. and Janssen Pharmaceuticals, Inc.*

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 its Acuform drug delivery technology for the development and commercialization of tapentadol extended release products, including NUCYNTA ER (tapentadol extended-release tablets). The Company received a \$10.0 million upfront license fee, which was recognized as revenue in 2012, and receives low single digit royalties on net sales of NUCYNTA ER in the U.S., Canada and Japan from and after July 2, 2012 through December 31, 2021.

In August 2010, the Company entered into a license agreement with Janssen that grants Janssen a non-exclusive license to certain patents related to Depomed's Acuform drug delivery technology to be used in developing fixed dose combinations of extended release metformin and Janssen's type 2 diabetes product candidate canagliflozin. In August 2010, the Company received \$10.0 million in upfront and milestone payments, which was recognized as revenue in 2010. The Company also granted Janssen a right to reference the Glumetza NDA in Janssen's regulatory filings covering the products. In February 2013 and December 2013, the Company completed two projects for Janssen related to this program and recognized \$2.2 million in revenue during the first quarter of 2013 and \$1.4 million during the fourth quarter of 2013.

In October 2013, the Company sold all of its rights to future payments under the license agreement relating to fixed dose combinations of metformin and canagliflozin to PDL.

*Ironwood Pharmaceuticals, Inc.*

In July 2011, the Company 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 Depomed's Acuform drug delivery technology for IW-3718, an Ironwood product candidate under evaluation for refractory GERD.

Since the inception of the contract, the Company has received \$3.4 million under the agreement, which includes an upfront payment, reimbursement of initial product formulation work and three milestones payments. The Company recognized a non-refundable milestone payment of \$1.0 million in March 2014 as a result of the initiation of clinical trials relating to IW-3718 by Ironwood. As the non-refundable milestone was both substantive in nature and related to past performance, the Company recognized the \$1.0 million as revenue in March 2014.

Table of Contents

***Salix Pharmaceuticals, Inc. (formerly Santarus, Inc.)***

In August 2011, the Company entered into a commercialization agreement with Santarus, Inc., which was acquired by Salix Pharmaceuticals, Inc. (Salix) in January 2014, granting Salix exclusive rights to manufacture and commercialize Glumetza in the United States. The commercialization agreement supersedes the promotion agreement between the parties previously entered into in July 2008. Under the commercialization agreement, we granted Salix exclusive rights to manufacture and commercialize Glumetza in the United States in return for a royalty on Glumetza net sales.

Under the commercialization agreement, Salix is also required to pay the Company royalties on net product sales of Glumetza in the United States of 26.5% in 2011; 29.5% in 2012; 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond, prior to generic entry of a Glumetza product. In the event of generic entry of a Glumetza product in the United States, the parties were to share proceeds equally based on a gross margin split. Royalty revenue from Salix for the three and nine months ended September 30, 2013 was \$14.6 million and \$42.1 million, respectively. In October 2013, the Company sold its interest in the Glumetza royalties to PDL.

Pursuant to the original promotion agreement, Salix paid the Company a \$12.0 million upfront fee in July 2008. The upfront payment received was originally being amortized as revenue ratably until October 2021, which represented the estimated length of time the Company's obligations existed under the promotion agreement related to manufacturing Glumetza and paying Salix promotion fees on gross margin of Glumetza. The commercialization agreement in August 2011 superseded the promotion agreement and removed the Company's promotion fee obligations and contemplated removal of its manufacturing obligations. The commercialization agreement included obligations with respect to manufacturing and regulatory transition to Salix and managing the patent infringement lawsuits against Sun Pharmaceutical Industries, Inc. (Sun) and Lupin Limited (Lupin). At the time of the commercialization agreement, all of these obligations were estimated to be completed in December 2013. During the fourth quarter of 2012, events occurred related to the transfer of manufacturing with one of the contract manufacturers of Glumetza that extended the estimated completion date of the Company's manufacturing obligations to February 2016, which is now the estimated date the Company expects its obligations will be completed under the commercialization agreement.

The Company recognized approximately \$0.4 million and \$1.1 million of revenue associated with this upfront license fee for the three and nine months ended September 30, 2014, respectively, and \$0.4 million and \$1.1 million for the three and nine months ended September 30, 2013 respectively. The remaining deferred revenue balance is \$1.9 million at September 30, 2014.

***Valeant Pharmaceuticals International, Inc. (formerly Biovail Laboratories, Inc.)***

In May 2002, the Company entered into a development and license agreement granting Valeant Pharmaceuticals International, Inc. (Valeant) an exclusive license in the United States and Canada to manufacture and market Glumetza. Under the terms of the agreement, the Company was responsible for completing the clinical development program in support of the 500mg Glumetza. In July 2005, Valeant received FDA approval to market Glumetza in the United States. In accordance with the license agreement, Valeant paid a \$25.0 million license fee payment to the Company.

The Company will recognize the \$25.0 million license fee payment as revenue ratably until October 2021, which represents the estimated length of time the Company's obligations exist under the arrangement related to royalties it is obligated to pay Valeant on net sales of the 500mg

## Edgar Filing: DEPOMED INC - Form 10-Q

Glumetza in the United States and to use Valeant as the sole supplier of the 1000mg Glumetza. The Company recognized \$0.4 million and \$1.2 million of license revenue related to the amortization of this upfront fee for the three and nine months ended September 30, 2014 and 2013, respectively. The remaining deferred revenue balance related to the \$25.0 million upfront payment was \$11.3 million as of September 30, 2014.

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 September 30,		Nine Months Ended September 30,			
	2014	2013	2014	2013		
Cost of sales	\$	\$	11	\$	32	
Research and development expense		70	71	174	270	
Selling, general and administrative expense		2,257	1,490	6,310	4,244	
Total	\$	2,327	\$	1,572	\$	4,546

At September 30, 2014, the Company had \$14.6 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants and restricted stock units that will be recognized over an average vesting period of 2.1 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):

	September 30,		December 31,	
	2014		2013	
Raw materials	\$	1,321	\$	1,951
Work-in-process		1,721		181
Finished goods		4,313		9,056
Less: allowance for obsolescence		(63)		(1,043)
Total	\$	7,292	\$	10,145

The fair value of inventories acquired included a step-up in the value of CAMBIA, Zipsor and Lazanda inventories of \$3.7 million, \$1.9 million and \$0.6 million, respectively, which is being amortized to cost of sales as the acquired inventories are sold. The cost of sales related to the step-up value of CAMBIA, Lazanda and Zipsor inventories was \$0.5 million, \$0.1 million and zero for the three months ended September 30, 2014, respectively. The cost of sales related to the step-up value of CAMBIA, Lazanda and Zipsor inventories was \$3.6 million, \$0.2 million, and zero for the nine months ended September 30, 2014, respectively. The cost of sales related to the step-up value of Lazanda and Zipsor for the three months ended September 30, 2013 was zero. The cost of sales related to the step-up value of Lazanda and Zipsor for the nine months ended September 30, 2013 was zero and \$0.7 million, respectively. The Company acquired CAMBIA in December 2013.

## Edgar Filing: DEPOMED INC - Form 10-Q

As of September 30, 2014, the unamortized portion of step-up related to CAMBIA, Lazanda and Zipsor inventories was zero, \$0.3 million and zero. As of December 31, 2013, the unamortized portion of step-up related to CAMBIA, Lazanda and Zipsor inventories was \$3.6 million, \$0.5 million and zero.

### NOTE 7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following (in thousands):

	September 30, 2014		December 31, 2013
Accounts payable	\$ 1,340	\$	2,232
Accrued compensation	6,661		7,077
Accrued rebates and sales discounts	15,566		8,594
Allowance for product returns	12,743		10,278
Accrued contract sales organization fees			962
Inventory and other contract manufacturing accruals	330		87
Other accrued liabilities	8,942		5,705
Total accounts payable and accrued liabilities	\$ 45,582	\$	34,935

Table of Contents

**NOTE 8. LIABILITY RELATED TO SALE OF FUTURE ROYALTIES**

In October 2013, the Company sold its interests in royalty and milestone payments under its license agreements in the Type 2 diabetes therapeutic area to PDL for \$240.5 million. The Company has significant continuing involvement in the PDL Transaction primarily due to an obligation to act as the intermediary for the supply of 1000mg Glumetza to Salix, the licensee of Glumetza. Under the relevant accounting guidance, because of the Company's significant continuing involvement, the PDL Transaction has been accounted for as debt and is being amortized using the interest method over the life of the arrangement. In order to determine the amortization of the debt, the Company is required to estimate the total amount of future royalty payments to be received by PDL and payments the Company is required to make to PDL, if any, over the life of the arrangement. The sum of these amounts less the \$240.5 million proceeds the Company received will be recorded as interest expense over the life of the debt. Consequently, the Company imputes interest on the unamortized portion of the debt and records interest expense using an estimated interest rate that is based on the amount and timing of royalty and milestone payments expected to be received by PDL over the life of the arrangement. The Company's estimate of this total interest expense resulted in an effective annual interest rate of approximately 10%.

The Company periodically assesses the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than its initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the debt and the interest rate.

As royalties are remitted to PDL from Depo DR Sub as described at Note 1 above, the balance of the debt will be effectively repaid over the life of the agreement. The Company will record non-cash royalty revenues and non-cash interest expense within its condensed consolidated statement of operations over the term of the agreement signed in connection with the PDL Transaction. The Company recognized \$19.8 million and \$95.9 million in non-cash royalty revenue for the three and nine months ended September 30, 2014. The Company incurred \$4.4 million and \$14.6 million in non-cash interest expense for the three and nine months ended September 30, 2014.

As of September 30, 2014, the liability related to the PDL Transaction was \$166.4 million. In addition, the amount receivable from the Company's collaborative partners with respect to the PDL Transaction was \$19.7 million, which has been reflected within Receivables from collaborative partners in the accompanying condensed consolidated balance sheets as of September 30, 2014. The amount receivable from the Company's collaborative partners with respect to the PDL Transaction was \$6.9 million as of December 31, 2013.

During September 2014, the Company, Salix and PDL executed an amended agreement which is effective from October 1, 2014, and eliminates any and all continuing obligations on the part of the Company in the supply of Glumetza 100mg tablets. The Company is evaluating the impact of this amendment on its accounting for the PDL transaction.

**NOTE 9. DEBT**

On September 9, 2014, the Company issued \$345.0 million aggregate principal amount of the 2021 Notes in a public offering. The convertible debt offering resulted in net proceeds of \$334.2 million after deducting the underwriting discount and offering expenses of \$10.4 million and \$0.4 million, respectively.



## Edgar Filing: DEPOMED INC - Form 10-Q

The 2021 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 2021 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.

Upon the occurrence of certain circumstances, holders may convert their 2021 Notes prior to the close of business on the business day immediately preceding March 1, 2021. On or after March 1, 2021, until the close of business on the second trading day immediately preceding the maturity date, holders may surrender their 2021 Notes for conversion at any time. Upon conversion, the Company will pay or deliver, at its option, cash, shares of its common stock or a combination of cash and shares of its common stock. The initial conversion rate of 51.9852 shares of common stock per \$1,000 principal amount of 2021 Notes is equivalent to a conversion price of approximately \$19.24 per share of common stock. The conversion rate is subject to adjustment upon the occurrence of certain events.

In addition, upon the occurrence of certain events defined in the indenture as a fundamental change, holders of the 2021 Notes may require us to purchase for cash all or any portion of their 2021 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the fundamental change purchase date.

Table of Contents

The 2021 Notes are accounted for in accordance with ASC Subtopic 470-20, *Debt with Conversion and Other Options*. Pursuant to ASC Subtopic 470-20, since the 2021 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 2021 Notes was 9.34%. This resulted in the recognition of \$226.0 million as the liability component net of \$119.0 million debt discount with a corresponding increase to paid-in capital, the equity component, for the 2021 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. Debt issuance costs of \$7.1 million are included in *Other assets* on the Consolidated Balance Sheets as of the issuance date. Equity issuance costs of \$3.7 million related to the convertible debt offering were recorded as an offset to additional paid-in capital.

The Company recognized a net deferred tax liability of \$43.3 million created by the book-tax basis difference for the liability component of our convertible debt offering. The deferred tax liability has been offset within the applicable *Deferred tax assets* sections of the condensed consolidated balance sheets and, under the applicable accounting guidance, a corresponding off-set was recorded to additional paid-in capital on the accompanying condensed consolidated balance sheets. The net deferred tax liability will be reduced and a deferred tax benefit will be recognized as the debt discount is amortized over the life of the instrument.

The following is a summary of the liability component of the 2021 Notes as of September 30, 2014 (in thousands):

	<b>September 30, 2014</b>	
Net carrying amount of the liability component	\$	226,772
Unamortized discount of the liability component		118,228
Principal amount of the 2021 Notes	\$	345,000

The debt discount and debt issuance costs will be amortized as interest expense through September 2021. The following is a summary of interest expense for the 2021 Notes (in thousands):

	<b>Three and Nine Months Ended September 30,</b>		
	<b>2014</b>		<b>2013</b>
Stated coupon interest	\$	527	\$
Amortization of debt discount and debt issuance costs		825	
Total interest expense	\$	1,352	\$

The balance of unamortized debt discount and debt issuance costs was \$125.3 million of which \$118.2 million is included in *Senior Convertible Notes* and \$7.1 million is included within *Other assets* as of September 30, 2014 on the accompanying Condensed Consolidated Balance Sheets.

**NOTE 10. SHAREHOLDERS' EQUITY**

*Option Exercises*

For the three and nine months ended September 30, 2014 employees exercised options to purchase 279,544 and 1,248,117 shares of the Company's common stock, respectively, with net proceeds to the Company of approximately \$1.7 million and \$6.5 million, respectively. For the three and nine months ended September 30, 2013, employees exercised options to purchase 248,846 and 436,627 shares of the Company's common stock with net proceeds to the Company of approximately \$1.2 million and \$1.8 million, respectively.

Table of Contents

***Employee Stock Purchase Plan***

In May 2014, the Company sold 98,089 shares under the ESPP. The shares were purchased at a purchase price of \$7.50 per share with proceeds to the Company of approximately \$0.7 million.

**NOTE 11. INCOME TAXES**

The income tax provision includes federal, state and local income taxes and is based on the application of a forecasted annual income tax rate applied to the current quarter's year-to-date pre-tax income (loss). In determining the estimated annual effective income tax rate, the Company estimates the annual impact of certain factors, including projections of the Company's annual earnings, taxing jurisdictions in which the earnings will be generated, the Company's ability to use tax credits and net operating loss carryforwards, and available tax planning alternatives. Discrete items, including the effect of changes in tax laws, tax rates, and certain circumstances with respect to valuation allowances or other unusual or non-recurring tax adjustments, are reflected in the period in which they occur as an addition to, or reduction from, the income tax provision, rather than being included in the estimated annual effective income tax rate.

For the three and nine months ended September 30, 2014, the difference between the recorded provision from income taxes and the tax provision, based on the federal statutory rate of 35%, was primarily attributable to the impact of net non-deductible expenses and discrete adjustments. For the three and nine months ended September 30, 2013, the difference between the recorded provision from income taxes and the tax benefit, based on the federal statutory rate of 35%, was primarily attributable to the net operating losses not benefitted, offset by non-deductible expenses.

At each of December 31, 2013 and September 30, 2014, the Company had \$3.9 million of unrecognized tax benefits. All tax years since inception remain open to examination by the Internal Revenue Service and the state taxing jurisdictions in which we operate until such time as the Company's net operating losses and credits are either utilized or expire. Interest and penalties, if any, related to unrecognized tax benefits, would be recognized as income tax expense by the Company. The Company has approximately \$0.2 million of accrued interest and penalties associated with unrecognized tax benefits. The Company does not foresee any material changes to unrecognized tax benefits within the next 12 months.

**NOTE 12. LEASES**

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 is obligated to lease approximately 8,000 additional rentable square feet commencing no later than December 1, 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 given by the Company to the landlord no later than 12 months prior to the lease expiration. The Company has the one-time right to terminate the lease in its entirety effective as of November 30, 2017 by delivering written notice to the landlord on or before December 1, 2016. In the event of such termination, the Company will pay the landlord (i) the unamortized portion of the tenant improvement allowance, (ii) specified additional allowances made by the landlord, (iii) waived base rent and (iv) leasing commissions, in each case amortized at 8% interest.

## Edgar Filing: DEPOMED INC - Form 10-Q

The Company became entitled to control physical access to the premises upon signing the lease in April 2012. Therefore, in accordance with the applicable accounting guidance, the lease term was deemed to have commenced as of such time. 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 \$12.4 million in aggregate base rent over the term of the lease for the above premises. Deferred rent for the lease was approximately \$1.7 million as of September 30, 2014.

Rent expense for the lease was approximately \$0.2 million and \$0.5 million for the three and nine months ended September 30, 2014. Rent expense for the lease was approximately \$0.2 million and \$0.8 million for the three and nine months ended September 30, 2013.

In December 2013, the Company entered into an operating lease agreement with Enterprise FM Trust (Enterprise) for the lease of vehicles to be used by the Company's sales force. The Company began receiving vehicles in the second quarter of 2014, with the lease terms ranging from 18 to 36 months. Lease expense was approximately \$0.4 million and \$0.6 million for the three and nine months ended September 30, 2014.

Table of Contents

**NOTE 13. BUSINESS COMBINATIONS**

*The CAMBIA Acquisition*

On December 17, 2013, the Company entered into an Asset Purchase Agreement (CAMBIA Asset Purchase Agreement) with Nautilus Neurosciences, Inc., a Delaware corporation (Nautilus), pursuant to which the Company acquired from Nautilus all of the rights to CAMBIA (diclofenac potassium for oral solution), including related product inventory, and assumed from Nautilus certain liabilities relating to CAMBIA, for an initial payment of \$48.7 million in cash and up to \$10.0 million in contingent consideration payable upon the achievement of certain specified events. In accordance with the authoritative guidance for business combinations, the transaction with Nautilus was determined to be a business combination and was accounted for using the acquisition method of accounting.

Under the acquisition method of accounting, the Company recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was approximately \$49.7 million. The Company estimated the fair value of the contingent consideration related to this transaction at \$1.0 million, which was booked as a long-term liability on the consolidated balance sheet. The Company determined this liability amount using a probability-weighted discounted cash flow model. The Company assesses the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of significant changes in the Company's forecast of net sales for CAMBIA. The fair values of the contingent consideration as of December 31, 2013 and September 30, 2014 were \$1.0 million and \$1.1 million, respectively. At December 31, 2013 accumulated amortization for the CAMBIA intangible was \$0.2 million. At September 30, 2014 accumulated amortization for the CAMBIA intangible was \$4.1 million.

*The Lazanda Acquisition*

On July 29, 2013, the Company entered into an Asset Purchase Agreement (Lazanda Asset Purchase Agreement) with each of Archimedes Pharma US Inc., a Delaware corporation, Archimedes Pharma Ltd., a corporation registered under the laws of England and Wales, and Archimedes Development Ltd., a company registered under the laws of England and Wales (collectively, Archimedes), pursuant to which the Company acquired all of the U.S. and Canadian rights to Archimedes' product Lazanda® (fentanyl) nasal spray and related inventory for an initial payment of \$4.0 million in cash and up to \$15.0 million in contingent consideration payable upon the achievement of certain specified events. The Company also assumed certain liabilities related to Lazanda. In accordance with the authoritative guidance for business combinations, the Lazanda acquisition from Archimedes was determined to be a business combination and was accounted for using the acquisition method of accounting.

Under the acquisition method of accounting, the Company recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was approximately \$12.0 million. The Company estimated the fair value of the contingent consideration related to this transaction at \$8.0 million, which was booked as a long-term liability on the consolidated balance sheet. The Company determined this liability amount using a probability-weighted discounted cash flow model. The Company assesses the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of significant changes in the Company's forecast of net sales for Lazanda. The fair values of the contingent consideration as of December 31, 2013 and September 30, 2014 were \$8.6 million and \$9.8 million, respectively. At December 31, 2013 accumulated amortization for the Lazanda intangible was \$0.5 million. At September 30, 2014

accumulated amortization for the Lazanda intangible was \$1.4 million.

***The Zipsor Acquisition***

On June 21, 2012, the Company entered into an Asset Purchase Agreement (Zipsor Asset Purchase Agreement) with Xanodyne Pharmaceuticals, Inc., a Delaware corporation (Xanodyne), pursuant to which the Company acquired Xanodyne's product Zipsor and related inventory for \$26.4 million in cash, up to \$5.0 million in contingent consideration payable upon the achievement of certain specified events and assumed certain product related liabilities relating to Zipsor. In accordance with the authoritative guidance for business combinations, the Zipsor acquisition from Xanodyne was determined to be a business combination and was accounted for using the acquisition method of accounting.

Under the acquisition method of accounting, the Company recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date in its consolidated financial statements. The determination of estimated fair value required management to make significant estimates and assumptions. As of the acquisition date, the estimated fair value of the assets acquired was approximately \$27.7 million. The Company estimated the fair value of the contingent consideration related to this transaction at \$1.3 million, which was booked as a long-term liability on the consolidated balance sheet. The Company determined this liability amount using a probability-weighted discounted cash flow model. The Company assesses the fair value of the contingent consideration quarterly, or whenever events or changes in circumstances indicate that the fair value may have changed, primarily as a result of significant changes in the Company's forecast of net sales for Zipsor. The fair values of the contingent consideration as of December 31, 2013 and September 30, 2014 were \$1.6 million and \$1.7 million, respectively. At December 31, 2013 accumulated amortization for the Zipsor intangible was \$5.9 million. At September 30, 2014 accumulated amortization for the Zipsor intangible was \$8.8 million.

**NOTE 14. SUBSEQUENT EVENTS**

Effective October 1, 2014, the Company, Valeant, Salix and PDL executed an amended agreement which eliminated any and all continuing obligations on the part of the Company in the supply of Glumetza 1000mg tablets. The Company is evaluating the impact of this amendment on its accounting for the PDL transaction and deferred license revenue related to upfront payments received from Valeant and Salix.

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, 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 Gralise® (gabapentin), our once-daily product for the management of postherpetic neuralgia, CAMBIA® (diclofenac potassium for oral solution), our non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, Zipsor® (diclofenac potassium) liquid filled capsules, our non-steroidal anti-inflammatory drug for the treatment of mild to moderate pain in adults, and Lazanda® (fentanyl) nasal spray, our product for the management of breakthrough cancer pain in adult, opioid-tolerant cancer patients;
- the results of our ongoing litigation against filers of Abbreviated New Drug Applications (each, an ANDA) to market generic versions of our products in the United States;
- the outcome of our ongoing patent infringement litigation against Purdue Pharma L.P. (Purdue) and Endo Pharmaceuticals Inc. (Endo);
- any additional patent infringement or other litigation or proceeding that may be instituted related to Gralise, CAMBIA, Zipsor, Lazanda or any other of our products or product candidates;
- our and our collaborative partners' compliance or non-compliance with legal and regulatory requirements related to the promotion of pharmaceutical products in the United States;
- our plans to acquire, in-license or co-promote other products;
- the results of our research and development efforts;
- submission, acceptance and approval of regulatory filings;
- our ability to raise additional capital; and
- our collaborative partners' compliance or non-compliance with obligations under our collaboration agreements.



## Edgar Filing: DEPOMED INC - Form 10-Q

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 CNS conditions. The products that comprise our current specialty pharmaceutical business are Gralise® (gabapentin), a once-daily product for the management of postherpetic neuralgia (PHN) that we launched in October 2011, CAMBIA® (diclofenac potassium for oral solution), our non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks that we acquired in December 2013, Zipsor® (diclofenac potassium) liquid filled capsules, our non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain that we acquired in June 2012, and Lazanda® (fentanyl) nasal spray, our 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 we acquired in July 2013. We actively seek to expand our product portfolio through in-licensing, acquiring or obtaining co-promotion rights to commercially available products or late-stage product candidates that could be marketed and sold effectively with our existing products through our sales and marketing capability.

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

Table of Contents

In October 2013, we sold our interests in royalty and milestone payments under our license agreements in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for \$240.5 million (PDL Transaction). The interests sold include royalty and milestone payments accruing from and after October 1, 2013 from: (a) Salix Pharmaceuticals, Inc. (Salix) with respect to sales of Glumetza® (metformin HCL extended-release tablets) in the United States; (b) Merck & Co. Inc. (Merck) with respect to sales of Janumet® XR (sitagliptin and metformin HCL extended-release); (c) Janssen Pharmaceutica N.V. and Janssen Pharma (collectively, Janssen) with respect to potential future development milestones and sales of Janssen's investigational fixed-dose combination of Invokana® (canagliflozin) and extended-release metformin; (d) Boehringer Ingelheim with respect to potential future development milestones and sales of the investigational fixed-dose combinations of drugs and extended-release metformin subject to our license agreement with Boehringer Ingelheim International GMBH (Boehringer Ingelheim); and (e) LG Life Sciences Ltd. (LG) and Valeant International Bermuda SRL (Valeant SRL) for sales of extended-release metformin in Korea and Canada, respectively.

**Commercialized Products and Product Candidate Development Pipeline**

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

***Depomed Commercialized Products***

<b>Product</b>	<b>Indication</b>	<b>Status</b>
Gralise®	Management of postherpetic neuralgia	Currently sold in the United States. <i>Launched in October 2011</i>
CAMBIA®	Acute treatment of migraine attacks in adults 18 years of age or older	Currently sold in the United States <i>Acquired in December 2013</i>
Zipsor®	Mild to moderate acute pain	Currently sold in the United States. <i>Acquired in June 2012</i>
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 United States <i>Acquired in July 2013</i>

***Partner Commercialized Products and Product Candidates***

<b>Product / Product Candidate</b>	<b>Indication</b>	<b>Partner</b>	<b>Status</b>
XARTEMIS XR (oxycodone hydrochloride and acetaminophen)	Management of acute pain severe enough to require opioid treatment and in patients for	Mallinckrodt	Approved by the FDA and launched in March 2014

Edgar Filing: DEPOMED INC - Form 10-Q

	whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate		
MNK-155	Pain	Mallinckrodt	New Drug Application (NDA) accepted for filing by the FDA in May 2014  Foreign regulatory filings in process
NUCYNTA® ER	Moderate to severe chronic pain; neuropathic pain associated with diabetic peripheral neuropathy (DPN)	Janssen	License covers sales of NUCYNTA® ER in the United States, Canada and Japan
IW-3718 Refractory GERD program using Acuform®	Refractory GERD	Ironwood	In clinical development

Table of Contents

*Depomed Product Pipeline*

Product	Indication	Status
DM-1992	Parkinson's disease	Top-line results of Phase 2 study reported in November 2012

**Commercialized Products**

*Gralise® (Gabapentin) Tablets for the Management of Postherpetic Neuralgia (PHN)*

In October 2011, we launched and announced the commercial availability of Gralise. Gralise is prescribed for the treatment of postherpetic neuralgia. Gralise product sales for the three and nine months ended September 30, 2014 were \$16.3 million and \$42.3 million, respectively. Gralise product sales for the three and nine months ended September 30, 2013 were \$9.8 million and \$24.5 million, respectively.

*CAMBIA® (Diclofenac Potassium for Oral Solution) for the Acute Treatment of Migraine Attacks in Adults 18 Years of Age or Older*

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 and related product inventory on December 17, 2013 from Nautilus Neurosciences, Inc. (Nautilus), for \$48.7 million and the assumption of certain product-related liabilities. We also assumed certain annual third party royalty obligations totaling not more than 11% of CAMBIA net sales.

We began selling CAMBIA in late December 2013 and began commercial promotion of CAMBIA in February 2014. Our CAMBIA product sales were \$5.8 million and \$15.4 million for the three and nine months ended September 30, 2014, respectively.

*Zipsor® (Diclofenac Potassium) Liquid-Filled Capsules for Mild to Moderate Acute Pain*

Zipsor is a NSAID indicated for relief of mild to moderate acute pain in adults. Zipsor uses proprietary ProSorb® delivery technology to deliver a finely dispersed, rapidly absorbed formulation of diclofenac. We acquired Zipsor in June 2012 from Xanodyne Pharmaceuticals, Inc. (Xanodyne) for \$25.9 million in cash and the assumption of certain product-related liabilities.

We began selling Zipsor in late June 2012 and began commercial promotion of Zipsor in July 2012. We recognized \$6.1 million and \$18.3 million in Zipsor product sales for the three and nine months ended September 30, 2014, respectively. We recognized \$6.0 million and \$14.6

million in Zipsor product sales for the three and nine months ended September 30, 2013, respectively.

***Lazanda® (Fentanyl) Nasal Spray 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***

Lazanda nasal spray is an intranasal fentanyl drug used to manage breakthrough pain in adults (18 years of age or older) who are already routinely taking other opioid pain medicines around-the-clock for cancer pain. We acquired Lazanda and certain related product inventory on July 29, 2013 from Archimedes Pharma US, Inc. and its affiliates for \$4.0 million in cash and the assumption of certain product-related liabilities.

We began selling Lazanda in August 2013 and began commercial promotion of Lazanda in October 2013. Lazanda product sales were \$2.3 million and \$4.3 million for the three and nine months ended September 30, 2014, respectively. Lazanda product sales were \$0.4 million for the three and nine months ended September 30, 2013, respectively.

Table of Contents

**License and Development Arrangements**

***Janssen Pharmaceuticals, Inc. NUCYNTA® ER***

In August 2012, we 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 our Acuform drug delivery technology for the development and commercialization of tapentadol extended release products, including NUCYNTA ER (tapentadol extended-release tablets). We received a \$10.0 million upfront license fee in August 2012 and receive low single digit royalties on net sales of NUCYNTA ER in the U.S., Canada and Japan from and after July 2, 2012 through December 31, 2021.

***Mallinckrodt Inc. (formerly Covidien, Ltd.) Acetaminophen/Opiate Combination Products***

In November 2008, we entered into a license agreement related to acetaminophen/opiate combination products with Mallinckrodt. The license agreement grants Mallinckrodt worldwide rights to utilize our Acuform technology for the exclusive development of up to four products containing acetaminophen in combination with opiates, two of which Mallinckrodt has elected to develop.

We have received \$27.5 million in upfront fees and milestones under the agreement. The upfront fees included a \$4.0 million upfront license fee and a \$1.5 million advance payment for formulation work we performed under the agreement. The milestone payments include four \$0.5 million clinical development milestones, a \$5.0 million milestone following the FDA's July 2013 acceptance for filing of the NDA for XARTEMIS XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII), previously known as MNK-795, a \$10.0 million milestone on FDA approval of XARTEMIS XR, and a \$5.0 million milestone following the FDA's May 2014 acceptance for filing of the NDA for MNK-155.

In March 2014, the FDA approved XARTEMIS XR for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated or would otherwise be inadequate. The approval of the NDA triggered a \$10.0 million milestone payment to us, which we recognized in first quarter 2014 and received in April 2014. In May 2014, the FDA accepted for filing the NDA for MNK-155. The acceptance for filing of the NDA triggered a \$5.0 million milestone payment to us which we recognized in the second quarter of 2014 and received in June 2014. We receive high single digit royalties on net sales of XARTEMIS XR, which was launched in March 2014, and we will receive the same high single digit royalty on net sales of MNK-155 if it is approved.

***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 an IW-3718, an Ironwood product candidate under evaluation for refractory GERD.

## Edgar Filing: DEPOMED INC - Form 10-Q

We have received \$3.4 million under the agreement, which includes an upfront payment, reimbursement of initial product formulation work, and three milestones payments. We recognized 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.

### **Licensing and Development Agreements Sold to PDL in October 2013**

In October 2013, we sold to PDL our milestone and royalty interests in our license agreements in the type 2 diabetes therapeutic area (and any replacements for the agreements) for \$240.5 million. The interests sold include royalty and milestone payments accruing from and after October 1, 2013 from: (a) Salix with respect to sales of Glumetza® (metformin HCL extended-release tablets) in the United States; (b) Merck with respect to sales of Janumet® XR (sitagliptin and metformin HCL extended-release); (c) Janssen with respect to potential future development milestones and sales of Janssen's investigational fixed-dose combination of Invokana® (canagliflozin) and extended-release metformin; (d) Boehringer Ingelheim with respect to potential future development milestones and sales of the investigational fixed-dose combinations of drugs and extended-release metformin subject to our license agreement with Boehringer Ingelheim; and (e) LG and Valeant SRL for sales of extended-release metformin in Korea and Canada, respectively. From and after October 1, 2013, PDL will receive all royalty and milestone payments due under the agreements until PDL has received payments equal to \$481 million, after which we and PDL will share evenly all net payments received.

Table of Contents

***Salix Pharmaceuticals, Inc. (formerly Santarus, Inc.) Glumetza®***

In August 2011, we entered into a commercialization agreement with Salix granting Salix exclusive rights to manufacture and commercialize Glumetza in the United States. The commercialization agreement supersedes the previous promotion agreement between the parties originally entered into in July 2008. Under the commercialization agreement, we granted Salix exclusive rights to manufacture and commercialize Glumetza in the United States in return for a royalty on Glumetza net sales. We recognized \$14.6 million and \$42.1 million in royalty revenue for the three and nine months ended September 30, 2013, respectively.

Salix pays royalties on Glumetza net product sales in the United States as follows: 26.5% in 2011; 29.5% in 2012; 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond, prior to generic entry of a Glumetza product. In the event of generic entry of a Glumetza product in the United States, the parties will thereafter equally share Glumetza proceeds based on a gross margin split.

***Janssen Pharmaceutica N.V.***

We have received \$10.0 million in upfront and milestone payments, and are eligible for additional milestone payments and royalties under an August 2010 non-exclusive license agreement between us and Janssen related to fixed dose combinations of extended release metformin and Janssen's type 2 diabetes product candidate canagliflozin.

Under the agreement, we granted Janssen a license to certain patents related to our Acuform drug delivery technology to be used in developing the combination products. We also granted Janssen a right to reference the Glumetza NDA in Janssen's regulatory filings covering the products.

In February 2013, we completed a project for Janssen related to this program and recognized \$2.2 million in revenue during the first quarter of 2013.

**Product Candidate**

***DM-1992 for Parkinson's Disease***

In January 2012, we initiated a Phase 2 study to evaluate DM-1992 for the treatment of motor symptoms associated with Parkinson's disease. The trial was a randomized, active-controlled, open-label, crossover study testing DM-1992 dosed twice daily against a generic version of immediate-release carbidopa-levodopa dosed as needed. The trial enrolled 34 patients at eight U.S. centers. The study assessed efficacy, safety and pharmacokinetic variables. The primary endpoint for the study was change in off time as measured by patient self-assessment and clinician assessment.



Enrollment was completed in July 2012 and the study was completed in September 2012. In November 2012, we reported top-line results of the Phase 2 study. We continue to evaluate clinical and regulatory strategies and commercial prospects for DM-1992.

### **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 stock-based compensation to be critical policies. There have been no changes to our critical accounting policies since we filed our 2013 Form 10-K with the SEC on March 17, 2014. For a description of our critical accounting policies, please refer to our 2013 Form 10-K.

On September 9, 2014, we issued and sold \$345.0 million aggregate principal amount of convertible senior notes in a public offering. The convertible debt offering resulted in net proceeds of \$334.2 million after deducting the underwriting discount and offering expenses of \$10.4 million and \$0.4 million, respectively. The 2021 Notes are accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Under ASC Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are 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. See Note 9 - Debt of the Note to Consolidated Financial Statements for further information regarding the 2021 Notes.

Table of Contents**RESULTS OF OPERATIONS***Three and Nine Months Ended September 30, 2014 and 2013***Revenue**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Product sales:</b>				
Gralise	\$ 16,331	\$ 9,812	\$ 42,301	\$ 24,455
Zipsor	6,147	6,022	18,312	14,614
Cambia	5,833		15,415	
Lazanda	2,273	444	4,307	444
Total product sales	30,584	16,278	80,335	39,513
<b>Royalties:</b>				
Glumetza US		14,578		42,060
Others	370	844	1,295	2,539
Total royalty revenue	370	15,422	1,295	44,599
Non-cash PDL royalty revenue	\$ 19,771	\$	\$ 95,852	\$
<b>License and Other revenue:</b>				
Glumetza	\$ 760	\$ 760	\$ 2,280	\$ 2,280
Mallinckrodt		5,000	15,000	5,000
Janssen				2,203
Other			1,000	1
Total license and other revenue:	760	5,760	18,280	9,484
Total revenues	\$ 51,485	\$ 37,460	\$ 195,762	\$ 93,596

***Product sales***

***Glalise.*** We launched and began commercial promotion of Gralise in October 2011. The increase in Gralise product sales in the first nine months of 2014 relative to the comparable period in 2013 is primarily the result of higher prescription demand and, to a lesser extent, price increases. We expect Gralise product sales and prescriptions to increase from current levels for the remainder of 2014.

## Edgar Filing: DEPOMED INC - Form 10-Q

CAMBIA. We acquired and began selling CAMBIA in December 2013. We began commercial promotion of CAMBIA in February 2014. We expect CAMBIA product sales and prescriptions to increase from current levels for the remainder of 2014.

Zipsor. We acquired and began selling Zipsor in late June 2012. We began commercial promotion of Zipsor in July 2012. The increase in Zipsor product sales in the first nine months of 2014 relative to the comparable period in 2013 is primarily the result of price increases.

Lazanda. We acquired Lazanda in July 2013 and began selling Lazanda in August 2013. We began commercial promotion of Lazanda in October 2013. We expect Lazanda product sales and prescriptions to increase from current levels for the remainder of 2014.

Table of Contents

***Royalties***

Glumetza US . Until October 1, 2013, we received royalties from Salix based on net sales of Glumetza in the United States. Royalty revenue from Salix for the three and nine months ended September 30, 2013 was \$14.6 million and \$42.1 million, respectively, which represents a 32.0% royalty on Salix's net sales of Glumetza. In October 2013, we sold our interest in the Glumetza royalties to PDL, as discussed below.

Other Royalties. Other royalties for the three and nine months ended September 30, 2014 include royalties from Janssen Pharma on net sales of NUCYNTA ER and royalties from Mallinckrodt on net sales of XARTEMIS XR, which was launched in March 2014. Other royalties in the three and nine months ended September 30, 2013 include royalties from Janssen Pharma on net sales of NUCYNTA ER, royalties from Merck on net sales of Janumet® XR, and royalties from Valeant SRL on net sales Glumetza in Canada. In October 2013, we sold our interests in Janumet® XR and Glumetza Canadian royalties to PDL.

Non-Cash Royalty Revenue Related to the PDL Transaction. In October 2013, as noted above, we sold our interests in royalty and milestone payments under our license agreements in the Type 2 diabetes therapeutic area to PDL for \$240.5 million. This transaction was accounted for as debt that will be amortized using the interest method over the life of the arrangement. As a result of the debt accounting, even though we did not retain the related royalties and milestones under the transaction (as the amounts are remitted to PDL), we will continue to record revenue related to these royalties and milestones until the amount of the associated debt and related interest is fully amortized. We recognized \$19.8 million and \$95.9 million of non-cash revenue associated with the PDL Transaction for the three and nine months ended September 30, 2014.

Effective October 1, 2014, Depomed, Valeant, Salix and PDL executed an amended agreement which eliminated any and all continuing obligations on the part of Depomed in the supply of Glumetza 1000mg tablets. We are evaluating the impact of this amendment on the accounting for the PDL transaction.

***License and Other Revenue***

Glumetza. Glumetza license revenue consists of license revenue recognized from the \$25.0 million upfront license fee received from Valeant in July 2005 and the \$12.0 million upfront fee received from Salix in July 2008.

We are recognizing the \$25.0 million upfront license fee payment from Valeant as revenue ratably until October 2021, which represents the estimated length of time our obligations exist under the arrangement related to royalties we are obligated to pay Valeant on net sales of Glumetza in the United States and for our obligation to use Valeant as our sole supplier of the 1000mg Glumetza.

We are recognizing the \$12.0 million upfront license payment from Salix as revenue ratably until February 2016, which is the estimated date we expect our obligations will be completed under the commercialization agreement.

## Edgar Filing: DEPOMED INC - Form 10-Q

Effective October 1, 2014, we assigned all of our rights and obligations under the Glumetza supply agreement to Salix, eliminated any and all continuing obligations on the part of Depomed in the supply of Glumetza 1000mg tablets. We are evaluating the impact of this amendment on our accounting for the deferred license revenue related to upfront payment received from Valeant and Salix.

*Mallinckrodt.* In March 2014, the FDA approved Mallinckrodt's NDA for XARTEMIS XR. The approval of the NDA triggered a \$10.0 million nonrefundable milestone payment to us under our license agreement with Mallinckrodt, which we received in April 2014. In May 2014, the FDA accepted for filing the NDA for MNK-155. The acceptance for filing triggered a \$5.0 million nonrefundable milestone payment to us under our license agreement with Mallinckrodt, which we received in July 2014. As the nonrefundable milestones were both substantive in nature and related to past performance, achievement was not reasonably assured at the inception of the agreement and the collectability of the milestones was reasonably assured, we recognized the entire \$10.0 million milestone payment related to XARTEMIS approval as revenue in the first quarter of 2014 and we recognized the entire \$5.0 million milestone payment related to FDA acceptance for filing of the NDA for MNK-155 in the second quarter of 2014.

*Janssen.* In February 2013, we completed a project for Janssen related to Janssen's type 2 diabetes product candidate canagliflozin and recognized \$2.2 million in revenue.

Table of Contents

*Other.* In March 2014, we recognized \$1.0 million in revenue relating to a milestone earned under our license agreement with Ironwood related to Ironwood's IW-3718 product candidate for refractory GERD commencing clinical trials. As the nonrefundable milestone was both substantive in nature and related to past performance, achievement was not reasonably assured at the inception of the agreement and the collectability of the milestone was reasonably assured, we recognized the entire \$1.0 million as revenue during the first quarter of 2013.

**Cost of Sales**

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, inventory write-downs, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales. Total cost of sales for the three and nine months ended September 30, 2014, as compared to the prior year, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of sales	\$ 3,523	\$ 1,751	\$ 11,900	\$ 4,923
Dollar change from prior year	1,772		6,977	
Percentage change from prior year	101.2%		141.7%	

Cost of sales for the three and nine months ended September 30, 2014 relates to Gralise, CAMBIA, Zipsor and Lazanda. Cost of sales for the three and nine months ended September 30, 2013 relates to Gralise, Zipsor and Lazanda. Cost of sales increased in 2014 as a result of increased unit sales of Gralise and the acquisition of CAMBIA and Lazanda products in 2013.

We began selling CAMBIA in December 2013 and began commercial promotion of CAMBIA in February 2014. The fair value of inventories acquired included a step-up in the value of CAMBIA inventories of \$3.7 million which is being amortized to cost of sales as the acquired inventories are sold. The cost of sales related to the step-up value of CAMBIA was \$0.5 million and \$3.6 million for the three and nine months ended September 30, 2014, respectively. We began selling Lazanda in August 2013 and began commercial promotion of Lazanda in October 2013. The fair value of inventories acquired included a step-up in the value of Lazanda inventories of \$0.6 million which is being amortized to cost of sales as the acquired inventories are sold. The cost of sales related to the step-up value of Lazanda was \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2014, respectively. The cost of sales related to the step-up value of Lazanda for the three and nine months ended September 30, 2013 was insignificant. The fair value of inventories acquired included a step-up in the value of Zipsor inventories of \$1.9 million, of which zero and \$0.7 million was amortized to cost of sales for the three and nine months ended September 30, 2013, respectively.

**Research and Development Expense**

Our research and development expenses currently include salaries, clinical trial costs, consultant fees, supplies, manufacturing costs for research and development programs and allocations of corporate costs. The scope and magnitude of future research and development expenses cannot be predicted at this time for our product candidates in development, as it is not possible to determine the nature, timing and extent of clinical trials and studies, the FDA's requirements for a particular drug and the requirements and level of participation, if any, by potential partners. As potential products proceed through the development process, each step is typically more extensive, and therefore more expensive, than the previous step. Success in development therefore, generally results in increasing expenditures until actual product approval. Total research and

## Edgar Filing: DEPOMED INC - Form 10-Q

development expense for the three and nine months ended September 30, 2014, as compared to the prior year, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development expense	\$ 1,644	\$ 1,339	\$ 5,083	\$ 6,049
Dollar change from prior year	305		(966)	
Percentage change from prior year	22.8%		-16.0%	

The decrease in research and development expense for the nine months ended September 30, 2014, as compared to the same period in 2013 was primarily due to reduced costs related to our Sefelsa program, which ceased in the first quarter of 2013. We expect research and development expense for the fourth quarter of 2014 to slightly increase from the third quarter of 2013.

Table of Contents**Selling, General and Administrative Expense**

Selling, general and administrative expenses primarily consist of personnel, contract personnel, marketing and promotion expenses associated with our commercial products, personnel expenses to support our administrative and operating activities, facility costs and professional expenses, such as legal fees and accounting fees. Total selling, general and administrative expense, as compared to the prior year, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Selling, general and administrative expense	\$ 27,078	\$ 26,374	\$ 92,166	\$ 77,705
Dollar change from prior year	704		14,461	
Percentage change from prior year	2.7%		18.6%	

The increase in selling, general and administrative expense for the three and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013 was primarily due to sales and marketing expense related to Lazanda and CAMBIA which we acquired in July 2013 and December 2013, respectively, and higher legal expenses related to our ongoing patent litigation. We expect selling, general and administrative expense in the fourth quarter of 2014 to increase slightly from the third quarter of 2014.

**Amortization of Intangible Assets**

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Amortization of intangible assets- Zipsor	\$ 964	\$ 964	\$ 2,894	\$ 2,888
Amortization of intangible assets- Lazanda	291	194	875	194
Amortization of intangible assets- CAMBIA	1,285		3,852	
	\$ 2,540	\$ 1,158	\$ 7,621	\$ 3,082

The Zipsor product rights of \$27.1 million have been recorded as intangible assets on the accompanying condensed consolidated balance sheet and are being amortized over the estimated useful life of the asset on a straight-line basis through July 2019. Total amortization expense for the three and nine months ended September 30, 2013 and September 30, 2014 was approximately \$1.0 million and \$2.9 million, respectively. The estimated amortization expense for each of the four succeeding fiscal years is expected to be \$3.9 million and \$2.1 million for 2019.

The Lazanda product rights of \$10.5 million have been recorded as intangible assets on the accompanying condensed consolidated balance sheet 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. Total amortization expense for the three and nine months ended September 30, 2014 was approximately \$0.3 million and \$0.9 million, respectively. The estimated amortization expense for each of the five succeeding fiscal years 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 sheet 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. Total amortization expense for the three and nine months ended September 30, 2014 was approximately \$1.3 million and \$3.9 million, respectively. The estimated amortization expense for each of the five succeeding fiscal years is expected to be \$5.1 million.

**Interest Income and Expense**

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Interest and other income	\$ 23	\$ 27	\$ 70	\$ 142
Change in fair value of contingent consideration and unfavorable contract	(558)	(285)	(1,784)	(440)
Interest expense on convertible debt	(1,352)		(1,352)	
Non-cash interest expense on liability related to sale of future royalties	(4,364)		(14,646)	
Other			(17)	
Net interest income (expense)	\$ (6,251)	\$ (258)	\$ (17,729)	\$ (298)

Interest and other income decreased during the three and nine months ended September 30, 2014, as compared to the corresponding period in 2013 as a result of lower interest rates on investment balances.

Table of Contents

The increase in non-cash interest expense on liability related to the PDL Transaction for the three and nine months ended September 30, 2014 compared to the same period 2013 is attributable to the royalty sale transaction that we completed in October 2013. As described above, this transaction has been recorded as debt under the applicable accounting guidance. We impute interest on the transaction and record interest expense based on the amount and timing of royalty and milestone payments expected to be received by PDL over the life of the arrangement. There are a number of factors that could materially affect the estimated interest rate and we will assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively.

Interest expense relates to the \$345.0 million aggregate principal amount of the 2021 Notes issued in September 2014. The offering resulted in net proceeds of \$334.2 million after deducting the underwriting discount and offering expenses of \$10.4 million and \$0.4 million, respectively. The interest rate for the 2021 Notes is fixed at 2.50% per annum and is payable semi-annually in arrears on March 1 and September 1 of each year, commencing on March 1, 2015. During the three and nine months ended September 30, 2014, we recognized \$0.5 million of accrued coupon interest expense related to the 2021 Notes.

In accordance with accounting guidance on embedded conversion features, we valued and bifurcated the conversion option associated with the 2021 Notes from the respective host debt instrument and initially recorded the conversion option of \$115.3 million for the 2021 Notes in Shareholders' equity on our Condensed Consolidated Balance Sheets. The resulting debt discounts on the 2021 Notes are being amortized to interest expense at an effective interest rate of 9.34% over the contractual term of the notes. During the three and nine months ended September 30, 2014, we recognized \$0.8 million of interest expense related to the amortization of these debt discounts. We expect interest expense to increase in future periods as the three months ended September 30, 2014 reflect accrued interest and amortization of the debt discount and debt issuance costs since September 9, 2014.

**Income Tax Provision**

At the end of 2013, we released our valuation allowance that impacts the comparison of the provision for income taxes for the three and nine months ended September 30, 2014 when compared to the comparable periods for 2013. For the three and nine months ended September 30, 2014, we recorded a provision from income taxes of \$4.0 million and \$24.1 million, respectively, compared to a provision from income taxes of \$0.1 million and \$0.1 million for the same period in 2013. The increase in the provision from income taxes in the three and nine months ended September 30, 2014, compared to the same period in 2013, is primarily attributable to an increase in income earned for the nine months ended September 30, 2014 compared to the same period in the prior year. We paid approximately zero and \$58.8 million in taxes for the three and nine month period ended September 30, 2014, respectively.

**LIQUIDITY AND CAPITAL RESOURCES**

The following table displays a summary of our cash, cash equivalents and marketable securities as of September 30, 2014 and December 31, 2013:

(In thousands)	<b>September 30, 2014</b>	<b>December 31, 2013</b>
----------------	-------------------------------	------------------------------

## Edgar Filing: DEPOMED INC - Form 10-Q

Cash, cash equivalents and marketable securities	\$	559,612	\$	276,017
--	----	---------	----	---------

Since inception through September 30, 2014, we have financed our product development efforts and operations primarily from private and public sales of equity securities, including convertible debt securities; the sale of rights to future royalties and milestones to PDL; upfront license, milestone and termination fees from collaborative and license partners; and product sales. In September 2014, we issued and sold \$345.0 million of 2021 Notes.

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 Galise, CAMBIA, Zipsor and Lazanda;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements;
- interest and principal payments on our 2021 Notes;
- financial terms of definitive license agreements or other commercial agreements we may enter into;
- results of research and development efforts;
- changes in the focus and direction of our business strategy and/or research and development programs; and
- results of clinical testing requirements of the FDA and comparable foreign regulatory agencies.

Table of Contents

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 which we may pursue, we will have to raise additional funds through the sale of our equity securities, through debt financing, or from development and licensing arrangements. 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 inability to raise any additional capital that may be required to fund our future operations or product acquisitions and strategic transactions which we may pursue could have a material adverse effect on our company.

**Cash Flows from Operating Activities**

Net cash used in operating activities during the nine months ended September 30, 2014 was \$59.1 million. Net cash provided by operating activities during the nine months ended September 30, 2013 was approximately \$10.4 million. Net cash used in the nine months ended September 30, 2014 was primarily related to income tax payments totaling approximately \$58.8 million related to the year ended December 31, 2013.

**Cash Flows from Investing Activities**

Net cash provided by investing activities during the nine months ended September 30, 2014 was approximately \$17.3 million primarily due to higher maturities of marketable securities relative to purchases of marketable securities. Net cash provided by investing activities during the nine months ended September 30, 2013 was approximately \$22.5 million primarily due to higher proceeds from maturities of marketable securities relative to purchases of marketable securities.

**Cash Flows from Financing Activities**

Cash provided by financing activities during the nine months ended September 30, 2014 was \$343.8 million, primarily due to \$334.4 million of net proceeds received from the issuance of the 2021 Notes and \$7.2 million of proceeds received from employee option exercises. Cash provided by financing activities during the nine months ended September 30, 2013 was \$2.3 million and consisted of proceeds from employee option exercises.

**Contractual Obligations**

As of September 30, 2014, our aggregate contractual obligations are as shown in the following table (in thousands):

Edgar Filing: DEPOMED INC - Form 10-Q

	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
Term loan - principal	\$	\$	\$	\$ 345,000	\$ 345,000
Term loan - interest	8,433	17,250	17,250	17,250	60,183
Operating leases(1)	3,073	5,554	3,083	5,263	16,973
Purchase commitments	5,775				5,775
	\$ 17,281	\$ 22,804	\$ 20,333	\$ 367,513	\$ 427,931

---

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

At September 30, 2014, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$5.8 million under our manufacturing agreements related to Gralise, Zipsor, Lazanda and CAMBIA. The amounts disclosed only represent minimum purchase requirements.

Table of Contents

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 and an additional 8,000 rentable square feet commencing no later than December 1, 2015. The Newark lease included free rent for the first five months of the lease. Lease payments began in May 2013. We have the one-time right to terminate the lease in its entirety effective as of November 30, 2017 by delivering written notice to the landlord on or before December 1, 2016. In the event of such termination, we will pay the landlord the unamortized portion of the tenant improvement allowance, specified additional allowances made by the landlord, waived base rent and leasing commissions, in each case amortized at 8% interest. Our previous lease in Menlo Park, California ended in January 2013.

The table above also excludes non-cancelable purchase orders and minimum purchase obligations of approximately \$1.4 million under our supply agreement with Valeant for the supply of 1000mg Glumetza, as these obligations will be fully reimbursed by Santarus.

**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 2013 Form 10-K.

**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 quarter ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

**Depomed v. Galise ANDA Filers**

Between March 2012 and May 2012, we filed lawsuits in the United States District Court for the District of New Jersey in response to six Abbreviated New Drug Applicants (ANDAs) filed by companies seeking to market generic versions of 300mg and 600mg dosage strengths of Galise prior to the expiration of our patents listed in the Orange Book for Galise. The lawsuits have been consolidated for purposes of all pretrial proceedings. Our lawsuits against two of the six Galise ANDA filers, Impax Laboratories and Watson Laboratories, have been dismissed as a result of the withdrawal of the ANDAs from consideration by the FDA. Our lawsuit against another ANDA filer, Par Pharmaceuticals Inc., has been dismissed because the ANDA filer no longer seeks approval of its Galise ANDA prior to the expiration of our Galise Orange Book-listed patents. In April 2014, we entered settlement agreements with Incepta Pharmaceuticals and Abon Pharmaceuticals LLC (collectively, Incepta) and with Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (collectively, Zydus) pursuant to which Incepta and Zydus may begin selling generic versions of Galise on January 1, 2024, or earlier under certain circumstances.

Table of Contents

A bench trial involving defendants Actavis Elizabeth LLC and Actavis Inc. (collectively, Actavis) was completed on May 20, 2014 as to U.S. Patent Nos. 6,635,280; 6,488,962; 7,438,927; 7,731,989; 8,192,756; 8,252,332; and 8,333,992, which expire between September 2016 and February 2024. In August 2014, the court ruled in our favor, finding that Actavis infringed all patent claims we asserted and upholding the validity of the patents. On September 15, 2014, Actavis filed a notice appealing the decision to the United States Court of Appeals for the Federal Circuit.

**Depomed v. FDA**

In November 2010, the FDA granted Galise Orphan Drug designation for the management of PHN, but did not recognize Orphan drug exclusivity for Galise in January 2011 when Galise was approved for marketing in the United States. In September 2012, we filed an action in federal district court for the District of Columbia against the FDA seeking an order requiring the FDA to grant Galise Orphan Drug exclusivity for the management of PHN. Briefing in the case was completed in March 2013 and a hearing on our summary judgment motion was held in August 2013. In September 2014, the court issued an order granting our request for summary judgment, and ordering the FDA to grant Orphan Drug exclusivity for Galise for the management of PHN, which the FDA did formally in October 2014. On November 3, 2014, the FDA filed a notice appealing the order to the United States Court of Appeals for the Federal Circuit. On November 5, 2014, we received notice the government intends to dismiss its appeal as soon as the case is docketed in the Court of Appeals.

**Depomed v. Purdue and Depomed v. Endo Pharmaceuticals Patent Infringement Litigation and Related *Inter Partes* Review Proceedings**

We have sued Purdue Pharma and Endo Pharmaceuticals for patent infringement in separate lawsuits filed in the United States District Court for the District of New Jersey. The lawsuits arise from Purdue's commercialization of OxyContin® (oxycodone hydrochloride controlled-release) in the United States and Endo's commercialization of OPANA® ER (oxymorphone hydrochloride extended-release) in the United States. We sued Purdue in January 2013 for infringement of U.S. Patent Nos. 6,340,475 (the 475 Patent) and 6,635,280 (the 280 Patent), which expire in September 2016. We sued Endo in April 2013 for infringement of the 475 Patent, the 280 Patent and U.S. Patent No. 6,723,340 (the 340 Patent), which expires in October 2021. The Purdue lawsuit has been stayed pending completion of the *inter partes* reviews described below. The District Court has not yet ruled on Endo's request to stay the Endo litigation.

In response to two petitions filed by Purdue and six petitions filed by Endo, the United States Patent and Trademark Office Patent Trial and Appeal Board (PTAB) has instituted *inter partes* reviews (each, an IPR) of certain of the claims asserted in our lawsuits against Purdue and Endo. 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. Patent owners may appeal decisions of the PTAB to the United States Court of Appeals for the Federal Circuit. The PTAB's decisions are final and non-appealable as to petitioners. 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 those claims are invalid on any ground the petitioner raised or reasonably could have raised in the IPR.

In the Purdue IPRs, 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 10 claims of the 280 Patent asserted against Purdue.



## Edgar Filing: DEPOMED INC - Form 10-Q

Endo filed two IPR petitions for each of the 475 Patent, the 280 Patent and the 340 Patent. The PTAB declined to institute an IPR as to three of Endo's petitions. The PTAB also declined to institute an IPR as to five claims of the 475 Patent, three claims of the 280 Patent and one claim of the 340 Patent in the Endo IPRs. The PTAB instituted an IPR as to the other 15 claims of the 475 Patent, as to the other seven claims of the 280 Patent and as to the other seven claims of the 340 patent asserted against Endo. The PTAB also declined to institute an IPR as to a number of Endo's requested grounds.

Discovery, briefing and oral argument is scheduled to be complete in the Purdue IPRs in March 2015 and in the Endo IPRs in June 2015. In accordance with the requirements of the AIA, we expect final decisions from the PTAB not later than one year after the PTAB's decisions to institute the IPRs, or not later than July 10, 2015 in the Purdue IPRs and not later than September 29, 2015 in the Endo IPRs.

Table of Contents

**Depomed v. Banner Pharmacaps**

On June 28, 2013, we received from Banner a Notice of Certification for U.S. Patent Nos. 6,365,180; 7,662,858; 7,884,095; 7,939,518; and 8,110,606 under 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) (Zipsor® Paragraph IV Letter) certifying that Banner has submitted and the FDA has accepted for filing an ANDA for diclofenac potassium capsules, 25mg. The letter states that the Banner ANDA product contains the required bioavailability or bioequivalence data to Zipsor® and certifies that Banner intends to obtain FDA approval to engage in commercial manufacture, use or sale of Banner's ANDA product before the expiration of the above identified patents, which are listed for Zipsor® in the Orange Book. U.S. Patent No. 6,365,180 expires in 2019 and U.S. Patent Nos. 7,662,858; 7,884,095; 7,939,518; and 8,110,606 expire in 2029. The Zipsor® Paragraph IV letter indicates Banner has granted to Watson Laboratories Inc. (Watson) exclusive rights to Banner's proposed generic Zipsor product.

On July 26, 2013, we filed a lawsuit in the United States District Court for District of New Jersey against Banner and Watson for infringement of the patents identified above. The lawsuit was commenced within the 45 days required to automatically stay, or bar, the FDA from approving Banner's ANDA for 25 mg diclofenac for 30 months or until a district court decision that is adverse to Depomed, whichever may occur earlier. Absent a court order, the 30-month stay would be expected to expire in December 2015.

On April 2, 2014, we filed an amended complaint to include infringement of U.S. Patent Nos. 6,287,594 and 8,623,920, which were recently added to the Orange Book listing for Zipsor® and expire in 2019 and 2029, respectively. Fact discovery and claim construction in the case are ongoing and no trial date has been set.

***General***

We cannot reasonably predict the outcome of the legal proceedings described above, nor can we estimate the amount of loss, or range of loss or other adverse consequence, if any, that may result from these proceedings. As such we are not currently able to estimate the impact of the above litigation on our financial position or results of operations.

We may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims, and other matters. 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, we are not currently involved in any matters that we believe may have a material adverse effect on our business, results of operations or financial condition. However, regardless of the outcome, litigation can have an adverse impact on us 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 2013 Form 10-K and our Form 10-Q for the quarter ended June 30, 2014.

## Edgar Filing: DEPOMED INC - Form 10-Q

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 Gralise, CAMBIA, Zipsor and Lazanda, our business will suffer.*

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 limited 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 Gralise, Zipsor, Lazanda and CAMBIA depend 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 market acceptance of 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 commercialize our products;
- maintain intellectual property protection for our products; and
- comply with applicable legal and regulatory requirements.

Table of Contents

If we are unable to successfully achieve or perform these functions, we will not be able to maintain or increase our revenues from Galrise, CAMBIA, Zipsor and Lazanda and our business will suffer.

*If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our products, our business will suffer.*

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

The FDCA requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we 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.

As described in greater detail under ITEM 1. LEGAL PROCEEDINGS above, we received a favorable ruling in our patent litigation against Actavis. The lawsuit was filed in March 2012 against Actavis for infringement of certain U.S. 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 Galrise. A bench trial was completed on May 20, 2014 and in August 2014 the court ruled in our favor, finding that Actavis infringed all asserted claims of all seven patents asserted in trial and upholding the validity of the patents, which expire between September 2016 and February 2024. On September 15, 2014, Actavis filed a notice appealing the decision to the United States Court of Appeals for the Federal Circuit. A successful appeal of the trial court's ruling by Actavis would harm our business, financial condition and results of operations.

On June 28, 2013, we received from Banner Pharmacaps Inc. (Banner) a Notice of Certification for U.S. Patent Nos. 6,365,180; 7,662,858; 7,884,095; 7,939,518 and 8,110,606 under 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) (Zipsor Paragraph IV Letter) certifying that Banner has submitted and the FDA has accepted for filing an ANDA for 25mg diclofenac potassium capsules, (Banner ANDA Product). Banner has granted exclusive rights to the Banner ANDA Product to Watson Laboratories, a subsidiary of Actavis plc. The letter states that the Banner ANDA Product contains the required bioavailability or bioequivalence data to Zipsor and certifies that Banner intends to obtain FDA approval to engage in commercial manufacture, use or sale of Banner's ANDA product before the expiration of the above identified patents, which are listed for Zipsor in the Orange Book. We commenced the lawsuit within the 45 days required to automatically bar the FDA from approving the Banner ANDA Product for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. Absent a court order, the 30-month stay is expected to expire in December 2015.

Any introduction of one or more products generic to Galrise, 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, or the successful appeal of the favorable ruling received in the Galrise litigation, could have an adverse impact on our stock price. Moreover, if the patents covering our products were 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.

Table of Contents

***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 will depend in part 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 these 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 are increasingly challenging the price and cost-effectiveness of medical products and services, including pharmaceuticals. Significant uncertainty exists as to the reimbursement status of pharmaceutical products. Our products may not be considered cost effective, and adequate third-party reimbursement may be unavailable to enable us to maintain price levels sufficient to realize an acceptable return on our investment. Any third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursement of, our products, including by 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.

Federal and state governments in the United States continue to propose and pass new legislation, such as the Affordable Care Act (ACA), which is designed to contain or reduce the cost of healthcare. Cost control initiatives could decrease the price that we receive for our products and any product that we may develop or acquire.

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

Gabapentin is currently sold by Pfizer Inc. as Neurontin® for adjunctive therapy for epileptic seizures and for PHN. Pfizer's basic U.S. patents relating to Neurontin have expired, and numerous companies have received approval to market generic versions of the immediate release product. Pfizer has also developed Lyrica® (pregabalin), which has been approved for marketing in the United States for post herpetic pain, fibromyalgia, diabetic nerve pain, adjunctive therapy, epileptic seizures and nerve pain associated with spinal cord injury. In June 2012, GlaxoSmithKline and Xenoport, Inc. received approval to market Horizant (gabapentin enacarbil extended-release tablets) for the management of PHN. 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 a NSAID that is approved in the United States 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 United States for the acute treatment of migraine in adults. CAMBIA competes with a number of triptans which are used to treat migraine and certain other headaches. Currently, seven triptans are available and sold in the United States (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan), as well as a fixed-dose combination product containing sumatriptan plus naproxen. There are other products prescribed for or under development for the treatment of migraines which are now or may become competitive with CAMBIA.

Fentanyl, an opioid analgesic, is currently sold by a number of companies for the treatment of breakthrough pain in opioid-tolerant cancer patients. Branded fentanyl products against which Lazanda currently competes include Subsys®, which is sold by Insys Therapeutics, Inc., Fentora® and Actiq®, which are sold by Cephalon Inc., Abstral®, which is sold by Galena Biopharma Inc., and Onsolis®, which is sold by BioDelivery Sciences International, Inc. (BDSI). Generic fentanyl products against which Lazanda currently competes are sold by Mallinckrodt, Par and Actavis.

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

Table of Contents

***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 uses 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 uses and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

***Pharmaceutical marketing is subject to substantial regulation in the United States 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 Gralise, Zipsor, Lazanda and CAMBIA, as well as marketing activities related to any other products which we 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.

***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 and prospects will be limited.***

Since June 2012, we have acquired Zipsor, Lazanda and CAMBIA. 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 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. Integrating any business, product or technology we may acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to enhance and broaden our product offerings, unable to effectively integrate any acquired businesses, products or technologies, or achieve the anticipated benefits of any acquired business, product or technology, our business and prospects will be limited. In addition, any amortization or charges resulting from the costs of such acquisitions will adversely affect our results of operations.



*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 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 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, 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.

***We depend on third parties that are single source suppliers to manufacture Gralise, CAMBIA, Zipsor and Lazanda. If these suppliers are unable to manufacture and supply Gralise, CAMBIA, Zipsor or Lazanda or our product candidates, our business will suffer.***

Patheon Puerto Rico Inc. 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. DPT Lakewood Inc. is our sole supplier for Lazanda pursuant to a manufacturing and supply agreement that we assumed in connection with our July 2013 acquisition of Lazanda. MiPharm, S.p.A is our sole supplier for CAMBIA pursuant to a manufacturing and supply agreement that we assumed in connection with our December 2013 acquisition of CAMBIA. 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 clinical trials and commercialization. Our dependence on third parties for the manufacture of our products and our product candidates may adversely affect our ability to deliver such products on a timely or competitive basis, if at all. Any failure to obtain Gralise, Zipsor, Lazanda or CAMBIA, or active pharmaceutical ingredients, excipients or components from our suppliers could 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 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 of these third-party manufacturers or suppliers fail to perform as required or fail to comply with the regulations of the FDA and other applicable governmental authorities, our ability to deliver our products on a timely basis or receive royalties or 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 United States and foreign jurisdictions to cover certain aspects of our technology. We hold issued United States patents and have patent applications pending in the United States. In addition, we are pursuing patent applications relating to our technologies in the United States 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

## Edgar Filing: DEPOMED INC - Form 10-Q

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, through 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.

Table of Contents

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 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 by others of our patents 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 are engaged in litigation against one Zipsor ANDA filer. Also, in January 2013 and April 2013, we filed lawsuits against Purdue and Endo, respectively, for infringement of certain of our Acuform drug delivery technology patents. In response to our lawsuits, Purdue and Endo are challenging the validity of the patents we asserted in *inter partes* review proceedings before the United States Patent Trial and Appeal Board (PTAB) at the United States Patent and Trademark Office. In these or other proceedings, 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 takes significant time, may be expensive, and may divert management attention from other business concerns. We may also be required to participate in derivation proceedings or other post-grant proceedings declared by the United States Patent and Trademark Office for the purposes of, respectively, determining the priority of inventions in connection with our patent applications or determining validity of claims in our issued patents. Adverse determinations in litigation or proceedings at the United States Patent and Trademark Office would 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.

***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, some of which became effective immediately upon President Obama signing the law, and others of which are scheduled to take effect over the next several years. 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 starting in 2013 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2014 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 the regulations that may be imposed in connection with the implementation of the ACA, could increase our expenses and adversely affect our ability to successfully commercialize our products and product candidates.

*Changes in laws and regulations may adversely affect our business.*

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 example, federal, state and local governments have recently given increased attention to the public health issue of opioid abuse. At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, United States 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. These and other changes in laws and regulations could adversely affect our business, financial condition and results of operations.

Table of Contents

***If we are unable to obtain or maintain regulatory approval, 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 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 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 a 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 FDA's 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

## Edgar Filing: DEPOMED INC - Form 10-Q

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 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.

Table of Contents

***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 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 use and administration of Lazanda 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 clinical trials currently underway and forecasted 2014 sales of our products, 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 Mallinckrodt, Janssen Pharma, Salix 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



## Edgar Filing: DEPOMED INC - Form 10-Q

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.

Table of Contents

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 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.

***Lazanda is a controlled substance and any failure by us or our partners to comply with applicable statutes or regulations could adversely affect our business.***

Lazanda is an opioid analgesic that contains fentanyl, a regulated controlled substance 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. Fentanyl is listed by the DEA as a Schedule II substance under the CSA. The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation. For example, generally all Schedule II substance prescriptions, 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 would adversely affect our business, results of operations and financial condition.

***Limitations on fentanyl production in the United States could limit our ability to successfully commercialize Lazanda.***

The availability and production of all Schedule II substances, including 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 fentanyl production in the United States based on the DEA's estimate of the quantity needed to meet commercial and scientific need. The aggregate quota of fentanyl that the DEA allows to be produced in the United States annually is allocated among individual fentanyl drug manufacturers, which must submit applications annually to the DEA for individual production quotas. In turn, the manufacturer of Lazanda has to obtain a procurement quota to source fentanyl for the production of Lazanda. 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 fentanyl

## Edgar Filing: DEPOMED INC - Form 10-Q

quota lower 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 manufacturer obtains a procurement quota for fentanyl for all fentanyl products manufactured at their facility, which is allocated to Lazanda at the manufacturer's discretion. If the available quota of fentanyl is insufficient to meet our commercial demand or clinical needs, our business, results of operations and financial condition could be adversely affected. In addition, any delay or refusal by the DEA or our manufacturer in establishing the production or procurement quota or any reduction by the DEA or our manufacturer in the allocated quota for fentanyl could adversely affect our business, results of operations and financial condition.

Table of Contents

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

Lazanda is 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 Transmucosal Immediate Release Fentanyl (TIRF) medicines, including Lazanda, for outpatient use. Many physicians, health care practitioners and pharmacies are unwilling to enroll and participate in the TIRF REMS program. As a result, there are relatively few prescribers and dispensers of TIRF products. If we are not able to successfully promote Lazanda to participants in the TIRF REMS program, our business, results of operations and financial condition could be adversely affected.

***We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays outside of our control.***

We 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. However, we may be unable to control the amount and timing of resources that the clinical sites that conduct the clinical testing may devote to our clinical trials. 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. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. 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.

***The development of drug candidates 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. Our own product candidates 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 clearances. 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. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

Other factors could delay or result in termination of our clinical trials, including:

## Edgar Filing: DEPOMED INC - Form 10-Q

- 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; and
- actual or perceived lack of efficacy or safety of the product candidate.

We are unable to predict whether any of our product candidates 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. Also, DM-1992 uses the Acuform technology. 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;
- cost-effective commercial scale production; and
- reimbursement under private or governmental health plans.

Table of Contents

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.

*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 March 31, 2013 through September 30, 2014, our stock price has ranged from \$4.99 to \$15.49 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 Gralise, CAMBIA, Zipsor and Lazanda;
- filings and other regulatory actions or proceedings related to our products and product candidates and those of our collaborative partners;
- the outcome of our patent infringement litigation against the filer of an ANDA for Zipsor;
- the reversal or any appeal of the district court's favorable ruling in our patent infringement litigation against the filer of an ANDA for Gralise;
- the outcome of our patent infringement litigation against Purdue and Endo;
- the reversal or any appeal of the district court's ruling in our litigation against the FDA;
- the amount and variability of our non-cash PDL revenue;
- developments concerning proprietary rights, including patents, infringement allegations, inter party review proceedings and litigation matters;
- our collaborative partners' compliance or non-compliance with legal and regulatory requirements and with obligations under our collaborative agreements;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- our plans to acquire, in-license or co-promote other products, or acquire or combine with other companies, and our degree of success in realizing the intended advantages of, and mitigating any risks associated with, any such transaction;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply, or other manufacture or supply difficulties;

## Edgar Filing: DEPOMED INC - Form 10-Q

- variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other contract revenues;
- adoption of new technologies by us or our competitors;
- sales of large blocks of our common stock or the dilutive effect of our 2021 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 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. For example, our non-cash PDL revenue for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014 was higher than expected. The amount and variability in our non-cash PDL revenue, including any decrease in such revenue or other adjustment to such revenue made by our collaborative partners, may cause our stock price to fluctuate. 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. 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 license fees, product sales, royalties, collaborative research and development arrangements and feasibility studies. For the nine months ended September 30, 2014, we recognized net income of \$37.1 million. For the year ended December 31, 2013, we recognized income of \$43.3 million. Although we have achieved profitability for certain prior periods, we may incur operating losses in 2014 and in future years. Any such losses may have an adverse impact on our total assets, shareholders' equity and working capital.

Table of Contents

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

***Our success is dependent in large part upon the continued services of our Chief Executive Officer and senior management with whom we do not have employment agreements.***

Our success is dependent in large part upon the continued services of our President and Chief Executive Officer, James A. Schoeneck, and other 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 Mr. Schoeneck or any of our other 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.

***Provisions in our restated certificate of incorporation and 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 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. 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 have adopted a shareholder rights plan, commonly known as a "poison pill" which contains provisions that may discourage, delay or prevent a third party from acquiring us. These provisions could also discourage proxy contests and make it more difficult for shareholders to elect directors of their choosing and to cause us to take other corporate actions they desire, any of which, under certain circumstances, could depress the market price of our common stock.

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



## Edgar Filing: DEPOMED INC - Form 10-Q

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation 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 publicly attest to such evaluation. 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 our future evaluations, 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.

*Changes in fair value of contingent consideration and/or the liability for the unfavorable contract 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 liability for the unfavorable contract arose from the acquisition of CAMBIA and represents the milestone payable to the vendor as well as the value of the amounts by which the contract terms are unfavorable compared to current market pricing. The contingent consideration and the liability for the unfavorable contract is initially recognized at its fair value on the acquisition date is re-measured to fair value at each reporting date until the contingency is resolved with changes in fair value recognized in earnings. The estimate of fair value contains 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.

Table of Contents

***The value of our deferred tax assets could become impaired, which could adversely affect our results of operations.***

As of September 30, 2014, we had a significant amount of net deferred tax assets. These deferred tax assets are principally comprised of a temporary difference related to the income tax recognition effect of the PDL transaction and other temporary differences that are expected to reverse in the future. We assess on a quarterly basis the probability of the realization of deferred tax assets, using significant judgments and estimates with respect to, among other things, historical operating results, expectations of future earnings and significant risks and uncertainties related to our business. If we determine in the future that there is not sufficient positive evidence to support the valuation of these assets, due to the risk factors described herein or other factors, we may be required to further adjust the valuation allowance to reduce our deferred tax assets. Such a reduction could result in material non-cash expenses in the period in which the valuation allowance is adjusted and could have an adverse effect on our results of operations.

***The investment of our cash is subject to risks, which may cause losses or adversely affect the liquidity of these investments and our results of operations, liquidity and financial condition.***

As of September 30, 2014, we had \$546.7 million in cash and cash equivalents and \$12.9 million in investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

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

We incurred significant indebtedness in the aggregate principal amount of \$345.0 million under our 2021 Notes. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance, the 2021 Notes, 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 desirable terms, which could result in a default on our obligations, including the 2021 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 us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;

## Edgar Filing: DEPOMED INC - Form 10-Q

- put us at a disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including funding possible acquisitions of, or investments in, additional products, technologies and companies.

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

*We may not have the ability to raise the funds necessary to settle conversions of the 2021 Notes in cash or to repurchase the 2021 Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the 2021 Notes.*

Table of Contents

Holders of the 2021 Notes will have the right to require us to repurchase all or a portion of their 2021 Notes upon the occurrence of certain events deemed to be a fundamental change at a repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the 2021 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 2021 Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of 2021 Notes surrendered therefor or pay cash with respect to 2021 Notes being converted. In addition, our ability to repurchase or to pay cash upon conversion of the 2021 Notes may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase 2021 Notes at a time when the repurchase is required by the indenture or to pay cash upon conversion of the 2021 Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. Moreover, the occurrence of a fundamental change under the indenture could constitute an event of default under any such agreements. If the payment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the 2021 Notes or to pay cash upon conversion of the 2021 Notes.

***The conditional conversion feature of the 2021 Notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the 2021 Notes is triggered, holders of 2021 Notes will be entitled to convert the 2021 Notes at any time during specified periods at their option. If one or more holders elect to convert their 2021 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 2021 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2021 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 2021 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 2021 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 2021 Notes is that the equity component is required to be included in the additional paid-in capital section of shareholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the 2021 Notes. As a result, we will be required to record a greater amount of non-cash interest expense as a result of the amortization of the discounted carrying value of the 2021 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 amortization 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, under certain circumstances, convertible debt instruments (such as the 2021 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be certain that

Edgar Filing: DEPOMED INC - Form 10-Q

the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the notes, then our diluted earnings per share would be adversely affected.

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

*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.*

Table of Contents

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

*Business interruptions could limit our ability to operate our business.*

Our operations are vulnerable to damage or interruption from computer viruses, human error, natural disasters, telecommunications failures, intentional acts of vandalism 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.

**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.

**ITEM 6. EXHIBITS**

(a) Exhibits

- 3.1 (1) Amended and Restated Articles of Incorporation
- 3.2 (2) Certificate of Amendment to Amended and Restated Articles of Incorporation
- 3.3 (3) Certificate of Determination of Series RP Preferred Stock of the Company
- 3.4 (4) Bylaws, as amended
- 4.1 (5) Rights Agreement, dated as of April 21, 2005, between the Company and Continental Stock Transfer and Trust Company as Rights Agent
- 4.2 (6) Senior Indenture dated as of September 9, 2014 between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee
- 4.3 (6) First Supplemental Indenture dated as of September 9, 2014 between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee, supplementing the Senior Indenture dated as of September 9, 2014
- 10.1 Offer Letter dated as of July 14, 2014 between the Company and Srinivas G. Rao, M.D., Ph.D.
- 10.2 Offer Letter dated as of July 31, 2014 between the Company and Richard Scott Shively
- 10.3 (6) Underwriting Agreement dated as of September 3, 2014 between the Company and Morgan Stanley & Co. LLC and RBC Capital Markets, LLC, as representatives of the several underwriters named therein
  
- 31.1 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of James A. Schoeneck
- 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 James A. Schoeneck
- 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
  - (3) Incorporated by reference to the Company's Form 10-Q filed on May 10, 2005
  - (4) Incorporated by reference to the Company's Form 8-K filed on April 19, 2005
  - (5) Incorporated by reference to the Company's Form 8-A filed on April 22, 2005
  - (6) Incorporated by reference to the Company's Form 8-K filed on September 9, 2014

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: November 6, 2014

DEPOMED, INC.

/s/ James A. Schoeneck  
James A. Schoeneck  
President and Chief Executive Officer

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