

DEPOMED INC  
Form 10-Q  
May 06, 2011  
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

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

**FOR THE QUARTERLY PERIOD ENDED March 31, 2011**

**OR**

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

**FOR THE TRANSITION PERIOD FROM      TO**

**COMMISSION FILE NUMBER 001-13111**

**DEPOMED, INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

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**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  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

The number of issued and outstanding shares of the Registrant's Common Stock, no par value, as of May 3, 2011 was 53,673,167.

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DEPOMED, INC.

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	<b>March 31, 2011 (Unaudited)</b>	<b>December 31, 2010 (1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 83,850	\$ 22,526
Marketable securities	51,895	47,825
Accounts receivable	6,195	6,094
Receivables from collaborative partners	10,583	253
Inventories	3,465	1,571
Prepaid and other current assets	2,327	1,330
Total current assets	158,315	79,599
Marketable securities, long-term	22,045	6,537
Property and equipment, net	782	698
Other assets	197	197
	\$ 181,339	\$ 87,031
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	18,788	18,473
Deferred product sales	515	1,041
Deferred license revenue	11,506	10,665
Other current liabilities	443	635
Current portion of long-term debt	1,160	2,170
Total current liabilities	32,412	32,984
Deferred license revenue, non-current portion	23,954	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 March 31, 2011 and December 31, 2010		
Common stock, no par value, 100,000,000 shares authorized; 53,653,030 and 52,957,787 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	194,404	191,343
Accumulated deficit	(69,489)	(168,306)
Accumulated other comprehensive gain	58	69
Total shareholders' equity	124,973	23,106
	\$ 181,339	\$ 87,031

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(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 Ended March 31,	
	2011	2010
Revenues:		
Product sales	\$ 15,311	\$ 12,601
Royalties	165	88
License and collaborative revenue	67,625	2,671
Total revenues	83,101	15,360
Costs and expenses:		
Cost of sales	1,635	1,481
Research and development expense	5,154	5,187
Selling, general and administrative expense:		
Promotion fee expense	10,262	8,879
Other selling, general and administrative expense	7,241	3,550
Total selling, general and administrative expense	17,503	12,429
Gain on settlement agreement	(40,000)	
Total costs and expenses	(15,708)	19,097
Income (loss) from operations	98,809	(3,737)
Other income (expense):		
Interest and other income	79	94
Interest expense	(69)	(183)
Total other income (expense)	10	(89)
Net income (loss) before income taxes	98,819	(3,826)
Benefit from (provision for) income taxes	(2)	(1)
Net income (loss)	\$ 98,817	\$ (3,827)
Basic net income (loss) per common share	\$ 1.85	\$ (0.07)
Diluted net income (loss) per common share	\$ 1.77	\$ (0.07)
Shares used in computing basic net income (loss) per common share	53,353,287	52,298,726
Shares used in computing diluted net income (loss) per common share	55,754,051	52,298,726

See accompanying notes to Condensed Financial Statements.

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## DEPOMED, INC.

## CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2011	2010
<b>Operating Activities</b>		
Net income (loss)	\$ 98,817	\$ (3,827)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	149	153
Stock-based compensation	702	545
Changes in assets and liabilities:		
Accounts receivable	(10,430)	(1,343)
Inventories	(1,894)	(195)
Other current assets	(998)	(1,449)
Accounts payable and other accrued liabilities	1,498	539
Accrued compensation	(1,390)	(1,331)
Deferred revenue	(6,656)	(2,712)
Net cash provided by (used in) operating activities	79,798	(9,620)
<b>Investing Activities</b>		
Purchases of property and equipment	(162)	(49)
Purchases of marketable securities	(31,627)	(32,546)
Maturities of marketable securities	11,991	20,932
Sales of marketable securities		2,490
Net cash used in investing activities	(19,798)	(9,173)
<b>Financing Activities</b>		
Principal payments on long-term debt	(1,034)	(921)
Proceeds from issuance of common stock	2,358	317
Net cash provided by (used in) financing activities	1,324	(604)
Net increase (decrease) in cash and cash equivalents	61,324	(19,397)
Cash and cash equivalents at beginning of period	22,526	26,821
Cash and cash equivalents at end of period	\$ 83,850	\$ 7,424

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 March 31, 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 our 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:
  - Glumetza®: The Company sells Glumetza® (metformin hydrochloride extended release tablets) to wholesalers and retail pharmacies subject to rights of return six months before product expiration and up to twelve months after product expiration. The Company recognizes revenue for Glumetza sales at the time title transfers to its customers, which occurs at the time product is delivered to its customers.
  - Proquin®XR: Until the fourth quarter of 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

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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 \$0.5 million at March 31, 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. 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

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accrues Medicaid rebates based on product pricing, current rebates and changes in the level of discounts the Company offers that may affect the level of Medicaid discount, historical and estimated future percentages of product sold to Medicaid recipients and estimated levels of inventory in the distribution channel.

- **Chargebacks** The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the

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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. 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 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. We elected to adopt this guidance prospectively, effective for our fiscal year beginning January 1, 2011. Upon adoption, the guidance did not have a material impact on our financial statements and is not expected to have a material impact on our future operating results.

**NOTE 2. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES**

Securities classified as cash and cash equivalents and available-for-sale marketable securities as of March 31, 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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March 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Cash and cash equivalents:</b>				
Cash	\$ 3,816	\$	\$	\$ 3,816
Money market funds	78,034			78,034
U.S. Treasury securities	2,000			2,000
<b>Total cash and cash equivalents</b>	<b>\$ 83,850</b>	<b>\$</b>	<b>\$</b>	<b>\$ 83,850</b>
<b>Available-for-sale securities:</b>				
<b>Total maturing within 1 year and included in marketable securities:</b>				
U.S. corporate debt securities	13,125	5		13,130
U.S. government agency debt securities	22,177	14		22,191
U.S. Treasury securities	16,532	42		16,574
<b>Total maturing between 1 and 2 years and included in marketable securities:</b>				
U.S. corporate debt securities				
U.S. government agency debt securities	12,054		(4)	12,050
U.S. Treasury securities	9,994	2	(1)	9,995
<b>Total available-for-sale securities</b>	<b>\$ 73,882</b>	<b>\$ 63</b>	<b>\$ (5)</b>	<b>\$ 73,940</b>
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 157,732</b>	<b>\$ 63</b>	<b>\$ (5)</b>	<b>\$ 157,790</b>

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

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 March 31, 2011, the Company had seven securities in an unrealized loss position. The following table shows the gross unrealized losses and fair value of the Company's investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at March 31, 2011 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government agency debt securities	\$ 12,050	\$ (4)	\$	\$	\$ 12,050	\$ (4)
U.S. Treasury securities	7,003	(1)			7,003	(1)
<b>Total available-for-sale</b>	<b>\$ 19,053</b>	<b>\$ (5)</b>	<b>\$</b>	<b>\$</b>	<b>\$ 19,053</b>	<b>\$ (5)</b>

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,

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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 March 31, 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.

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

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 78,034	\$	\$	\$ 78,034
U.S. corporate debt securities		13,130		13,130
U.S. government agency debt securities		34,241		34,241
U.S. Treasury securities		28,569		28,569
<b>Total</b>	<b>\$ 78,034</b>	<b>\$ 75,940</b>	<b>\$</b>	<b>\$ 153,974</b>

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
<b>Total</b>	<b>\$ 17,613</b>	<b>\$ 55,362</b>	<b>\$</b>	<b>\$ 72,975</b>

There are no financial liabilities measured at fair value on a recurring basis as of March 31, 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 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:

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(in thousands, except for per share amounts)</b>	
<b>Numerator:</b>		
Net income (loss)	\$ 98,817	\$ (3,827)
Denominator for basic net income (loss) per share	53,353	52,298
Net effect of dilutive common stock equivalents	2,401	
Denominator for diluted net income (loss) per share	55,754	
<b>Basic net income (loss) per share</b>	<b>\$ 1.85</b>	<b>\$ (0.07)</b>



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Diluted net income (loss) per share	\$	1.77	\$	(0.07)
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For the three months ended March 31, 2011 and 2010, 0.5 million and 5.6 million common stock equivalents, respectively, were not included in dilutive shares because their effect is anti-dilutive.

### NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

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

In November 2008, the Company entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) granting Solvay exclusive rights to develop and commercialize Gralise™ (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

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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 Galise license agreement; (ii) the transition of Galise 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 scheduled to be recognized 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 \$1.6 million, for a net receipt of approximately \$8.4 million in April 2011. The Company expects to receive the remaining \$1.6 million of taxes previously withheld directly from German tax authorities by the end of the third quarter of 2011.

The \$10.0 million upfront fee is being amortized ratably through October 2011, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. The Company recognized approximately \$1.0 million of revenue associated with this upfront license fee during the three months ended March 31, 2011. The remaining deferred revenue balance is \$9.0 million at March 31, 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.

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 \$0.1 million of revenue associated with the reimbursement of formulation work under the

service agreement during the three months ended March 31, 2011.

*Santarus, Inc.*

Under the Company's promotion agreement with Santarus, Inc. (Santarus) originally entered into in July 2008, Santarus has exclusive rights to promote Glumetza in the United States. Santarus began promotion of Glumetza in October 2008. Santarus is required to meet certain minimum promotion obligations during the term of the agreement, and is required to make certain minimum marketing, advertising, medical affairs and other commercial support expenditures. The Company continues to record revenue from the sales of Glumetza product, and starting in October 2008, began paying Santarus a promotion fee equal to 80% of the gross margin earned from net sales of Glumetza product in the United States. The promotion fee was reduced to 75% of gross margin beginning in the fourth quarter of 2010. For the three months ended March 31, 2011 and 2010, the Company recognized \$10.3 million and \$8.9 million, respectively, in promotion fee expense under the agreement, which is classified within selling, general and administrative expense.

The Company is also entitled to receive sales milestones payments from Santarus totaling up to \$16.0 million, based on achieving certain levels of net product sales of Glumetza. In January 2011, the Company achieved the first of these sales milestones

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related to net sales of Glumetza reaching \$50.0 million for the 13 month period ending January 31, 2011. As the milestone was achieved and related to past performance the entire \$3.0 million was recognized in its entirety as milestone revenue in the first quarter of 2011.

**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 \$0.1 million and \$0.2 million for the three months ended March 31, 2011 and 2010 respectively.

As of March 31, 2011, the outstanding balance under the facility was \$1.2 million, and the unamortized portion of the debt issuance costs was approximately \$0.1 million. The credit facility is expected to be fully repaid by July 2011.

The obligations of the Company under the loan agreement are secured by interests in all of the Company's personal property, and proceeds from any intellectual property, but not by the Company's intellectual property.

The credit facility contains affirmative and negative covenants with which the Company must comply, and imposes restrictions with regards to additional indebtedness, liens, various fundamental changes (including mergers and acquisitions), payments, investments, transactions with affiliates, and other limitations customary in secured credit facilities. The Company was in compliance with such covenants as of March 31, 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 Ended March 31,**

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	2011		2010	
Cost of sales	\$	19	\$	3
Research and development expense		155		166
Selling, general and administrative expense		528		376
Total	\$	702	\$	545

At March 31, 2011, the Company had \$3.6 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 1.9 years.

**NOTE 7. COMPREHENSIVE INCOME (LOSS)**

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

	Three Months Ended March 31,	
	2011	2010
Net income (loss)	\$ 98,817	\$ (3,827)
Unrealized (loss) on available-for-sale securities	(11)	
Total comprehensive income (loss)	\$ 98,806	\$ (3,827)

Table of Contents**NOTE 8. INVENTORIES**

Inventories relate to the manufacture of the Company's GLUMETZA and Proquin XR products. Inventories are stated at the lower of cost or market and consist of the following (in thousands):

	March 31, 2011	December 31, 2010
Raw materials	\$ 73	\$ 74
Work-in-process		202
Finished goods	3,371	1,254
Deferred costs	21	41
Total	\$ 3,465	\$ 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):

	March 31, 2011	December 31, 2010
Accounts payable	\$ 464	\$ 1,655
Accrued compensation	1,248	2,638
Accrued clinical trial expense	905	307
Accrued rebates and sales discounts	2,973	2,625
Allowance for product returns	5,859	5,355
Accrued promotion fee	3,348	2,490
Other accrued liabilities	3,991	3,403
Total accounts payable and accrued liabilities	\$ 18,788	\$ 18,473

**NOTE 10. SHAREHOLDERS' EQUITY***Option Exercises*

For the three months ended March 31, 2011, employees and consultants exercised options to purchase 695,243 shares of the Company's common stock with net proceeds to the Company of approximately \$2.4 million.

**NOTE 11. INCOME TAXES**

As of December 31, 2010 and March 31, 2011, the Company had \$3.4 million of unrecognized tax benefits, which is netted against deferred tax assets and the remainder is fully offset by a valuation allowance. 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 12. SUBSEQUENT EVENTS**

*Carl A. Pelzel Separation Agreement*

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 will be 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 will also pay 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 expects to record a one-time severance charge of approximately \$1.0 million in the second quarter of 2011 with respect to this separation agreement, consisting of approximately \$0.4 million in stock-based compensation related to the accelerated vesting of Mr. Pelzel's awards and approximately \$0.6 million of severance expense related to future payments and health care benefits.

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**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 prepare for and launch Gralise™ (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);
- the commercial success and market acceptance of Gralise and our own efforts, or those of any future commercialization partner, with respect to the commercialization of Gralise;
- results and timing of our clinical trials, including the results of Breeze 3, our Phase 3 trial evaluating Serada® for menopausal hot flashes;
- the commercial success and market acceptance of Serada if we receive approval to market Serada in the United States;
- any patent infringement or other litigation that may be instituted related to Serada or Gralise 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 results of our ongoing litigation against Lupin Limited (Lupin) related to Lupin's abbreviated New Drug Application (ANDA) 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;
- 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. In January 2011, the U.S. Food and Drug Administration (FDA) approved Galise (gabapentin) once-daily tablets for the management of postherpetic neuralgia. In March 2011, we and our former licensee, Abbott Products, terminated our Galise exclusive license agreement and the rights to Galise reverted back to us. We intend to commercialize Galise on our own or with the assistance of a promotion partner or licensee.

In October 2009, we announced the results of our Breeze 1 and Breeze 2 clinical trials for Serada, our proprietary extended release formulation of gabapentin for the treatment of menopausal hot flashes. The higher dose formulation of Serada evaluated in the studies met five of eight co-primary endpoints across the two studies, while the lower dose formulation evaluated met four of eight co primary endpoints. In August 2010, we commenced one additional Phase 3 clinical trial evaluating Serada for menopausal hot flashes, known as Breeze 3, after reaching an agreement with the FDA regarding a Special Protocol Assessment (SPA) on the design and analysis of Breeze 3. In March 2011, we completed enrollment in Breeze 3.

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

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compounds upon which they are based and may be promoted together within a specialty pharmaceutical field, such as 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), and Boehringer Ingelheim International GMBH (Boehringer Ingelheim) and our license agreement with Merck & Co., Inc. (Merck) are examples of this strategy.

In addition to Gralise, we have developed two other products which have been approved by the FDA. Glumetza (metformin hydrochloride extended-release tablets) is a once-daily treatment for adults with type 2 diabetes that we commercialize in the United States with Santarus. Proquin® XR (ciprofloxacin hydrochloride) is a once-daily treatment for uncomplicated urinary tract infections that we no longer manufacture or market.

The following table summarizes our product pipeline and marketed products.

*Product Pipeline*

Product	Indication	Status
Serada®	Menopausal hot flashes	Two Phase 3 studies completed (Breeze 1 and Breeze 2). One additional Phase 3 study (Breeze 3) initiated in August 2010. Enrollment completed in March 2011. Top-Line results expected in the fourth quarter of 2011.
DM-1992	Parkinson's disease	Second Phase 1 study completed in February 2011.
DM-3458	Gastroesophageal reflux disease	Proof of concept studies completed.

*Approved Products\**

Product	Indication	Status
GLUMETZA®	Type 2 diabetes	Currently sold in the United States and Canada. <i>Co-promoted in the United States with Santarus.</i> <i>Canadian rights held by Valeant.</i>
Gralise™	Postherpetic neuralgia	Approved by the FDA in January 2011. Commercial launch expected in late 2011.

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\* We also developed Proquin XR (ciprofloxacin hydrochloride) extended-release tablets, a product approved for marketing in the United States for the treatment of uncomplicated urinary tract infections. We no longer manufacture or market this product.

*Significant Developments and Highlights for the Quarter Ended March 31, 2011*

- 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 that we received in February 2011.
- In January 2011, we resumed supply of the 500mg Glumetza.
- In February 2011, we completed our Phase 1 trial of DM-1992 for Parkinson's Disease.
- In March 2011, we completed enrollment of our Breeze 3 clinical trial for Serada for the treatment of menopausal hot flashes.
- In March 2011, the Company received a \$3.0 million sales milestone payment from Santarus, as we achieved the first sales milestone under the agreement with Santarus related to net sales of Glumetza reaching \$50.0 million for the 13 month period ending January 31, 2011.
- In March 2011, the Company and Abbott Products terminated the license agreement for Gralise, which provided for the transition of Gralise back to Depomed, and a \$40.0 million payment to Depomed, which we received in March 2011.
- In March 2011, we entered into a license and service agreement with Boehringer Ingelheim granting Boehringer a license to the Company's Acuform drug delivery technology to be used in developing fixed dose combinations of

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extended release metformin and proprietary Boehringer Ingelheim compounds in development for type 2 diabetes. In connection with the license and service arrangement, Boehringer agreed to pay a \$10.0 million upfront license fee.

- Revenue for the three months ended March 31, 2011 was \$83.1 million, compared to \$15.4 million for the three months ended March 31, 2010.
- Cash, cash equivalents and marketable securities were \$157.8 million as of March 31, 2011, compared to \$76.9 million as of December 31, 2010.

***PRODUCT DEVELOPMENTS AND TRANSACTIONS***

***Gralise™ (gabapentin) tablets for the Management of Postherpetic Neuralgia***

We are currently engaged in preparation, commercial manufacturing and a build-up of our commercial infrastructure in order to launch Gralise in 2011. We intend to launch Gralise on our own or with the assistance of a promotion partner or licensee.

Abbott Products. 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 the Company 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 March 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

***Serada® for Menopausal Hot Flashes***

Phase 3 Study-Breeze 3 Clinical Trial. 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. Breeze 3 is expected to be completed by the end of the third quarter of 2011, with top-line results expected to be reported in the fourth quarter of 2011.

*Study Design.* Breeze 3 is a randomized, double-blind, placebo-controlled study of up to 600 patients. Patients are 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 are 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 is 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.

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) up to 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, resulting in a more stable baseline, and thereby potentially reducing the placebo effect; and (iv) an alternative statistical analysis method, known as a non-parametric analysis, that is designed to reduce the influence significant outliers can have on the achievement of efficacy endpoints.

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***Glumetza for Type 2 Diabetes***

***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 \$1.6 million, for a net receipt of approximately \$8.4 million in April 2011. We expect to receive the remaining \$1.6 million of taxes previously withheld directly from German tax authorities by the end of the third quarter of 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.

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

***Santarus, Inc.***

Pursuant to our promotion agreement with Santarus in July 2008 and letter agreement with Santarus in October 2010, the Company received a \$3.0 million sales milestone payment from Santarus in March 2011, as we achieved the first sales milestone under the agreement with Santarus related to net sales of Glumetza reaching \$50.0 million for the 13 months ended January 31, 2011.

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

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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.

### **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.

Table of Contents**RESULTS OF OPERATIONS***Three Months Ended March 31, 2011 and 2010***Revenue**

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Product sales:</b>		
Glumetza	\$ 15,297	\$ 12,545
Proquin XR	14	56
Total product sales	15,311	12,601
<b>Royalties:</b>		
Glumetza	165	88
<b>License and collaborative revenue:</b>		
Gralise	60,593	1,561
Glumetza	3,635	626
Boehringer Ingelheim	1,094	
Covidien		458
Janssen	2,250	
Proquin XR (EU)		26
DM-1992	53	
Total license and collaborative revenue:	67,625	2,671
<b>Total revenues</b>	<b>\$ 83,101</b>	<b>\$ 15,360</b>

***Product sales***

***Glumetza.*** The increase in Glumetza product sales in the three months ended March 31, 2011 as compared to the three months ended March 31, 2010 is primarily driven by price increases as well as increased penetration of the 1000mg Glumetza in the branded metformin prescription market. This was partially offset by lower shipments of the 500mg Glumetza resulting from the 500mg Glumetza recall in 2010. We temporarily suspended product shipments of 500mg Glumetza product in June 2010 and did not resume shipments until January 2011. The 1000mg Glumetza product was not subject to the recall.

Product sales for Glumetza relative to its current runrate will depend in part on the success of product promotion efforts and any price adjustments.



***Royalties***

***Glumetza.*** Glumetza royalties relate to royalties we received from Valeant Pharmaceuticals International, Inc. (Valeant), based on net sales of Glumetza in Canada and royalties we received from LG based on net sales of LG's version of Glumetza, Novamet GR, in Korea. We began receiving royalties from Valeant in the first quarter of 2006 and from LG in the first quarter of 2007.

***License and collaborative revenue***

***Gralise.*** 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 the Company a \$25.0 million upfront fee in February 2009. The upfront payment received was originally scheduled to be recognized as revenue ratably until January 2013, which represented the estimated length of time 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.

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Glumetza. Glumetza license revenue increased during the three months ended March 31, 2011 as a result of recognition of a \$3.0 million sales milestone under the Santarus agreement. In January 2011, we achieved the first sales milestone under its 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 months ended March 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. We are recognizing the \$12.0 million upfront payment from Santarus as revenue ratably until October 2021, which represents the estimated length of time our obligations exist under the arrangement related to promotion fees we are obligated to pay Santarus on gross margin of Glumetza in the United States.

Boehringer Ingelheim. Under our license and services agreement with Boehringer Ingelheim entered into in March 2011, Boehringer Ingelheim paid the Company 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 expect to receive a refund payment from the German government in the third quarter of 2011 with respect to the withholding taxes previously withheld. The \$10.0 million is being amortized ratably through October 2011, which is the estimated length of time we are obligated to perform formulation work under the agreements. We recognized approximately \$1.0 million of revenue associated with this upfront license fee during the three months ended March 31, 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 of revenue associated with the reimbursement of formulation work under the service agreement during the three months ended March 31, 2011.

Janssen. In August 2010, we entered into a non-exclusive license agreement with Janssen granting Janssen a license to certain patents related to the Company's 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 Depomed is obligated to perform formulation work under the agreements. We recognized approximately \$1.9 million of revenue associated with this upfront license fee during the three months ended March 31, 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 three months ended March 31, 2011.

All formulation work under the agreement was complete at March 31, 2011 and there is no remaining deferred revenue at March 31, 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 and Proquin XR. Total cost of sales for the three months ended March 31, 2011, as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended March 31,</b>			
	<b>2011</b>		<b>2010</b>	
Cost of sales	\$	1,635	\$	1,481

Cost of sales also increased in 2011 as a result of an increase in 1000mg Glumetza product sales partially offset by lower shipments of the 500mg Glumetza.

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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 Galise back to us; 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.

Total research and development expense for the three months ended March 31, 2011 as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Research and development expense	\$ 5,154	\$ 5,187
Dollar change from prior year	(33)	
Percentage change from prior year	(1)%	

The slight decrease in research and development expense for the three months ended March 31, 2011 as compared to the three months ended March 31, 2010 was primarily due to reductions in research and development expense for Galise, which received FDA approval in the first quarter of 2011 partially offset by higher clinical research organization costs associated with our ongoing Breeze 3 Phase 3 clinical trial for Serada.

We expect to continue to incur significant research and development expenses resulting from the progress of Breeze 3, which is expected to be completed in the fourth quarter of 2011.

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

(In thousands)	Three Months Ended March 31,	
	2011	2010
Gralise	\$	\$ 1,377
Serada	3,253	1,948
Other projects	1,901	1,862
Total research and development expense	\$ 5,154	\$ 5,187

### 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, Glumetza and Proquin XR, 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 Ended March 31,	
	2011	2010
Selling, general and administrative expense:		
Promotion fee expense	\$ 10,262	\$ 8,879
Other selling, general and administrative expense	7,241	3,550
Total selling, general and administrative expense	\$ 17,503	\$ 12,429
Dollar change from prior year	5,074	
Percentage change from prior year	41%	

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The increase in selling, general and administrative expense was primarily due to increased market research costs and commercial infrastructure costs related to the anticipated launch of Galise in late 2011, an increase in Glumetza promotion fees to Santarus which was driven by an increase in Glumetza product sales, and increased legal expenses due to our mediation and settlement with Abbott Products and ongoing Lupin litigation with respect to Glumetza. We expect to selling, general and administrative expense to increase as we continue to build out our commercial infrastructure costs in anticipation for a product launch of Galise.

**Interest Income and Expense**

(in thousands)	Three Months Ended March 31,			
	2011		2010	
Interest and other income	\$	79	\$	94
Interest expense		(69)		(183)
Net interest income (expense)		10		(89)

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

**LIQUIDITY AND CAPITAL RESOURCES**

(in thousands)	March 31,		December 31,	
	2011		2010	
Cash, cash equivalents and marketable securities	\$	157,790	\$	76,888

In February 2011, we received a \$48.0 million development milestone payment from Abbott Products related to the FDA approval of Galise for the treatment of postherpetic neuralgia.

In March 2011, the Company and Abbott Products entered into a settlement agreement providing for the termination of the license agreement for Galise and a \$40.0 million payment to Depomed, which the Company received in March 2011.

Since inception through March 31, 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.

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 are 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%. As of March 31, 2011, the entire outstanding balance on the credit facility was \$1.2 million at an interest rate of 11.59%. We expect the credit facility will be fully repaid by July 2011.

Our obligations under the loan agreement are secured by interests in all of our personal property, and proceeds from any intellectual property, but not by our intellectual property. The loan agreement contains conditions precedent that must be satisfied prior to any borrowing and affirmative and negative covenants with which we must comply. The loan agreement imposes restrictions with regards to additional indebtedness, liens, various fundamental changes (including mergers and acquisitions), payments, investments, transactions with affiliates, and other limitations customary in secured credit facilities. As of March 31, 2011, we were in compliance with such covenants. The loan agreement provides that events of default will exist in certain circumstances, including failure to make payment of principal or interest on the loans when required, failure to perform certain obligations under the loan agreement and related documents, defaults in certain other indebtedness and certain other events. Upon an event of default, the principal amount of the loan may become due immediately.

As of March 31, 2011, we have accumulated net losses of \$69.5 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.

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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 and development efforts, including arrangements we make for the commercialization of Galise;
- 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 for the three months ended March 31, 2011 was approximately \$79.8 million, compared to cash used in operating activities of approximately \$9.6 million for the three months ended March 31, 2010. Cash provided by operating activities for the three months ended March 31, 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 three months ended March 31, 2010 was primarily due to our net loss adjusted for movements in working capital, stock-based compensation and depreciation expense.

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

Net cash used in investing activities during the three months ended March 31, 2011 was approximately \$19.8 million and consisted primarily of a net increase in marketable securities resulting from a partial investment of the milestone payment and settlement fee received from Abbott during the first quarter of 2011. Net cash used in investing activities during the three months ended March 31, 2010 was approximately \$9.2 million and consisted primarily of a net increase in marketable securities as a result of a shift in purchasing slightly longer term securities.

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

Cash provided by financing activities during the three months ended March 31, 2011 was approximately \$1.3 million and consisted of proceeds from employee and consultant option exercises offset by repayments of principal on our credit facility. Cash

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used in financing activities during the three months ended March 31, 2010 was approximately \$0.6 million and consisted of repayments of principal on our credit facility offset by proceeds from employee and consultant option exercises.

**Contractual Obligations**

As of March 31, 2011, our aggregate contractual obligations are as shown in the following table (in thousands):

	Less than 1 year		1-3 years		Total
Operating leases	\$ 1,408	\$	67	\$	1,475
Principal on debt	1,209				1,209
Interest on debt	27				27
Purchase commitments	3,659				3,659
	\$ 6,303	\$	67	\$	6,370

At March 31, 2011, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$2.3 million under our manufacturing agreement with Patheon Puerto Rico, Inc. for the manufacture of 500mg Glumetza, \$1.3 million under our supply agreement with Valeant for the supply of 1000mg Glumetza, and \$0.1 million under our supply agreement with Farmhispania, S.A., for the supply of metformin hydrochloride. The amounts disclosed only represent minimum purchase requirements. Actual purchases are expected to exceed these amounts.

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 or any promotion fees associated with our promotion agreement with Santarus.

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

There have been no significant changes in our market risk compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2010.

**ITEM 4. CONTROLS AND PROCEDURES***Evaluation of Disclosure Controls and Procedures*

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An evaluation was performed under the supervision and with the participation of our management, including the Company's Chief Executive Officer and Vice President, Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this quarterly report. Based on that evaluation, our management, including the Company's 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 March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

In November 2009, we filed a lawsuit 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 the patents listed in the Orange Book for Glumetza. The lawsuit is in response to an Abbreviated New Drug Application 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 four listed patents (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; and 6,723,340). The Company commenced the lawsuit 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 may occur 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 case, 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 in January 2011. An adverse outcome in this matter could substantially weaken our U.S. intellectual property.

*Biovail and Depomed v. Apotex (Canadian Generic Glumetza Litigation)*

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, Valeant and Depomed filed a complaint in the Federal Court in Canada against Apotex for infringement of the Company's Canadian Patent No. 2,290,624.

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

**ITEM 1A. RISK FACTORS**

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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 Galise, which would harm our business.*

Although Galise has been approved for marketing, our ability to generate significant revenue from Galise requires that we successfully commercialize the product on our own or with the assistance of a collaborative co-promotion or licensing partner. We retained marketing rights to Galise in March 2011 in connection with the termination of our Galise exclusive license agreement with Abbott Products, and we do not currently have a collaborative partner to assist us with the commercialization of Galise. 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 build or maintain the necessary sales, marketing, managed markets or other capabilities on our own required to successfully commercialize Galise, and we may not enter into arrangements with a collaborative partner or other third parties to perform those functions for us. 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 experience and expertise of our current staff, 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 Galise may be delayed or limited.

If we enter into a collaborative co-promotion or licensing arrangement related to Galise, 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 Galise in PHN.*

The FDA has granted Galise 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 Galise 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 Galise, we were informed additional

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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. 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.

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.

***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 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.

The filing of the Lupin ANDA described above, or any other ANDA 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.

*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.*

In October 2009, our Phase 3 trials evaluating Serada for menopausal hot flashes failed to meet all of their primary endpoints. In December 2009, we met and discussed with the FDA the results of the trials and any additional clinical development that may be required to complete the program and obtain regulatory approval to market Serada in the United States. We initiated an additional Phase 3 trial for Serada in August 2010, known as Breeze 3. There can be no assurance the results of the Breeze 3 trial will demonstrate the product candidate is sufficiently safe and effective to obtain approval for marketing.

We will incur significant additional expenses and will not know for at least another 9 to 12 months whether a New Drug Application could be submitted to the FDA to be approved for marketing. 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. Accordingly, our additional Phase 3 trial may not demonstrate that Serada is effective for menopausal hot flashes. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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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.

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

In July 2008, we entered into a promotion agreement with Santarus, Inc. pursuant to which Santarus will promote Glumetza in the United States through its sales force beginning in the fourth quarter of 2008. Under the agreement, in exchange for promotion fees, Santarus is required to market and promote Glumetza to physicians in the United States, to deliver annual detail calls to potential Glumetza prescribers, and to maintain a sales force of a minimum size. Although we have retained rights to promote Glumetza to obstetricians/gynecologists, or ob/gyns, and to retain a significant portion of the revenues from incremental sales generated by ob/gyns we call upon, ob/gyns generally do not prescribe significant amounts of metformin products. In addition, we do not have any immediate plans to establish a sales force, or contract with a third party to act as our sales force, for the purpose of exercising our Glumetza co-promotion rights. Accordingly, the success of the commercialization of Glumetza will depend in large part on Santarus' marketing and promotion efforts. Other factors that may affect the success of our promotion 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;
- The outcome of our ongoing litigation against Lupin Limited seeking to prevent Lupin from marketing a generic version of Glumetza in the United States;
- Santarus may experience financial difficulties; and
- Santarus may fail to comply with its obligations under our promotion agreement.



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In addition to the factors described above, Santarus' business and product revenue have been adversely affected by the introduction of a generic version of its Zegerid® (omeprazole/sodium bicarbonate) prescription products in the third quarter of 2010. Any of the preceding factors could affect Santarus' commitment to the collaboration, which, in turn, could adversely affect the commercial success of Glumetza. Any failure to successfully commercialize Glumetza could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

*We cannot be certain of the extent to which commercialization of Glumetza will continue to be negatively impacted by the recent recall of Glumetza.*

In June 2010, we initiated a voluntary, wholesaler-level recall of 500mg Glumetza product due to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole, or TBA, in bottles containing 500mg Glumetza tablets. In connection with the recall, we temporarily suspended product shipments of the 500mg Glumetza. We resumed supply of the 500mg Glumetza in January 2011.

The supply disruption of the 500mg Glumetza has adversely impacted our product revenue and profitability of Glumetza. In addition, other pharmaceutical companies have encountered complex TBA-related supply issues and the issues may be difficult to remediate. Many of the patients who were previously prescribed Glumetza may be taking other prescription metformin products, and we may not be able to ever regain the lost share of the business. We may also suffer damage to our reputation and face product liability claims.

*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.*

We have the following programs in clinical development: Serada for menopausal hot flashes and DM-1992 for Parkinson's. 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 2009.

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We are unable to predict whether any of these 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 three months ended March 31, 2011, we recorded total revenues of \$83.1 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 in the first quarter of 2011 and for 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 timing of the launch and 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, including Serada;
- filings and other regulatory actions related to Serada and our other 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 for Glumetza;

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- variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other contract revenues;
- market acceptance of the Acuform technology;
- adoption of new technologies by us or our competitors;
- the introduction of new products by our competitors;
- the status of our compliance with laws and regulations applicable to the commercialization of pharmaceutical products;
- any limitations to access to physician prescription data, which may make our marketing efforts more effective;
- manufacturing costs;
- third-party reimbursement policies; and
- the status of our compliance with the provisions of the Sarbanes-Oxley Act of 2002.

As a result of these factors, our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Additionally, any significant drops in our stock price, such as the one we experienced following the announcement of our Serada Phase 3 trial results in October 2009, 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.***

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

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Collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs.

We may be unable to enter into future collaborative arrangements on acceptable terms, which could harm our ability to develop and commercialize our current and potential future products. 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;
- premature termination of a collaboration agreement; or
- Failure by a collaborative partner to devote sufficient resources to the development and commercial sales of products using the Acuform technology.

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.

***Our credit facility contains operating covenants that may restrict our business and financing activities.***

We entered into a \$15.0 million credit facility with Oxford Finance Corporation and General Electric Capital Corporation in June 2008. We have drawn \$9.4 million under the facility and will not make any further draws under the facility. As of March 31, 2011, we have \$1.2 million of principal outstanding under the facility. The credit facility is secured by a pledge of all of our assets other than intellectual property, and contains a variety of operational covenants, including limitations on our ability to incur liens or additional debt, make dispositions, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions and transactions with affiliates, among other restrictions. Any future debt financing we enter into may involve similar or more restrictive covenants affecting our operations. Our borrowings under the credit facility or any future debt financing will need to be repaid, which creates additional financial risk for our company, particularly if our business, or prevailing financial market conditions, are not conducive to paying off or refinancing our outstanding debt obligations. Furthermore, our failure to comply with the covenants in the credit facility could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, which could have a material adverse effect on our cash position and significantly harm our business.

*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.

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*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 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.*

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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. Accordingly, physicians could prescribe another manufacturer's gabapentin to treat hot flashes in menopausal women rather than Serada, or pharmacists could 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 may be difficult and costly.

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*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.*



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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 products. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary considerably from our estimates depending on numerous factors, some of which are beyond our control, including:

- the efforts of our marketing partners with respect to the commercialization of our products;
- the rate of progress, costs and results of our clinical trial and research and development activities, including the extent of scheduling conflicts with participating clinicians and clinical institutions and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;
- other actions by regulators;
- 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
- the costs of ramping up and maintaining manufacturing operations, as necessary.

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

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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 (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 include certifications, known as Paragraph IV certifications, that certify any patents listed in the FDA's Orange Book publication in respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving 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

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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 antikickback statute prohibits giving things of value to induce the prescribing or purchase of products that are reimbursed by federal healthcare programs, such as Medicare and Medicaid. In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Under this law, the federal government in recent years has brought claims against drug manufacturers alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations, which apply to items and services reimbursed under Medicaid and other state programs, or, in some states, regardless of the payer. If we, or our collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunction, and exclusion of our products from reimbursement under government programs, as well as other regulatory actions against our product candidates, our collaborative partners or us.

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

Companies may not promote drugs for off-label uses that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. 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 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.

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***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.

If reimbursement is not available for our products or product candidates, demand for these products may be limited. Further, any delay in receiving approval for reimbursement from third-party payers could have an adverse effect on our future revenues. Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, including pharmaceuticals. Our products may not be considered cost effective, and adequate third-party reimbursement may be unavailable to enable us to maintain price levels sufficient to realize an acceptable return on our investment.

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

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Laboratories, Inc. and Teva Pharmaceutical Industries, Ltd. have received FDA approval for and are selling a controlled-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 Horizant™ (gabapentin enacarbil extended-release tablets) received FDA approval in the United States for restless leg syndrome.

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 Glumetza, Gralise and our other product candidates. If these suppliers are unable to manufacture Glumetza, Gralise or our product candidates, our business will be harmed.***

We are responsible for the supply and distribution of Glumetza, and Patheon is our sole supplier for tablets of the 500mg strength of Glumetza pursuant to a supply agreement we entered into with Patheon in December 2006. Valeant is our sole supplier for the

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1000mg formulation Glumetza. We will be unable to manufacture Glumetza in a timely manner if we are unable to obtain 500mg Glumetza tablets from our contract manufacturer, active pharmaceutical ingredient from suppliers, or excipient suppliers, or 1000mg Glumetza tablets from Valeant.

Patheon is also our sole supplier for Gralise and Serada tablets. We currently have no long-term supply arrangement with respect to Gralise or Serada. Any failure to obtain Gralise or Serada 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.

*A successful product liability claim against us could materially harm our business.*

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.

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

Certain provisions of our articles of incorporation and the California General Corporation Law could discourage a third party from acquiring, or make it more difficult for a third party to acquire, control of our company without approval of our board of directors. These provisions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain provisions allow the board of directors to authorize the issuance of preferred stock with rights superior to those of the common stock. We are also subject to the provisions of Section 1203 of the California General Corporation Law which requires a fairness opinion to be provided to our shareholders in connection with their consideration of any proposed interested party reorganization transaction.

We have adopted a shareholder rights plan, commonly known as a poison pill. The provisions described above, our poison pill and provisions of the California General Corporation Law may discourage, delay or prevent a third party from acquiring us.

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

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

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

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**ITEM 3.                   DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4.                   RESERVED**

Not applicable.

**ITEM 5.                   OTHER INFORMATION**

Not applicable.

**ITEM 6.                   EXHIBITS**

- (a) Exhibits
  - 10.1 Offer Letter between the Company and James. A. Schoeneck
  - 10.2 Separation Agreement and Release between the Company and Carl A. Pelzel
  - 10.3 Management Continuity Agreement between the Company and James A. Schoeneck
  - 31.1 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of James A. Schoeneck
  - 31.2 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Tammy L. Cameron
  - 32.1 Certification pursuant to 18 U.S.C. Section 1350 of James A. Schoeneck
  - 32.2 Certification pursuant to 18 U.S.C. Section 1350 of Tammy L. Cameron

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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: May 6, 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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