DEPOMED INC Form 10-Q November 07, 2011 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, 2011

 \mathbf{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 (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)

94-3229046 (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 3, 2011 was 55,400,451.

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PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

DEPOMED, INC.

CONDENSED BALANCE SHEETS

(in thousands, except share amounts)

	ptember 30, 2011 Unaudited)	December 31, 2010 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,945	\$ 22,526
Marketable securities	89,018	47,825
Accounts receivable	827	6,094
Receivables from collaborative partners	6,645	253
Inventories	3,292	1,571
Prepaid and other current assets	5,516	1,330
Total current assets	125,243	79,599
Marketable securities, long-term	45,233	6,537
Property and equipment, net	1,140	698
Other assets	169	197
	\$ 171,785	\$ 87,031
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 25,788	\$ 18,473
Deferred product sales	379	1,041
Deferred license revenue	7,664	10,665
Other current liabilities	387	635
Current portion of long-term debt		2,170
Total current liabilities	34,218	32,984
Deferred license revenue, non-current portion	19,320	30,926
Other long-term liabilities		15
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, 2011 and December 31, 2010		
Common stock, no par value, 100,000,000 shares authorized; 55,398,067 and		
52,957,787 shares issued and outstanding at September 30, 2011 and December 31,		
2010, respectively	202,022	191,343
Accumulated deficit	(83,743)	(168,306)
Accumulated other comprehensive gain (loss)	(32)	69
Total shareholders equity	118,247	23,106
	\$ 171,785	\$ 87,031

(1) Derived from the audited financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2010.

See accompanying notes to Condensed Financial Statements.

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DEPOMED, INC.

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	,	Three Months End	ed Sep	otember 30, 2010	Nine Months End	ember 30, 2010	
Revenues:							
Product sales	\$	9,205	\$	9,829 \$	40,669	\$	34,086
Royalties		2,179		75	2,412		254
License and collaborative revenue		5,138		10,223	77,760		25,565
Total revenues		16,522		20,127	120,841		59,905
Costs and expenses:							
Cost of sales		1,150		2,499	4,925		6,961
Research and development expense		3,208		4,602	12,405		14,360
Selling, general and administrative expense:							
Promotion fee expense		6,023		6,791	27,339		23,769
Other selling, general and administrative expense		15,451		4,313	32,667		12,403
Total selling, general and administrative expense		21,474		11,104	60,006		36,172
Gain on settlement agreement					(40,000)		
Total costs and expenses		25,832		18,205	37,336		57,493
Income (loss) from operations		(9,310)		1,922	83,505		2,412
Other income (expense):							
Interest and other income		410		100	846		251
Interest expense		(24)		(130)	(133)		(471)
Total other income (expense)		386		(30)	713		(220)
Net income (loss) before income taxes		(8,924)		1,892	84,218		2,192
Benefit from (provision for) income taxes		348		(1)	345		(4)
Net income (loss)	\$	(8,576)	\$	1,891 \$	84,563	\$	2,188
Basic net income (loss) per common share	\$	(0.15)	\$	0.04 \$	1.56	\$	0.04
Diluted net income (loss) per common share	\$	(0.15)	\$	0.04 \$	1.51	\$	0.04
Shares used in computing basic net income (loss)							
per common share		55,371,954		52,595,214	54,267,829		52,444,627
Shares used in computing diluted net income (loss) per common share		55,371,954		53,306,449	56,071,870		53,061,251

See accompanying notes to Condensed Financial Statements.

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DEPOMED, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Endo	led September 30, 2010		
Operating Activities				
Net income	\$ 84,563	\$	2,188	
Adjustments to reconcile net income to net cash provided by (used in) operating activities:				
Depreciation and amortization	232		331	
Loss on disposal of property and equipment			46	
Stock-based compensation	2,807		1,537	
Changes in assets and liabilities:				
Accounts receivable	(1,125)		(4,337)	
Inventories	(1,722)		1,603	
Prepaid and other assets	(4,157)		(772)	
Accounts payable and other accrued liabilities	6,862		1,331	
Accrued compensation	189		(408)	
Deferred revenue	(15,268)		(4,956)	
Net cash provided by (used in) operating activities	72,381		(3,437)	
Investing Activities				
Purchases of property and equipment	(665)		(86)	
Purchases of marketable securities	(153,875)		(56,110)	
Maturities of marketable securities	41,117		47,482	
Sales of marketable securities	32,832		7,485	
Net cash provided by (used in) investing activities	(80,591)		(1,229)	
Financing Activities				
Principal payments on long-term debt	(2,243)		(2,840)	
Proceeds from issuance of common stock	7,872		910	
Net cash provided by (used in) financing activities	5,629		(1,930)	
Net increase (decrease) in cash and cash equivalents	(2,581)		(6,596)	
Cash and cash equivalents at beginning of period	22,526		26,821	
Cash and cash equivalents at end of period	\$ 19,945	\$	20,225	

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

Basis of Presentation

These unaudited condensed financial statements and the related footnote information of Depomed, Inc. (the Company or Depomed) 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, 2011 are not necessarily indicative of results to be expected for the entire year ending December 31, 2011 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, 2010, included in the Company s Annual Report on Form 10-K filed with the SEC. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date.

Reclassifications

Certain reclassifications have been made to the December 31, 2010 balance sheet in order to conform to the Company s current presentation. The Company has now classified receivables from collaborative partners as a separate line-item on its balance sheet, which was previously included under accounts receivable.

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. Actual results could differ 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.

- Product Sales:
- <u>Glumetza</u>®: Up until August 2011, the Company distributed and recorded product sales on shipments of Glumetza® (metformin hydrochloride extended release tablets) to wholesalers and retail pharmacies. The Company and Santarus, Inc. (Santarus) entered into a commercialization agreement in August 2011, under which Depomed transferred the rights to distribute Glumetza in the United States to Santarus. Santarus commenced distribution of Glumetza in September 2011 and began recording product sales. See Note 4 for further information on the Santarus commercialization agreement.

Product distributed by Depomed up until 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.

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- <u>Proquin</u>®XR: Up until October 2010, the Company sold Proquin® XR (ciprofloxacin hydrochloride) to wholesalers and retail pharmacies subject to rights of return six months before product expiration and up to twelve months after product expiration. Given the Company s limited history of selling Proquin XR and declining prescription demand for Proquin XR, the Company was not able to reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Proquin XR until the right of return no longer exists, which occurs at the earlier of the time Proquin XR 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 \$0.4 million at September 30, 2011 related to Proquin XR product shipments that have not been recognized as revenue, which is net of wholesaler fees, retail pharmacy discounts and prompt payment discounts. In addition, the costs of manufacturing Proquin XR associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.
- Product Sales Allowances The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company s agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from the Company s estimates, the Company may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company s product sales allowances include:
- Product Returns The Company estimates product returns on sales of Glumetza that were originally distributed by the Company. 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. On product launch in August 2006 and through the second quarter of 2008, the shelf life of 500mg Glumetza product shipped was 36 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 Company monitors actual return history on 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.
- 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 discount on shipment to the respective 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 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 certain 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

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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.
- Patient Discount Programs The Company offers loyalty card programs to patients for Glumetza in which patients receive certain discounts at participating retail pharmacies that are reimbursed by the Company. The Company estimates and accrues future redemptions based on historical redemption activity.
- 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. Royalties from Santarus are recognized in the period earned as the royalty amounts can reliably be estimated and collectability is reasonably assured. See Note 4 for further information on the Santarus commercialization agreement.

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

Recently Issued Accounting Standards

In September 2009, the Financial Accounting Standards Board (FASB) revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one

unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company elected to adopt this guidance prospectively, effective for the Company s fiscal year beginning January 1, 2011. Upon adoption, the guidance did not have a material impact on the Company s financial statements and is not expected to have a material impact on the Company s future operating results.

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, the Company will 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 does not anticipate the adoption of this guidance will have a material impact on its 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, 2011 and December 31, 2010 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

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	Amortized	Gross Unrealized	Gross Unrealized	
September 30, 2011	Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 5,086	\$	\$ \$	5,086
Money market funds	6,410			6,410
U. S. corporate debt securities	8,449			8,449
Total cash and cash equivalents	\$ 19,945	\$	\$ \$	19,945
Available-for-sale securities:				
Total maturing within 1 year and included in				
marketable securities:				
U.S. corporate debt securities	44,865	3	(24)	44,844
U.S. government agency debt securities	2,997	2		2,999
U.S. Treasury securities	41,129	45		41,174
Total maturing between 1 and 2 years and				
included in marketable securities:				
U.S. corporate debt securities	19,225	6	(89)	19,142
U.S. government agency debt securities	21,061	18	(5)	21,074
U.S. Treasury securities	5,006	12		5,018
Total available-for-sale securities	\$ 134,283	\$ 86	\$ (118) \$	134,251
Total cash, cash equivalents and marketable				
securities	\$ 154,228	\$ 86	\$ (118) \$	154,196

	Amortized	Gross Unrealized	Gross Unrealized	
December 31, 2010	Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 3,913	\$	\$ \$	3,913
Money market funds	17,613			17,613
U.S. Treasury securities	1,000			1,000
Total cash and cash equivalents	\$ 22,526	\$	\$ \$	22,526
Available-for-sale securities:				
Total maturing within 1 year and included in				
marketable securities:				
U.S. corporate debt securities	12,099	4	(2)	12,101
U.S. government agency debt securities	25,667	21		25,688
U.S. Treasury securities	10,015	21		10,036
Total maturing between 1 and 2 years and				
included in marketable securities:				
U.S. corporate debt securities				
U.S. government agency debt securities				
U.S. Treasury securities	6,512	25		6,537
Total available-for-sale securities	\$ 54,293	\$ 71	\$ (2) \$	54,362
Total cash, cash equivalents and marketable				
securities	\$ 76,819	\$ 71	\$ (2) \$	76,888

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 high quality, U.S. financial 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 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, 2011, the Company had thirty-two 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-

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temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at September 30, 2011 (in thousands):

		Less than 12 months			12 months or greater			Total			
			1	Gross Unrealized		Gross Unrealized				Gross Unrealized	
	Fa	ir Value		Losses	Fair Value	Losses		Fair Value		Losses	
U.S. corporate debt securities	\$	45,741	\$	(113)			\$	45,741	\$	(113)	
U.S. government agency debt											
securities		15,010		(5)				15,010		(5)	
U.S. Treasury securities											
Total available-for-sale	\$	60,751	\$	(118)	\$	\$	\$	60,751	\$	(118)	

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 Company s securities. 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, 2011.

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 measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 6,410	\$	\$	6,410
U.S. corporate debt securities		72,435		72,435
U.S. government agency debt securities		24,073		24,073

U.S. Treasury securities		46,192	46,192
Total	\$ 6,410 \$	142,700 \$	\$ 149,110

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, 2010 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 17,613	\$	\$	\$ 17,613
U.S. corporate debt securities		12,101		12,101
U.S. government agency debt securities		25,688		25,688
U.S. Treasury securities		17,573		17,573
Total	\$ 17,613	\$ 55,362	\$	\$ 72,975

There are no financial liabilities measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010.

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

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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:

	Three Months End	ded Se	. ,	Nine Months Ended September 30,			
(in thousands, except for per share amounts)	2011		2010	2011		2010	
Numerator:							
Net income (loss)	\$ (8,576)	\$	1,891	\$ 84,563	\$	2,188	
Denominator for basic net income (loss) per share	55,372		52,595	54,268		52,445	
Net effect of dilutive common stock equivalents			711	1,804		616	
Denominator for diluted net income (loss) per share:	55,372		53,306	56,072		53,061	
Basic net income (loss) per share	\$ (0.15)	\$	0.04	\$ 1.56	\$	0.04	
Diluted net income (loss) per share	\$ (0.15)	\$	0.04	\$ 1.51	\$	0.04	

For the three and nine months ended September 30, 2011, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 4.9 million and 1.2 million, respectively. For the three and nine months ended September 30, 2010, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 3.0 million and 3.4 million, respectively.

NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

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 will transition 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 for advertising and promotional marketing activities for Glumetza.

Santarus will be 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.

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 will be 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 begins distributing Glumetza. Depomed will be financially responsible for Glumetza rebates and chargebacks up to the amount of its reserve accounts for those items. Santarus will be responsible for all other Glumetza returns, rebates and chargebacks.

Pursuant to the terms of the commercialization agreement, Deponde has the option to co-promote Glumetza products to physicians other than those called on by Santarus, subject to certain limitations. Deponde will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by its called on physicians over a pre-established baseline.

Under the commercialization agreement, Depomed will continue to manage the ongoing patent infringement lawsuits against Sun Pharmaceutical Industries, Inc. (Sun) and Lupin Limited (Lupin), 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 these two existing infringement cases.

The commercialization agreement will continue in effect for so long as Santarus commercializes branded Glumetza or authorized generic products, unless terminated sooner. Subject to 60 days prior written notice to Santarus, Deponded may terminate the

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agreement if Santarus fails to meet its obligations with respect to minimum promotion and expenditure obligations and fails to cure such breach within a specified time period. Either party may terminate the agreement if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period. In addition, either party may terminate the agreement if a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed. Santarus has a voluntary right to terminate the agreement upon 120 days written notice.

During the quarter ended September 30, 2011, Depomed distributed Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus. Santarus sold Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid Depomed a royalty equal to 26.5% of net sales.

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. For the three and nine months ended September 30, 2010, the Company recognized \$6.8 million and \$23.8 million, respectively, in promotion fee expense to Santarus. Promotion fee expense is classified within selling, general and administrative expense.

Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus distributing Glumetza under the commercialization agreement. There were no royalty revenue amounts from Santarus in the prior year.

The Company accounted for the transaction as a sale of a business as defined by FASB Accounting Standards Codification Topic 805, *Business Combinations*. In connection with entering into the commercialization agreement with Santarus, no additional consideration was exchanged between the two parties. Accordingly, the Company did not record a gain or loss with respect to this transaction and related transfer of Glumetza manufacturing and distribution activities. As the Company will have significant continuing cash inflows with respect to receiving royalties on net sales of Glumetza by Santarus, the previously reported and future activities related to Glumetza will continue to be presented in income from continuing operations in the Company s income statement.

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 and managing the ongoing 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. The Company recognized approximately \$0.6 million and \$1.0 million of license revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. For the three and nine months ended September 30, 2010, the Company recognized \$0.2 million and \$0.7 million of license revenue associated with this upfront license fee. The remaining deferred revenue balance related to this upfront payment is \$8.8 million at September 30, 2011.

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, will provide sales force recruiting, training, deployment and ongoing operational support to the Company to promote Gralise. The agreement provides for a sales force of 164 full-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 \$1.8 million, which is subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of Ventiv's monthly management fee will be subject to payment by the Company only to the extent that specified performance objectives are met. The Company will also pay certain pass-through costs of Ventiv incurred in connection with the agreement, which primarily include bonuses, travel costs and certain administrative expenses. 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.

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The agreement will expire on the second anniversary of the date on which sales representatives hired by Ventiv are deployed. The agreement is subject to early termination under certain circumstances and may be terminated by either party upon advance notice beginning in October 2012.

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 GraliseTM (gabapentin) for pain indications in the United States, Canada and Mexico. In February 2010, Abbott Laboratories acquired the pharmaceutical business of Solvay and Abbott Products, a subsidiary of Abbott Laboratories, became responsible for the Gralise license agreement with the Company.

In March 2010, Abbott Products submitted an NDA for Gralise to the U.S. Food and Drug Administration (FDA) for the management of postherpetic neuralgia (PHN). In May 2010, the FDA accepted the NDA filing for Gralise, which triggered a \$10.0 million milestone payment from Abbott Products which Depomed received in June 2010. 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 \$10.0 million as revenue in the second quarter of 2010.

In January 2011, Abbott Products received FDA approval of Gralise for the management of PHN, which triggered a \$48.0 million development milestone from Abbott Products 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 entire \$48.0 million was recognized as license revenue in the first quarter of 2011.

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.

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.

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 fee is being amortized ratably through November 2011, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. 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. The remaining deferred revenue balance is \$1.4 million at September 30, 2011.

Under the terms of the agreement, the Company may receive an additional \$2.5 million upon delivery of experimental batches of prototype formulations that meet certain specification. 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.

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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 \$0.2 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 is being amortized ratably through June 2012, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. 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. The remaining deferred revenue balance related to this upfront payment is \$0.7 million at September 30, 2011.

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 three and nine months ended September 30, 2011.

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.

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 will be paid in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable 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 fully repaid in July 2011.

NOTE 6. STOCK-BASED COMPENSATION

The following table presents stock-based compensation expense recognized for stock options, stock awards and the Company s employee stock purchase program (ESPP) in the Company s statements of operations (in thousands):

	Three Months En	ided Sept	ember 30, 2010	Nine Months En 2011	ided Sept	ember 30, 2010
Cost of sales	\$ 17	\$	8	\$ 50	\$	14
Research and development expense	155		119	465		429
Selling, general and administrative						
expense	769		348	2,292		1,094
Total	\$ 941	\$	475	\$ 2,807	\$	1,537

For the three and nine months ended September 30, 2011, the Company recognized zero and approximately \$0.4 million in stock-compensation expense, respectively, associated with the accelerated vesting of stock options in connection with a separation

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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.

At September 30, 2011, the Company had \$7.6 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants that will be recognized over an average vesting period of 2.6 years.

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,			
		2011		2010	2011		2010	
Net income (loss)	\$	(8,576)	\$	1,891	\$ 84,563	\$	2,188	
Unrealized gain (loss) on								
available-for-sale securities		(187)		19	(101)		66	
Total comprehensive income (loss)	\$	(8,763)	\$	1,910	\$ 84,462	\$	2,254	

NOTE 8. INVENTORIES

Inventories relate to the manufacture of the Company s Gralise and Proquin XR products at September 30, 2011 and Gralise, Glumetza and Proquin XR products at December 31, 2010. In August 2011, the Company sold its Glumetza inventory, at cost, to Santarus as part of the commercialization agreement. See Note 4 for further information with regards to the Santarus commercialization agreement. Inventories are stated at the lower of cost or market and consist of the following (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	\$ 1,273	\$ 74
Work-in-process	258	202
Finished goods	1,746	1,254
Deferred costs	15	41
Total	\$ 3,292	\$ 1,571

Deferred costs represent the costs of Proquin XR product shipped for which recognition of revenue has been deferred.

NOTE 9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	September 30, 2011	December 31, 2010
Accounts payable	\$ 3,380	\$ 1,655
Accrued compensation	2,827	2,638
Accrued clinical trial expense	1,094	307
Accrued rebates and sales discounts	2,232	2,625
Allowance for product returns	9,333	5,355
Accrued promotion fee		2,490
Other accrued liabilities	6,922	3,403
Total accounts payable and accrued liabilities	\$ 25,788	\$ 18,473

NOTE 10. SHAREHOLDERS EQUITY

Option Exercises

For the three and nine months ended September 30, 2011, employees and consultants exercised options to purchase 58,105 and 2,370,358 shares of the Company s common stock with net proceeds to the Company of approximately \$0.3 million and \$7.6 million, respectively.

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Employee Stock Purchase Plan

In May 2011, the Company sold 69,922 shares under the ESPP. The shares were purchased at a weighted average purchase price of \$4.37 per share with proceeds of approximately \$0.3 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 is 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.

NOTE 12. INCOME TAXES

As of December 31, 2010 and September 30, 2011, the Company had \$3.4 million and \$3.5 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. LEASE AMENDMENTS

In June 2011, the Company entered into amendments to its existing leases for the Company s premises located at 1330 and 1360 O Brien Drive, Menlo Park, California, consisting of approximately 46,000 rentable square feet. The lease amendments extend the term of the existing leases for twelve months, from February 1, 2012 through January 31, 2013. All material provisions of the leases remain the same, except that the Company may not extend either of the lease terms. The lease for the Company s premises located at 1430 O Brien Drive, consisting of approximately 9,000 rentable square feet, was not amended by the lease amendments, and has a term through January 31, 2012.

NOTE 14. SUBSEQUENT EVENTS

In October 2011, the Company announced the commercial availability of Gralise and began distributing Gralise to wholesalers and retail pharmacies.

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:

• our ability to successfully launch GraliseTM (gabapentin), our product for the management of postherpetic neuralgia that was transferred to us in March 2011 from our former licensee, Abbott Products Inc. (a wholly-owned subsidiary of Abbott Laboratories, or Abbott Products);

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- the commercial success and market acceptance of Gralise and our own efforts, or those of Ventiv or of any future commercialization partner, with respect to the commercialization of Gralise;
- discussions with the U.S. Food and Drug Administration regarding the results of Breeze 3, our Phase 3 trial evaluating Serada® for menopausal hot flashes that did not meet all primary endpoints;
- any patent infringement or other litigation that may be instituted related to Gralise or Serada under the Hatch-Waxman Act;
- 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 commercial success and market acceptance of Serada if we receive approval to market Serada in the United States;
- the results of our ongoing litigation against Lupin Limited (Lupin) and Sun Pharmaceuticals related to their respective abbreviated New Drug Applications (ANDAs) to market generic Glumetza in the United States;
- 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;
- 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;
- our collaborative partners compliance or non-compliance with obligations under our collaboration agreements; and
- our plans to develop other product candidates.

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 to update or revise these forward-looking statements to reflect new events or circumstances.

ABOUT DEPOMED

Depomed is a specialty pharmaceutical company focused on the development and commercialization of differentiated products that address large and growing markets and are based on proprietary oral drug delivery technologies. We have two products approved by the U.S. Food and Drug Administration (FDA) that are currently be marketed. Gralise (gabapentin) is our once-daily tablet for the management of postherpetic neuralgia that we launched and made commercially available in October 2011. Glumetza is our once-daily treatment for adults with type 2 diabetes that is commercialized in the United States by Santarus, Inc. (Santarus).

In October 2011, we announced the results of our additional Phase 3 clinical trial known as Breeze 3 for Serada, our proprietary extended release formulation of gabapentin for the treatment of menopausal hot flashes. The formulation of Serada evaluated in the trial met three of the four pre-specified endpoints of frequency and severity at four and 12 weeks but did not meet the key secondary endpoints of frequency and severity at 24 weeks. We intend to meet with and discuss the results of our three completed Phase 3 clinical trials for Serada with the FDA. However, there can be no assurance that the FDA will determine the product candidate is sufficiently safe and effective to allow a New Drug Application to be submitted to and approved by the FDA.

We seek to optimize the use and value of our product candidates and drug delivery technologies in three ways. First, we are seeking to assemble a number of pharmaceutical products that can be highly differentiated from immediate release versions of the compounds upon which they are based and may be promoted together within a specialty pharmaceutical field, such as neurologists or women s health care providers. Our development of Serada, and our retention of co-promotion rights within the obstetrics/gynecology field in our commercialization arrangements with Covidien, Ltd. (Covidien) and Santarus, Inc. (Santarus), are examples of this aspect of our business strategy. Second, we out-license product candidates after we have increased their value through our formulation and clinical development efforts. Third, we enter into collaborative partnerships with other companies where our technology can add value to a partner s product candidate. Our license and development arrangements with Covidien, Janssen Pharmaceutica N.V. (Janssen), Boehringer Ingelheim International GMBH (Boehringer Ingelheim), and Ironwood Pharmaceuticals, Inc. (Ironwood) and our license agreement with Merck & Co., Inc. (Merck) are examples of this strategy.

The following table summarizes our product pipeline and marketed products.

Product Pipeline

Product	Indication	Status
Serada®	Menopausal hot flashes	Three Phase 3 studies completed (Breeze 1, Breeze 2, and Breeze 3).
DM-1992	Parkinson s disease	Second Phase 1 study completed in February 2011.
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Commercialized Products

GraliseTM	Postherpetic neuralgia	Currently sold in the United States. <i>Approved by the FDA in January 2011. Launched in October 2011.</i>
Glumetza®	Type 2 diabetes	Currently sold in the United States and Canada. <i>United States rights held by Santarus</i> . <i>Canadian rights held by Valeant</i> .

Significant Developments and Highlights for the Quarter Ended September 30, 2011

- In July 2011, we entered into a research collaboration and license agreement with Ironwood Pharmaceuticals, Inc. granting Ironwood a license for worldwide rights to our Acuform drug delivery technology for an undisclosed Ironwood early stage development program.
- In August 2011, we entered into a commercialization agreement with Santarus, Inc. pursuant to which Santarus assumed commercial, manufacturing and regulatory responsibility for the commercial activities of Glumetza.
- In September 2011, our contract sales organization, Ventiv Commercial Services, LLC, (Ventiv) hired 164 sales representatives to promote Gralise.
- In September 2011, we entered into a manufacturing and supply agreement with Patheon Puerto Rico, Inc. (Patheon) for the manufacture, package and supply of commercial quantities of Gralise.
- Revenue for the three months ended September 30, 2011 was \$16.5 million, compared to \$20.1 million for the three months ended September 30, 2010.
- Cash, cash equivalents and marketable securities were \$154.2 million as of September 30, 2011, compared to \$76.9 million as of December 31, 2010.

PRODUCT DEVELOPMENTS AND TRANSACTIONS

GraliseTM (gabapentin) tablets for the Management of Postherpetic Neuralgia

In October 2011, we launched and announced the commercial availability of Gralise.

<u>Ventiv Commercial Services, LLC.</u> In June 2011, we entered in to a service agreement with Ventiv Commercial Services, LLC (Ventiv), pursuant to which in Ventiv Selling Solutions, Ventiv s outsourced sales business, will provide us with sales force recruiting, training, deployment and ongoing operational support to the Company to promote Gralise. The agreement provides for a sales force of 164 full-time sales

representatives dedicated to the Company, all of whom are employees of	f Ventiv, who began employment in September 2011. Members of sales
management are our employees.	

In October 2011, our contract sales representatives began promoting Gralise to physicians.

Under the terms of the agreement, we will incur an upfront implementation fee, and agreed upon fixed monthly management fees, which are subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of Ventiv s monthly management fee will be subject to payment by us only to the extent that specified performance objectives are met. We will also pay certain pass-through costs of Ventiv incurred in connection with the Agreement.

The agreement will expire on the second anniversary of the date on which sales representatives hired by Ventiv are deployed. The Agreement is subject to early termination under certain circumstances and may be terminated by either party upon advance notice after the first anniversary of the deployment date.

<u>Patheon Puerto Rico, Inc.</u> In September 2011, we entered into a manufacturing agreement with Patheon Puerto Rico, Inc. (Patheon), pursuant to which Patheon will manufacture, package and supply commercial quantities of Gralise.

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Under the Agreement, we will provide rolling forecasts to Patheon of its requirements for the product, a portion of which will be considered a firm purchase order. We may obtain a portion of its product requirements from a second manufacturing source. The Company will be responsible for providing Patheon with the active pharmaceutical ingredient in Gralise.

The agreement will expire on May 31, 2016, subject to early termination under certain circumstances.

<u>Abbott Products.</u> In November 2008, we entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) granting Solvay exclusive rights to develop and commercialize Gralise in the United States, Canada and Mexico for pain indications. The agreement became effective in January 2009. In February 2010, Abbott Laboratories completed its acquisition of the pharmaceutical business of Solvay. Abbott Products, a subsidiary of Abbott Laboratories, assumed responsibility for the Gralise license agreement with us in connection with the acquisition.

Pursuant to the license agreement with Solvay, we received a \$25.0 million upfront fee in February 2009. In March 2010, Abbott Products submitted an NDA for Gralise to the FDA for the management of postherpetic neuralgia. In May 2010, the FDA accepted the NDA for Gralise for the management of postherpetic neuralgia, which triggered a \$10.0 million milestone payment from Abbott Products to us in June 2010.

In January 2011, the FDA approved Gralise for once-daily management of postherpetic neuralgia. The approval triggered a \$48.0 million milestone from Abbott Products to us, which we received in February 2011.

Pursuant to a settlement agreement entered into in March 2011, we and Abbott Products terminated our license agreement for Gralise. The settlement agreement provided for (i) the transition of Gralise back to Depomed and (ii) a \$40.0 million payment to Depomed which we received in March 2011. 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 the first quarter of 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

Serada® for Menopausal Hot Flashes

Serada is our extended-release formulation of gabapentin for the treatment of menopausal hot flashes. In October 2011, we announced top-line results for Breeze 3, our third Phase 3 study for Serada.

Study Design. Breeze 3 was a randomized, double-blind, placebo-controlled study of up to 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 includes 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, our ongoing Phase 3 clinical trial evaluating Serada for menopausal hot flashes. 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.

Modifications to the design of Breeze 3 relative to Breeze 1 and 2 include: (i) a single active arm rather than two arms, and therefore a required statistical p value of .05 rather than .025 to achieve statistical significance; (ii) 65% more patients in the active treatment arm than in Breeze 1 and 2 (iii) a two-week run in period prior to randomization, rather than one week, which is designed to reduce the regression to the mean observed in Breeze 1 and 2; and (iv) an alternative statistical analysis method, known as a non-parametric analysis, that was designed to reduce the influence significant outliers can have on the achievement of efficacy endpoints.

Study Results. 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 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.

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We intend to meet with and discuss the results of our three completed Phase 3 clinical trials for Serada with the FDA. However, there can be no assurance that the FDA will determine the product candidate is sufficiently safe and effective to allow a New Drug Application to be submitted to the FDA. In the event the FDA allows us to file a New Drug Application for Serada based on the results of our three completed Phase 3 clinical trials, there can be no assurance that such New Drug Application will be approved.

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 will transition 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 will continue to be 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 the sole commercial supplier of Santarus Glumetza 500 mg prescription products in the U.S.

Santarus will be required to pay us 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 pay no additional sales milestones to us as was originally required under the prior promotion agreement.

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 its reserve account for those items. Santarus will be responsible for all other Glumetza returns, rebates and chargebacks.

Pursuant to the terms of the commercialization agreement, we have the option to co-promote Glumetza products to physicians other than those called on by Santarus, subject to certain limitations. If we exercise this option, we will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by our called upon physicians over a pre-established baseline.

Under the commercialization agreement, we will continue to manage the ongoing patent infringement lawsuits against Sun Pharmaceutical Industries, Inc. (Sun) and Lupin Limited (Lupin), subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. Santarus will reimburse us for 70% of it out-of-pocket costs, and we will reimburse Santarus for 30% of its out-of-pocket costs related to these two existing infringement cases.

The commercialization agreement will continue in effect for so long as Santarus commercializes branded Glumetza or authorized generic products, unless terminated sooner. Subject to 60 days prior written notice to Santarus, we may terminate the agreement if Santarus fails to meet its obligations with respect to minimum promotion and expenditure obligations and fails to cure such breach within a specified time period. Either party may terminate the agreement if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period. In addition, either party may terminate the agreement if a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed. Santarus has a voluntary right to terminate the agreement upon 120 days written notice.

During the quarter ended September 30, 2011, we sold Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus sold Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid us a royalty equal to 26.5% of net sales.

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. For the three and nine months ended September 30, 2010, the Company recognized \$6.8 million and \$23.8 million, respectively, in promotion fee expense to Santarus. Promotion fee expense is classified within selling, general and administrative expense

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Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus selling Glumetza under the commercialization agreement. There were royalty revenue amounts from Santarus in the prior year.

500mg Glumetza Recall. In June 2010, we conducted a voluntary class 2 recall of fifty-two lots of 500mg Glumetza product from wholesalers due to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA) in bottles containing 500mg Glumetza tablets. In June 2010, we temporarily suspended product shipments of 500mg Glumetza product to our customers. We resumed shipments of the 500mg Glumetza to customers in January 2011. The 1000mg Glumetza product was not subject to the recall.

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 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.

We are also eligible to receive an additional \$2.5 million upon delivery of experimental batches of prototype formulations that meet certain specifications, and may receive additional milestone payments based on regulatory filings and approval events, as well as royalties on worldwide net sales of products.

We are responsible for providing certain initial formulation work associated with the fixed dose combination products. Services performed by us under the agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon rate, and out-of-pocket expenses will be reimbursed.

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 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.

Under the terms of the agreement, we 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 may also receive additional payments pending achievement of certain development and regulatory milestones, as well as royalties on product sales.

DM-1992 for Parkinson s Disease

In September 2010, we initiated our second pharmacokinetic-pharmacodynamic Phase 1 study for the DM-1992 program. The second Phase 1 trial in DM-1992 was a randomized, open-label crossover study that enrolled 16 patients with stable Parkinson s disease at two leading neurology centers in Russia. The objective of the study was to compare the pharmacokinetics-pharmacodynamics of two distinct twice-daily formulations of DM-1992 and a generic version of Sinemet CR sustained-release levodopa/carbidopa dosed three-times daily, as well as the safety and tolerability of the formulations. Patients in the trial received a full day s dose of each of the three treatments being studied, two doses of each DM-1992 (460mg levodopa and 150mg carbidopa per dose) twelve hours apart, and three doses of generic levodopa/carbidopa over a 12 hour period (200mg of levodopa and 50mg of carbidopa per dose). During the 24 hour period following administration of each treatment, blood samples were drawn and a standard finger tapping test was given to assess efficacy.

In February 2011, we completed the second Phase 1 study. Both formulations are projected at steady state to consistently maintain levodopa blood levels above the efficacious threshold of 300ng/mL for 24 hours, as mean levodopa blood levels after 24 hours exceeded 300ng/mL.

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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 2010 Annual Report on Form 10-K with the Securities and Exchange Commission on March 16, 2011. For a description of our critical accounting policies, please refer to our 2010 Annual Report on Form 10-K.

RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2011 and 2010

Glumetza

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.

We ceased shipments of Glumetza in August 2011 and Santarus began distributing and recognizing product sales on shipments of Glumetza in September 2011. Santarus will be required to pay us 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 pay no additional sales milestones to us as was originally required under the prior promotion agreement.

Prior to the effective date commercialization agreement, we were required to pay Santarus 75% of gross margin on Depomed sales of Glumetza under the promotion agreement.

During the quarter ended September 30, 2011, we distributed Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus. Santarus distributed Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid us a royalty equal to 26.5% of net sales.

Glumetza product sales of \$9.2 million, Glumetza cost of goods sold of \$1.0 million and promotion fee expense to Santarus of \$6.0 million during the quarter ended September 2011 represents two months in the quarter of Depomed distributing Glumetza under the prior agreement. Glumetza royalties of \$2.1 million during the third quarter of 2011 represents one month in the quarter of royalties from on Santarus net sales of Glumetza under the new commercialization agreement. In the corresponding quarter of the prior year, Glumetza product sales were \$9.8 million, Glumetza cost of goods sold were \$2.5 million and promotion fee expense to Santarus was \$6.8 million, which represented a full quarter of Depomed selling product under the parties promotion agreement,

Glumetza product sales of \$40.7 million, Glumetza cost of goods sold of \$3.7 million and promotion fee expense to Santarus of \$27.3 million during the nine months ended September 2011 represents eight months in 2011 of Depomed distributing Glumetza under the prior agreement. Glumetza royalties of \$2.1 million during the nine months ended September 2011 represents one month in 2011 of royalties on Santarus net sales of Glumetza under the new commercialization agreement. In the corresponding period of the prior year, Glumetza product sales were \$34.0 million, Glumetza cost of goods sold were \$6.9 million and promotion fee expense to Santarus was \$23.8 million, which represented nine months of Depomed selling product under the parties promotion agreement.

We accounted for the transaction as a sale of a business as defined by FASB Accounting Standards Codification Topic 805, *Business Combinations*. In connection with entering into the commercialization agreement with Santarus, no additional consideration was exchanged between the two parties. Accordingly, we did not record a gain or loss with respect to this transaction and related transfer of Glumetza manufacturing and distribution activities. As we will have significant continuing cash inflows with respect to receiving royalties on net sales of Glumetza by Santarus, the previously reported and future activities related to Glumetza will be continue to presented in income from continuing operations in the Company s income statement.

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Revenue

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

	Three Months En 2011	ded Sep	otember 30, 2010	Nine Months Ended September 30, 2011 2010		
Product sales:						
Glumetza	\$ 9,205	\$	9,807	\$ 40,657	\$	33,976
Proquin XR			22	12		110
Total product sales	9,205		9,829	40,669		34,086
Royalties:						
Glumetza	2,179		75	2,412		254
License and collaborative						
revenue:						
Gralise			1,561	60,592		14,684
Glumetza	962		626	5,222		1,877
Boehringer Ingelheim	3,902			9,368		
Janssen			6,508	2,251		6,508
Ironwood	274			274		
Covidien			1,458			2,375
Proquin XR (EU)			26			77
DM-1992			44	53		44
Total license and collaborative						
revenue:	5,138		10,223	77,760		25,565
Total revenues	\$ 16,522	\$	20,127	\$ 120,841	\$	59,905

Product sales

Glumetza. The decrease in Glumetza product sales in the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 was primarily due to Depomed distributing and recognizing product sales of Glumetza for only two months in the third quarter of 2011 as opposed to the full quarter in the third quarter of 2010. This change resulted from the Santarus commercialization agreement entered into in August 2011. This decrease was offset by price increases as well as the resumption of shipments of the 500mg Glumetza in 2011. We did not ship any 500mg Glumetza in the third quarter of 2010 following the recall of 500mg Glumetza in June 2010. We temporarily suspended product shipments of 500mg Glumetza in June 2010 and did not resume shipments until January 2011. The 1000mg Glumetza was not subject to the recall.

The increase in Glumetza product sales during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 is primarily due to price increases and the resumption of shipments of the 500mg Glumetza in January 2011.

As a result of the Santarus commercialization agreement entered into in August 2011, we will no longer be recognizing Glumetza product sales
going forward as we have transitioned the distribution and selling efforts related to Glumetza to Santarus. We will receive royalties on Santarus
net sales of Glumetza going forward.

The Company launched Gralise in October 2011 and will begin recognizing Gralise product sales in the fourth quarter of 2011.

Royalties

<u>Glumetza</u>. Glumetza royalties relate to royalties we received from Santarus, Valeant Pharmaceuticals International, Inc. (Valeant), based on net sales of Glumetza in Canada and royalties we received from LG Life Sciences (LG) based on net sales of LG s version of Glumetza, Novamet GR. in Korea.

Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus distributing and recording product sales on shipments of Glumetza under the commercialization agreement. There were no royalty revenue amounts from Santarus in the prior year. We expect royalty revenue to increase on a forward basis as a result of the commercialization agreement.

License and collaborative 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,

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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>. 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.

Glumetza license revenue for the three and nine months ended September 30, 2011 and 2010 also 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.

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 ongoing 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 \$0.6 million and \$1.0 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. The remaining deferred revenue balance is \$8.8 million at September 30, 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 is being amortized ratably through November 2011, which is the estimated length of time we are obligated to perform formulation work under the agreements. 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. The remaining deferred revenue balance is \$1.4 million at September 30, 2011.

We are also responsible for providing certain initial formulation work associated with the fixed dose combination products. Work performed by us under the service agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon FTE rate per hour plus out-of-pocket expenses. 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.

<u>Janssen</u>. In August 2010, we entered into a non-exclusive license agreement with Janssen granting Janssen 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 are 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.

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<u>Ironwood Pharmaceuticals, Inc.</u> In July 2011, the 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 program. In connection with the research collaboration and license agreement, the Company received an upfront payment of \$0.9 million which is being amortized ratably through June 2012, which is the estimated length of time Deponde is obligated to perform formulation work under the agreement. We recognized approximately \$0.2 million of revenue associated with this upfront license fee for the three and nine months ended September 30, 2011. The remaining deferred revenue balance is \$0.7 million at September 30, 2011.

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 \$0.1 million of revenue associated with the reimbursement of formulation work under the agreement during the three and nine months ended September 30, 2011.

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 Glumetza, Gralise and Proquin XR. Total cost of sales for the three and nine months ended September 30, 2011, as compared to the prior year, was as follows (in thousands):

	Th	ree Months En	ded September 30,			Nine Months End	nber 30,	
		2011	_	2010		2011	_	2010
Cost of sales	\$	1,150	\$	2,499	\$	4,925	\$	6,961

Cost of sales for the three months ended September 30, 2011 decreased as compared to the prior year mainly as a result of \$1.2 million in inventory write-offs for unsalable inventory related to the 500mg Glumetza recall during the three months ended September 30, 2010. Additionally, the Company only sold Glumetza for two of the three months ended September 30, 2011 as a result of the Santarus commercialization agreement. These decreases were partially offset by manufacturing and supply costs related to the Company s launch of Gralise in October 2011.

Cost of sales for the nine months ended September 30, 2011 decreased as compared to the prior year mainly as a result of \$2.6 million in inventory write-offs for unsalable inventory related to the 500mg Glumetza recall during the nine months ended September 30, 2010.

The costs of manufacturing associated with deferred revenue on Proquin XR product shipments are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

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 made in March 2011. The \$40.0 million payment was recognized as a gain within operating income in the first quarter of 2011.

Research and Development Expense

Our research and development expenses currently include costs for scientific personnel, supplies, equipment, outsourced clinical and other research activities, consultants, depreciation, facilities and utilities. The scope and magnitude of future research and development expenses cannot be predicted at this time for our product candidates in the early phases of 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 launch.

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Total research and development expense for the three and nine months ended September 30, 2011 as compared to the prior year, was as follows (in thousands):

	Thi	ee Months End	led Sep	tember 30,	Nine Months Ended September 30,			
	2	2011		2010	2011		2010	
Research and development								
expense	\$	3,208	\$	4,602	\$ 12,405	\$	14,360	
Dollar change from prior year		(1,394)			(1,955)			
Percentage change from prior								
year		(30.3)%			(13.6)%			

The decrease in research and development expense for the three and nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010 was primarily due to reductions in research and development expense for Gralise, which received FDA approval in the first quarter of 2011 partially offset by higher clinical research organization costs associated with our Breeze 3 Phase 3 clinical trial for Serada, which was completed in October 2011.

We categorize our research and development expense by project. The table below shows research and development costs for our major clinical development

	Tl	Three Months Ended September 30,				Nine Months Ended September 30,			
(In thousands)		2011		2010		2011		2010	
Serada	\$	2,519	\$	1,577	\$	8,258	\$	5,587	
Gralise				1,132				3,378	
Other projects		689		1,893		4,147		5,395	
Total research and development									
expense	\$	3,208	\$	4,602	\$	12,405	\$	14,360	

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Selling, General and Administrative Expense

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

	Three Months End	otember 30,	Nine Months Ended September 30,			
	2011		2010	2011		2010
Selling, general and administrative expense:						
Promotion fee expense	\$ 6,023	\$	6,791	\$ 27,339	\$	23,769
Other selling, general and administrative						
expense	15,451		4,313	32,667		12,403
Total selling, general and administrative						
expense	\$ 21,474	\$	11,104	\$ 60,006	\$	36,172
Dollar change from prior year	10,370			23,834		
Percentage change from prior year	93.4%			65.9%		

The increase in selling, general and administrative expense was primarily due to increased sales and marketing costs related to the launch of Gralise including pre-launch marketing activities and costs associated with our contract sales organization. In March 2011, we received the rights to market Gralise back from Abbott and commenced pre-launch commercial activities to support the launch of Gralise. During 2011, we advanced our commercial infrastructure with the hiring of employees for our sales management and marketing organizations. In June 2011, we entered into a service agreement with Ventiv as our contract sales organization, pursuant to which Ventiv will provide 164 full-time sales representatives dedicated to promoting Gralise. The Ventiv sales representatives were hired and commenced training in September. In October, we initiated commercial sales of Gralise.

As a result of the Santarus commercialization agreement entered into in August 2011, we will no longer have promotion fee expense to Santarus going forward. However, we expect selling, general and administrative expense to increase as we incur costs associated with our contract sales organization and related marketing for Gralise.

Interest Income and Expense

	1	Three Months End	ded Sep	tember 30,	Nine Months End	ded Sept	tember 30,
(in thousands)		2011		2010	2011		2010
Interest and other income	\$	410	\$	100 \$	846	\$	251
Interest expense		(24)		(130)	(133)		(471)
Net interest income (expense)	\$	386	\$	(30) \$	713	\$	(220)

Interest and other income increased during the three and nine months ended September 30, 2011 as compared to the corresponding period in 2010 as a result of higher investment balances.

Interest expense 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.

Benefit From Income Taxes

The income tax benefit of \$0.3 million for the three months and nine months ended September 30, 2011 represents a tax benefit from our ability to carry back our taxable loss in the current period to offset income taxes previously paid. As a result of the enactment of the American Recovery and Reinvestment Act of 2009 in February 2009, we are able to carry back fiscal year 2011 operating losses to the extent of our taxable income for our fiscal year 2007. We received this refund in the fourth quarter of 2011. The income tax benefit for the three months and nine months ended September 30, 2011 was partially offset by state income tax expenses.

LIQUIDITY AND CAPITAL RESOURCES

	Se	eptember 30,]	December 31,
(in thousands)		2011		2010
Cash, cash equivalents and marketable securities	\$	154,196	\$	76,888

Since inception through September 30, 2011, 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.

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In June 2008, we entered into a credit facility with GECC and Oxford. The credit facility was available in up to three tranches. The first tranche of \$3.8 million was advanced to us upon the closing of the loan agreement. In July 2008, we received the second tranche of \$5.6 million. The third tranche of \$5.6 million was not drawn and it is no longer available to us, and GECC and Oxford waived the 2% unused line fee related to the third tranche.

We paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Thereafter we were required to pay principal on the first tranche, plus interest at such rate, in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments with an interest rate of 11.59%. The credit facility was fully repaid in July 2011.

As of September 30, 2011, we have accumulated net losses of \$83.7 million. We may incur operating losses for the remainder of 2011. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of 2012. 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, including our contractual obligations to Ventiv and other arrangements we make for the commercialization of Gralise;
- 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 enter into;
- results of research and development efforts;
- changes in the focus and direction of our business strategy and/or research and development programs;
- technological advances;
- results of clinical testing, requirements of the FDA and comparable foreign regulatory agencies; and
- acquisitions or investment in complementary businesses, products or technologies.

We will need substantial funds of our own or from third parties to:

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

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 support 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 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:

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

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 provided by operating activities during the nine months ended September 30, 2011 was approximately \$72.4 million, compared to cash used in operating activities of approximately \$3.4 million during the nine months ended September 30, 2010. 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 million termination fee received from Abbott Products during the first quarter of 2011. Cash used in operating activities during the nine months ended September 30, 2010 was primarily due to our net income adjusted for movements in working capital, stock-based compensation and depreciation expense.

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Cash Flows from Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2011 was approximately \$80.6 million and consisted of an increase in marketable securities resulting from a partial investment of the milestone payment and settlement fee received from Abbott during the first quarter of 2011. Net cash used in investing activities during the nine months ended September 30, 2010 was approximately \$1.2 million and consisted primarily of a slight net increase in marketable securities resulting from investment of the milestone payment received from Abbott (\$10.0 million) in 2010.

Cash Flows from Financing Activities

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. Cash used in financing activities during the nine months ended September 30, 2010 was approximately \$1.9 million and consisted of repayments of principal on our credit facility offset by proceeds from employee and consultant option exercises.

Contractual Obligations

As of September 30, 2011, our aggregate contractual obligations are as shown in the following table (in thousands):

	Less than			
	1 year	1-3 years		Total
Operating leases	\$ 1,717	\$ (614	\$ 2,331
Related parties	303			303
Contract sales organization	19,059			19,059
Purchase commitments	1,522			1,522
	\$ 22,601	\$ (614	\$ 23,215

At September 30, 2011, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$1.5 million under our manufacturing agreement with Patheon Puerto Rico, Inc. for the manufacture of Gralise. The amounts disclosed only represent minimum purchase requirements. Actual purchases are expected to exceed these amounts.

Pursuant to the separation agreement and release entered into with Carl A. Pelzel, our former President and Chief Executive Officer, we are obligated to pay Mr. Pelzel \$43,333 per month through April 2012.

In June 2011, we entered in to a service agreement with Ventiv, who will provide us with sales force recruiting, training, deployment and ongoing operational support to promote Gralise in the U.S. through 164 full-time sales representatives. Each month we are required to pay

Ventiv a monthly fixed fee of \$1.8 million during the term of the Ventiv Agreement. We may terminate the service agreement on the one year anniversary of the deployment date of the sales representatives. We have included an estimate of our expected contractual obligations to Ventiv based upon this fee and expected one year anniversary of deployment date of the sales representatives.

The contractual obligations reflected in this table exclude \$3.0 million of contingent milestone payments we may be obligated to pay in the future under our sublicense agreement with PharmaNova related to the development of Serada. The payments relate to various milestones for the product candidate under the sublicense agreement, including submission to the FDA of an NDA, and FDA approval of an NDA. The above table also excludes any future royalty payments we may be required to pay on products we have licensed.

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, 2010.

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 Vice President, Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of

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the end of the period covered by this quarterly report. Based on that evaluation, our management, including our Chief Executive Officer and Vice President, Finance, 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, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Depomed v. Sun Pharmaceutical (U.S. Generic Glumetza Litigation)

In June, 2011, a lawsuit was filed 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. (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. 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.

Depomed v. Lupin (U.S. Generic Glumetza Litigation)

In November 2009, a lawsuit was filed in the United States District Court for the Northern District of California against Lupin Limited and its wholly-owned subsidiary, Lupin Pharmaceutical, Inc. (Lupin), for infringement of four (4) 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 Lupin with the FDA regarding Lupin s intent to market generic versions of 500mg and 1000mg dosage strengths of Glumetza prior to the expiration of the Orange Book, which

includes U.S. Patent Nos.: 6,340,475; 6,488,962; 6,635,280; and 6,723,340. U.S. Patent No. 6,723,340 was subsequently removed from the litigation proceedings in an amended complaint. The lawsuit commenced within the 45 days required to automatically stay, or bar, the FDA from approving Lupin s ANDA for 30 months or until a district court decision that is adverse to the patents, whichever occurs earlier. Absent a court decision, the 30-month stay is expected to expire in May 2012. Lupin has prepared and filed an answer in the lawsuit, principally asserting non-infringement and invalidity of the Orange Book patents, and has also filed counterclaims. Discovery is currently underway and a hearing for claim construction, or Markman hearing, was held on January 2011, which resulted in all ten (10) claim terms at issue in the lawsuit, construed in Depomed s favor. A bench trial is currently scheduled for August 13, 2012.

Diovan ana Depomea v. Aboiex (Canaaian Generic Giumeiza Lingano)	pomed v. Apotex (Canadian Generic Glumetza Litigati	Generic ((Canadian	Apotex	pomed v.	l and	Biovail
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In December 2007, Apotex, Inc. (Apotex) filed the Canadian equivalent of an U.S. Abbreviated New Drug Application (ANDA) in Canada seeking approval to market a generic version of the 500mg formulation of the Glumetza product in Canada.

In February 2010, Valeant and Depomed filed a complaint in the Federal Court in Canada against Apotex for infringement of Canadian Patent No. 2,290,624, which is owned in its entirety by Depomed.

Also, in February 2010, Apotex received clearance from the Canadian Minister of Health to market the generic version of the 500mg formulation, however, to date, Apotex has not launched the generic version of Glumetza in Canada. This litigation is currently stayed.

An adverse outcome in this matter could substantially weaken our Canadian intellectual property.

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ITEM 1A. RISK FACTORS

The risk factors presented below amend and restate the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

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.

We may not successfully commercialize Gralise, which would harm our business.

Although Gralise has been approved for marketing, our ability to generate significant revenue from Gralise requires that we successfully commercialize the product on our own or with the assistance of a collaborative co-promotion or licensing partner. We began commercial sales of Gralise in October 2011. Other than Ventiv, with whom we have contracted to provide sales force recruiting, training, deployment and operational support for this product, we do not currently have other partners assisting us with the commercialization of Gralise. We are a small organization with limited experience selling and marketing pharmaceutical products, and have had little time to build capabilities necessary to commercialize the product. We may not be able to adequately or timely build or maintain the necessary sales, marketing, manufacturing, managed markets or other capabilities on our own that are required to successfully commercialize Gralise, and we may not enter into arrangements with other collaborative partners or other third parties to perform those functions for us. Ventiv and other contract parties and partners may not perform as required under their contracts with us or as expected. Also, the establishment and maintenance of those capabilities may require us to divert capital from other intended purposes.

Given the small size of our company and the limited experience and expertise of our current staff in selling and marketing pharmaceutical products, effectively managing a significant number of collaborative partners and third-party contractors may be challenging. If our management of collaborative partners and third-party contractors is not effective, the commercial acceptance and success of Gralise may be limited and our business would be harmed.

If we enter into a collaborative co-promotion or licensing arrangement related to Gralise, some or all of the revenues we receive will depend upon the efforts of one or more third parties, which may not be successful.

We may not be able to obtain orphan drug exclusivity for Gralise in PHN.

The FDA has granted Gralise Orphan Drug designation for the management of PHN based on the size of the PHN population and the reduced 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. Subsequent to the FDA s approval of Gralise, we were informed additional submissions or evidence to

demonstrate the clinical superiority of Gralise based on improved safety will be required to be provided to the FDA in order to obtain a seven-year period of orphan exclusivity in PHN. In October 2011, the FDA proposed regulations to amend its 1992 Orphan Drug regulations implementing the Orphan Drug Act. According to the FDA, the proposed amendments are intended to clarify certain provisions of the regulations and make minor improvements to address issues that have arisen since the regulations were issued. If adopted as proposed, it is possible the amendments will adversely affect our request for orphan drug exclusivity for Gralise.

If we obtain the orphan exclusivity, the FDA may not approve another application to market the same drug for the same indication until January 2018, except in very limited circumstances.

We cannot be certain that the FDA will grant Gralise orphan exclusivity in PHN. If we do not obtain orphan exclusivity for Gralise, the period of market exclusivity in the United States for Gralise may be reduced, which would adversely affect our revenues.

Our prior clinical trials evaluating Serada for menopausal hot flashes failed to meet all of their primary endpoints and there can be no assurance this product will be approved for marketing.

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 primary endpoints. Although we intend to meet with and discuss the results of the trials with the FDA, there can be no assurance that the FDA will determine the product candidate is sufficiently safe and effective to allow a New Drug Application to be submitted to the FDA. In the event the FDA allows us to file a New Drug Application for Serada based on the results of our three completed Phase 3 clinical trials, there can be no assurance that such New Drug Application will be approved.

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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 such patent(s) are not upheld or if the generic competitor is found not to infringe such patent(s). 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.

In November 2009, we filed a lawsuit in the United States District Court for the Northern District of California against Lupin for infringement of U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; and 6,723,340 listed in the Orange Book for Glumetza. The lawsuit is in response to an ANDA filed by Lupin with the FDA regarding Lupin s intent to market generic versions of the 500mg and 1000mg strengths of Glumetza prior to the expiration date of the asserted patents. We commenced the lawsuit against Lupin within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Lupin s ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. The 30-month stay expires in May 2012. 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 Glumetza prior to resolution of the litigation. Any introduction of one or more products generic to Glumetza would harm our business, financial condition, results of operations and cash flows.

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. (Sun), for infringement of the patents listed in the Orange Book for Glumetza. The lawsuit is in response to an Abbreviated New Drug Application 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. We commenced the lawsuit 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 may occur earlier.

In December 2007, Apotex, Inc. (Apotex) filed the Canadian equivalent of an Abbreviated New Drug Application in Canada seeking approval to market a generic version of the 500mg formulation of Glumetza in Canada. In February 2010, Apotex received clearance from the Minister of Health in Canada to market the generic version of the 500mg formulation of Glumetza. However, to date, Apotex has not launched a generic version of Glumetza in Canada. Also in February 2010, the Company and Valeant filed a complaint in the Federal Court in Canada against Apotex for infringement of our Canadian Patent No. 2,290,624. If we are not able to successfully enforce our patent and prevent the launch of Apotex s product, the resulting competition would reduce our sales and revenue for Glumetza.

The filing of the Lupin and Sun ANDAs described above, Apotex s generic Glumetza, 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, financial condition and cash flows.

We depend heavily on Santarus, Inc. for the successful commercialization of Glumetza in the United States.

In August 2011, we entered into a commercialization agreement with Santarus, Inc. (Santarus) pursuant to which Santarus assumed broad commercial, manufacturing and regulatory responsibility for the commercialization of Glumetza. The commercialization agreement replaces the promotion agreement we entered into with Santarus in July 2008. Under the commercialization agreement, we transitioned most U.S. commercial activities relating to Glumetza to Santarus, as well as the New Drug Application for Glumetza. Santarus will pay us royalties on net sales of Glumetza and will not pay any additional sales milestones that were required under the promotion agreement. The commercialization agreement provides for a reduced minimum spend obligation. Although we have retained rights to promote Glumetza to physicians not called on by us, we do not have any immediate plans to exercise our Glumetza co-promotion rights. Accordingly, the success of the commercialization of Glumetza will depend in large part on Santarus

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commercia	alization efforts. Other factors that may affect the success of our commercialization arrangement with Santarus include the following:
•	Santarus may acquire or develop alternative products (as it did in the third quarter of 2010);
•	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;
• in the Unit	the outcome of our ongoing litigation against Lupin Limited seeking to prevent Lupin from marketing a generic version of Glumetzated States;
• version of	the outcome of our ongoing litigation against Sun Pharmaceuticals Industries Ltd. seeking to prevent Sun from marketing a generic Glumetza in the United States;
•	Santarus may experience financial difficulties; and
•	Santarus may fail to comply with its obligations under our commercialization agreement.
version of affect Sant	n to the factors described above, Santarus business and product revenue have been adversely affected by the introduction of a generi its Zegerid® (omeprazole/sodium bicarbonate) prescription products in the third quarter of 2010. Any of the preceding factors could tarus commitment to the collaboration, which, in turn, could adversely affect the commercial success of Glumetza. Any failure by a successfully commercialize Glumetza could have a material adverse effect on our business, financial condition, results of operations lows.

The development of drug candidates is inherently uncertain and we cannot be certain that any of our product candidates will be approved for

marketing or, if approved, will achieve market acceptance.

Our drug candidate DM-1992 for Parkinson s is in clinical development. We also have other product candidates in earlier stages of development.

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. Additionally, clinical trial results in earlier trials may not be indicative of results that will be obtained in subsequent larger trials, as was the case with the Phase 3 trial for Gralise for the management of postherpetic neuralgia that we completed in 2007, and with the Phase 3 trials evaluating Serada for menopausal hot flashes we completed in October 2011.

Clinical development is a long, expensive and uncertain process and is subject to delays. Positive or encouraging results of prior clinical trial are not necessarily indicative of the results we will obtain in later clinical trials. 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
- real or perceived lack of effectiveness or safety of the product candidate.

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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 frames for commercialization of any products are 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.

We 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, 2011, we recorded total revenues of \$120.8 million and for the years ended December 31, 2010, 2009 and 2008, we recorded total revenues of \$80.8 million, \$57.7 million, and \$34.8 million, respectively. Collaborative milestones and settlement fees received from Abbott Products, Janssen and Merck resulted in the Company reaching profitability for the nine months ended September 30, 2011 and the year ended December 31, 2010. For the years ended December 31, 2009 and 2008, we incurred net losses of \$22.0 million and \$15.3 million, respectively. We may incur operating losses for the remainder of 2011. Any such losses may have an adverse impact on our total assets, shareholders equity and working capital.

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;
- our efforts to secure a commercialization partner for Gralise;
- 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;
•	the degree of commercial success of Glumetza;
•	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 Lupin and Sun for Glumetza;
• contract re	variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other evenues;
•	market acceptance of the Acuform technology;
•	adoption of new technologies by us or our competitors;
•	the introduction of new products by our competitors;
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support key programs.

•	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.		
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.		
Ironwood. less defini	tly have collaboration or license arrangements with Santarus, Covidien, Merck, Janssen, Boehringer Ingelheim, PharmaNova and In addition, we have in the past and may in the future enter into other collaborative arrangements, some of which have been based on tive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not finitive agreements formalizing these arrangements.	
parties, inc provisions potential p preclude u arrangeme Moreover,	ive relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the cluding the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of roducts, and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements may also limit or s from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these nts might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could be enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to	

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. Further, even if we do enter into collaboration arrangements, it is possible that our collaborative partners may not choose to develop and commercialize products using the Acuform technology. 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;

• failure by a collaborative partner to devote sufficient resources to the development and commercial sales of products using the Acuform technology.

premature termination of a collaboration agreement; or

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.

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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 that our capital resources are insufficient to meet our future capital requirements, in order to continue our development programs, 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:

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

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 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. For example, Pfizer has initiated several suits against companies marketing generic gabapentin products, claiming that these products infringe Pfizer s patents. The results of this litigation could adversely impact the commercialization of pharmaceutical products that contain gabapentin as an active pharmaceutical ingredient. Also, 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

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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.

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. 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 prescriptions for Serada 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. Such competition would reduce sales of Serada and our revenues which could have a material adverse effect on our business.

It is difficult to develop a successful product. If we do not continue to develop successful products, our financial position and liquidity will be adversely affected.

The drug development process is costly, time-consuming and subject to unpredictable delays and failures. Before we or others make commercial sales of products using the Acuform technology, other than Gralise and Glumetza, we, our current and any future collaborative partners will need to:

- conduct preclinical and clinical tests showing that these products are safe and effective; and
- obtain regulatory approval from the FDA or foreign regulatory authorities.

We will have to curtail, redirect or eliminate our product development programs if we or our collaborative partners find that:

- the Acuform technology has unintended or undesirable side effects; or
- product candidates that appear promising in preclinical or early-stage clinical studies do not demonstrate efficacy in later-stage, larger scale clinical trials.

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.		
If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed and our stock price may decline.		
For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development and commercialization goals. These milestones may include our expectations regarding the commercial launch of our products by us or our licensees, and the commencement or completion of scientific studies and clinical trials and the submission or approval of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, or the commercial launch of		
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•	the efforts of our marketing partners with respect to the commercialization of our products;
• conflicts v	the rate of progress, costs and results of our clinical trial and research and development activities, including the extent of scheduling with participating clinicians and clinical institutions and our ability to identify and enroll patients who meet clinical trial eligibility
•	our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;

products. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary considerably from our

- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including materials for our Acuform technology;
- our available capital resources; and

other actions by regulators;

• the costs of ramping up and maintaining manufacturing operations, as necessary.

estimates depending on numerous factors, some of which are beyond our control, including:

If we fail to achieve our announced milestones in the timeframes we announce and expect, our business and results of operations may be harmed and the price of our stock may decline.

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.

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 be harmed.

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

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(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.

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 or 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. Any such fines or sanctions could adversely affect our financial condition and results of operations.

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.

Pharmaceutical marketing is subject to substantial regulation in the United States.

All marketing activities associated with Gralise 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

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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. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG, the FDA, and DOJ allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. If the OIG or the FDA takes the position that we are not in compliance with such requirements, and, if such non-compliance is proven, 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.

The approval process outside the United States is uncertain and may limit our ability to develop, manufacture and sell our products internationally.

To market any of our products outside of the United States, we and our collaborative partners, including Janssen, Merck, Boehringer Ingelheim, Ironwood and Madaus, are subject to numerous and varying foreign regulatory requirements, implemented by foreign health authorities, governing the design and conduct of human clinical trials and marketing approval for drug products. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country, nor does the approval by foreign health authorities ensure approval by the FDA.

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

In both domestic and foreign markets, sales of our 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.
receiving a	sement is not available for our products or product candidates, demand for these products may be limited. Further, any delay in approval for reimbursement from third-party payers could have an adverse effect on our future revenues. Third-party payers are ly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty

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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 any product we may develop.

We may be unable to compete successfully in the pharmaceutical product and drug delivery technology industries.

Other companies that have oral drug delivery technologies competitive with the Acuform technology include Elan Corporation, Bristol-Myers Squibb, TEVA Pharmaceutical Industries, Ltd., Johnson & Johnson, SkyePharma plc, Flamel Technologies S.A., Ranbaxy Laboratories, Ltd., and Intec Pharma, all of which develop oral tablet products designed to release the incorporated drugs over time. Each of these companies has patented technologies with attributes different from ours, and in some cases with different sites of delivery to the gastrointestinal tract.

Bristol-Myers Squibb is currently marketing a sustained release formulation of metformin, Glucophage XR, with which Glumetza competes. The limited license that Bristol-Myers Squibb obtained from us under our 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, including Barr Pharmaceuticals, Inc., Mylan Laboratories, Inc. and Teva Pharmaceutical Industries, Ltd. have received FDA approval for and are selling an extended-release metformin product. There may be other companies developing products competitive with Glumetza of which we are unaware.

Gabapentin is currently marketed by Pfizer as Neurontin® for adjunctive therapy for epileptic seizures and for postherpetic 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 postherpetic pain, fibromyalgia, diabetic nerve pain and for adjunctive therapy for epileptic seizures. In April 2011, GlaxoSmithKline and Xenoport, Inc. s HorizantTM (gabapentin enacarbil extended-release tablets) received FDA approval in the United States for restless leg syndrome. There may be other companies developing products competitive with Gralise of which we are unaware.

Competition in pharmaceutical products and drug delivery systems is intense. We expect competition to increase. Competing technologies or products developed in the future may prove superior to the Acuform technology or products using the Acuform technology, either generally or in particular market segments. These developments could make the Acuform technology or products using the Acuform technology noncompetitive or obsolete.

Most of our principal competitors have substantially greater financial, sales, marketing, personnel and research and development resources than we do. In addition, many of our potential collaborative partners have devoted, and continue to devote, significant resources to the development of their own drug delivery systems and technologies.

We depend on third parties who are single source suppliers to manufacture Gralise and our product candidates. If these suppliers are unable to manufacture Gralise or our product candidates, our business will be harmed.

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. Any failure to obtain Gralise tablets from Patheon, active pharmaceutical ingredient from suppliers, or excipient suppliers, could adversely affect our operating results.

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 products using the Acuform technology may adversely affect our ability to deliver such products on a timely or competitive basis. The manufacturing processes of our third party manufacturers may be found to violate the proprietary rights of others. If 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, the market introduction and commercial sales of our products will be delayed, and our future revenue will suffer.

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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 2011 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 harmed.

Our success is dependent in large part upon the continued services of our CEO 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.

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. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or such investment. 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 harm our operating results.

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.

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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. To the extent these costs are significant, our selling, general and administrative expenses are likely to increase.

If we sell shares of our common stock in future financings, existing common shareholders will experience immediate dilution and, as a result, our stock price may go down.

As capital raising opportunities present themselves, we may enter into financing arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common shareholders will experience dilution and this dilution will be greater if we find it necessary to sell securities at a discount to prevailing market prices.

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.

ITEM 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
Not applicable.	
ITEM 3.	DEFAULTS UPON SENIOR SECURITIES
Not applicable.	
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	ITEM 4	•	RESERVED
	Not appl	icable.	
ITEM 5.			OTHER INFORMATION
	Not appl	icable.	
	ITEM 6	. EXHIBIT	rs
	(a)	Exhibits 10.1* 10.2* 31.1 31.2	Commercial Manufacturing Services Agreement dated September 2, 2011 between the Company and Patheon Puerto Rico, Inc. Commercialization Agreement dated August 22, 2011 between the Company and Santarus, Inc. 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 Tammy L. Cameron

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Certification pursuant to 18 U.S.C. Section 1350 of James A. Schoeneck

Certification pursuant to 18 U.S.C. Section 1350 of Tammy L. Cameron

Interactive Data Files pursuant to Rule 405 of Regulation S-T

^{*} Confidential Treatment Requested

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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 7, 2011 DEPOMED, INC.

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

/s/ Tammy L. Cameron Tammy L. Cameron Vice President, Finance

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