DEPOMED INC Form 10-Q November 05, 2012 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

# **FORM 10-Q**

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED September 30, 2012

OR

o 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)

CALIFORNIA 94-3229046

(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)

(I.R.S. EMPLOYER IDENTIFICATION NUMBER)

### 1360 O BRIEN DRIVE

### **MENLO PARK, CALIFORNIA 94025**

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

(650) 462-5900

(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 x No o

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 x No o

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 o

Accelerated filer x

Non-accelerated filer o

Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The number of issued and outstanding shares of the Registrant s Common Stock, no par value, as of November 2, 2012 was 56,103,162.

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### PART I FINANCIAL INFORMATION

# ITEM 1. CONDENSED FINANCIAL STATEMENTS

# DEPOMED, INC.

### CONDENSED BALANCE SHEETS

(in thousands, except share amounts)

	S	September 30, 2012 (Unaudited)	December 31, 2011 (1)
ASSETS			
Current assets:			
Cash and cash equivalents	\$	27,372	\$ 24,043
Marketable securities		52,537	62,106
Accounts receivable		4,848	4,420
Receivables from collaborative partners		10,054	8,135
Inventories		7,795	5,395
Prepaid and other current assets		2,748	5,390
Total current assets		105,354	109,489
Marketable securities, long-term		7,749	53,644
Property and equipment, net		5,250	1,070
Intangible assets, net		26,037	
Other assets		526	169
	\$	144,916	\$ 164,372
LIABILITIES AND SHAREHOLDERS EQUITY			
Current liabilities:			
Accounts payable and accrued liabilities	\$	32,240	\$ 26,784
Deferred product sales		4,535	6,960
Deferred license revenue		5,781	6,032
Other current liabilities		332	64
Total current liabilities		42,888	39,840
Deferred license revenue, non-current portion		13,770	17,932
Other long-term liabilities		2,610	682
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, 2012 and December 31, 2011			
Common stock, no par value, 100,000,000 shares authorized; 56,085,641 and 55,506,120			
shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively		209,217	203,511
Accumulated deficit		(123,657)	(97,580)
Accumulated other comprehensive gain (loss)		88	(13)
Total shareholders equity		85,648	105,918
	\$	144,916	\$ 164,372

(1) Derived from the audited financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

See accompanying notes to Condensed Financial Statements.

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# DEPOMED, INC.

# CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

# (in thousands, except share and per share amounts)

# (Unaudited)

		Three Months Ended September 30, 2012 2011			Nine Months End 2012	led Sept	tember 30, 2011
Revenues:							
Product sales	\$	9,684	\$	9,205 \$		\$	40,669
Royalties		12,201		2,179	31,199		2,412
License and other revenue		11,397		5,138	18,033		77,760
Total revenues		33,282		16,522	64,226		120,841
Costs and expenses:							
Cost of sales		1,763		1,150	3,723		4,925
Research and development expense		5,270		3,208	12,277		12,405
Selling, general and administrative expense:							
Promotion fee expense				6,023			27,339
Other selling, general and administrative							
expense		26,832		15,451	73,625		32,667
Total selling, general and administrative expense		26,832		21,474	73,625		60,006
Amortization of intangible assets		958			1,063		
Gain on settlement agreement							(40,000)
Total costs and expenses		34,823		25,832	90,688		37,336
Income (loss) from operations		(1,541)		(9,310)	(26,462)		83,505
Other income (expense):							
Interest and other income		96		410	444		846
Interest expense		(39)		(24)	(39)		(133)
Total other income		57		386	405		713
Net income (loss) before income taxes		(1,484)		(8,924)	(26,057)		84,218
Benefit from (provision for) income taxes		(11)		348	(20)		345
Net income (loss)	\$	(1,495)	\$	(8,576) \$	(26,077)	\$	84,563
Unrealized gains (losses) on available-for-sale							
securities		17		(187)	101		(101)
Comprehensive income (loss)	\$	(1,478)	\$	(8,763) \$	(25,976)	\$	84,462
Basic net income (loss) per common share	\$	(0.03)	\$	(0.15) \$	(0.47)	\$	1.56
Diluted net income (loss) per common share	\$	(0.03)	\$	(0.15) \$		\$	1.51
price net income (1655) per common siture	Ψ	(0.03)	Ψ	(0.13) ψ	(0.17)	Ψ	1.51
Shares used in computing basic net income (loss) per common share		56,039,186		55,371,954	55,794,357		54,267,829
Shares used in computing diluted net income		50,059,100		55,571,954	JJ, 19 <del>4</del> ,JJ 1		J <del>1</del> ,207,629
(loss) per common share		56,039,186		55,371,954	55,794,357		56,071,870

See accompanying notes to Condensed Financial Statements.

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# DEPOMED, INC.

# CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months End 2012	ed September 30, 2011		
Operating Activities				
Net income (loss)	\$ (26,077)	\$	84,563	
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:				
Depreciation and amortization	1,405		296	
Amortization of investments	267		(64)	
Gain on bargain purchase	(92)			
Allowance for inventory obsolescence	696			
Stock-based compensation	3,822		2,807	
Changes in assets and liabilities:				
Accounts receivable	(2,347)		(1,125)	
Inventories	(667)		(1,722)	
Prepaid and other assets	2,384		(4,157)	
Accounts payable and other accrued liabilities	2,309		6,862	
Accrued compensation	(129)		189	
Deferred revenue	(6,838)		(15,268)	
Net cash (used in) provided by operating activities	(25,267)		72,381	
Investing Activities				
Purchases of property and equipment	(2,149)		(665)	
Acquisition of businesses	(26,435)			
Purchases of marketable securities	(29,993)		(153,875)	
Maturities of marketable securities	44,880		41,117	
Sales of marketable securities	40,408		32,832	
Net cash provided by (used in) investing activities	26,711		(80,591)	
Financing Activities				
Principal payments on long-term debt			(2,243)	
Proceeds from issuance of common stock	1,885		7,872	
Net cash provided by financing activities	1,885		5,629	
Net increase (decrease) in cash and cash equivalents	3,329		(2,581)	
Cash and cash equivalents at beginning of period	24,043		22,526	
Cash and cash equivalents at end of period	\$ 27,372	\$	19,945	

See accompanying notes to Condensed Financial Statements.

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### DEPOMED, INC.

### NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

### NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Organization

Depomed, Inc. (Depomed or the Company) was incorporated in California in 1995 and is a specialty pharmaceutical company focused on pain and other conditions and diseases of the central nervous system. The Company has developed two products approved by the U.S. Food and Drug Administration (FDA) that are currently being marketed. Gralise® (gabapentin) is the Company s once-daily tablet for the management of postherpetic neuralgia that was launched and made commercially available in October 2011. Glumetza® (metformin hydrochloride extended release tablets) is the Company s once-daily treatment for adults with type 2 diabetes that is commercialized in the United States by Santarus, Inc. (Santarus).

On June 21, 2012, the Company acquired all rights to Zipsor® (diclofenac potassium) liquid filled capsules (Zipsor), from Xanodyne Pharmaceuticals, Inc (Xanodyne). Zipsor is a non-steroidal anti-inflammatory drug (NSAID) indicated for the relief of mild to moderate acute pain in adults. The purchase price for this transaction was \$26.4 million in cash for the rights to Zipsor and related inventory as well as potential milestone payments based on sales of Zipsor and assumption of certain liabilities. The Company began distributing Zipsor to wholesalers and retail pharmacies subsequent to the acquisition date. See Note 14 for further information on the acquisition of Zipsor.

The Company also has two product candidates under clinical development, Serada for the treatment of menopausal hot flashes and DM-1992 for Parkinson's disease.

#### **Basis of Presentation**

These unaudited condensed 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 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 interim period ended September 30, 2012 are not necessarily indicative of results to be expected for the entire year ending December 31, 2012 or future operating periods.

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2011, included in the Company s Annual Report on Form 10-K filed with the SEC. The balance sheet at December 31, 2011 has been derived from the audited financial statements at that date.

#### 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 those estimates.

### Revenue Recognition

The Company recognizes revenue from the sale of its products, royalties earned, and on payments received and services performed under contractual arrangements. Revenue arrangements with multiple elements are evaluated to determine whether the multiple elements met 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 we remain obligated to perform services.

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.

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• Gralise: The Company sells Gralise (gabapentin) once-daily tablets to wholesalers and retail pharmacies and began shipping to customers in October 2011. The Company accepts returns of unsalable product from customers within a return period of six months prior to, and twelve months following product expiration. Gralise tablets currently have a shelf-life of 24 months from date of manufacture. In October 2011, the Company offered launch incentives for customers to stock Gralise at pharmacies and wholesalers, which included discounts and extended payment terms. Given the limited history of prescriptions of Gralise and launch incentives associated with stocking Gralise, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Gralise until the right of return no longer exists, which occurs at the earlier of the time Gralise units are dispensed through patient prescriptions or expiration of the right of return. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. As a result of this policy, the Company has a deferred revenue balance of \$4.5 million at September 30, 2012 related to Gralise product shipments that have not been recognized as revenue, which is net of wholesaler fees, retail pharmacy discounts, launch discounts and prompt payment discounts. The Company has recognized \$4.8 million and \$9.7 million in product sales, which is net of wholesaler fees, retail pharmacy discounts, prompt payment discounts, managed care rebates, patient support programs, and government chargebacks and rebates for the three and nine months ended September 30, 2012, respectively. If the Company underestimates or overestimates patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in f

In addition, the costs of manufacturing Gralise associated with the deferred revenue are recorded as deferred costs, which are included in inventory until the related deferred revenue is recognized.

Glumetza: The Company sold and recorded product sales on shipments of Glumetza (metformin hydrochloride extended release tablets) to wholesalers and retail pharmacies through August 2011. The Company and Santarus entered into a commercialization agreement in August 2011 under which Depomed transferred the rights to manufacture and distribute Glumetza in the United States to Santarus commenced selling Glumetza in September 2011 and began recording product sales. See Note 4 for further information on the Santarus commercialization agreement.

Product distributed by Depomed through August 2011 is subject to rights of return six months before product expiration and up to twelve months after product expiration. The Company recognized revenue for Glumetza sales at the time title transferred to its customers, which occurred at the time product was delivered to its customers. Revenue from sales of Glumetza was recorded net of estimated allowances for returns, wholesaler and retail pharmacy fees, prompt pay discounts, patient discount programs, government rebates and chargebacks and managed care rebates.

• Zipsor: On June 21, 2012 (the acquisition date), the Company acquired all rights to Zipsor (diclofenac potassium) liquid filled capsules from Xanodyne and began distributing Zipsor to wholesalers and retail pharmacies. The Company accepts returns of unsalable product from customers within a return period of six months prior to, and twelve months following product expiration. The Company recognizes revenue for Zipsor sales at the time title transfers to its customers, which occurs at the time product is delivered to its customers. Revenue from sales of Zipsor is recorded net of estimated allowances for returns, wholesaler and retail pharmacy fees, prompt pay discounts, patient discount programs, government rebates and chargebacks. See Note 14 for further information on the acquisition of Zipsor.

- 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 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 adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company s product sales allowances include:
- Product Returns The Company estimates product returns on sales of Glumetza through August 2011 and on sales of Zipsor since the acquisition date. Under the terms of the Zipsor Asset Purchase Agreement, the

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Company also assumed certain liabilities relating to product returns, governmental rebates and chargebacks and patient discount programs associated with Zipsor sales that were previously recorded by Xanodyne. See Note 14 for further information on the acquisition of Zipsor.

The Company allows customers to return product that is within six months before, and up to twelve months after, its product expiration date. The shelf life of the 500mg Glumetza is currently 48 months from the date of tablet manufacture. The shelf life of the 1000mg Glumetza is 24 to 36 months from the date of tablet manufacture. The shelf life of Zipsor is 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, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

As noted earlier, the Company currently does not estimate product returns on sales of Gralise.

- Managed Care Rebates The Company offers rebates under contracts with certain managed care organizations. The Company establishes an accrual equal to its estimates of future managed care rebates attributable to sales and recognizes the estimated rebates as a reduction of revenue in the same period the related revenue is recognized. The Company estimates its managed care rebates based on the terms of each agreement, estimated levels of inventory in the distribution channel, and historical and expected future utilization of product by the managed care organization.
- Wholesaler and Retail Pharmacy Discounts The Company offers discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the applicable contractual discount on shipment to wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.
- 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 prompt payment terms to earn the cash discount. The Company accounts for cash discounts by reducing accounts receivable by the full amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.
- Medicaid Rebates The Company participates in Medicaid rebate programs, which provide assistance to eligible 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 the prescription is filled. The Company estimates and accrues Medicaid rebates based on product pricing, current rebates and changes in the level of discounts the Company offers that may affect the level of Medicaid discount, historical and estimated future percentages of product sold to Medicaid recipients and estimated levels of inventory in the distribution channel.
- 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 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. The Company estimates and accrues chargebacks based on estimated wholesaler inventory

levels, current contract prices and historical chargeback activity.

- Medicare Part D Coverage Gap The Company participates in the Medicare Part D Coverage Gap Discount Program under which the Company provides rebates on prescriptions that fall within the donut hole coverage gap. The Company estimates and accrues rebates based on historical utilization and recognizes the rebate as a reduction of revenue in the same period the related revenue is recognized.
- Patient Discount Programs The Company offers patient discount card programs in which patients receive discounts at participating retail pharmacies that are reimbursed by the Company. The Company estimates and accrues future redemptions based on historical redemption activity.

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• 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.

Under the commercialization agreement between the Company and Santarus, the Company receives royalties on net sales of Glumetza distributed by Santarus in the United States. Santarus commenced distributing and recording product sales on shipments of Glumetza in September 2011. See Note 4 for further information on the Santarus commercialization agreement.

Royalties received from Santarus, Merck, Inc. (Merck) and Janssen Pharmaceuticals, Inc. (Janssen) are recognized in the period earned as the royalty amounts can be estimated and collectability is reasonably assured.

Royalties received under the Company s agreements with Valeant Pharmaceuticals International, Inc. (Valeant) and LG Life Sciences (LG) are recognized when the royalty payments are received as they cannot reliably be estimated.

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

### Recently Issued Accounting Standards

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. Companies have the option to report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. The Company adopted the presentation requirement effective January 1, 2012 and elected to report the components of comprehensive income in one single continuous statement as part of the Condensed Statement of Operations and Comprehensive Income. The adoption of this guidance did not have a material impact on the Company s financial statements.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (ASU 2011-4). ASU 2011-04 is intended to provide a consistent definition of fair value and improve the comparability of fair value measurements presented and disclosed in financial statements prepared in accordance with U.S. GAAP and IFRS. The amendments include those that clarify the FASB s intent about the application of existing fair value measurement and disclosure requirements, as well as those that change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This update is effective for annual and interim periods beginning after

December 15, 2011. This ASU did not have a material impact on the Company s financial statements.

In December 2011, the FASB issued ASU 2011-11, Balance Sheet: Disclosures about Offsetting Assets and Liabilities . The differences in the requirements for offsetting assets and liabilities in the presentation of financial statements prepared in accordance with U.S. GAAP and financial statements prepared in accordance with International Financial Reporting Standards (IFRS) makes the comparability of those statements difficult. The objective of this update is to facilitate comparison between those financial statements, specifically within the scope instruments and transaction eligible for offset in the form of derivatives, sale and repurchase agreements and reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. This ASU is effective for annual reporting periods beginning on or after January 1, 2013 and interim periods within that fiscal year. Management does not expect this ASU to have a material impact on the Company s financial statements.

In December 2011, the FASB issued Accounting Standards Update No. 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassification of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 (ASU 2011-12). ASU 2011-12 defers the requirement in ASU 2011-05 to present reclassification adjustments for each component of accumulated other comprehensive income in both other comprehensive income and net income on the face of the

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financial statements and the presentation of reclassification adjustments is not required in interim periods. The effective dates of ASU 2011-12 are consistent with the effective dates of ASU 2011-05, which is effective for fiscal years and interim periods beginning after December 15, 2011. The adoption of this standard did not have a material impact on our consolidated financial statements.

### 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, 2012 and December 31, 2011 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2012				
Cash and cash equivalents:				
Cash	\$ 23,699	\$	\$	\$ 23,699
Money market funds	3,673			3,673
Total cash and cash equivalents	\$ 27,372	\$	\$	\$ 27,372
Available-for-sale securities:				
Total maturing within 1 year and included in marketable				
securities:				
Corporate debt securities	\$ 30,657	\$ 55	\$	\$ 30,712
Government agency debt securities	19,801	16		19,817
U.S. Treasury securities	2,008			2,008
Total maturing between 1 and 2 years and included in				
marketable securities:				
Corporate debt securities	2,226	5		2,231
U.S. government agency debt securities	5,506	12		5,518
Total available-for-sale securities	\$ 60,198	\$ 88	\$	\$ 60,286
Total cash, cash equivalents and marketable securities	\$ 87,570	\$ 88	\$	\$ 87,658

Amortized		Gross Unrealized		Gross Unrealized	
Cost		Gains		Losses	Fair Value
\$ 5,629	\$		\$	\$	5,629
12,467					12,467
5,947					5,947
\$ 24,043	\$		\$	\$	24,043
\$ 49,717	\$	10	\$	(9) \$	49,718
5,503		2			5,505
6,870		13			6,883
\$	\$ 5,629 12,467 5,947 \$ 24,043 \$ 49,717 5,503	\$ 5,629 \$ 12,467 \$ 5,947 \$ 24,043 \$ \$ 49,717 \$ 5,503	Amortized Cost Unrealized Gains  \$ 5,629 \$ 12,467	*** Amortized Cost	Amortized Cost         Unrealized Gains         Unrealized Losses           \$ 5,629         \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$

Total maturing between 1 and 2 years and included in				
marketable securities:				
Corporate debt securities	17,767	7	(62)	17,712
U.S. government agency debt securities	35,906	30	(4)	35,932
Total available-for-sale securities	\$ 115,763	\$ 62	\$ (75)	\$ 115,750
Total cash cash equivalents and marketable securities	\$ 139.806	\$ 62	\$ (75)	\$ 139.793

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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, money market instruments and commercial paper. The Company places its cash, cash equivalents and marketable securities with U.S. Treasury and government agency securities, and high quality securities of U.S. and international financial and commercial institutions and, to date has not experienced material losses on any of its balances. All marketable securities are classified as available-for-sale since these instruments are readily marketable. 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 (loss) within shareholders equity. 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 statement of operations.

At September 30, 2012 the Company had four 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, 2012 (in thousands):

		Less than 1	2 month	ıs	12 months		Total			
	Fa	ir Value	Unr	Gross realized osses I	Fair Value	Gross Unrealized Losses	Fa	nir Value	1	Gross Unrealized Losses
Corporate debt securities	\$	3,553	\$	(1) \$		\$	\$	3,553	\$	(1)

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, 2012.

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.

The following table represents the Company s fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2012 (in thousands):

	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$ 3,673	\$	\$	\$ 3,673
Corporate debt securities		32,944		32,944
Government agency debt securities		25,334		25,334
U.S. Treasury securities		2,008		2,008
Total	\$ 3,673	\$ 60,286	\$	\$ 63,959
Liabilities:				
Contingent consideration	\$	\$	\$ 1,342	\$ 1,342

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The fair value measurement of the contingent consideration obligations arises from the Zipsor acquisition and relates to the potential future milestone payments under the Zipsor agreement which is 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 being achieved. At each reporting date, the Company will re-measure the contingent consideration obligation arising from the Zipsor acquisition to its estimated fair value. Any changes in the fair value of contingent consideration will be recognized in operating expenses until the contingent consideration arrangement is settled.

The following table represents the Company s fair value hierarchy for its financial assets measured at fair value on a recurring basis as of December 31, 2011 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 12,467	\$	\$	\$ 12,467
U.S. corporate debt securities		73,378		73,378
U.S. Government agency debt securities		41,437		41,437
U.S. Treasury securities		6,882		6,882
Total	\$ 12,467	\$ 121,697	\$	\$ 134,164

There were no financial liabilities measured at fair value on a recurring basis as of December 31, 2011.

#### NOTE 3. NET INCOME (LOSS) PER COMMON SHARE

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period, plus dilutive common shares 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 (loss) per share when their effect is dilutive. Basic and diluted earnings per share are calculated as follows:

(in thousands, except for per share amounts)	Three Months End 2012	led Sej	ptember 30, 2011	Nine Months Endo 2012	ed Sep	otember 30, 2011
Numerator:						
Net income (loss)	\$ (1,495)	\$	(8,576) \$	(26,077)	\$	84,563
Denominator for basic net income (loss) per						
share	56,039		55,372	55,794		54,268
Net effect of dilutive common stock equivalents						1,804
Denominator for diluted net income (loss) per						
share:	56,039		55,372	55,794		56,072
Basic net income (loss) per share	\$ (0.03)	\$	(0.15) \$	(0.47)	\$	1.56
Diluted net income (loss) per share	\$ (0.03)	\$	(0.15) \$	(0.47)	\$	1.51

For the three and nine months ended September 30, 2012, 6.0 million common stock equivalents were not included in dilutive shares because their effect is anti-dilutive. For the three and nine months ended September 30, 2011, the total number of antidilutive outstanding common stock equivalents excluded from the diluted net income per share computation was 4.9 million and 1.2 million, respectively.

### NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

Janssen Pharmaceuticals, Inc.

In August 2012, the Company entered into a non-exclusive license agreement with Janssen Pharmaceuticals, Inc. (Janssen) granting Janssen a license to the Company s Acuform gastric retentive drug delivery technology as well as other rights to certain Acuform patents.

In exchange, the Company received a \$10.0 million upfront fee in the third quarter of 2012. The Company is also eligible to receive a one-time sales milestone upon achievement of a specified level of quarterly net sales, as well as low single digit royalties on net sales of NUCYNTA® ER (tapentadol extended-release tablets) in the U.S., Canada and Japan from and after July 2, 2012 through December 31, 2021. The Company has no development obligations under the agreement. The Company recognized the entire \$10.0 million upfront fee as license revenue in the third quarter of 2012.

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Santarus, Inc.

In August 2011, the Company entered into a commercialization agreement with Santarus granting Santarus 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, the Company transitioned to Santarus responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs. The Company ceased shipments of Glumetza in August 2011 and Santarus began distributing and recording product sales on shipments of Glumetza in September 2011. Santarus will continue to be responsible at its expense for advertising and promotional marketing activities for Glumetza.

Santarus is 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 will equally share proceeds based on a gross margin split. Santarus has the exclusive right to commercialize authorized generic versions of the Glumetza products. Santarus will not pay additional sales milestones to the Company as was required under the prior promotion agreement. Royalty revenue from Santarus for the three and nine months ended September 30, 2012 was \$11.6 million and \$30.2 million, respectively.

In connection with its assumption of distribution and sales responsibility of Glumetza, Santarus purchased Depomed s existing inventory of Glumetza and bulk metformin hydrochloride at cost. Depomed is financially responsible for returns of Glumetza distributed by Depomed, up to the amount of the product returns reserve account for Glumetza product returns on the date immediately before Santarus began distributing Glumetza. Depomed is financially responsible for Glumetza rebates and chargebacks up to the amount of its reserve accounts for those items. Santarus is responsible for all other Glumetza returns, rebates and chargebacks.

Under the commercialization agreement, Depomed is responsible for managing the patent infringement lawsuit against Sun Pharmaceutical Industries, Inc. (Sun) subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. Santarus will reimburse Depomed for 70% of its out-of-pocket costs, and Depomed will reimburse Santarus for 30% of its out-of-pocket costs related to this infringement case. The Company was previously responsible for managing the patent infringement lawsuit against Lupin Limited (Lupin), which was settled in February 2012.

During 2011, Depomed distributed Glumetza for the first eight months of the year, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. For the three and nine months ended September 30, 2011, the Company recognized \$6.0 million and \$27.3 million, respectively, in promotion fee expense to Santarus related to sales of Glumetza by Depomed. In August 2011, the distribution and sales responsibility transitioned to Santarus, and Depomed no longer recorded sales of Glumetza and no longer was responsible for paying promotion fees to Santarus. Accordingly, there was no promotion fee expense in 2012.

Pursuant to the promotion agreement originally entered into in July 2008, Santarus paid the Company a \$12.0 million upfront fee. 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 Santarus promotion fees on gross

margin of Glumetza. The commercialization agreement in August 2011 superseded the promotion agreement and removed the manufacturing and promotion fee obligations of the Company. The commercialization agreement includes obligations with respect to manufacturing and regulatory transition to Santarus, managing the ongoing patent infringement lawsuit against Sun and managing the patent infringement lawsuit against Lupin. These obligations are estimated to be completed in December 2013. Accordingly, on the effective date of the commercialization agreement, the amortization period related to remaining deferred revenue on the \$12.0 million upfront fee has been adjusted, and the remaining deferred revenue will be recognized ratably until December 2013. The Company recognized approximately \$1.0 million and \$3.0 million of license revenue associated with this upfront license fee for the three and nine months ended September 30, 2012, respectively. The Company recognized approximately \$0.6 million and \$1.0 million of license revenue associated with this upfront license fee for the three and nine months ended September 30, 2011, respectively. The remaining deferred revenue balance related to this upfront payment is \$4.8 million at September 30, 2012.

### Ventiv Commercial Services, LLC

In June 2011, the Company entered into a service agreement with Ventiv Commercial Services, LLC (Ventiv), pursuant to which in Ventiv Selling Solutions, Ventiv s outsourced sales business, provides sales force recruiting, training, deployment and ongoing operational support to the Company to promote Gralise. The agreement provided for a sales force of 164 full-time sales representatives dedicated to the Company, all of whom were employees of Ventiv.

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Under the terms of the agreement, the Company paid Ventiv an upfront implementation fee and an agreed upon fixed monthly management fee of approximately \$1.8 million, which was subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of Ventiv's monthly management fee was subject to payment by the Company only to the extent that specified performance objectives were met. The Company also paid certain pass-through costs of Ventiv incurred in connection with the agreement, which primarily included bonuses, travel costs and certain administrative expenses. The agreement provided for conversion of sales representatives from Ventiv employees to Depomed employees beginning in September 2012 at an agreed-upon cost per employee converted. In June 2012, the Company exercised an early termination clause under the agreement to end the agreement in September 2012 in conjunction with converting the sales representatives to Depomed employees at that time. In September 2012, the Company established 155 full-time field sales territories and converted 142 of the Ventiv employees to Depomed employees.

In May 2012, the Company entered into an additional service agreement with Ventiv that provides for a sales force of 78 part-time sales representatives dedicated to the Company, all of whom are employees of Ventiv. Under the terms of the agreement, the Company paid Ventiv an upfront implementation fee and will pay an agreed upon fixed monthly management fee of approximately \$0.5 million, which is subject to adjustment based on actual staffing levels. The term of the agreement is for one year beginning in June 2012.

The Company incurred \$8.8 million and \$23.3 million of expense related to Ventiv under these two agreements for the three and nine months ended September 30, 2012. The Company incurred \$1.6 million and \$2.5 million of expense related to Ventiv for the three and nine months ended September 30, 2011.

Abbott Products Inc. (formerly Solvay Pharmaceuticals, Inc.)

In November 2008, the Company entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) granting Solvay exclusive rights to develop and commercialize Gralise for pain indications in the United States, Canada and Mexico. In February 2010, Abbott Laboratories acquired the pharmaceutical business of Solvay and Abbott Products (Abbott Products), a subsidiary of Abbott Laboratories, became responsible for the Gralise license agreement with the Company.

In January 2011, Abbott Products received FDA approval of Gralise for the management of postherpetic neuralgia. This triggered a \$48.0 million development milestone from Abbott to the Company, which the Company received in February 2011. As the nonrefundable milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement and the milestone was related to past performance, the Company recognized the entire \$48.0 million as revenue in the first quarter of 2011.

In January 2011, Abbott Products notified the Company that Abbott Products did not intend to commercialize Gralise. In March 2011, the Company entered into a settlement agreement with Abbott Laboratories which provided for (i) the immediate termination of the Gralise license agreement, (ii) the transition of Gralise back to Depomed; and (iii) a \$40.0 million payment to Depomed which the Company received in March 2011. The \$40.0 million payment was recognized as a gain within operating income in the first quarter of 2011.

Pursuant to the exclusive license agreement originally entered into in November 2008, Solvay paid the Company a \$25.0 million upfront fee in February 2009. The upfront payment received was originally being amortized as revenue ratably until January 2013, which represented the estimated length of time the Company s development and supply obligations existed under the agreement. In connection with the termination of

the license agreement with Abbott Products, the Company no longer has continuing obligations to Abbott Products. Accordingly, all remaining deferred revenue related to the \$25.0 million upfront license fee previously received from Abbott Products was fully recognized as revenue in March 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue in the first quarter of 2011.

### **Boehringer Ingelheim International GMBH**

In March 2011, the Company entered into a license and service agreement with Boehringer Ingelheim International GMBH (Boehringer Ingelheim) granting Boehringer Ingelheim a license to certain patents related to the Company s Acuform drug delivery technology to be used in developing fixed dose combinations of extended release metformin and proprietary Boehringer Ingelheim compounds in development for type 2 diabetes. Under the terms of the agreement, Boehringer Ingelheim was also granted a right of reference to the New Drug Application covering the Company s Glumetza product and associated data for use in potential regulatory submission processes.

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In connection with the license and service agreement, the Company received an upfront payment of \$10.0 million less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million in April 2011. The Company received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

The \$10.0 million upfront was amortized ratably through November 2011, which was the estimated length of time Depomed was obligated to perform formulation work under the agreement. Accordingly, the Company recognized approximately \$3.8 million and \$8.6 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively.

Under the terms of the agreement, the Company received an additional nonrefundable \$2.5 million payment in March 2012 upon delivery of experimental batches of prototype formulations that met required specifications. As the milestone event was substantive in nature, achievement was not reasonably assured at the inception of the agreement and the milestone was related to past performance, the Company recognized the entire amount of this payment as revenue in the first quarter of 2012. The Company is also eligible to receive additional milestone payments based on regulatory filing and approval events, as well as royalties on worldwide net sales of products.

Depomed is responsible for providing certain initial formulation work associated with the fixed dose combination products. Work performed by the Company under the service agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon FTE rate per hour plus out-of-pocket expenses. The Company recognized approximately zero and \$0.1 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2012, respectively. The Company recognized approximately \$0.1 million and \$0.8 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2011, respectively.

### Ironwood Pharmaceuticals, Inc.

In July 2011, the Company entered into a collaboration and license agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) granting Ironwood a license for worldwide rights to the Company s Acuform drug delivery technology for an undisclosed Ironwood early stage development program.

In connection with the agreement, the Company received an upfront payment of \$0.9 million which was amortized ratably through June 2012, which was the estimated length of time Depomed was obligated to perform formulation work under the agreement. The Company recognized approximately zero and \$0.5 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2012. The Company recognized approximately \$0.2 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011. There is no remaining deferred revenue related to this upfront payment at September 30, 2012.

Under the terms of the agreement, the Company will assist with initial product formulation and Ironwood will be responsible for all development and commercialization of the product. The initial formulation work performed by the Company under the agreement will be reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses. The Company recognized approximately \$0.1 million of revenue associated with the reimbursement of formulation work under the agreement during the nine months ended September 30, 2012 and 2011.

In March 2012, the Company achieved the first milestone under the agreement with respect to delivery of experimental batches of prototype formulations that meet required specifications. The associated \$1.0 million milestone payment is nonrefundable and was received in June 2012. As the nonrefundable milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement, the milestone was related to past performance, the Company recognized the \$1.0 million as revenue during the first quarter of 2012. Under the terms of the agreement, the Company may receive additional payments pending achievement of certain development and regulatory milestones, as well as royalties on product sales.

### NOTE 5. LONG-TERM DEBT

In June 2008, the Company entered into a loan and security agreement with General Electric Capital Corporation, as agent (GECC), and Oxford Finance Corporation (Oxford) that provided the Company with a \$15.0 million credit facility. The credit facility was available in up to three tranches. The first tranche of \$3.8 million was advanced to the Company upon the closing of the loan agreement. The second tranche of \$5.6 million was advanced to the Company in July 2008. The third tranche of \$5.6 million was not drawn and is no longer available to the Company, and GECC and Oxford waived the 2% unused line fee related to the unused portion of the credit facility.

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The Company paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Beginning in January 2009, the Company began principal payments on the first tranche, plus interest at such rate, which was paid in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest paid thereafter in 30 equal monthly installments at an interest rate of 11.59%. Interest expense, which includes amortization of debt issuance costs, was approximately \$24,000 and \$133,000 for the three and nine months ended September 30, 2011, respectively. The credit facility was paid in full by July 2011.

### NOTE 6. 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 statements of operations (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,			
	2012		2011		2012		2011
Cost of sales	\$ 10	\$	17	\$	32	\$	50
Research and development expense	114		155		460		465
Selling, general and administrative expense	1,157		769		3,330		2,292
Total	\$ 1,281	\$	941	\$	3,822	\$	2,807

At September 30, 2012, the Company had \$8.7 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 2.6 years.

For the nine months ended September 30, 2011, the Company recognized approximately \$0.4 million in stock-compensation expense associated with the accelerated vesting of stock options in connection with a separation agreement and release with Carl A. Pelzel, the Company s former President and Chief Executive Officer. See Note 11 for further information with regards to the separation agreement and release.

### NOTE 7. COMPREHENSIVE INCOME (LOSS)

The following table summarizes components of total comprehensive income (loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,			
	2012		2011	2012		2011
Net income (loss)	\$ (1,495)	\$	(8,576) \$	(26,077)	\$	84,563
Change in unrealized gains (losses) on						
available-for-sale securities	17		(187)	101		(101)
Total comprehensive income (loss)	\$ (1,478)	\$	(8,763) \$	(25,976)	\$	84,462

# **NOTE 8. 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):

	•	mber 30, 2012	December 31, 2011
Raw materials	\$	1,415 \$	1,244
Work-in-process		1,316	643
Finished goods		5,382	2,831
Deferred costs		378	677
Less: allowance for obsolescence		(696)	
Total	\$	7,795 \$	5,395

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The fair value of inventories acquired included a step-up in the value of Zipsor inventories of \$1.9 million which is being amortized to cost of sales as the acquired inventories are sold.

Deferred costs at September 30, 2012 represent the costs of Gralise product shipped for which recognition of revenue has been deferred. Deferred costs at December 31, 2011 represent the costs of Gralise and Proquin XR products shipped for which recognition of revenue was deferred.

### NOTE 9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	Sep	otember 30, 2012	December 31, 2011
Accounts payable	\$	2,857	\$ 2,417
Accrued compensation		3,105	3,235
Accrued rebates and sales discounts		3,167	2,626
Allowance for product returns		10,718	9,843
Accrued contract sales organization fees		3,448	3,365
Other accrued liabilities		8,945	5,298
Total accounts payable and accrued liabilities	\$	32,240	\$ 26,784

The other accrued liabilities include approximately \$2.0 million costs related to leasehold improvements being performed at the new office building in Newark.

### NOTE 10. SHAREHOLDERS EQUITY

### **Option Exercises**

For the three and nine months ended September 30, 2012, employees and consultants exercised options to purchase 167,323 and 470,239 shares of the Company s common stock with net proceeds to the Company of approximately \$0.4 million and \$1.4 million, respectively.

### Employee Stock Purchase Plan

In May 2012, the Company sold 109,282 shares under the ESPP. The shares were purchased at a weighted average purchase price of \$4.18 per share with proceeds of approximately \$0.5 million.

### NOTE 11. RELATED PARTY TRANSACTIONS

Carl A. Pelzel

In April 2011, the Company entered into a separation agreement and release with Carl A. Pelzel, the Company s former President and Chief Executive Officer. Pursuant to the separation agreement, Mr. Pelzel was being paid \$520,000, which is equivalent to one year of his base salary. Payments are being made over one year, and will be reduced dollar-for-dollar by any compensation Mr. Pelzel receives in connection with employment (or full-time consulting) by another employer (or third party). The Company is also paying Mr. Pelzel s health and dental insurance COBRA premiums for up to 18 months following his separation from the Company. The separation agreement further provides for three months accelerated vesting of Mr. Pelzel s options to purchase the Company s common stock, and a release of claims in favor of the Company. The Company incurred a one-time severance charge of approximately \$1.0 million in the second quarter of 2011 with respect to this separation agreement, consisting of approximately \$0.4 million in stock-based compensation related to the accelerated vesting of Mr. Pelzel s awards and approximately \$0.6 million of severance expense related to future payments and health care benefits.

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#### NOTE 12. INCOME TAXES

As of September 30, 2012 and December 31, 2011, the Company had \$3.6 million and \$3.6 million of unrecognized tax benefits, respectively. All tax years since inception remain open to examination by the Internal Revenue Service and the California Franchise Tax Board until such time 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 does not have any accrued interest or penalties associated with unrecognized tax benefits. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months except as related to any new items impacting the current year operations.

#### **NOTE 13. 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 made to the landlord no later than 12 months prior to the lease expiration. The Company will 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, the Company 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.

The Company was allowed to control physical access to the premises upon signing the lease therefore, in accordance with the applicable accounting guidance, the lease term was deemed to have commenced in April 2012. Accordingly, the rent free periods and the escalating rent payments contained within the lease are being recognized on a straight-line basis from April 2012. The Company will pay approximately \$12.2 million in aggregate as rent over the term of the lease for the above premises. Rent expense and deferred rent for the new lease was approximately \$0.3 million and \$0.6 million for the three and nine months ended September 30, 2012.

### NOTE 14. BUSINESS COMBINATIONS

On June 21, 2012, the Company entered into an Asset Purchase Agreement with Xanodyne, pursuant to which Depomed acquired Xanodyne s product Zipsor and related inventory for \$26.4 million in cash, and assumed certain product related liabilities relating to Zipsor. In addition, the Company will make a one-time contingent payment to Xanodyne of \$2.0 million in cash at the end of the first calendar year in which Depomed s net sales of Zipsor® products exceed \$30.0 million and an additional, one-time contingent payment to Xanodyne of \$3.0 million in cash at the end of the first year in which Depomed s net sales of Zipsor® products exceed \$60.0 million.

In accordance with the authoritative guidance for business combinations, the Asset Purchase Agreement with Xanodyne was determined to be a business combination and was accounted for using the acquisition method of accounting. Neither separate financial statements nor pro forma results of operations have been presented because the acquisition transaction does not meet the qualitative or quantitative materiality tests under Regulation S-X.

Pursuant to the Asset Purchase Agreement, \$3.0 million of the initial payment will be held in escrow for eighteen months and applied towards the indemnification obligations of Xanodyne as set forth in the Asset Purchase Agreement.

The following table presents a summary of the purchase price consideration for the Zipsor acquisition (in thousands):

Cash for Zipsor and related inventories	\$ 26,436
Fair Value of contingent consideration	1,303
Purchase Price	\$ 27.739

The contingent consideration was recognized and measured at fair value as of the acquisition date and is included within other long-term liabilities in the accompanying balance sheet. The Company determined the acquisition date fair value of the contingent consideration obligation based on an income approach derived from Zipsor revenue estimates and a probability assessment with respect to the likelihood of achieving the level of net sales that would trigger the contingent payment. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The key assumptions in determining the fair value are the discount rate and the probability assigned to the potential milestones being achieved. At each reporting date, the Company will re-measure the contingent consideration obligation to estimated fair value. Any changes in the fair value of contingent consideration will be recognized in operating expenses until the contingent consideration arrangement is settled.

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The following table summarizes the fair values of the tangible and identifiable intangible assets acquired and liabilities assumed at the acquisition date (in thousands):

Intangible asset - Zipsor product rights	\$ 27,100
Inventories	2,428
Other assets	100
Property, plant and equipment	43
Current liabilities	(1,840)
Bargain purchase	(92)
	\$ 27,739

The Zipsor product rights of \$27.1 million have been recorded as intangible assets on the accompanying condensed 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, 2012 was approximately \$1.0 million and \$1.1 million, respectively.

The fair value of inventories acquired included a step-up in the value of Zipsor inventories of \$1.9 million which is being amortized to cost of sales as the acquired inventories are sold. The bargain purchase amount has been recorded within Interest and other income in the accompanying condensed statement of operations and comprehensive income.

### NOTE 15. COMMITMENTS AND CONTINGENCIES

### Legal matters

### Depomed v. Sun Pharmaceuticals and Depomed v. Watson Laboratories (Glumetza ANDA Litigation)

In June 2011, the Company filed a lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Inc., Sun Pharma Global FZE and Sun Pharmaceuticals Industries Ltd. (collectively, Sun), for infringement of five (5) U.S. patents listed in the Orange Book for the Glumetza product. The lawsuit is in response to an Abbreviated New Drug Application (ANDA) filed by Sun with the FDA regarding Sun s intent to market generic versions of 500mg and 1000mg dosage strengths of Glumetza prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340 and 7,780,987. U.S. Patent No. 7,736,667 is also being asserted against Sun in the lawsuit. Valeant International Bermuda (f/k/a Valeant International (Barbados) SRL) is joined in the lawsuit as a co-plaintiff as the owner of U.S. Patent No. 7,780,987. The lawsuit commenced within the 45 days required to automatically stay, or bar, the FDA from approving Sun s ANDA for 30 months or until a district court decision that is adverse to the patents, whichever occurs earlier. A claim construction hearing, known as a Markman hearing, was conducted before Judge Pisano on July 18, 2012. Absent a court order, the 30-month stay is expected to expire in November 2013.

In April 2012, the Company filed a lawsuit in the United States District Court for the District of Delaware against Watson Laboratories, Inc. Florida, Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively, Watson), for infringement of the two patents listed in the Orange

Book for Glumetza 1000 mg (U.S. Patent Nos. 6,488,962 and 7,780,987). The lawsuit is in response to an ANDA filed by Watson with the FDA regarding Watson s intent to market a generic version of the 1000 mg dosage strength of Glumetza prior to the expiration of the asserted patents. Valeant International Bermuda (f/k/a Valeant International (Barbados) SRL) is joined in the lawsuit as a co-plaintiff as the owner of U.S. Patent No. 7,780,987. The Company commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving Watson s ANDA for 30 months or until a district court decision that is adverse to the patents, whichever may occur earlier. Absent a court order, the 30-month stay is expected to expire in September 2014.

#### Depomed v. Gralise ANDA Filers

In March 2012, the Company filed a lawsuit in the United States District Court for the District of New Jersey against Actavis Elizabeth LLC and Actavis Inc. (collectively Actavis), Watson Laboratories, Inc. Florida, Watson Pharma, and Watson Laboratories (collectively Watson) and Incepta Pharmaceuticals (Incepta) for infringement of six (6) U.S. patents listed in the Orange Book for the Gralise product. The lawsuit is in response to ANDAs filed by each of Actavis, Watson and Incepta with the FDA regarding the defendants intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. The Company commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs 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 stays are expected to expire in July 2014 and August 2014. In August 2012, the Company amended the complaint to assert U.S. Patent No. 8,192,756 and add Abon Pharmaceuticals LLC as a defendant. In September 2012, the Company amended the complaint to assert U.S. Patent No. 8,252,332. Each of these patents is listed in the Orange Book.

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In April 2012, the Company filed a lawsuit in the United States District Court for the District of New Jersey against Impax Laboratories (Impax) and Par Pharmaceuticals (Par) for infringement of six (6) U.S. patents listed in the Orange Book for the Gralise product. The lawsuit is in response to ANDAs filed by each of Impax and Par with the FDA regarding the defendants intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. In October 2012, Impax withdrew its Gralise ANDA. As a result, we and Impax agreed to stipulate to this dismissal of the Company s lawsuit against Impax for infringement of the Gralise Orange Book listed patents. The Company commenced the lawsuit against Par within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs 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 September 2014. In August 2012 and September 2012, the Company amended the complaint to assert respectively U.S. Patent No. 8,192,756 and U.S. Patent No. 8,252,332, which are now listed in the Orange Book.

In May 2012, the Company filed lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals Inc. and Cadila Healthcare Limited (collectively Zydus) for infringement of six (6) U.S. patents listed in the Orange Book for the Company s Gralise product. The lawsuit is in response to the ANDAs filed by Zydus with the FDA regarding Zydus s intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. The Company commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs 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 stays are expected to expire in October and November 2014. In August 2012 and September 2012, the Company amended the complaint to assert respectively U.S. Patent No. 8,192,756 and U.S. Patent No. 8,252,332, which are now listed in the Orange Book.

On June 13, 2012, the Court held the Case Management Conference. The Court ordered all three suits to be consolidated for purposes of all pretrial proceedings. The Pretrial Conference in the suits is scheduled for March 13, 2014. No specific trial date has been set. The Company expects a Markman claim construction hearing to occur in the spring 2013. No specific date for the Markman hearing has been set.

### Depomed v. FDA

In November 2010, the FDA granted Gralise Orphan Drug designation for the management of PHN based on a plausible hypothesis that Gralise is clinically superior to immediate release gabapentin due to the incidence of adverse events observed in Gralise clinical trials relative to the incidence of adverse events reported in the package insert for immediate release gabapentin. Generally, an Orphan-designated drug approved for marketing is eligible for seven years of regulatory exclusivity for the orphan-designated indication. If granted, Orphan Drug exclusivity for Gralise will run for seven years from January 28, 2011. However, the FDA has indicated to us that Gralise is not currently eligible for Orphan Drug exclusivity because the hypothesis upon which the product s Orphan Drug designation was granted has not been proven. In September 2012, the Company filed an action in federal district court for the District of Columbia against the FDA seeking an order requiring the FDA to grant Gralise Orphan Drug exclusivity for the management of PHN. The Company believes Gralise is entitled to Orphan Drug exclusivity as a matter of law, and the FDA s action is not consistent with the statute or FDA s regulations related to orphan drugs. The lawsuit seeks a determination by the court that Gralise is protected by Orphan Drug exclusivity, and an order that FDA act accordingly. The FDA has not yet filed an answer to the complaint filed by the Company.

The Company cannot reasonably predict the outcome of these legal proceedings, nor can it estimate the amount of loss, or range of loss, if any, that may result from these proceedings. As such the Company is not currently able to estimate the impact of the above litigations on its financial position or results of operations.

# NOTE 16. SUBSEQUENT EVENTS

In October 2012, the FDA accepted for review the NDA filing for Serada for the treatment of menopausal hot flashes. The NDA will be subject to a standard review and will have a Prescription Drug User Fee Act (PDUFA) action date of May 31, 2013. The FDA has informed the Company that the FDA s Reproductive Health Drugs Advisory Committee will discuss the Serada NDA at an Advisory Committee meeting tentatively scheduled for March 4, 2013.

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

#### FORWARD-LOOKING INFORMATION

Statements made in this Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q that are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. 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, and Zipsor® (diclofenac potassium) liquid filled capsules, our NSAID for the treatment of mild to moderate pain in adults;
- the commercial success of Glumetza® (metformin hydrochloride extended-release tablets) in the United States, and the efforts of our Glumetza commercial partner, Santarus, Inc. (Santarus);
- the results of our ongoing litigation against filers of abbreviated New Drug Applications (each, an ANDA) to market generic Gralise in the United States;
- the results of our ongoing litigation with the FDA to obtain orphan drug exclusivity for Gralise in the United States;
- the outcome of our ongoing litigation against filers of ANDAs to market generic Glumetza in the United States;
- any additional patent infringement or other litigation that may be instituted related to Gralise, Zipsor, Glumetza 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 in-license, acquire or co-promote other products;
- the commercial success and market acceptance of Serada if we receive approval to market Serada in the United States;
- the results and timing of our clinical trials;
- the results of our research and development efforts;
- submission, acceptance and approval of regulatory filings;
- our need for, and ability to raise, additional capital; and

our collaborative partners compliance or non-compliance with obligations under our collaboration agreements.

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. We disclaim any intent or obligation to update or revise these forward-looking statements to reflect new events or circumstances.

#### ABOUT DEPOMED

Depomed is a specialty pharmaceutical company initially focused on pain and other conditions and diseases of the central nervous system. The centerpieces of our specialty pharmaceutical business are Gralise® (gabapentin), a once-daily product for the management of postherpetic neuralgia that we launched and made commercially available in October 2011, and Zipsor® (diclofenac potassium) liquid filled capsules, a product for the treatment of mild to moderate acute pain that we acquired from Xanodyne Pharmaceuticals, Inc. (Xanodyne) in June 2012. We promote Gralise and Zipsor with a field force of 155 full-time sales representatives who are Depomed employees, and 78 part-time sales representatives dedicated to the Company and employed by a contract sales organization. We are actively seeking 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 assets based on our proprietary drug delivery technologies. The cornerstone of that portion of our business is Glumetza®, a once-daily treatment for adults with type 2 diabetes that we licensed to, and is currently being commercialized by, Santarus, Inc. (Santarus) in the United States. We have license and development arrangements associated with our Acuform gastroretentive drug delivery technology with Covidien, Ltd. (Covidien), Janssen Pharmaceutica N.V. (Janssen N.V.), Janssen Pharmaceuticals, Inc. (Janssen), Boehringer Ingelheim International GMBH (Boehringer Ingelheim) and Ironwood Pharmaceuticals, Inc. (Ironwood) and a license agreement with Merck & Co., Inc. (Merck).

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In addition, we have two product candidates in clinical development, Serada® and DM-1992. We submitted a New Drug Application, or NDA, in July 2012 for Serada for the treatment of menopausal hot flashes. The NDA has been accepted for review by the United States Food and Drug Administration, or FDA, and we have a Prescription Drug User Fee Act, or PDUFA, goal date of May 31, 2013. The FDA has tentatively scheduled an Advisory Committee meeting to discuss the Serada NDA for March 4, 2013. DM-1992 is currently in Phase 2 trials for Parkinson s disease.

### **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**

Product	Indication	Status
Gralise®	Postherpetic neuralgia	Currently sold in the United States.  Launched in October 2011
Zipsor®	Mild to moderate acute pain	Currently sold in the United States.  Acquired by Deponed in June 2012

#### Partner Commercialized Products and Product Candidates

Product / Product Candidate	Indication	Partner	Status
Glumetza®	Type 2 diabetes	United States rights held by Santarus; Canadian rights held by Valeant	Currently sold in the United States and Canada
Janumet® XR	Type 2 diabetes	Merck	Currently sold in the United States, 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
SGLT2 inhibitor/metformin XR combination product	Type 2 diabetes	Janssen N. V.	NDA for SGLT2 inhibitor filed June 2012
	Type 2 diabetes	Boehringer Ingelheim	

Boehringer compounds/metformin XR combination product			Twice daily combination of metformin and DPP4 inhibitor approved in United States in February 2012
Acetaminophen/opiate combination	Pain	Covidien	1st and 2nd formulation
		22	

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products			launch as early as 2014
			<b>.</b>
Undisclosed Ironwood compounds using Acuform® drug delivery	Gastrointestinal	Ironwood	Early stage development
technology			

### **Depomed Product Pipeline**

Product	Indication	Status
Serada®	Menopausal hot flashes	Three Phase 3 studies completed (Breeze 1, Breeze 2, and Breeze 3); NDA submitted July 31, 2012; FDA accepted for review the NDA filing in October 2012
DM-1992	Parkinson s disease	Phase 2 study completed in September 2012 Data evaluation and program assessment ongoing

### Significant Developments and Highlights for the Quarter Ended September 30, 2012

- In July 2012, we submitted a New Drug Application (NDA) for Serada for the treatment of menopausal hot flashes to the FDA. In October 2012, the FDA accepted for review the NDA filing for Serada.
- In July 2012, our sales force began promotion of Zipsor, which we acquired in June 2012.
- In August 2012, we entered into a non-exclusive license agreement with Janssen Pharmaceuticals, Inc granting Janssen a license to certain patents related to the Company s Acuform technology for Nucynta ER, which triggered a \$10.0 million upfront payment which was received and recognized in the third quarter.
- In September 2012, we converted our full-time contract sales representatives to direct Depomed employees.
- In September, we filed an action in federal district court for the District of Columbia against the Food and Drug Administration, seeking an order requiring the FDA to grant Gralise Orphan Drug exclusivity for the management of postherpetic neuralgia.

### PRODUCT DEVELOPMENTS AND TRANSACTIONS

### Gralise® (gabapentin) tablets for the Management of Postherpetic Neuralgia

In October 2011, we launched and announced the commercial availability of Gralise. Gralise product sales for the three and nine months ended September 30, 2012 were \$4.8 million and \$9.7 million, respectively.

<u>Ventiv Commercial Services, LLC.</u> In June 2011, we entered into a service agreement with Ventiv Commercial Services, LLC (Ventiv), pursuant to which Ventiv s outsourced sales business, in Ventiv Selling Solutions, provided us with sales force recruiting, training, deployment and ongoing operational support to promote Gralise. The agreement provided for a sales force of 164 full-time sales representatives dedicated to the Company, all of whom were employees of Ventiv. The sales representatives were hired in September 2011, began promoting Gralise to physicians in October 2011 and began promoting Zipsor to physicians at the end of July 2012. Members of sales management are our employees.

Under the terms of the agreement, we incurred an upfront implementation fee, and we paid fixed monthly management fees. The monthly management fee was subject to adjustment for actual staffing levels. A portion of the monthly management fee was payable only on Ventiv s achievement of specified performance objectives. We also paid certain pass-through costs of Ventiv. In June 2012, we exercised an early termination clause under the agreement to end the agreement in September 2012 in conjunction with converting the sales representatives to Depomed employees. In September 2012, the Company converted the full-time sales representatives to Depomed employees to fill 155 territories.

In May 2012, we entered into an additional service agreement with Ventiv, which provides for 78 part-time contract sales representatives dedicated to the Company, all of whom are employees of Ventiv. Under the terms of the agreement, we incurred an upfront implementation fee, and we pay fixed monthly management fees. The monthly management fee is subject to adjustment for actual staffing levels. The initial term of the agreement is for one year, with the option to extend the agreement for a longer period.

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### Zipsor (diclofenac potassium) liquid-filled capsules for Mild to Moderate Acute Pain

On June 21, 2012, we entered into an Asset Purchase Agreement with Xanodyne, pursuant to which we acquired Xanodyne s product Zipsor and related inventory for \$26.4 million in cash, and assumed certain liabilities relating to Zipsor. In addition, the agreement requires a one-time contingent payment to Xanodyne of \$2.0 million in cash at the end of the first calendar year in which our net sales of Zipsor products exceed \$30.0 million and an additional, one-time contingent payment to Xanodyne of \$3.0 million in cash at the end of the first year in which our net sales of Zipsor products exceed \$60.0 million. We also purchased Xanodyne s existing inventory and samples of Zipsor for approximately \$0.5 million. We assumed responsibility for returns on product previously sold by Xanodyne with a fair value of \$1.8 million as of the date of purchase. We began commercial sales of Zipsor in June 2012. We recognized \$4.9 million in Zipsor revenue for the three months ended September 30, 2012.

### Glumetza for Type 2 Diabetes

<u>Santarus</u>. In August 2011, we entered into a commercialization agreement with Santarus granting Santarus 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 Santarus exclusive rights to manufacture and commercialize Glumetza in the United States in return for a royalty on Glumetza net sales.

Pursuant to the commercialization agreement, we transitioned to Santarus responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs. We ceased shipments of Glumetza in August 2011, and Santarus began selling Glumetza in September 2011. Santarus is responsible for advertising and promotional marketing activities for Glumetza. In November 2011, we and Santarus entered into an assignment and assumption agreement pursuant to which Santarus assumed all of our rights and obligations under our commercial manufacturing agreement with Patheon, which provides that Patheon will serve as Santarus sole commercial supplier of the 500mg Glumetza in the United States. Santarus pays us royalties on net product sales of Glumetza in the United States of 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. Santarus has the exclusive right to commercialize authorized generic versions of the Glumetza products. In the event of generic entry of a Glumetza product in the territory, the parties will equally share proceeds based on a gross margin split.

In connection with its assumption of distribution and sales responsibility of Glumetza, Santarus purchased our existing inventory of Glumetza and bulk metformin hydrochloride at cost. We will be financially responsible for returns of Glumetza distributed by us, up to the amount of our product returns reserve account for Glumetza product returns on the date immediately before Santarus began distributing Glumetza. We will also be financially responsible for Glumetza rebates and chargebacks up to the amount of our reserve account for those items. Santarus will be responsible for all other Glumetza returns, rebates and chargebacks.

Under the commercialization agreement, we will continue to manage the ongoing patent infringement lawsuit against Sun Pharmaceutical Industries, Inc. (Sun), subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. Santarus will reimburse us for 70% of our out-of-pocket costs, and we will reimburse Santarus for 30% of its out-of-pocket costs related to these two infringement cases. We were also responsible for managing the patent infringement lawsuit with Lupin Limited (Lupin), which was settled in February 2012.

During 2011, we sold Glumetza for the first eight months of the year, recognized Glumetza product sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In August 2011, the distribution and sales responsibility transitioned to Santarus and Santarus started paying us a royalty on net sales of Glumetza. For the three and nine months ended September 30, 2011, the Company recognized \$6.0 million and \$27.3 million, respectively, in promotion fee expense to Santarus related to sales of Glumetza by Depomed.

We recognized \$11.6 million and \$30.2 million in royalty revenue for the three and nine months ended September 30, 2012, respectively, under the commercialization agreement.

Litigation.

We are involved in patent litigation associated with Glumetza against Sun and Watson, as described below under Legal Proceedings . In February 2012, we and Santarus entered into a settlement and license agreement with Lupin to resolve patent litigation involving Glumetza. The agreement grants Lupin the right to begin selling a generic version of Glumetza on February 1, 2016, or earlier under certain circumstances.

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#### Serada® for Menopausal Hot Flashes

Serada is our proprietary extended release formulation of gabapentin in development for the treatment of menopausal hot flashes. We have completed three Phase 3 clinical trials evaluating Serada for menopausal hot flashes.

Study Design. Breeze 3 was a randomized, double-blind, placebo-controlled study of 600 patients. Patients were randomized into one of two treatment arms, with patients receiving either placebo or a total dose of 1800mg of Serada dosed 600mg in the morning and 1200mg in the evening. The co-primary efficacy endpoints in the study were reductions in the mean frequency of moderate-to-severe hot flashes, and the average severity of hot flashes, measured after four and 12 weeks of stable treatment. As in the prior Breeze 1 trial, the treatment duration of the study was 24 weeks, to address the FDA s view that an effective drug should also show statistically significant persistence of efficacy at 24 weeks. The trial also included a responder analysis to assess the clinical meaningfulness of any reduction in the frequency of hot flashes in the active arm relative to the placebo arm.

In August 2010, we reached agreement with the FDA regarding a Special Protocol Assessment (SPA) on the design and analysis of Breeze 3. An SPA is an agreement with the FDA that a proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support a product candidate s regulatory approval. We began enrollment in Breeze 3 in August 2010 and completed enrollment in March 2011.

Study Results. Under the statistical analyses set forth in the SPA, certain primary endpoints did not meet statistical significance. The primary severity endpoints were achieved with statistical significance at four weeks (p < 0.001) and 12 weeks (p < 0.01). The frequency endpoint at four weeks was achieved with statistical significance (p < 0.001). The frequency endpoint at 12 weeks, as well as the key secondary frequency and severity endpoints at 24 weeks, were not met.

Serada was generally well tolerated in Breeze 3. The most common adverse events were dizziness and somnolence. The incidence of dizziness in the active arm was 12.7% compared to 3.4% for the placebo arm. Somnolence was 6.0% in the active arm compared to 2.7% in the placebo arm. Withdrawals due to adverse events in the active arm were 17%, compared to 12% in the placebo arm.

In April 2012, we completed a Type B Pre-NDA meeting with the FDA to discuss the results of our three completed Phase 3 clinical trials for Serada. Based on the results of that meeting, we submitted a New Drug Application with the FDA in July 2012. In October 2012, the FDA accepted for review the NDA filing for Serada. The NDA will be subject to a standard review and will have a Prescription Drug User Fee Act (PDUFA) action date of May 31, 2013. The FDA has informed us that the FDA s Reproductive Health Drugs Advisory Committee will discuss the Serada NDA at an Advisory Committee meeting tentatively scheduled for March 4, 2013.

### Janssen Pharmaceutica N.V.

In August 2010, we entered into a non-exclusive license agreement with Janssen N.V. granting Janssen N.V. a license to certain patents related to our Acuform drug delivery technology to be used in developing fixed dose combinations of canagliflozin and extended release metformin. Janssen paid us a \$5.0 million upfront license fee associated with the license agreement. The \$5.0 million was amortized ratably through

March 2011, which is the estimated length of time we were obligated to perform formulation work under the agreements. We recognized approximately \$1.9 million of revenue associated with this upfront license fee during the first quarter of 2011.

We also entered into a service agreement with Janssen under which we provide formulation work for Janssen and are reimbursed by Janssen on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately \$0.3 million of revenue associated with the reimbursement of formulation work under the service agreement during the first quarter of 2011.

All formulation work under the agreement was completed at March 31, 2011 and there is no remaining deferred revenue.

Janssen Pharmaceuticals, Inc.

In August 2012, we entered into a non-exclusive license agreement with Janssen Pharmaceuticals, Inc. (Janssen) granting Janssen a license to the Company s Acuform technology as well as other rights to certain Acuform patents. In exchange, we received a \$10.0 million upfront fee in the third quarter of 2012. We are also eligible to receive a one-time sales milestone upon achievement of a specified level of quarterly net sales, as well as low single digit royalties on net sales of NUCYNTA® ER (tapentadol extended-release tablets) in the U.S., Canada and Japan from and after July 2, 2012 through December 31, 2021. We have no development obligations under the agreement. We recognized the entire \$10.0 million as license revenue in the third quarter of 2012.

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#### Merck & Co., Inc.

We have received \$12.5 million in upfront and milestone payments and will receive very low single digit royalties on Merck s net sales of Janumet XR in the United States and other licensed territories through the expiration of the licensed patents under a July 2009 license agreement with Merck & Co., Inc. (Merck). The non-exclusive license agreement grants Merck a license as well as other rights to certain of our patents directed to metformin extended release technology for Janumet XR, Merck s fixed-dose combination product for type 2 diabetes containing sitagliptin and extended release metformin that was approved by the FDA in January 2012. Merck began selling Janumet XR during the first quarter of 2012.

#### Boehringer Ingelheim

In March 2011, we entered into a license and service agreement with Boehringer Ingelheim granting Boehringer Ingelheim a license to certain patents related to our Acuform drug delivery technology to be used in developing fixed dose combinations of extended release metformin and proprietary Boehringer Ingelheim compounds in development for type 2 diabetes.

In connection with the license and service agreement, we received the upfront license payment of \$10.0 million less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million in April 2011. We received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

In March 2012, we received an additional \$2.5 million upon delivery of experimental batches of prototype formulations that met agreed-upon specifications, and we may receive additional milestone payments based on regulatory filings and approval events, as well as royalties on worldwide net sales of products.

We were responsible for providing certain initial formulation work associated with the fixed dose combination products. Services performed by us under the agreement were reimbursed by Boehringer Ingelheim on an agreed-upon rate, and out-of-pocket expenses were reimbursed. All formulation work required by Depomed has been completed.

### Ironwood Pharmaceuticals, Inc.

In July 2011, we entered into a collaboration and license agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for an undisclosed Ironwood early stage development program. In connection with the research collaboration and license agreement, we received an upfront payment of \$0.9 million.

In March 2012, we achieved the first milestone under the agreement upon delivery of experimental batches of prototype formulations that met agreed-upon specifications. This triggered a nonrefundable \$1.0 million milestone payment which we received in May 2012. We may also receive milestone payments based on achievement of certain development and regulatory milestones, as well as royalties on product sales.

Under the agreement, we are responsible for assisting with initial product formulation and Ironwood is responsible for all development and commercialization of the product. The initial formulation work we perform is reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses.

#### 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 enrolled 34 patients at 8 U.S. centers and enrollment was completed in July 2012. The trial is 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 study will assess efficacy, safety and pharmacokinetic variables. The primary endpoint for the study is change in off time as measured by patient self-assessment and clinician assessment.

### 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 2011 Annual Report on Form 10-K with the Securities and Exchange Commission on March 8, 2012. For a description of our critical accounting policies, please refer to our 2011 Annual Report on Form 10-K.

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#### RESULTS OF OPERATIONS

Our results of operations in 2012 will differ significantly from our reported results for 2011. For example, in 2011 we recognized \$48 million in milestone revenue and a \$40 million gain on settlement with regard to termination of our agreement with Abbott relating to Gralise. These were one-time payments and will not recur in 2012. In 2011, we reflect eight months of Glumetza product revenue, cost of sales and corresponding promotion expense to Santarus and four months of Glumetza royalty revenue from Santarus. As a result of the restructuring of our agreement with Santarus in August 2011, we will recognize royalty revenue from Santarus in 2012, but no product revenue or promotion expense for Glumetza. In 2011, we recognized \$0.5 million of revenue from sales of Gralise and a partial year of corresponding sales and marketing expense. We expect to recognize a full year of Gralise sales in 2012 and to incur a full year of sales and marketing expense in 2012. Accordingly, we expect Gralise product sales and selling, general and administrative expense to be substantially higher in 2012 than in 2011. In addition, we acquired Zipsor in June 2012 and Zipsor revenue and expense is reflected in our results of operations for the quarter ended September 30, 2012.

Three and Nine Months Ended September 30, 2012 and 2011

#### Revenue

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

	<u>.</u>	Three Months End 2012	led Sept	ember 30, 2011	Nine Months End 2012	led Septe	ember 30, 2011
Product sales:							
Gralise	\$	4,758	\$		\$ 9,708	\$	
Zipsor		4,926			4,926		
Glumetza				9,205			40,657
Proquin XR					360		12
Total product sales		9,684		9,205	14,994		40,669
Royalties:							
Santarus		11,603		2,091	30,249		2,105
Other		598		88	950		307
Total royalty revenue		12,201		2,179	31,199		2,412
License and other revenue:							
Gralise	\$		\$		\$	\$	60,592
Glumetza		1,388		962	4,162		5,222
Boehringer Ingelheim				3,902	2,617		9,368
Janssen		10,005			10,005		2,251
Other		4		274	1,249		327
Total license and other revenue:		11,397		5,138	18,033		77,760
Total revenues	\$	33,282	\$	16,522	\$ 64,226	\$	120,841

#### Product sales

Gralise. In October 2011, we announced the commercial availability of Gralise and began distributing Gralise to wholesalers and retail pharmacies. We defer recognition of revenue on product shipments of Gralise until the right of return no longer exists, which occurs at the earlier of (a) the time Gralise units are dispensed through patient prescriptions or (b) expiration of the right of return. At September 30, 2012, we have a deferred revenue balance, which is classified as a liability on the balance sheet, of \$4.5 million associated with the deferral of revenue on Gralise product shipments, which is net of estimated wholesaler fees, retail pharmacy discounts, stocking allowances and prompt payment discounts. We will recognize revenue upon the earlier of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred. We expect Gralise product sales and prescriptions to increase for the remainder of 2012.

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<u>Zipsor</u>. We acquired Zipsor in June 2012 and our sales force began promoting Zipsor at the end of July 2012. Product sales for the period between the acquisition date and June 30, 2012 were immaterial. Product sales for the quarter ended September 30, 2012 were \$4.9 million.

<u>Glumetza</u>. In August 2011, we restructured our agreement with Santarus and entered into a commercialization agreement that superseded the July 2008 promotion agreement. Under the commercialization agreement, we granted Santarus exclusive rights to manufacture and commercialize Glumetza in the United States in return for a royalty on Glumetza net sales. We ceased shipments of Glumetza in August 2011, and Santarus began selling Glumetza in September 2011.

<u>Proquin XR</u>. We ceased shipments of Proquin XR in the fourth quarter of 2010 and because of estimated significant levels of inventory at wholesalers and pharmacies in comparison to prescription demand, we deferred revenue recognition on product shipments of Proquin XR until the right of return no longer existed, which occurred at the earlier of the time Proquin XR units were dispensed through patient prescriptions or expiration of the right of return. At March 31, 2012, all rights of return expired and the remaining deferred revenue balance for Proquin XR was recognized as revenue during the first quarter of 2012.

#### Royalties

<u>Santarus</u>. Santarus royalties relate to royalties we receive from Santarus based on net sales of Glumetza in the United States. Royalty revenue from Santarus for the three and nine months ended September 30, 2012 was \$11.6 million and \$30.2 million and represents a 29.5% royalty on Santarus net sales of Glumetza. Santarus royalties for the three and nine months ended 2011 only reflect one month of royalties as we began receiving royalties from Santarus in September 2011.

<u>Other Royalties</u>. Under our license agreement with Janssen with respect to NUCYNTA ER, we are entitled to receive low single digit royalties on net sales of NUCYNTA ER in the United States, Canada and Japan beginning on sales made on July 2, 2012. We began recognizing NUCYNTA ER royalty revenue in the third quarter of 2012.

In January 2012, Merck received FDA approval to market Janumet XR in the United States, and Merck began selling Janumet XR during the first quarter of 2012. We currently receive very low single digit royalties on net product sales of Janumet XR.

Other royalties also include royalties we received from Valeant on net sales of Glumetza in Canada and from LG Life Sciences on net sales of LG s version of Glumetza, Novamet GR, in Korea.

#### License and other revenue

<u>Gralise</u>. In January 2011, Abbott Products received FDA approval of Gralise for the management of postherpetic neuralgia, which triggered a \$48.0 million development milestone from Abbott to us, which we received in February 2011. Because the milestone was substantive in nature, achieved and based on past performance, the entire \$48.0 million was recognized as license revenue in the first quarter of 2011.

Pursuant to the exclusive license agreement originally entered into in November 2008, Solvay paid us a \$25.0 million upfront fee in February 2009. The upfront payment received was originally scheduled to be recognized as revenue ratably until January 2013, which represented the estimated length of time our development and supply obligations existed under the agreement. In connection with the termination of the license agreement with Abbott Products, we no longer have continuing obligations to Abbott Products. Accordingly, all remaining deferred revenue related to the \$25.0 million upfront license fee previously received from Abbott Products was fully recognized as revenue in March 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

<u>Glumetza</u>. Glumetza license revenue for the three and nine months ended September 30, 2012 and 2011 consisted of license revenue recognized from the \$25.0 million upfront license fee received from Biovail in July 2005 and the \$12.0 million upfront fee received from Santarus in July 2008.

We are recognizing the \$25.0 million upfront license fee payment from Biovail 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 Biovail on net sales of Glumetza in the United States and for our obligation to use Biovail as our sole supplier of the 1000mg Glumetza.

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Pursuant to the promotion agreement originally entered into in July 2008, Santarus paid us a \$12.0 million upfront fee. The upfront payment received was originally being amortized as revenue ratably until October 2021, which represented the estimated length of time our obligations existed under the promotion agreement related to manufacturing Glumetza and paying Santarus promotion fees on gross margin of Glumetza. The commercialization agreement in August 2011 superseded the promotion agreement and removed our manufacturing and promotion fee obligations. The commercialization agreement includes obligations with respect to manufacturing and regulatory transition to Santarus and managing the patent infringement lawsuits against Sun and Lupin. These obligations are estimated to be completed in December 2013. Accordingly, on the effective date of the commercialization agreement, the amortization period related to remaining deferred revenue on the \$12.0 million upfront fee has been adjusted, and the remaining deferred revenue will be recognized ratably until December 2013. We recognized approximately \$1.0 million and \$3.0 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2012, respectively. We recognized approximately \$0.6 million and \$1.0 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2012.

In January 2011, we achieved the first sales milestone under the promotion agreement with Santarus related to net sales of Glumetza reaching \$50.0 million for the 13 month period ending January 31, 2011, which triggered a milestone payment of \$3.0 million, which we received in March 2011. As the milestone was achieved and related to past performance the entire \$3.0 million was recognized as milestone revenue in the first quarter of 2011.

<u>Boehringer Ingelheim</u>. Under our license and services agreement with Boehringer Ingelheim entered into in March 2011, Boehringer Ingelheim paid us a \$10.0 million upfront license fee which we received in April 2011, less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million. We received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

The \$10.0 million was amortized ratably through November 2011, which was the estimated length of time we were obligated to perform formulation work under the agreements. As such the entire amount was recognized as license revenue in 2011. We recognized approximately \$3.8 million and \$8.6 million of revenue associated with this upfront license fee for the three and nine months ended September 30, 2011, respectively.

Under the terms of the agreement, we received an additional nonrefundable \$2.5 million payment in March 2012 upon delivery of experimental batches of prototype formulations that meet required specifications. As the milestone event was substantive in nature, achievement was not reasonably assured at the inception of the agreement and the milestone was related to past performance, we recognized the entire amount of this payment as revenue during the first quarter of 2012.

We also provided certain initial formulation work associated with the fixed dose combination products. Work performed by us under the service agreement was reimbursed by Boehringer Ingelheim on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately zero and \$0.1 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2012. We recognized approximately \$0.1 million and \$0.8 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2011, respectively.

<u>Janssen N.V.</u> In August 2010, we entered into a non-exclusive license agreement with Janssen N.V. granting Janssen N.V. a license to certain patents related to our Acuform drug delivery technology to be used in developing fixed dose combinations of canagliflozin and extended release

metformin. Janssen N.V. paid us a \$5.0 million upfront license fee associated with the license agreement. The \$5.0 million was amortized ratably through March 2011, which is the estimated length of time we were obligated to perform formulation work under the agreements. We recognized approximately \$1.9 million of revenue associated with this upfront license fee during the first quarter of 2011.

We also entered into a service agreement with Janssen N.V. under which we provide formulation work for Janssen N.V. and are reimbursed by Janssen N.V. on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately \$0.3 million of revenue associated with the reimbursement of formulation work under the service agreement during the first quarter of 2011.

All formulation work under the agreement was completed at March 31, 2011 and there is no remaining deferred revenue.

<u>Nucynta.</u> In August 2012, we entered into a non-exclusive license agreement with Janssen Pharmaceuticals, Inc. (Janssen) granting Janssen a license to the Company s Acuform gastric retentive drug delivery technology to be used in developing products that compromises tapentadol in extended release formulation.

In exchange, we received a \$10.0 million upfront fee in the third quarter of 2012. We are also eligible to receive a one-time sales milestone upon achievement of a specified level of quarterly net sales, as well as low single digit royalties on net sales of NUCYNTA® ER (tapentadol extended-release tablets) in the U.S., Canada and Japan from and after July 2, 2012 through December 31, 2021. We have no development obligations under the agreement. We recognized the entire \$10.0 million as license revenue in the third quarter of 2012.

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Other. In July 2011, we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to the Company s Acuform drug delivery technology for an undisclosed Ironwood early stage development programIn connection with the research collaboration and license agreement, the Company received an upfront payment of \$0.9 million which was amortized ratably through June 2012, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. We recognized zero and \$0.5 million of revenue associated with this upfront license fee for the three and nine months ended September 30, 2012. We recognized approximately \$0.2 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011. There is no remaining deferred revenue related to this upfront payment at September 30, 2012.

In March 2012, we achieved a milestone under the agreement with respect to delivery of experimental batches of prototype formulations that meet required specifications. The associated \$1.0 million milestone payment is nonrefundable and was received in May 2012. As the nonrefundable milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement, the milestone was related to past performance, and the collectability of the milestone is reasonably assured, we recognized the \$1.0 million as revenue during the first quarter of 2012.

Under the terms of the agreement, the Company will assist with initial product formulation and Ironwood will be responsible for all development and commercialization of the product. The initial formulation work performed by the Company under the agreement will be reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately zero and \$0.1 million of revenue associated with the reimbursement of formulation work under the agreement during the three and nine months ended September 30, 2012.

### **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 of Gralise, Glumetza, Zipsor and Proquin XR. Total cost of sales for the three and nine months ended September 30, 2012, as compared to the prior year, was as follows (in thousands):

	Three Months En	ded Sep	tember 30,	Nine Months Ended September 30,			
	2012		2011		2012		2011
Cost of sales	\$ 1.763	\$	1,150	\$	3.723	\$	4,925

Cost of sales for the three and nine months ended September 30, 2012 relates to Gralise and Zipsor. Cost of sales for the nine months ended September 30, 2012 includes a \$0.7 million charge related to slow-moving Gralise starter pack inventory that is not expected to be sold prior to expiry. We commenced product sales of Zipsor in June 2012. The fair value of inventories acquired included a step-up in the value of Zipsor inventories of \$1.9 million which is being amortized to cost of sales as the acquired inventories are sold. The unamortized amount is \$1.2 million at September 30, 2012. We expect cost of sales to increase in the fourth quarter of 2012 as we expect product sales of Gralise to increase from current levels.

Cost of sales for the three and nine months ended September 30, 2011 primarily relates to Glumetza.

# **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 research and 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 development expense for the three and nine months ended September 30, 2012 as compared to the prior year, was as follows (in thousands):

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		ree Months End 2012	led Sep	tember 30, 2011		Nine Months Endo 2012	ded September 30, 2011		
Research and development expense	\$	5,270	\$	3,208	\$	12,277	\$	12,405	
Dollar change from prior year		2,062				(128)			
Percentage change from prior year	64.3%				-1.0%				

We categorize our research and development expense by project. The table below shows research and development costs for our major clinical development programs, as well as other expenses associated with all other projects in our product pipeline.

(In thousands)	Three Months End 2012	ded Sept	ember 30, 2011	Nine Months End 2012	ed Sept	ember 30, 2011
Serada	\$ 3,043	\$	2,519	\$ 5,760	\$	8,258
DM-1992	1,181		659	3,304		1,147
Other projects	1,046		30	3,214		3,000
Total research and development						
expense	\$ 5,270	\$	3,208	\$ 12,277	\$	12,405

The increase in research and development expense for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was due to costs related to the Serada New Drug Application (NDA) filed in July 2012 and costs related our Phase 2 trial for DM-1992. Research and development expenses in 2011 primarily related to clinical research organization costs associated with our Breeze 3 Phase 3 trial costs for Serada, which was completed in October 2011.

In the third quarter of 2012, we incurred expense of \$1.8 million for the Serada NDA application fee and \$0.6 million in milestone expense to PharmaNova related to the NDA application submission, under our sublicense agreement for Serada. We expect research and development expense to decrease in the fourth quarter of 2012 because of the one-time nature of these expenses.

# 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. Total selling, general and administrative expense, as compared to the prior year, were as follows (in thousands):

	Three Months End 2012	ed Septe	ember 30, 2011	Nine Months Ende 2012	ed Septe	ember 30, 2011
Selling, general and administrative						
expense:						
Promotion fee expense	\$	\$	6,023	\$	\$	27,339
Other selling, general and administrative						
expense	26,832		15,451	73,625		32,667

Total selling, general and administrative				
expense	\$ 26,832	\$ 21,474 \$	73,625	\$ 60,006
Dollar change from prior year	5,358		13,619	
Percentage change from prior year	25.0%		22.7%	

The increase in selling, general and administrative expenses in 2012 primarily relates to the build out of our commercial infrastructure related to the launch of Gralise in October 2011 and acquisition of Zipsor in June 2012. In October 2011, we began promoting Gralise through an agreement with our contract sales organization, Ventiv, which provided for 164 full-time sales representatives. In June 2012, we expanded our sales force and added an additional 78 part-time sales representatives through Ventiv. In September 2012, we established 155 full-time field sales territories and converted 142 of the Ventiv employees to Depomed employees. We did not convert the part-time sales representatives, and the conversion of the full-time sales representatives is not expected to materially change selling, general and administrative expense. We expect selling, general and administrative expense to decrease slightly in the fourth quarter of 2012.

The promotion fee expense in 2011 relates to our promotion fees to Santarus related to Glumetza. As a result of the Santarus commercialization agreement entered into in August 2011, we no longer have promotion fee expense to Santarus.

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### **Amortization of Intangible Assets**

	Thre	ee Months End	led September 30,	Ni	Nine Months Ended September 30,			
(In thousands)	2	012	2011		2012	2011		
Amortization of intangible assets	\$	958	\$	\$	1,063	\$		

The Zipsor product rights of \$27.1 million have been recorded as intangible assets on the accompanying condensed balance sheet and are being amortized over the estimated useful life of the asset on a straight-line basis through July 2019. Amortization commenced on June 21, 2012, the date we acquired Zipsor.

#### Gain on Settlement with Abbott Products

In March 2011, we entered into a settlement agreement with Abbott Products which provided for (i) the immediate termination of the parties license agreement; (ii) the transition of Gralise back to Depomed; and (iii) a \$40.0 million payment from Abbott to us which was paid in March 2011. The \$40.0 million payment was recognized as a gain within operating income in the first quarter of 2011.

### **Interest Income and Expense**

(In thousands)	ree Months End 2012	ded Sept	Nine Months Ended September 30, 2012 2011			
Interest and other income	\$ 96	\$	410 \$	444	\$	846
Interest expense	(39)		(24)	(39)		(133)
Net interest income (expense)	\$ 57	\$	386 \$	405	\$	713

Interest and other income for the nine months ended September 30, 2012 include \$0.1 million in respect of the gain from a bargain purchase relating to the Zipsor acquisition.

Interest expense in 2011 relates to interest on the credit facility we entered into in June 2008 with General Electric Capital Corporation and Oxford Finance Corporation. The credit facility was fully repaid in July 2011.

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### LIQUIDITY AND CAPITAL RESOURCES

The following table displays a summary of our cash, cash equivalents and marketable securities as of September 30, 2012 and December 31, 2011:

(In thousands)	S	eptember 30, 2012	December 31, 2011
Cash, cash equivalents and marketable securities	\$	87,658	\$ 139,793

The decrease in cash, cash equivalents and marketable securities is attributable to the \$26.4 million that we paid for the Zipsor acquisition and the utilization of cash to finance our operations.

In September 2012, we received a \$10.0 million upfront payment from Janssen related to our non-exclusive license agreement with Janssen related to Nucynta ER.

Since inception through September 30, 2012, we have financed our product development efforts and operations primarily from private and public sales of equity securities, upfront license, milestone and termination fees from collaborative and license partners, and product sales.

As of September 30, 2012, we have accumulated net losses of \$123.7 million. We may incur operating losses in future years. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements for at least the next two years. We base this expectation on our current operating plan, which may change as a result of many factors.

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

- sales of our marketed products;
- expenditures related to our commercialization of Gralise and Zipsor, including our contractual obligations to Ventiv and other arrangements we make for the commercialization of Gralise and Zipsor;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements;
- acquisitions or licenses of complementary businesses, products or technologies.
- expenditures related to our commercialization and development efforts, including arrangements we make for the commercialization of Serada, if the product is approved for marketing;

- 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.

We will need substantial funds to:

- conduct preclinical and clinical testing;
- manufacture (or have manufactured) and market (or have marketed) our marketed products and product candidates; and
- conduct research and development programs.

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. We currently do not have any other committed sources of capital. To the extent that our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds through the sale of our equity securities or from development and licensing arrangements to continue our commercial and development programs. 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. If adequate funds are not available we may have to:

- significantly curtail commercialization of our marketed products or other operations
- obtain funds through entering into collaboration agreements on unattractive terms; and/or
- delay, postpone or terminate clinical trials;

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The inability to raise any additional capital required to fund our operations could have a material adverse effect on our company.

#### **Cash Flows from Operating Activities**

Cash used in operating activities during the nine months ended September 30, 2012 was approximately \$25.3 million, compared to cash provided by operating activities of approximately \$72.4 million during the nine months ended September 30, 2011. Cash used in operating activities during the nine months ended September 30, 2012 was primarily due to our net loss adjusted for movements in working capital, stock-based compensation and depreciation expense. Cash provided by operating activities during the nine months ended September 30, 2011 was primarily as a result of the \$48.0 million milestone payment and \$40.0 million termination fee received from Abbott Products during the first quarter of 2011.

### **Cash Flows from Investing Activities**

Net cash provided by investing activities during the nine months ended September 30, 2012 was approximately \$26.7 million and consisted of a decrease in marketable securities to fund our operations offset by the acquisition of Zipsor for \$26.4 million in cash in June 2012. Net cash used in investing activities during the nine months ended September 30, 2011 was approximately \$80.6 million and consisted primarily of a net increase in marketable securities resulting from a partial investment of the milestone payment and settlement fee received from Abbott Products during the first quarter of 2011.

### **Cash Flows from Financing Activities**

Cash provided by financing activities during the nine months ended September 30, 2012 was approximately \$1.9 million and consisted of proceeds from employee and consultant option exercises. Cash provided by financing activities during the nine months ended September 30, 2011 was approximately \$5.6 million and consisted of proceeds from employee and consultant option exercises offset by repayments of principal on our credit facility.

### **Contractual Obligations**

As of September 30, 2012, our aggregate contractual obligations are as shown in the following table (in thousands):

	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
Operating leases	\$ 992	\$ 2,383	\$ 2,517	\$ 7,234	\$ 13,126

Contract sales organization	3,600				3,600
Purchase commitments	6,410				6,410
	\$ 11,002 \$	2,383 \$	2,517 \$	7,234 \$	23,136

At September 30, 2012, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$6.4 million under our manufacturing agreements related to Gralise and Zipsor. The amounts disclosed only represent minimum purchase requirements. Actual purchases are expected to exceed these amounts.

In May 2012, the Company entered into a service agreement with Ventiv which provides for a sales force of 78 part-time sales representatives dedicated to the Company, all of whom are employees of Ventiv. Under the terms of the agreement, we are required to pay Ventiv a monthly fixed fee of \$0.5 million during the term of the agreement. The term of the agreement is for one year beginning in June 2012.

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 Newark lease includes free rent for the first five months of the lease. Lease payments begin in May 2013. The Company s Menlo Park lease ends in January 2013.

The contractual obligations reflected in this table exclude a \$2.0 million contingent milestone payment we may be obligated to pay in the future under our sublicense agreement with PharmaNova related to FDA approval of an NDA for Serada. The above table also excludes any future royalty payments we may be required to pay on products we have licensed.

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The contractual obligations reflected in the above table also exclude up to \$5.0 million in contingent sales milestones we may be obligated to pay in the future under our asset purchase agreement with Xanodyne for Zipsor. The Company is obligated to pay Xanodyne a one-time \$2.0 million milestone payment at the end of the first calendar year in which net sales of Zipsor exceed \$20 million, and a one-time \$3.0 million milestone payment at the end of the first calendar year in which net sales of Zipsor exceed \$60 million.

The table above also excludes non-cancelable purchase orders and minimum purchase obligations of approximately \$2.1 million under our supply agreement with Valeant for the supply of 1000mg Glumetza, which will be fully reimbursed by Santarus.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no significant changes in our market risk compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2011.

#### 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, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Depomed v. Sun Pharmaceuticals and Depomed v. Watson Laboratories (Glumetza ANDA Litigation)

In June 2011, we filed a lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Inc., Sun Pharma Global FZE and Sun Pharmaceuticals Industries Ltd. (collectively, Sun), for infringement of five (5) U.S. patents listed in the Orange Book for the Glumetza product. The lawsuit is in response to an Abbreviated New Drug Application (ANDA) filed by Sun with the FDA regarding Sun s intent to market generic versions of 500mg and 1000mg dosage strengths of Glumetza prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340 and 7,780,987. U.S. Patent No.7,736,667 is also being asserted against Sun in the lawsuit. Valeant International Bermuda (f/k/a Valeant International (Barbados) SRL) is joined in the lawsuit as a co-plaintiff as the owner of U.S. Patent No. 7,780,987. The lawsuit commenced within the 45 days required to automatically stay, or bar, the FDA from approving Sun s ANDA for 30 months or until a district court decision that is adverse to the patents, whichever occurs earlier. A claim construction hearing, known as a Markman hearing, was conducted before Judge Pisano on July 18, 2012. Absent a court order, the 30-month stay is expected to expire in November 2013.

In April 2012, we filed a lawsuit in the United States District Court for the District of Delaware against Watson Laboratories, Inc. Florida, Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively, Watson), for infringement of the two patents listed in the Orange Book for Glumetza 1000 mg (U.S. Patent Nos. 6,488,962 and 7,780,987). The lawsuit is in response to an ANDA filed by Watson with the FDA regarding Watson s intent to market a generic version of the 1000 mg dosage strength of Glumetza prior to the expiration of the asserted patents. Valeant International Bermuda (f/k/a Valeant International (Barbados) SRL) is joined in the lawsuit as a co-plaintiff as the owner of U.S. Patent No. 7,780,987. We commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving Watson s ANDA for 30 months or until a district court decision that is adverse to the patents, whichever may occur earlier. Absent a court order, the 30-month stay is expected to expire in September 2014.

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### Depomed v. Gralise ANDA Filers

In March 2012, we filed a lawsuit in the United States District Court for the District of New Jersey against Actavis Elizabeth LLC and Actavis Inc. (collectively Actavis), Watson Laboratories, Inc. Florida, Watson Pharma, and Watson Laboratories (collectively Watson) and Incepta Pharmaceuticals (Incepta) for infringement of six (6) U.S. patents listed in the Orange Book for our Gralise product. The lawsuit is in response to ANDAs filed by each of Actavis, Watson and Incepta with the FDA regarding the defendants intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. We commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs 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 stays are expected to expire in July 2014 and August 2014. In August 2012, we amended our complaint to assert U.S. Patent No. 8,192,756 and add Abon Pharmaceuticals LLC as a defendant. In September 2012, we amended our complaint to assert U.S. Patent No. 8,252,332. Each of these patents is listed in the Orange Book.

In April 2012, we filed a lawsuit in the United States District Court for the District of New Jersey against Impax Laboratories (Impax) and Par Pharmaceuticals (Par) for infringement of six (6) U.S. patents listed in the Orange Book for our Gralise product. The lawsuit is in response to ANDAs filed by each of Impax and Par with the FDA regarding the defendants—intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. In October 2012, Impax withdrew its Gralise ANDA. As a result, we and Impax agreed to stipulate to this dismissal of our lawsuit against Impax for infringement of the Gralise Orange Book listed patents. We commenced the lawsuit against Par within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs 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 September 2014. In August 2012 and September 2012, we amended our complaint to assert respectively U.S. Patent No. 8,192,756 and U.S. Patent No. 8,252,332, which are now listed in the Orange Book.

In May 2012, we filed lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals Inc. and Cadila Healthcare Limited (collectively Zydus) for infringement of six (6) U.S. patents listed in the Orange Book for our Gralise product. The lawsuit is in response to the ANDAs filed by Zydus with the FDA regarding Zydus s intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. We commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs 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 stays are expected to expire in October and November 2014. In August 2012 and September 2012, we amended our complaint to assert respectively U.S. Patent No. 8,192,756 and U.S. Patent No. 8,252,332, which are now listed in the Orange Book.

On June 13, 2012, the Court held the Case Management Conference. The Court ordered all three suits to be consolidated for purposes of all pretrial proceedings. The Pretrial Conference in the suits is scheduled for March 13, 2014. No specific trial date has been set. We expect a Markman claim construction hearing to occur in the spring 2013. No specific date for the Markman hearing has been set.

### Depomed v. FDA

In November 2010, the FDA granted Gralise Orphan Drug designation for the management of PHN based on a plausible hypothesis that Gralise is clinically superior to immediate release gabapentin due to the incidence of adverse events observed in Gralise clinical trials relative to the

incidence of adverse events reported in the package insert for immediate release gabapentin. Generally, an Orphan-designated drug approved for marketing is eligible for seven years of regulatory exclusivity for the orphan-designated indication. If granted, Orphan Drug exclusivity for Gralise will run for seven years from January 28, 2011. However, the FDA has indicated to us that Gralise is not currently eligible for Orphan Drug exclusivity because the hypothesis upon which the product s Orphan Drug designation was granted has not been proven. 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 Gralise Orphan Drug exclusivity for the management of PHN. We believe Gralise is entitled to Orphan Drug exclusivity as a matter of law, and the FDA s action is not consistent with the statute or FDA s regulations related to orphan drugs. The lawsuit seeks a determination by the court that Gralise is protected by Orphan Drug exclusivity, and an order that FDA act accordingly. The FDA has not yet filed an answer to our complaint.

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

#### ITEM 1A. RISK FACTORS

The risk factors presented below amend and restate the risk factors previously disclosed in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2012 and March 31, 2012, which amended and restated the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

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 Report 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 are not able to successfully commercialize Gralise and Zipsor, our business will suffer.

In October 2011, we began commercial sales of Gralise. In June 2012, we acquired and began commercial sales of Zipsor. As a company, we have limited experience selling and marketing pharmaceutical products. We may not be able to adequately maintain or scale the necessary sales, marketing, manufacturing, managed markets or other capabilities on our own that are required to successfully commercialize Gralise and Zipsor, and we may not enter into arrangements with other collaborative partners or other third parties to perform those functions on terms that are acceptable to us, if at all. If we enter into a collaborative co-promotion or licensing arrangement related to Gralise or Zipsor, some of the revenues we receive will depend upon the efforts of one or more third parties, which may not be successful and over which we will have little or no control.

Our third-party contractors and partners may not perform as required under their contracts with us or as expected. If our management of collaborative partners and third-party contractors is not effective or such partners or contractors do not perform as required or as expected, the commercial acceptance and success of Gralise and Zipsor may be limited and our business, financial condition and results of operations would be materially and adversely affected.

If Santarus does not successfully commercialize Glumetza in the United States, our business will suffer.

In August 2011, we entered into a commercialization agreement with Santarus pursuant to which Santarus assumed broad commercial, manufacturing and regulatory responsibility for the commercialization of Glumetza and we transferred the Glumetza NDA to Santarus. The commercialization agreement replaced the promotion agreement we entered into with Santarus in July 2008. Santarus pays us royalties on net sales of Glumetza and will not pay any additional sales milestones that were required under the promotion agreement. Although we have

retained rights to promote Glumetza to physicians not targeted by Santarus, we do not have any immediate plans to exercise our Glumetza co-promotion rights. As a result, the commercial success of Glumetza depends almost entirely on Santarus commercialization efforts. Other factors that may affect the success of our commercialization arrangement with Santarus include the following:

- Santarus may acquire or develop alternative products;
- Santarus may pursue higher-priority programs, or change the focus of its marketing programs;
- Santarus may in the future choose to devote fewer resources to Glumetza;
- Glumetza may fail to achieve greater market acceptance;
- the outcome of our ongoing litigation against ANDA filers seeking to prevent the ANDA filers from marketing a generic version of Glumetza in the United States;
- Santarus may experience financial difficulties; and
- Santarus may fail to comply with its obligations under our commercialization agreement.

Any of the preceding factors could affect Santarus commitment to the commercialization agreement, which, in turn, could adversely affect the commercial success of Glumetza. Any failure by Santarus to successfully commercialize Glumetza would have a material adverse effect on our business, financial condition and results of operations.

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If we are unable to successfully integrate Zipsor in a cost-effective and non-disruptive manner, our business will suffer.

In June 2012, we acquired Zipsor from Xanodyne. We do not have experience acquiring and integrating new products and we do not know if we will be able to successfully integrate Zipsor with our existing business. Integrating Zipsor may be expensive and time consuming, disrupt our ongoing business and distract our management and our sales force. If we are unable to integrate Zipsor effectively, our business will suffer and we will need to perform an impairment test on the related intangible asset and, if evidence of impairment exists, we would be required to take an impairment charge with respect to the asset. Such a charge could have a material adverse effect on our results of operations and financial condition.

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.

We are involved in patent infringement litigation against filers of two ANDAs to Glumetza. In June 2011, we filed a lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Inc., Sun Pharma Global FZE and Sun Pharmaceuticals Industries Ltd. (collectively, Sun), for infringement of the patents listed in the Orange Book for Glumetza. The lawsuit is in response to an ANDA filed by Sun with the FDA regarding Sun s intent to market generic versions of 500mg and 1000mg strengths of Glumetza prior to the expiration of the five listed U.S. patents (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; 6,723,340 and 7,780,987). We also are asserting U.S. Patent 7,736,667 in the lawsuit. In April 2012, we filed a lawsuit in the United States District Court for the District of Delaware against Watson Laboratories, Inc. Florida, Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively, Watson) for infringement of U.S. Patent Nos. 6,488,962 and 7,780,987. The lawsuit is in response to an ANDA filed by Watson with the FDA regarding Watson s intent to market a generic version of the 1000 mg dosage strength of Glumetza prior to the expiration of the asserted patents. We commenced both lawsuits within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs for 30 months or until a district court decision that is adverse to the patents, whichever may occur earlier. Absent a court decision, the 30-month stay on the Sun ANDA is expected to expire in November 2013, and the 30-month stay on the Watson ANDA is expected to expire in September 2014. In February 2012, we and Santarus entered into a settlement and license agreement with Lupin to resolve patent litigation involving Glumetza we initiated in November 2009. The agreement grants Lupin the right to begin selling a generic version of Glumetza on February 1, 2016, or earlier under certain circumstances. The introduction of one or more products generic to Glumetza would harm our business, financial condition, results of operations and cash flows.

We are involved in patent infringement litigation against filers of five ANDAs to Gralise. In March 2012, we filed a lawsuit in the United States District Court for the District of New Jersey against Actavis Elizabeth LLC (Actavis), Watson Laboratories (Watson) and Incepta Pharmaceuticals (Incepta) for infringement of six (6) U.S. patents listed in the Orange Book for the Gralise product. In April 2012, we filed a lawsuit in the same court against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par) for infringement of the same patents. In May 2012, we filed a lawsuit in the same court against Zydus Pharmaceuticals USA (Zydus) for infringement of the same patents. Since May 2012, two additional patents have been listed in the Orange Book for Gralise (U.S. Patent Nos. 8,192,756 and 8,252,332) and have been asserted against each of the Gralise ANDA filers. The lawsuits are in response to ANDAs filed by each of Actavis, Watson, Incepta, Par and Zydus with the FDA regarding the defendants intent to market generic versions of 300mg and 600mg dosage strengths of Gralise prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927, 7,731,989, 8,192,756 and 8,252,332. We commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving the ANDAs for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. The 30-month stays expire between July 2014 and September 2014. If the litigation is still ongoing after expiration of the applicable 30-month stay, the termination of the stay could result in the introduction of one or more products generic to Gralise prior to resolution of the litigation. Any introduction of one or more products generic to Gralise would harm our business, financial condition and results of operations.

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The filing of the ANDAs described above, or any other ANDA or similar application in respect to any of our products could have an adverse impact on our stock price. Moreover, if the patents covering our products 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, results of operations and financial condition.

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

Patheon is our sole supplier for Gralise pursuant to a manufacturing and supply agreement we entered into with Patheon in September 2011 and our sole supplier of Serada. Accucaps is our sole supplier for Zipsor pursuant to a manufacturing agreement we assumed in connection with our acquisition of Zipsor from Xanodyne in June 2012. 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 adversely affect our ability to deliver such products on a timely or competitive basis, if at all. Any failure to obtain Gralise tablets from Patheon, active pharmaceutical ingredient from suppliers, or excipient suppliers, could adversely affect our business, results of operation 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 would 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 their 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 would be adversely affected.

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

We currently have collaboration or license arrangements with Santarus, Covidien, Merck, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Boehringer Ingelheim, Ironwood and PharmaNova. In addition, we have in the past and may in the future enter into other collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements.

Collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents 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.

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;

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- premature termination of a collaboration agreement; or
- failure by a collaborative partner to devote sufficient resources to the development and commercial sales of products using our current and potential future products and technologies.

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

If we do not obtain orphan drug exclusivity for Gralise in PHN, our business could suffer.

In November 2010, the FDA granted Gralise Orphan Drug designation for the management of PHN based on a plausible hypothesis that Gralise is clinically superior to immediate release gabapentin due to the incidence of adverse events observed in Gralise clinical trials relative to the incidence of adverse events reported in the package insert for immediate release gabapentin. Generally, an Orphan-designated drug approved for marketing is eligible for seven years of regulatory exclusivity for the orphan-designated indication. If granted, Orphan Drug exclusivity for Gralise will run for seven years from January 28, 2011. However, the FDA has indicated to us that Gralise is not currently eligible for Orphan Drug exclusivity because the hypothesis upon which the product s Orphan Drug designation was granted has not been proven. 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 Gralise Orphan Drug exclusivity for the management of PHN. We believe Gralise is entitled to Orphan Drug exclusivity as a matter of law, and the FDA s action is not consistent with the statute or FDA s regulations related to orphan drugs. The lawsuit seeks a determination by the court that Gralise is protected by Orphan Drug exclusivity, and an order that FDA act accordingly. The FDA has not yet filed an answer to our complaint.

If we do not secure orphan exclusivity in PHN for Gralise, the period of market exclusivity in the United States for Gralise may be reduced, which would adversely affect our business, results of operations and financial condition.

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 and Glumetza, as well as marketing activities related to any other products 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, the federal government in recent years 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, which apply to items and services reimbursed under Medicaid and other state programs, or, in some states, 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, injunction, and exclusion of our products from reimbursement under government programs, as well as other regulatory actions against our product candidates, our collaborative partners or us.

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

Companies may not promote drugs for off-label 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

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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.

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

In both domestic and foreign markets, sales of our products and product candidates will depend in part on the availability of adequate reimbursement from third-party payers such as:

- government health administration authorities;
- private health insurers;
- health maintenance 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. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, including pharmaceuticals. 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.

Federal and state governments in the United States and foreign governments continue to propose and pass new legislation designed to contain or reduce the cost of healthcare. Existing regulations affecting pricing may also change before many of our product candidates are approved for marketing. Cost control initiatives could decrease the price that we receive for our products and any product that we may develop.

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

Gabapentin is currently marketed by Pfizer as Neurontin® for adjunctive therapy for epileptic seizures and for post herpetic pain. 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, for adjunctive therapy for epileptic seizures and nerve pain associated with spinal cord injury. In June 2012, GlaxoSmithKline and Xenoport, Inc. received approval to market HorizantTM (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 non-steroidal anti-inflammatory drug (NSAID) that is approved in the United States for the treatment of mild to moderate pain and inflammation, 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.

Bristol-Myers Squibb is currently selling a sustained release formulation of metformin, Glucophage XR, with which Glumetza competes. A limited license that Bristol-Myers Squibb obtained from us under a November 2002 settlement agreement extends to certain current and internally-developed future compounds, which may increase the likelihood that we will face competition from Bristol-Myers Squibb in the future on products in addition to Glumetza. Several other companies have received FDA approval for and are selling an extended-release metformin product. There are a number other products prescribed for Type 2 diabetes that are competitive with Glumetza, and there are a number of products under development for the treatment of Type 2 diabetes that may become competitive with Glumetza in the future.

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

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Our prior clinical trials evaluating Serada for menopausal hot flashes failed to meet all of their pre-specified primary endpoints, and we cannot be certain that this product will be approved for marketing. The development of drug candidates is inherently difficult and uncertain and we cannot be certain that any of our product candidates will be approved for marketing or, if approved, will achieve market acceptance.

Each of our three Phase 3 trials evaluating Serada for menopausal hot flashes, including our Phase 3 trial known as Breeze 3, failed to meet all of their pre-specified primary endpoints. Although the FDA has accepted for filing our New Drug Application for Serada and has tentatively scheduled an advisory committee meeting to discuss the NDA in March 2013, we cannot be certain that the New Drug Application will be approved.

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 trial 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 Serada 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.

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

- negative or inconclusive results;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- FDA inspections of our clinical operations; and
- actual or perceived lack of efficacy or safety of the product candidate.

We are unable to predict whether any of our product candidates 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, substantially all of our product candidates use 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 when or if our products obtain regulatory approval, successful commercialization requires:

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

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

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 preparing patent applications relating to our expanding technology for filing 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 others—applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or may not provide us with competitive advantages against competing products. We also rely on trade secrets and proprietary know-how, which are difficult to protect. We seek to protect such information, in part, through entering into confidentiality agreements with employees, consultants, collaborative partners and others before such persons or

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entities have access to our proprietary trade secrets and know-how. These confidentiality agreements may not be effective in certain cases, due to, among other things, the lack of an adequate remedy for breach of an agreement or a finding that an agreement is unenforceable. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

Our ability to develop our technologies and to make commercial sales of products using our technologies also depends on not infringing others patents or other intellectual property rights. We are not aware of any 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 others—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 in the future to enforce any patents issued or licensed to us or to determine the scope and validity of third-party proprietary rights. Our issued or licensed patents may not be held valid by a court of competent jurisdiction. Whether or not the outcome of litigation is favorable to us, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns. We may also be required to participate in interference proceedings declared by the United States Patent and Trademark Office for the purpose of determining the priority of inventions in connection with our patent applications or other parties patent applications. Adverse determinations in litigation or interference proceedings 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.

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.

For example, the active ingredients in the products utilizing our Acuform delivery technology that are being developed pursuant to our collaboration with Covidien include acetaminophen in combination with opiates. In connection with concerns that consumers may inadvertently take more than the recommended daily dose of acetaminophen, potentially causing liver damage, an FDA advisory committee has recommended that prescription products containing acetaminophen in combination with prescription analgesics (including opiates) should include black box warnings and/or be removed from the market. The FDA is evaluating the recommendations and has indicated that such an evaluation will take some time. The FDA is not required to accept advisory committee recommendations. Covidien s ability or willingness to develop and market the

products subject to our collaboration may be adversely affected by actions of the FDA in response to the advisory committee recommendations.

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). The FDCA, the Controlled Substances Act 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. The failure to comply with these regulations can 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 criminal prosecution.

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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 cannot be certain that the FDA will determine that we adequately addressed the matters that led to this recall or that the FDA will not seek to impose fines or sanctions against us as a result of this recall.

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 an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For instance, the NDA for Gralise relies on the FDA s prior approval of Neurontin® (gabapentin), the immediate release formulation of gabapentin initially approved by the FDA. An NDA for Serada would also rely in part on the FDA s prior approval of Neurontin.

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 includes 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 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.

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 and production of pharmaceutical products. We have obtained product liability insurance for clinical trials currently underway and forecasted 2012 sales of our products, but:

- 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 maintain product liability insurance on acceptable terms;

- we may be unable to secure increased coverage as the commercialization of the Acuform technology proceeds; or
- our insurance may not provide adequate protection against potential liabilities.

Our inability to obtain 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, financial condition and results of operations could be materially and adversely affected.

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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.

Our licensed patent covering the use of gabapentin to treat hot flashes associated with menopause is a method-of-use patent, which increases the risk that prescriptions for gabapentin to treat hot flashes in menopausal women could be written for, or filled with, generic gabapentin.

We have an exclusive sublicense from PharmaNova, Inc. (PharmaNova) to a patent held by the University of Rochester to develop and commercialize in the United States a gabapentin product for the treatment of hot flashes associated with menopause. Because a method-of-use patent, such as the patent we have sublicensed from PharmaNova, covers only a specified use of a particular compound, not a particular composition of matter, we cannot prevent others from commercializing gabapentin for other indications for use. Accordingly, physicians can already prescribe another manufacturer s gabapentin to treat hot flashes in menopausal women, or pharmacists could in the future seek to fill future prescriptions for Serada, if any, with another manufacturer s gabapentin. Although any such off-label use could violate our licensed patent, effectively monitoring compliance with our licensed patent and enforcing our patent rights against individual physicians and pharmacies may be ineffective, impractical, difficult and costly.

In the event the FDA approves our New Drug Application for Serada based on the results of our three completed Phase 3 clinical trials and we initiate commercial sales of Serada, such competition would reduce any revenues generated by such sales.

Our collaborators and licensors may not adequately protect our intellectual property rights.

In addition to our exclusive sublicense of the University of Rochester patent from PharmaNova, we hold an exclusive worldwide license from AAIPharma Inc. (AAIPharma) that includes rights to: (i) an issued U.S. patent with claims to the formulation of a pharmaceutical product, such as Zipsor, that consists of the formulation technology ProSorb® in combination with diclofenac; and (ii) four issued U.S. patents that expire in 2029 with claims to uses of certain diclofenac formulations (including Zipsor) for certain pain conditions. The ProSorb technology patent expires in 2019 and includes claims to the use of ProSorb to facilitate the rapid, consistent and complete absorption of diclofenac from the

gastrointestinal tract.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not, our ability to maintain and defend our intellectual property rights may be comprised by the acts or omissions of these third parties.

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 scientific, financial and commercial 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.

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If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost effective and non-disruptive manner.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. One 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. Other than our contingent milestone payment obligations to Xanodyne relating to our sales of Zipsor, we have no current commitments with respect to any acquisition, in-licensing or co-promotion. We do not know if we would be able to successfully complete any 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 acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we were to be unable to integrate any acquired businesses, products or technologies effectively, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could adversely affect our operating results.

#### Our operating results may fluctuate and affect our stock price.

The following factors will affect our operating results and may result in a material adverse effect on our stock price:

- the degree of commercial success of Gralise, Zipsor and Glumetza;
- announcements and results regarding clinical trial results and plans for our drug candidates;
- filings and other regulatory actions related to our product candidates;
- developments concerning proprietary rights, including patents, infringement allegations and litigation matters;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply, or other manufacture or supply difficulties;
- the outcome of our patent infringement litigation against filers of abbreviated new drug applications for Glumetza;
- the outcome of our patent infringement litigation against filers of abbreviated new drug applications for Gralise;
- 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;
- the introduction of new products by our competitors;

- the status of our compliance with laws and regulations applicable to the commercialization of pharmaceutical products;
- any limitations to access to physician prescription data, which may make our marketing efforts more effective;
- manufacturing costs;
- third-party reimbursement policies; and
- the status of our compliance with the provisions of the Sarbanes-Oxley Act of 2002.

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. Additionally, any significant drops in our stock price, such as the ones we experienced following the announcement of our Serada Phase 3 trial results in October 2009 and October 2011, 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.

We expect to incur operating losses this year 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, 2012, we incurred a net loss of \$26.1 million. Collaborative milestones and settlement fees received from Abbott Products, Janssen and Merck resulted in our reaching profitability of \$70.7 million and \$3.9 million in 2011 and 2010, respectively. For the year ended December 31, 2009, we incurred a net loss of \$22.0 million. We expect to incur operating losses in 2012, and we may incur operating losses in future years. Any such losses may have an adverse impact on our total assets, shareholders equity and working capital.

Our existing resources may not be sufficient to fund our operations until such time as we may be able to consistently generate sufficient revenues to support our operations.

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to consistently support our operations. We currently do not have any committed sources of capital. To the extent

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that our capital resources are insufficient to meet our future capital requirements, in order to continue our operations, 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. If adequate funds are not available we may have to:

- significantly curtail commercialization of our marketed products or other operations;
- delay, postpone or terminate clinical trials; and/or
- obtain funds through entering into collaboration agreements on unattractive terms.

#### We have implemented certain anti-takeover provisions.

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 . The provisions described above, our poison pill and provisions of the California General Corporation Law may discourage, delay or prevent a third party from acquiring us.

Increased costs associated with corporate governance compliance may significantly impact our results of operations.

Changing laws, regulations and standards relating to corporate governance, public disclosure and compliance practices, including the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating uncertainty for companies such as ours in understanding and complying with these laws, regulations and standards. As a result of this uncertainty and other factors, devoting the necessary resources to comply with evolving corporate governance and public disclosure standards has resulted in and may in the future result in increased general and administrative expenses and a diversion of management time and attention to compliance activities. We also expect these developments to increase our legal compliance and financial reporting costs. In addition, these developments may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. Moreover, we may be unable to comply with these new rules and regulations on a timely basis.

These developments could make it more difficult for us to attract and retain qualified members of our board of directors, or qualified executive officers. We are presently evaluating and monitoring regulatory developments and cannot estimate the timing or magnitude of additional costs

we may incur as a result. In the event these costs are significant, our selling, general and administrative expenses are likely to increase.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of 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 were 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.

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.

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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	
31.1 31.2 32.1 32.2 101*	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of James A. Schoeneck Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of August J. Moretti Certification pursuant to 18 U.S.C. Section 1350 of James A. Schoeneck Certification pursuant to 18 U.S.C. Section 1350 of August J. Moretti Interactive Data Files pursuant to Rule 405 of Regulation S-T

<sup>\*</sup> Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.

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### **SIGNATURES**

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

Date: November 5, 2012 DEPOMED, INC.

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

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

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