

DEPOMED INC  
Form 10-Q  
May 05, 2009  
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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, 2009**

**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)

**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

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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 4, 2009 was 51,214,710.

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**PART I FINANCIAL INFORMATION**

**ITEM 1. CONDENSED FINANCIAL STATEMENTS**



## DEPOMED, INC.

## CONDENSED BALANCE SHEETS

(in thousands, except share amounts)

	March 31, 2009 (Unaudited)	December 31, 2008 (1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,588	\$ 22,127
Marketable securities	67,554	59,932
Accounts receivable	3,454	3,099
Unbilled accounts receivable	544	576
Inventories	2,902	2,849
Prepaid and other current assets	3,471	5,404
Total current assets	87,513	93,987
Marketable securities	16,997	
Property and equipment, net	777	900
Other assets	197	197
	\$ 105,484	\$ 95,084
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 874	\$ 559
Accrued compensation	1,123	2,601
Accrued clinical trial expense	1,830	661
Other accrued liabilities	7,233	9,027
Deferred product sales	1,645	1,702
Deferred license revenue	10,684	4,362
Other current liabilities	119	110
Current portion of long-term debt	3,423	3,356
Total current liabilities	26,931	22,378
Deferred license revenue, non-current portion	49,319	33,209
Long-term debt, non-current portion	5,020	5,775
Other long-term liabilities	561	569
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 zero shares outstanding at March 31, 2009 and December 31, 2008		
Common stock, no par value, 100,000,000 shares authorized; 51,214,710 and 51,171,377 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	183,917	183,196
Accumulated deficit	(160,349)	(150,194)
Accumulated other comprehensive gain	85	151
Total shareholders' equity	23,653	33,153
	\$ 105,484	\$ 95,084

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

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,	
	2009	2008
Revenues:		
Product sales	\$ 6,840	\$ 5,226
Royalties	464	112
License revenue	2,568	363
Total revenues	9,872	5,701
Costs and expenses:		
Cost of sales	1,032	1,209
Research and development	10,021	6,069
Selling, general and administrative	9,002	6,507
Total costs and expenses	20,055	13,785
Loss from operations	(10,183)	(8,084)
Other income (expense):		
Interest and other income	314	803
Interest expense	(285)	
Total other income (expense)	29	803
Net loss before income taxes	(10,154)	(7,281)
Provision for income taxes	1	
Net loss	(10,155)	(7,281)
Deemed dividend on preferred stock		175
Net loss applicable to common stock shareholders	\$ (10,155)	\$ (7,456)
Basic and diluted net loss applicable to common stock shareholders per common share	\$ (0.20)	\$ (0.16)
Shares used in computing basic and diluted net loss per common share	51,207,540	47,866,093

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,	
	2009	2008
<b>Operating Activities</b>		
Net loss	\$ (10,155)	\$ (7,281)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	214	215
Employee and director stock-based compensation	685	552
Stock-based compensation related to consultants	9	69
Changes in assets and liabilities:		
Accounts receivable	(323)	695
Inventories	(53)	1,057
Prepaid and other current assets	1,933	(1,214)
Accounts payable and other accrued liabilities	(309)	116
Accrued compensation	(1,478)	(609)
Deferred revenue	22,376	530
Net cash provided by (used in) operating activities	12,899	(5,870)
<b>Investing Activities</b>		
Purchases of property and equipment	(84)	(46)
Purchases of marketable securities	(63,523)	(22,202)
Maturities of marketable securities	32,847	24,350
Sales of marketable securities	6,010	983
Net cash (used in) provided by investing activities	(24,750)	3,085
<b>Financing Activities</b>		
Principal payments on long-term debt	(714)	
Proceeds from issuance of common stock	26	3
Net cash (used in) provided by financing activities	(688)	3
Net decrease in cash and cash equivalents	(12,539)	(2,782)
Cash and cash equivalents at beginning of period	22,127	14,374
Cash and cash equivalents at end of period	\$ 9,588	\$ 11,592

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*



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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, 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, 2009 are not necessarily indicative of results to be expected for the entire year ending December 31, 2009 or future operating periods.

The balance sheet as of December 31, 2008 has been derived from the audited financial statements at that date. The balance sheet does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. For further information, refer to the financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2008 filed with the SEC.

### *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.

### *Stock-Based Compensation*



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The Company calculates stock-based compensation for all periods presented in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R)), as interpreted by SEC Staff Accounting Bulletin No. 107 (SAB 107), using the modified prospective transition method. FAS 123(R) is a revision of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (FAS 123), and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). FAS 123(R) requires companies to recognize the cost of employee and director services received in exchange for awards of equity instruments, based on the grant-date fair value of those awards, in the statement of operations. Using the modified prospective transition method of FAS 123(R), Depomed began recognizing fair-value compensation expense for stock-based awards, including stock options granted and purchase rights issued under its employee purchase plan after January 1, 2006. The compensation expense for stock-based compensation is based on the single-option approach, includes an estimate for forfeitures and is recognized over the vesting term of the options using the straight-line method. FAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Depomed estimates forfeitures based on historical experience. See Note 6 of the Notes to Condensed Financial Statements for further information regarding Depomed's stock-based compensation expense.



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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



**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 divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

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 began selling GLUMETZA® (metformin hydrochloride extended release tablets) in August 2006 to wholesalers and retail pharmacies that is subject to rights of return up to twelve months after product expiration. Beginning in the third quarter of 2008, the Company began recognizing revenue for GLUMETZA sales at the time title transfers its customers, which occurs at the time product is delivered to its customers. Prior to the third quarter of 2008, the Company was unable to reasonably estimate expected returns of the product at the time of shipment, and therefore, deferred revenue on product shipments of GLUMETZA until the product was dispensed through patient prescriptions. The quantity of prescription units dispensed was estimated based on analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. Based on the actual shipment trends, prescription trends and product returns history for GLUMETZA and based on an analysis of return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, the Company concluded it had the information needed to reasonably estimate product returns beginning in the third quarter of 2008.
  - Proquin®XR: The Company sells Proquin® XR (ciprofloxacin hydrochloride extended release tablets) to wholesalers and retail pharmacies that is subject to rights of return up to twelve months after product expiration. Given the Company's limited history of selling Proquin XR, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Proquin XR until the right of return no longer exists, which occurs at the earlier of the time Proquin XR units are dispensed through patient prescriptions or expiration of the right of return. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. As a result of this policy, the Company has a deferred revenue balance of \$1.6 million at March 31, 2009 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. The Company will recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in net revenue related to the recognition of revenue previously deferred. 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.



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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



- **Product Sales Allowances** The Company recognizes products 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, the Company may need to adjust these estimates, which could have an effect on earnings in the period of adjustment. The Company's product sales allowances include:
- **Managed Care Rebates** The Company offers rebates under contracts with certain managed care customers. 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 our product by the managed care organization.
- **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 one year 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 by the Company was 36 months. 1000mg GLUMETZA tablets, which became available in June 2008, currently have a shelf life of 24 months from the date of tablet manufacture. The Company estimates GLUMETZA product returns based on an analysis of return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, trends in historical returns, shipments and prescriptions and estimated channel inventory levels.
- **Wholesaler and Retail Pharmacy Discounts** The Company offers discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.
- **Prompt Pay Discounts** - The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. Based on the Company's experience, the Company expects its customers to comply with the payment terms to earn the cash discount. The Company accounts for cash discounts by reducing accounts receivable by the full amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.
- **Medicaid Rebates** The Company participates in Medicaid rebate programs, which provide assistance to certain eligible low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three months after the quarter in which the prescription is filled. The Company estimates and accrues Medicaid rebates based on product pricing, current rebates and changes in the level of discounts the Company offers that may affect the level of Medicaid discount, historical and estimated future percentages of our product sold to Medicaid recipients and

estimated levels of inventory in the distribution channel.



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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



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- **Chargebacks** - The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity.
- **Royalties** - Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured.

In April 2008, the Company entered into a settlement and license agreement with Teva Pharmaceuticals USA, Inc. (Teva) in which the Company is entitled to receive royalties from Teva on sales by Teva or its affiliates of generic Glucophage®XR in the United States, subject to a \$2.5 million aggregate cap. The royalties are calculated as a percentage of sales by Teva of generic Glucophage XR in the United States, as reported by a third-party market research company. The Company accrues royalties from Teva each quarter based on Teva's sales of generic Glucophage XR reported by the third-party market research company for that quarter. See Note 4 of the Notes to Condensed Financial Statements for further information on the settlement and license agreement.

Royalties received under the Company's agreements with Biovail Laboratories s.r.l. (Biovail) and LG Life Sciences (LG) are recognized when the royalty payments are received as they are not estimable.

- **License Revenue** - Revenue from license 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 fees are recognized over the estimated performance period. License fee payments received in excess of amounts earned are classified as deferred revenue until earned.

### *Recently Issued Accounting Standards*



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In April 2009, the FASB issued Statement of Financial Position (FSP FAS) No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, and is effective for the Company beginning July 1, 2009. FSP FAS 157-4 provides additional guidance for estimating fair value in accordance with FASB Statement No. 157, *Fair Value Measurements*, when the volume and level of activity for the asset or liability have significantly decreases and includes guidance on identifying circumstances that indicate a transaction is not orderly. The Company does not expect the adoption of FSP FAS 157-4 to have a material effect on its financial statements.

In April 2009, the FASB issued Statement of Financial Position (FSP FAS) No. 115-2 and No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, and is effective for the Company beginning July 1, 2009. FSP FAS 115-2 and 124-2 amends the other-than-temporary impairment guidance in US GAAP for the debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments debt and equity securities. The Company does not expect the adoption of FSP FAS 115-2 and No 124-2 to have a material effect on its financial statements.

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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



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

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. The Company records cash equivalents at amortized cost, which approximates their fair value. 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 loss within shareholders' equity. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in interest and other income in the condensed statement of operations. As March 31, 2009, the individual contractual period for all available-for-sale debt securities is less than two years.

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, 2009 (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
<b>U.S. Debt Securities</b>						
Commercial paper	\$ 2,987	\$ (5)	\$ 2,987	\$ (5)	\$ 2,987	\$ (5)
U.S. corporate debt securities	10,319	(46)	10,319	(46)	10,319	(46)
U.S. government agency debt securities						
U.S. treasury securities						
<b>Total available-for-sale</b>	<b>\$ 13,306</b>	<b>\$ (51)</b>	<b>\$ 13,306</b>	<b>\$ (51)</b>	<b>\$ 13,306</b>	<b>\$ (51)</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, 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, 2009.

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, Fair Value Measurements (FAS 157). FAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under FAS 157 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 under FAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- 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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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



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The adoption of FAS 157 did not have a material impact on the Company's financial position, results of operations or cash flows. In accordance with FAS 157, 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, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 880			\$ 880
Commercial paper		12,674		12,674
U.S. corporate debt securities		17,852		17,852
U.S. government agency debt securities		55,117		55,117
U.S. treasury securities		3,904		3,904
Total	\$ 880	\$ 89,547		\$ 90,427

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, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 20,155			\$ 20,155
Commercial paper		2,991		2,991
U.S. corporate debt securities		7,647		7,647
U.S. government agency debt securities		18,985		18,985
U.S. treasury securities		30,309		30,309
Total	\$ 20,155	\$ 59,932		\$ 80,087

### NOTE 3. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share is computed using the weighted-average number of shares of common stock outstanding. Common stock equivalent shares, which are based on the number of shares underlying outstanding stock options, warrants and other convertible securities, are not included as their effect is antidilutive. At March 31, 2009 and 2008, the total number of outstanding common stock equivalents excluded from the loss per share computation were 6,531,827 and 8,842,590, respectively.

### NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

#### *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 DM-1796 for pain indications in the United States, Canada and Mexico. The agreement became effective in January 2009, upon clearance of the transaction under Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.

Pursuant to the agreement, Solvay Pharmaceuticals paid the Company a \$25.0 million upfront fee in February 2009. The Company is also eligible to receive milestone payments for acceptance and FDA approval of the New Drug Application for DM-1796 for PHN, and sales milestone payments upon reaching certain sales milestones. Solvay will pay the Company royalties of 14 to 20 percent of net product sales, depending on the level of product sales.

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The Company will remain responsible for completion of the ongoing Phase 3 clinical trial for DM-1796 in PHN, and will be responsible for certain other regulatory support activities through NDA approval. Solvay will be responsible for NDA filing and has the option to develop DM-1796 in further pain indications other than PHN. If Solvay elects to develop DM-1796 in fibromyalgia, the Company has a right of first negotiation for co-promote rights in the obstetrics/gynecology field upon fibromyalgia indication regulatory approval.

The license agreement will expire with the last to expire of the Company's patents covering the Product, subject to early termination in certain circumstances.

The Company will be responsible for the manufacture of DM-1796 for up to four years from the effective date of the license agreement, pursuant to a supply agreement to be entered into by Depomed and Solvay by July 2009.

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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



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The Company is recognizing the \$25.0 million upfront payment ratably over the period of the Company's development and supply obligations under the agreement which is estimated to be through January 2013. The Company recognized \$1.5 million in license revenue under the arrangement for the quarter ended March 31, 2009. The remaining deferred revenue balance is \$23.5 million at March 31, 2009.

### *Covidien, Ltd.*

In November 2008, the Company entered into a license agreement with Mallinckrodt, Inc., a subsidiary of Covidien, Ltd. (Covidien) granting Covidien worldwide rights to utilize our AcuForm® technology for the exclusive development of four undisclosed products. Through November 2008, Covidien paid the Company a total of \$5.5 million in upfront fees, representing a \$4.0 million upfront license fee and a \$1.5 million upfront payment for formulation work to be performed by Depomed under the agreement. Under the agreement, the Company may also receive certain developmental milestone payments, if achieved, and is also entitled to receive royalties on sales of the products.

The entire \$5.5 million in upfront payments is being accounted for as a single unit of accounting and being amortized ratably through November 2011, which is the length of time Depomed is obligated to perform formulation work under the agreement. For the three months ended March 31, 2009, the Company recognized \$0.5 million in license revenue under the agreement. The remaining deferred revenue balance is \$4.8 million at March 31, 2009.

### *Santarus, Inc.*

In July 2008, the Company entered into a promotion agreement with Santarus, Inc. (Santarus) granting Santarus exclusive rights to promote GLUMETZA in the United States. Santarus paid the Company a \$12.0 million upfront fee, and based on the achievement of specified levels of annual GLUMETZA net product sales, Santarus may be required to pay the Company additional one-time sales milestones, totaling up to \$16 million.

Santarus began promotion of GLUMETZA in October 2008. Santarus is required to meet certain minimum promotion obligations during the term of the agreement, and 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 ranging from 75% to 80% of the gross margin earned from net sales of GLUMETZA product in the United States. For the three months ended March 31, 2009, the Company recognized \$4.5 million in promotion fee expense under the agreement, which is classified within selling, general and administrative expense.

Santarus is responsible for all costs associated with its sales force and for all other marketing expenses associated with its promotion of GLUMETZA product. Depomed is responsible for overseeing product manufacturing and supply. A joint commercialization committee has been formed to oversee and guide the strategic direction of the GLUMETZA alliance.

Pursuant to the terms of the promotion agreement, Depomed retains the option to co-promote GLUMETZA product in the future to obstetricians and gynecologists. The promotion agreement will continue in effect until the expiration of the last-to-expire patent or patent application with a valid claim in the territory covering a GLUMETZA product, unless terminated sooner.



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The Company is recognizing the \$12.0 million upfront payment ratably until November 2021, which represents the estimated length of time the Company's obligations exist under the arrangement for promotion fees it is obligated to pay Santarus. For the three months ended March 31, 2009, the Company recognized \$0.2 million in license revenue related to the amortization of the upfront payment. The remaining deferred revenue balance is \$11.4 million at March 31, 2009.

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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



**Watson Pharma, Inc.**

In February 2009, the Company and Watson Pharma, Inc. (Watson) amended the promotion agreement between the parties, pursuant to which Watson performed a specified number of physician details during the first quarter of 2009, and will make an agreed upon number of sales calls in which samples of Proquin XR are delivered to physicians in each of the last three quarters of 2009. The promotion agreement will terminate effective December 31, 2009, or upon notice from the Company to Watson prior to that date. The Company has no obligation to pay Watson promotion fees in 2009, and thereafter.

**Settlement with TEVA Pharmaceuticals USA, Inc.**

In April 2008, the Company entered into a settlement and license agreement with Teva related to the patent infringement lawsuit filed by the Company against Teva affiliates IVAX Corporation and IVAX Pharmaceuticals, Inc. The settlement agreement provided for a one-time payment to the Company of \$7.5 million, which the Company received in April 2008, and for a non-exclusive license in favor of Teva (including IVAX) to continue to market its generic Glucophage XR product in the United States. The \$7.5 million one-time payment received by the Company was recognized as a gain on litigation settlement within operating income during the second quarter of 2008.

The Company also receives ongoing royalty payments from Teva on sales by Teva (including IVAX) of generic Glucophage XR in the United States, which is calculated as a percentage of sales, as reported by a third-party market research company. The royalty is subject to a \$2.5 million aggregate cap. For the quarter ended March 31, 2009, the Company recognized \$0.4 million in royalty revenue related to this arrangement. As of March 31, 2009, a cumulative total of \$1.6 million in royalties has been recognized to date, with \$0.9 million remaining under the aggregate cap.

**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 on the first tranche for the first six months at an interest rate of 11.59%. Beginning in January 2009, the Company is required to pay the 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 at an interest rate of 11.59%. Interest expense, which includes amortization of debt issuance costs, was \$0.3 million for the three months ended March 31, 2009.

As of March 31, 2009, the outstanding balance under the facility was \$8.7 million. Future contractual principal and interest payments are as follows (in thousands):

	Principal	Interest
Less than 1 year (April 2009 - March 2010)	\$ 3,520	\$ 837

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1-2 years (April 2010 - March 2011)		3,957		400
More than 2 years (April 2011 - July 2011)		1,209		27
Total	\$	8,686	\$	1,264

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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



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The Company has the right to voluntarily prepay any tranches received under the facility, in full or in part. Upon any voluntary prepayment of any of the tranches, the Company will be required to pay the lenders, a prepayment premium equal to: (i) 5% on such prepayment amount, if such prepayment is made within 14 months after the closing date, (ii) 4% on such prepayment amount, if such prepayment is made more than 14 months after the closing date but within 29 months after the closing date, and (iii) 3% on such prepayment amount, if such prepayment is made more than 29 months after the closing date, but on or before the maturity date of the respective tranche.

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 with, 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, 2009.

### NOTE 6. STOCK-BASED COMPENSATION

The following table presents stock-based compensation expense recognized under FAS 123(R) for stock options, stock awards and the Company's employee stock purchase program (ESPP) in the Company's statements of operations (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Cost of sales	\$ 9	\$ 5
Research and development expense	208	201
Selling, general and administrative expense	477	415
Total	\$ 694	\$ 621

At March 31, 2009, Depomed had \$4.5 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants that will be recognized over an average vesting period of 2.1 years.

### NOTE 7. COMPREHENSIVE LOSS

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Net loss	\$ (10,154)	\$ (7,281)
Unrealized (loss) gain on available-for-sale securities	(66)	34
Total comprehensive loss	\$ (10,220)	\$ (7,247)



**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):

	<b>March 31, 2009</b>		<b>December 31, 2008</b>	
Raw materials	\$	187	\$	266
Work-in-process		414		127
Finished goods		2,238		2,392
Deferred costs		63		64
Total	\$	2,902	\$	2,849

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

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**DEPOMED, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

*(Unaudited)*



**NOTE 9. SHAREHOLDERS EQUITY**

*Option Exercises*

During the three months ended March 31, 2009, employees and consultants exercised options to purchase 13,333 shares of the Company's common stock with net proceeds to the Company of approximately \$26,000.

**NOTE 10. RELATED PARTY TRANSACTIONS**

*John W. Fara, Ph.D.*

In August 2007, John W. Fara, Ph.D. retired from his positions as President, Chief Executive Officer and Chairman of the Company. Dr. Fara continued to serve as a member of the Company's Board of Directors until May 2008. The Company entered into a consulting agreement with Dr. Fara, pursuant to which Dr. Fara will provide consulting services to the Company through December 31, 2009. From August 2007 through December 31, 2008, the Company paid Dr. Fara \$20,833 per month for his consulting services and reimbursed Dr. Fara for COBRA and life insurance premiums. Dr. Fara will be paid on an hourly basis for consulting services provided in 2009. For the three months ended March 31, 2009, the Company did not incur any expenses for consulting services.

During the period of his consultancy, Dr. Fara will continue to vest in all of his currently unvested stock options, and his vested stock options will remain exercisable. For the three months ended March 31, 2009, the Company recognized approximately \$4,800 in stock compensation expense associated with these awards. In the event of a change in control of the Company, as defined by the Company's 2004 Equity Incentive Plan, all of Dr. Fara's unvested options will fully vest.

**NOTE 11. INCOME TAXES**

As of December 31, 2008 and March 31, 2009, the Company had \$2.8 million and \$2.9 million of unrecognized tax benefits, which is netted against deferred tax assets and 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.

**NOTE 12. SUBSEQUENT EVENTS**

*Rottapharm/Madaus GmbH*

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In April 2009, the Company and Madaus GmbH, a successor in interest to Madaus S.r.l. and subsidiary of Rottapharm, (Rottapharm/Madaus) entered into an amended and restated license agreement for Proquin XR in Europe, which amended the parties' distribution and supply agreement originally entered into in November 2005 and subsequently amended in November 2006. Under the amended and restated license agreement, the Company will no longer be obligated to supply commercial quantities of Proquin XR tablets in bulk form to Rottapharm/Madaus as contemplated under the distribution and supply agreement, and the Company will now receive royalties on net sales of Proquin XR in Europe sold by Rottapharm/Madaus. Depomed will be obligated to provide regulatory and manufacturing support and consultation for up to an agreed upon number of hours per month through December 31, 2010 as reasonably requested by Rottapharm/Madaus. The term of the amended and restated license agreement is through July 2023.

In August 2008, Rottapharm/Madaus paid the Company an advance payment of \$0.3 million intended for future product supply under the amended distribution and supply agreement. The \$0.3 million advance payment will now be applied toward future royalties due to Depomed under the amended and restated license agreement.

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

**FORWARD-LOOKING INFORMATION**



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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:

- results and timing of our clinical trials, including the results of our DM-1796 and Serada trials;
- the commercial success and market acceptance of Serada if we receive approval to market Serada in the United States;
- the commercial success and market acceptance of DM-1796 if it is approved for marketing in the United States, and the efforts of Solvay Pharmaceuticals, Inc. (Solvay) with respect to the commercialization of DM-1796;
- the commercial success of GLUMETZA® (metformin hydrochloride extended release tablets) in the United States, and the efforts of Santarus, Inc. (Santarus) with respect to the commercialization of GLUMETZA;
- the results of our internal research and development efforts;
- acceptance and approval of regulatory filings;
- our need for, and ability to raise, additional capital;
- our collaborative partners' compliance or non-compliance with their obligations under our agreements with them; and
- our plans to develop other product candidates.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the **RISK FACTORS** section and elsewhere in this Quarterly Report on Form 10-Q. We disclaim any intent to update or revise these forward-looking statements to reflect new events or circumstances.



## ABOUT DEPOMED

Depomed is a specialty pharmaceutical company focused on the development and commercialization of differentiated products that address large and growing markets and are based on proprietary oral drug delivery technologies. We have two product candidates in Phase 3 clinical trials. In March 2008, we initiated a Phase 3 clinical trial for DM-1796, an extended release formulation of gabapentin for the treatment of postherpetic neuralgia that we have licensed to Solvay. In September and October 2008, we initiated Breeze 1 and Breeze 2, our Phase 3 clinical trials for Serada, an extended release formulation of gabapentin for the treatment of menopausal hot flashes. In February 2009, we completed enrollment of our Breeze 1 trial, and in March 2009 we completed enrollment in our Breeze 2 trial for Serada. In 2009, we expect to complete enrollment of our DM-1796 Phase 3 clinical trial and expect to report top-line results for all three trials.

We seek to optimize the use and value of our product candidates and drug delivery technologies in three ways. First, we are seeking to assemble a number of pharmaceutical products that can be highly differentiated from immediate release versions of the compounds upon which they are based and may be promoted together to 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. and Santarus, Inc., 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. Our DM-1796 license and development arrangement with Solvay Pharmaceuticals is an example of this strategy. Third, we enter into collaborative partnerships with other companies where the unique capabilities of our technology can provide superior value to a partner's product candidate, resulting in greater value for Depomed than traditional fee-for-service arrangements. Our license and development arrangement with Covidien, Ltd. is an example of this strategy.

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We developed two additional products which have been approved by the FDA and are currently marketed. 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, Inc. Proquin® XR (ciprofloxacin hydrochloride extended release tablets) is a once-daily treatment for uncomplicated urinary tract infections that we commercialize in the United States with Watson Pharma.

The following table summarizes our product pipeline and marketed products.

**Product Pipeline**

Serada™	Menopausal hot flashes	Phase 3 studies underway (Breeze 1 and Breeze 2).
DM-1796	Postherpetic neuralgia	Second Phase 3 study underway. <i>Licensed by Solvay in the United States, Mexico and Canada.</i>
DM-3458	Gastroesophageal reflux disease	Proof of concept studies completed.
DM-1992	Parkinson's disease	Phase 1 study underway.
One undisclosed compound	Confidential	Preclinical development ongoing.

**Marketed Products**

<b>Product</b>	<b>Indication</b>	<b>Status</b>
GLUMETZA®	Type 2 diabetes	Currently sold in the United States, Canada and Korea. <i>Co-promoted in the United States with Santarus. Canadian rights held by Biovail. Korean rights held by LG Life Sciences.</i>
Proquin® XR	Uncomplicated urinary tract infection	Currently sold in the United States. <i>Co-promoted in the United States with Watson Pharma through December 31, 2009.</i>  Regulatory application approved in Sweden. <i>European rights held by Rottapharm/Madaus.</i>

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Our intellectual property position includes twelve issued patents and nineteen patent applications pending in the United States.

### *Significant Developments for the Quarter Ended March 31, 2009.*

- In January 2009, our license agreement with Solvay related to DM-1796 became effective after clearance of the transaction under the HSR Antitrust Improvements Act of 1976. Pursuant to the agreement, Solvay paid us a \$25.0 million upfront fee in February 2009.
- In February 2009 and in March 2009, we completed enrollment of our Breeze 1 and Breeze 2 Phase 3 clinical trials for Serada for the treatment of menopausal hot flashes.
- In February 2009, we dosed the first patient in a Phase 1 clinical trial for our DM-1992 program in Parkinson's disease.

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- In February 2009, we amended our promotion agreement with Watson, pursuant to which we are no longer obligated to pay Watson promotion fees beginning in the first quarter of 2009. Watson made a specified number of details in the first quarter of 2009, and will make an agreed upon number of sales calls in which samples of Proquin XR are delivered to physicians in each of the last three quarters of 2009. The promotion agreement will terminate effective December 31, 2009, or upon notice from us to Watson prior to that date.
- Revenue for the three months ended March 31, 2009 was \$9.9 million, compared to \$5.7 million for the three months ended March 31, 2008.
- Operating expenses for the three months ended March 31, 2009 were \$19.0 million, compared to \$12.6 million for the three months ended March 31, 2008.
- Cash, cash equivalents and marketable securities were \$94.1 million as of March 31, 2009, compared to \$82.1 million as of December 31, 2008.

**RECENT PRODUCT DEVELOPMENTS**

*Serada* **for Menopausal Hot Flashes**



*Phase 3 Registration Program.* Our Phase 3 registration program for Serada in menopausal hot flashes includes two randomized, double-blind, placebo-controlled studies of approximately 540 patients per study, Breeze 1 and Breeze 2. In September 2008, we enrolled and dosed the first patient in Breeze 1, and in October 2008, we enrolled and dosed the first patient in Breeze 2. In each study, patients will be randomized into three treatment arms: (i) placebo; (ii) 1200mg of Serada dosed once daily; or (iii) a total dose of 1800mg of Serada dosed 600mg in the morning and 1200mg in the evening. We completed enrollment in Breeze 1 in February 2009, and completed enrollment in Breeze 2 in March 2009.

The treatment duration of the Breeze 1 study will be six months, with primary efficacy endpoints assessed at 4 and 12 weeks. Persistence of efficacy will be assessed at 6 months as one of the secondary endpoints. The treatment duration in the second study, Breeze 2, will be three months, with assessment of efficacy at 4 and 12 weeks only.

The primary efficacy endpoints in both studies will be reductions in the mean frequency of moderate to severe hot flashes, and the average severity of hot flashes. Various secondary efficacy endpoints will be measured as well.

We expect that preliminary top-line results of the studies will be available in the fourth quarter of 2009.

*DM-1796 for Postherpetic Neuralgia*



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Solvay Pharmaceuticals, Inc. In November 2008, we entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. granting Solvay exclusive rights to develop and commercialize DM-1796 in the United States, Canada and Mexico for pain indications. The agreement became effective in January 2009, upon clearance of the transaction under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.

Pursuant to the agreement, Solvay Pharmaceuticals paid us a \$25 million upfront fee in February 2009. We are also eligible to receive aggregate milestone payments of up to \$70 million for acceptance and FDA approval of the New Drug Application for DM-1796 for PHN, and up to \$300 million in potential sales milestone payments. Solvay will pay us royalties of 14 to 20 percent of net product sales, depending on the level of net product sales.

We will remain responsible for completion of the ongoing Phase 3 clinical trial for DM-1796 in PHN, and will be responsible for certain other regulatory support activities through NDA approval. Solvay will be responsible for NDA filing and has the option to develop DM-1796 in further pain indications other than PHN. If Solvay elects to develop DM-1796 in fibromyalgia, we have a right of first negotiation for co-promotion rights in the obstetrics/gynecology field upon fibromyalgia indication regulatory approval.

We will be responsible for the manufacture of DM-1796 for up to four years from the effective date of the License Agreement, pursuant to a supply agreement to be entered into by Depomed and Solvay by July 2009. The License Agreement will expire with the last to expire of our patents covering DM-1796, subject to early termination in certain circumstances.

Phase 3 Registration Program. In March 2008, we initiated dosing of the first patient in a second Phase 3 clinical trial for DM-1796 for PHN. The study is a randomized, double-blind, placebo-controlled study of approximately 450 PHN patients. Patients in the study are randomized into two treatment arms: placebo, or 1800mg of DM-1796 dosed once daily. The study is being conducted at sites in the United States, Russia and Argentina.



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The primary objective of the study is to assess the efficacy of DM-1796 in reducing the pain associated with PHN, measured from baseline pain scores to the end of a ten-week treatment period on the basis of the Likert pain scale. Secondary objectives include an assessment of changes from baseline in sleep interference, and additional patient and clinician assessments of pain and quality of life.

The primary differences in the ongoing study relative to the Phase 3 PHN study we concluded in 2007 are: (a) there is only one active treatment arm (1800 mg once daily) rather than two; and (b) patients enrolled in the study must have stable PHN disease for at least six months, rather than three months, following healing of the shingles rash.

We expect the Phase 3 PHN study to be fully enrolled by the end of August 2009. We expect preliminary top-line results from the study will be available in the fourth quarter of 2009.

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

In July 2008, The Michael J. Fox Foundation awarded the Company a preclinical development grant to support the DM-1992 program. In January 2009, we commenced a Phase 1 study in Parkinson's patients designed to provide us with insight into our formulation strategy for our DM-1992 program.

***Proquin® XR***

Watson Pharma. In February 2009, we amended our promotion agreement with Watson related to Proquin XR. Pursuant to the amended agreement, Watson performed a specified number of details in the first quarter of 2009, and will make an agreed upon number of sales calls in which samples of Proquin XR are delivered to physicians in each of the last three quarters of 2009. The agreement will terminate effective December 31, 2009, or upon notice from us to Watson prior to that date. We have no obligation to pay Watson promotion fees in 2009, and thereafter.

We are currently evaluating our options for the future of Proquin, which include seeking to divest Proquin XR in the United States.

Rottapharm/Madaus GmbH. In April 2009, we and Madaus GmbH, a successor in interest to Madaus S.r.l. and subsidiary of Rottapharm, (Rottapharm/Madaus) entered into an amended and restated license agreement for Proquin XR in Europe, which amended the parties' distribution and supply agreement originally entered into in November 2005 and subsequently amended in November 2006. Under the amended and restated license agreement, we will no longer be obligated to supply commercial quantities of Proquin XR tablets in bulk form to Rottapharm/Madaus as contemplated under the distribution and supply agreement, and we will now receive royalties on net sales of Proquin XR in Europe sold by Rottapharm/Madaus. We will be obligated to provide regulatory and manufacturing support and consultation

for up to an agreed upon number of hours per month through December 31, 2010 as reasonably requested by Rottapham/Madaus. The term of the amended and restated license agreement is through July 2023.

In August 2008, Rottapharm/Madaus paid us an advance payment of \$0.3 million intended for future product supply under the amended distribution and supply agreement. The \$0.3 million advance payment will now be applied toward future royalties due to us under the amended and restated license agreement.

#### **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 2008 Annual Report on Form 10-K with the Securities and Exchange Commission on March 6, 2009. For a description of our critical accounting policies, please refer to our 2008 Annual Report on Form 10-K.

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**RESULTS OF OPERATIONS**



*Three Months Ended March 31, 2009 and 2008*



**Revenue**





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

	Three Months Ended March 31,	
	2009	2008
<b>Product sales:</b>		
GLUMETZA	\$ 6,643	\$ 5,166
Proquin XR	197	60
Total product sales	6,840	5,226
<b>Royalties:</b>		
GLUMETZA	36	112
Teva	428	
Total royalties	464	112
<b>License revenue:</b>		
DM-1796	1,477	
GLUMETZA	626	363
AcuForm technology	458	
Proquin XR	7	
Total license revenue	2,568	363
Total revenues	\$ 9,872	\$ 5,701

**Product sales**

GLUMETZA. The increase in GLUMETZA product sales in the first quarter of 2009 as compared to the first quarter of 2008 is primarily attributable to price increases of the 500mg GLUMETZA and the introduction of the 1000mg GLUMETZA in June 2008.

Beginning in the third quarter of 2008, we began to recognize GLUMETZA product sales at time title transfers to our customer, which is at the time our customer receives the product shipment, and provide for an estimate of future product returns at that time. Prior to the third quarter of 2008, we were unable to reasonably estimate expected returns of the product at the time of shipment, and therefore, deferred revenue on product shipments until the product was dispensed through patient prescriptions.

Santarus began promotion of GLUMETZA in October 2008. From February 2008 through September 2008, we promoted GLUMETZA through a contract sales organization. Product sales for GLUMETZA relative to its current runrate will depend on the promotional success of Santarus.

Proquin XR. We defer 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. At March 31, 2009, we have a deferred revenue balance, which is classified as a liability on the balance sheet, of \$1.6 million associated with the deferral of revenue on Proquin XR product shipments, which is net of estimated wholesaler fees, retail pharmacy discounts, stocking allowances and prompt payment discounts.

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The increase in Proquin XR product sales in the first quarter of 2009 as compared to the first quarter of 2008 is primarily due to a full year of promotion by Watson, which began promotion in October 2007. In February 2009, we amended our promotion agreement with Watson, pursuant to which Watson will perform a specified number of details in the first quarter of 2009, and will make an agreed upon number of sales calls in which samples of Proquin XR are delivered to physicians in each of the last three quarters of 2009. The agreement will terminate effective December 31, 2009, or upon notice from us to Watson prior to that date. Product sales for Proquin XR relative to its current runrate may decrease as a result of a decrease in promotion efforts by Watson resulting from the amended promotion agreement. We are currently evaluating our options for the future of Proquin, which include seeking to divest Proquin XR in the United States.

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***Royalties***

Teva. In April 2008, we entered into a settlement and license agreement with Teva related to the patent infringement lawsuit against Teva affiliates IVAX Corporation and IVAX Pharmaceuticals, Inc. we initiated in January 2006 related to Teva's generic Glucophage XR tablets. In connection with the settlement and license agreement we may receive up to a total of \$2.5 million in future royalties on Teva's generic Glucophage XR product in the United States. For the three months ended March 31, 2009, we recognized \$0.4 million in royalty revenue related to this arrangement. As of March 31, 2009, a cumulative total of \$1.6 million in royalties has been recognized to date, with \$0.9 million remaining under the aggregate cap.

GLUMETZA. GLUMETZA royalties relate to royalties we received from Biovail 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 Biovail in the first quarter of 2006 and from LG in the first quarter of 2007. GLUMETZA royalties decreased during the first quarter of 2009 as compared to the first quarter of 2008 primarily as a result of a temporary increase in the royalty rate on sales GLUMETZA in Canada for the royalty payment received from Biovail in the first quarter of 2008, with the royalty rate returning back to its normal rate on FDA approval of the 1000mg GLUMETZA in the United States.

***License revenue***

DM-1796. DM-1796 license revenue for the three months ended March 31, 2009 relates to the \$25.0 million upfront payment received from Solvay under our license agreement granting Solvay exclusive rights to develop and commercialize DM-1796 in the United States, Canada and Mexico for pain indications. We are recognizing the \$25.0 million upfront payment received from Solvay as revenue ratably until January 2013, which represents the expected maximum length of time our development and supply obligations exist under the agreement.

GLUMETZA. GLUMETZA license revenue for the three months ended March 31, 2009 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. License revenue for the quarter ended March 31, 2008 consisted solely of license revenue recognized from the \$25.0 million upfront license fee received from Biovail.

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 for GLUMETZA in the United States.

AcuForm Technology. In November 2008, we entered into a license agreement with Covidien granting Covidien worldwide rights to utilize our AcuForm technology for the exclusive development of four undisclosed products.

Through November 2008, Covidien paid us a total of \$5.5 million in upfront fees, representing a \$4.0 million upfront license fee and a \$1.5 million upfront payment for formulation work to be performed by Depomed under the agreement. The entire \$5.5 million is being accounted for as a single unit of accounting and being amortized ratably through November 2011, which is the length of time Depomed is obligated to perform formulation work under the agreement.

**Cost of Sales**

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, inventory write-downs, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales. Total cost of sales for the three months ended March 31, 2009, as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended March 31,</b>			
	<b>2009</b>		<b>2008</b>	
Cost of sales	\$	1,032	\$	1,209

Cost of sales for the three months ended March 31, 2009 and 2008 relates primarily to costs associated with the sale of GLUMETZA and Proquin XR. Cost of sales decreased slightly in three months ended March 31, 2009 as compared to the prior year, primarily because the three months ended March 31, 2008 included approximately \$0.3 million in inventory write-downs related to slow moving Proquin XR inventory that we expected would not be sold prior to its expiration date.

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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.

**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, 2009, as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Research and development expense	\$ 10,021	\$ 6,069
Dollar change from prior year	3,952	
Percentage change from prior year	65.1%	

The increase in research and development expense for the three months ended March 31, 2009 as compared to the three months ended March 31, 2008 was primarily due to higher clinical research organization expenses related to our two Phase 3 clinical trials for Serada for the treatment of menopausal hot flashes, which started in September 2008. In February 2009, we completed enrollment of our Breeze 1 Phase 3 clinical trial for Serada and in March 2009, we completed enrollment of our Breeze 2 Phase 3 clinical trial for Serada. The treatment duration of the Breeze 1 study is six months, and the treatment duration of the Breeze 2 study is three months.

In March 2008, we initiated dosing of the first patient in a Phase 3 clinical trial for DM-1796 for post-herpetic neuralgia. The treatment duration is ten weeks, and we expect the Phase 3 clinical trial to be fully enrolled by the end of August 2009.

Because of these three ongoing Phase 3 clinical trials, we expect research and development expense to remain flat or slightly increase from its current runrate for at least the next two quarters of 2009.

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

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	Three Months Ended March 31,			
	2009		2008	
DM-1796	\$	4,081	\$	3,966
Serada		3,575		1,416
Other projects		2,365		687
Total research and development expenses	\$	10,021	\$	6,069

**Selling, General and Administrative Expense**

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

	Three Months Ended March 31,			
	2009		2008	
Selling, general and administrative	\$	9,002	\$	6,507
Dollar change from prior year		2,495		
Percentage change from prior year		38.3%		

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The increase in selling, general and administrative expense for the three March 31, 2009 as compared to the three months ended March 31, 2008 was primarily due to \$4.5 million in GLUMETZA promotion fee expense under our promotion agreement with Santarus, who began promotion of GLUMETZA in October 2008, which is partially offset by decreases in other sales and marketing expenses for GLUMETZA for the three months ended March 31, 2009, as the majority of those efforts have been transferred to Santarus, as well as a decrease in legal expenses in the three months ended March 31, 2009 resulting from our litigation settlement with IVAX in April 2008.

**Interest Income and Expense**

(in thousands)	Three Months Ended March 31,	
	2009	2008
Interest and other income	\$ 314	\$ 803
Interest expense	(285)	
Net interest income (expense)	29	803

Interest and other income decrease during the three months March 31, 2009 as compared to the corresponding period in 2008 as a result of lower interest rates on our investments.

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,
	2009	2008
Cash, cash equivalents and marketable securities	\$ 94,139	\$ 82,059

In February 2009, we received a \$25.0 million upfront payment from Solvay related to our license agreement for DM-1796.

Since inception through March 31, 2009, we have financed our product development efforts and operations primarily from private and public sales of equity securities and from license and termination fees from collaborative and license partners.

In December 2006, we entered into a common stock purchase agreement with Azimuth Opportunity, Ltd., pursuant to which Azimuth is committed to purchase, from time to time and at our sole discretion, up to the lesser of (a) \$30.0 million of our common stock, or (b) 8,399,654 shares of common stock. In August 2008, the agreement was amended and the term of the agreement was extended until December 2010. Sales to Azimuth under the agreement, if any, will be made at a price equal to the average closing price of our common stock over a given pricing period, minus a discount ranging from approximately 3.8% to 6.4%, which varies based on a threshold price set by us. Upon each sale of the our

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common stock to Azimuth under the agreement, we have also agreed to pay Reedland Capital Partners a placement fee equal to approximately 1.1% of the aggregate dollar amount of common stock purchased by Azimuth. Azimuth is not required to purchase our common stock when the price of our common stock is below \$2 per share. As of March 31, 2009, we have not sold any common stock to Azimuth under this common stock purchase agreement.

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.



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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 and has an interest rate of 11.59%. As of March 31, 2009, the outstanding balance on the credit facility was \$8.7 million at an interest rate of 11.59%.

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, 2009, 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, 2009, we have accumulated net losses of \$160.3 million. We expect to continue to incur operating losses for the remainder of 2009. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of 2010. We base this expectation on our current operating plan, which may change as a result of many factors.

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

- sales of our marketed products;
- expenditures related to our commercialization and development efforts;
- financial terms of definitive license agreements or other commercial agreements we enter into, if any;
- results of research and development efforts;
- changes in the focus and direction of our research and development programs;
- technological advances;
- results of clinical testing, requirements of the FDA and comparable foreign regulatory agencies; and
- acquisitions or investment in complimentary businesses, products or technologies.

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

- conduct research and development programs;
- 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 have limited credit facilities and, except for the common stock purchase agreement with Azimuth, we have no 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 additional capital would have a material adverse effect on our company.

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**Cash Flows from Operating Activities**



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Cash provided by operating activities during the three months ended March 31, 2009 was approximately \$12.9 million, compared to cash used in operating activities of approximately \$5.9 million for the three months ended March 31, 2008. The increase in cash provided by operating activities for the three months ended March 31, 2009 as compared to cash used in operating activities three months ended March 31, 2008 was primarily due to an increase in deferred revenue as a result of the receipt of the \$25.0 million upfront payment from Solvay in February 2009 offset by an increase in net loss for Q1 2009.

### Cash Flows from Investing Activities

Net cash used in investing activities during the three months ended March 31, 2009 was approximately \$24.8 million and consisted primarily of a net increase in marketable securities resulting from investment of the upfront payment received from Solvay in February 2009. Net cash provided by investing activities during the three months ended March 31, 2008 was approximately \$3.1 million and consisted of net decrease in marketable securities.

### Cash Flows from Financing Activities

Cash used in financing activities during the three months ended March 31, 2009 was approximately \$0.7 million compared to cash provided by financing activities of approximately \$3,000 for the same period in 2008. For the three months ended March 31, 2009, cash used in financing activities primarily consisted of repayments of principal on our credit facility. For the three months ended March 31, 2008, cash provided by financing activities consisted of cash proceeds from exercises of stock options.

### Contractual Obligations

As of March 31, 2009, our aggregate contractual obligations are as shown in the following table (in thousands):

	Less than 1 year	1-3 years	3-5 years	Total
Operating leases	\$ 1,587	\$ 2,986	\$	\$ 4,573
Long-term debt (principal)	3,520	5,166		8,686
Long-term debt (interest)	837	427		1,264
Purchase commitments	1,034			1,034
	\$ 6,978	\$ 8,579	\$	\$ 15,557

At March 31, 2009, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$0.8 million under our manufacturing agreement with Patheon Puerto Rico, Inc. for the manufacture of the 500mg GLUMETZA and \$0.2 million under our supply agreement with Biovail for the supply of the 1000mg GLUMETZA. 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. These payments relate to various milestones for the product candidate under the

sublicense agreement, including dosing of the first patient in any Phase 3 trial, 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, 2008.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

An evaluation was performed under the supervision and with the participation of our management, including the Company's President and interim principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this quarterly report. Based on that evaluation, our management, including the Company's President and interim principal accounting and financial officer, concluded that our disclosure controls and procedures were effective.

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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, 2009 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. IVAX*

Between January 2006 and April 2008, we were involved in legal proceedings relating to some of our intellectual property rights. In January 2006, we filed a complaint against IVAX Corporation (IVAX) in the U.S. District Court for the Northern District of California for infringement of U.S. Patent Nos. 6,340,475 and 6,635,280, both of which we own. The patents relate to our AcuForm delivery technology. The complaint alleged infringement of our patents by IVAX's extended release metformin hydrochloride tablets.

In April 2008, we entered into a settlement and license agreement with Teva Pharmaceuticals USA, Inc., an affiliate of IVAX, related to the litigation. Pursuant to the settlement agreement: (a) the parties dismissed the patent litigation and released all claims associated with the litigation; (b) we received a one-time payment of \$7.5 million in April 2008; (c) we granted Teva a non-exclusive license to the Asserted Patents (including IVAX) to continue to market its generic Glucophage® XR (metformin hydrochloride extended release tablets) product in the United States under the Asserted Patents; and (d) we will receive ongoing royalty payments from Teva on sales by Teva (including IVAX) of generic Glucophage XR in the United States. The royalty is subject to a \$2.5 million aggregate cap, and cumulatively through March 31, 2009, we have recognized \$1.6 million in royalty revenue under this agreement.

*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. Apotex's regulatory filing alleges that certain of the Canadian patents that we have licensed to Biovail in connection with Biovail's commercialization of GLUMETZA in Canada are invalid and unenforceable, and that Apotex's formulation does not infringe our patents. Pursuant to the intellectual property enforcement provisions of our Canadian license agreement with Biovail for GLUMETZA, Biovail has the first right to prosecute, and pay for expenses related to, any Canadian litigation related to generic challenges to GLUMETZA. In January 2008, Biovail filed suit against Apotex in Canada in response to Apotex's regulatory filing, and we have been joined to the lawsuit as a co-plaintiff with Biovail because we are the licensor of the patents at issue in the suit. The initiation of the lawsuit automatically stays approval of Apotex's formulation for 24 months. In October 2008, the court issued a ruling requiring that Apotex present its evidence in the case by mid-January 2009, and that Biovail present its evidence by mid-April 2009. Each party has presented its evidence in the case. 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, 2008.

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.

**Our prior Phase 3 trial for DM-1796 failed to meet the primary efficacy endpoint and there can be no assurance this product will be approved.**

In July 2007, we announced that our drug candidate DM-1796 failed to meet the primary efficacy endpoint in a Phase 3 trial for postherpetic neuralgia (PHN). In March 2008, we initiated another Phase 3 registration trial for the product for the PHN indication.

We submitted to the FDA a protocol for a Phase 3 registration trial for DM-1796 to the FDA for a special protocol assessment, or SPA, pursuant to which we requested that the FDA assess whether the protocol is adequate to meet the scientific and regulatory requirements necessary to support marketing approval of DM-1796 for PHN. The FDA did provide us with guidance and comments on our proposed protocol, but indicated that the protocol was not eligible for an SPA under FDA requirements. Accordingly, there can be no assurance that the FDA will approve DM-1796 for PHN for marketing even if the primary endpoint in our current Phase 3 trial is met.

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**We depend on Solvay Pharmaceuticals for certain aspects of the development and commercialization of DM-1796, which subjects us to risks related to Solvay and its business that are outside our control.**

In January 2009, our exclusive license agreement with Solvay Pharmaceuticals Inc. related to the development and commercialization of DM-1796 became effective. The license agreement grants Solvay exclusive rights to develop and commercialize DM-1796 in the United States, Canada and Mexico for pain indications. We depend on Solvay to obtain regulatory approval and complete any further development of DM-1796, which subjects us to a number of risks, including the following:

- we may not be able to control the amount and timing of resources that Solvay devotes to the development or commercialization of DM-1796;
- we and Solvay may not be successful in our efforts to obtain regulatory approval of DM-1796 in a timely manner, or at all;
- Solvay may experience financial difficulties; or
- Solvay may change its business strategy, due to a combination with another company or for another reason unrelated to the DM-1796 commercial opportunity, in a manner that adversely affects the development or commercialization of DM-1796

**Our clinical trials may not demonstrate that Serada™ for menopausal hot flashes is safe and effective. If our clinical trials of Serada for menopausal hot flashes do not demonstrate safety and efficacy, or if the clinical trials are delayed or terminated, our business will be harmed.**

To gain regulatory approval from the FDA to market Serada for menopausal hot flashes, our planned Phase 3 registration trials must demonstrate the safety and efficacy of the product candidate. Clinical development is a long, expensive and uncertain process and is subject to delays. The results of our Phase 2 clinical trial are not necessarily indicative of the results we will obtain in later clinical trials. Accordingly, future clinical trials 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. To obtain marketing approval, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional pivotal clinical or other studies. These trials could significantly delay the approval and commercialization of Serada for menopausal hot flashes and would require us to commit significant additional financial resources. Even after we conduct these additional clinical trials, we may not receive regulatory approval to market the product.

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 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. Factors that may affect the success of our promotion arrangement with Santarus include the following:

- Santarus may acquire or develop alternative products;
- Santarus may pursue higher-priority programs, or change the focus of its marketing programs;

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- Santarus may in the future choose to devote fewer resources to GLUMETZA;
- GLUMETZA may fail to achieve greater market acceptance; and
- Santarus may fail to comply with its obligations under our promotion agreement.

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.

**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: DM-1796 for neuropathic pain and Serada for menopausal hot flashes. 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 DM-1796 for the treatment of postherpetic neuralgia that we completed in 2007.

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 would be significantly harmed.

**We have limited in-house sales and marketing resources, which we will require in order to successfully co-promote GLUMETZA through our own sales force.**

Although we have the rights to promote GLUMETZA through our own sales force, or through third parties, we have no sales force and limited marketing and sales staff. The success of our own promotion efforts for GLUMETZA and any other product candidates that receive regulatory approval that we choose to market or co-market, will require that we substantially enhance our in-house marketing and sales force with technical

expertise, or make arrangements with third parties to perform these services for us. The development of the infrastructure associated with these activities involves substantial resources, and considerable attention of our management and key personnel. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to fully develop marketing and sales capabilities, or enter into arrangements with third parties, our revenues may suffer.

**We are responsible for the distribution of GLUMETZA and Proquin XR, and we have limited experience with distribution of pharmaceutical products.**

We are responsible for the distribution of GLUMETZA and Proquin XR in the United States. Our in-house commercial operations and distribution capabilities are limited. In addition, we have entered into distribution arrangements with third parties, including Cardinal Health, AmerisourceBergen and McKesson, and we will depend on them to ensure that our marketed products are widely available. To continue to support our commercialization effort related to our marketed products, we must continue to enhance our internal commercial infrastructure, and continue to contract with capable third parties to assist us in our commercialization efforts. The continued development of that infrastructure will also require substantial resources, which may divert the attention of our management and key personnel. The efforts of third parties with whom we contract for distribution of our products may not be successful.

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**We depend on our marketing partners for the successful commercialization of GLUMETZA in Canada and Korea, and of Proquin XR in Europe.**

We have licensed exclusive marketing rights to the 500mg GLUMETZA in Canada to Biovail, and in Korea to LG Life Sciences. Biovail launched the 500mg GLUMETZA in Canada in November 2005, and LG launched a 500mg product in Korea in 2006 under the trade name Novamet GR. We have also entered into a license agreement with Madaus, a company acquired by Rottapharm in June 2007, related to the commercialization of Proquin XR in Europe. If our international commercial partners fail to successfully commercialize products we have licensed to them, our business and future revenues may be adversely affected.

**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. 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 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 support our operations. We have limited credit facilities and, except for our common stock purchase agreement with Azimuth, we have no other committed sources of capital. Our late stage clinical development programs will require considerable financial resources, and we may not be successful in entering into development and marketing arrangements in which a collaborative partner will pay for the costs of those programs. 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.

Some economists are now predicting that the United States economy, and possibly the global economy, may enter into a prolonged downturn or recession as a result of recent economic events, including the deterioration of the credit and capital markets and related financial crisis. Though the ultimate effect of these developments cannot be predicted, they may have a material adverse effect on our liquidity and financial condition and our ability to raise additional funds, whether pursuant to our existing or future financing arrangements. In addition, if these developments negatively impact the ability of our collaborative partners to develop, manufacture, promote or commercialize our products and product candidates, our revenues may suffer and our business, financial condition and results of operations could be materially and adversely affected. Similarly, any negative impact of an economic downturn or recession on our potential collaborative partners could adversely affect the terms on which collaborative partnerships may be available to us, if at all.



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**We are expecting 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, 2009, we recorded total revenues of \$9.9 million and for the years ended December 31, 2008, 2007 and 2006, we recorded total revenue of \$34.8 million, \$65.6 million, and \$9.6 million, respectively. For the three months ended March 31, 2009, we incurred a net loss of \$10.2 million and for the years ended December 31, 2008 and 2006 we incurred net losses of \$15.3 million and \$39.7 million, respectively. The termination of our license agreement with Esprit in July 2007, including the accelerated recognition of previously deferred revenue under the arrangement, and termination fees received associated with the termination of our promotion agreement with King resulted in our reaching profitability in 2007. However, as we continue our research and development efforts, preclinical testing and clinical trial activities, we anticipate that we will incur operating losses for the remainder of 2009. Therefore, we expect our cumulative losses to increase. These losses, among other things, have had, and we expect that they will continue to 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:

- results of clinical trials for our product candidates;
- announcements regarding clinical trial results and plans for our drug candidates, including DM-1796 and Serada;
- the degree of commercial success of GLUMETZA;
- regulatory actions;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply;
- results of litigation;

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- developments concerning proprietary rights, including patents, infringement allegations and litigation matters;
- variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other contract revenues;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- market acceptance of the AcuForm technology;
- adoption of new technologies by us or our competitors;
- the introduction of new products by our competitors;
- manufacturing costs and difficulties;
- 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 DM-1796 Phase 3 trial results in July 2007, 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 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 arrangements with Solvay, Santarus, Covidien, and Patheon, Inc. In addition, we have in the past and may in the future enter into other collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements. Collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements

may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs.

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We may be unable to enter into future collaborative arrangements on acceptable terms, which would 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.

**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 currently hold ten issued United States patents, and have seventeen 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.

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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 would 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.

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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.**

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 would violate our licensed patent, effectively monitoring compliance with our licensed patent may be difficult and costly.

**It is difficult to develop a successful product. If we do not develop a successful product, 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 GLUMETZA and Proquin XR, 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 would adversely impact our financial position and liquidity.

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**If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed and our stock price may decline.**

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development and commercialization goals. These milestones may include our expectations regarding the commercial launch of our products by us or our licensees, and the commencement or completion of scientific studies and clinical trials and the submission 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:

- our available capital resources;
- 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; 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 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 would 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.

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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, including compliance with FDA regulations governing current Good Manufacturing Practices (cGMP). Failure to comply with manufacturing regulations can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution.

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

All marketing activities associated with GLUMETZA and Proquin XR, 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.

**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 Madaus, are subject to numerous and varying foreign regulatory requirements, implemented by foreign health authorities, governing the design and conduct of human clinical trials and marketing approval for drug products. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country, nor does the approval by foreign health authorities ensure approval by the FDA.

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

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

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

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 would 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.

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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 system industries.**

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

Bristol-Myers Squibb is currently marketing a sustained release formulation of metformin, Glucophage XR, with which GLUMETZA competes. The limited license that Bristol-Myers Squibb obtained from us under our November 2002 settlement agreement extends to certain current and internally-developed future compounds, which may increase the likelihood that we will face competition from Bristol-Myers Squibb in the future on products in addition to GLUMETZA. Several other companies, including Barr Pharmaceuticals, Inc., Mylan Laboratories, Inc. and Teva Pharmaceutical Industries, Ltd. have received FDA approval for and are selling a controlled-release metformin product.

Bayer Corporation developed a once-daily ciprofloxacin product for the treatment of urinary tract infections, which is currently marketed by Schering-Plough Corporation. There are also generic versions of that product on the market. There may be other companies developing products competitive with GLUMETZA and Proquin XR 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. In addition, Pfizer has developed Lyrica® (pregabalin), which has been approved for marketing in the United States and the European Union.

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

We are responsible for the supply and distribution of GLUMETZA, and Patheon, Puerto Rico Inc. is our sole supplier for tablets of the 500mg strength of GLUMETZA pursuant to a supply agreement we entered into with MOVA Pharmaceuticals in December 2006. Biovail is our sole supplier for the 1000mg formulation GLUMETZA. We will be unable to manufacture GLUMETZA in a timely manner if we are unable to obtain GLUMETZA 500mg tablets from our contract manufacturer, active pharmaceutical ingredient from suppliers, or excipient suppliers, or GLUMETZA 1000mg tablets from Biovail.

We are also responsible for supply and distribution of Proquin XR. For the manufacture of Proquin XR tablets, we have entered into an agreement with Patheon, Puerto Rico, Inc., as our sole supplier. We purchase the active ingredient for Proquin XR from Uquifa Mexico, S.A., a sole supplier to us, on a purchase order basis. We will also be responsible for the manufacture of bulk Proquin XR tablets to Madaus for the European market, if the product is approved for marketing in European jurisdictions. We intend to purchase Proquin XR tablets from Patheon, Puerto Rico, Inc. for that purpose. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or Proquin XR tablets from our contract manufacturers, we may be unable to manufacture Proquin XR in a timely manner, if at all.

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Although we have obtained clinical batches of DM-1796 and Serada from a contract manufacturer, we currently have no long-term supply arrangement with respect to DM-1796 and Serada. Any failure to obtain clinical supplies of DM-1796 and Serada could adversely affect these clinical development programs.

**We depend on third parties to manufacture our products, which could adversely affect our ability to deliver our products to market on a timely or competitive basis.**

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 Phase 3 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 2009 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.

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Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Defending a lawsuit would 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, Carl A. Pelzel, 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. Pelzel or any of our other executive officers that provide for their continued employment with us. Our former Chairman, President and Chief Executive Officer retired in August 2007, and our Chief Financial Officer retired in October 2007; we have not yet replaced our Chief Financial Officer on a permanent basis. 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 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 under our equity line of credit arrangement or in other future financings, existing common shareholders will experience immediate dilution and, as a result, our stock price may go down.**

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our existing common shareholders will experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. For example, in December 2006, we entered into a common stock purchase agreement with Azimuth Opportunity Ltd., pursuant to which we may sell shares of common stock at a discount to the prevailing market price ranging from approximately 3.8% to 6.4%, excluding an additional placement agent fee of approximately 1.1% payable by us on the gross offering proceeds. In addition, as other capital raising opportunities present themselves, we may enter into financing or similar 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.

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

Our operations are vulnerable to damage or interruption from computer viruses, human error, natural disasters, telecommunications failures, intentional acts of vandalism and similar events. In particular, our corporate headquarters are located in the San Francisco Bay area, which has a history of seismic activity. We have not established a formal disaster recovery plan, and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses that occur. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

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

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

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**ITEM 6. EXHIBITS**

- (a) Exhibits
  - 10.1 Amendment to Amended and Restated Promotion Agreement dated February 18, 2009 between the Company and Watson Pharma, Inc.
  - 10.2 Form of Management Continuity Agreement between the Company and certain officers of the Company
  - 31.1 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Carl A. Pelzel
  - 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 Carl A. Pelzel
  - 32.2 Certification pursuant to 18 U.S.C. Section 1350 of Tammy L. Cameron

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**SIGNATURES**



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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 5, 2009

DEPOMED, INC.

/s/ Carl A. Pelzel  
Carl A. Pelzel  
President and Chief Executive Officer

/s/ Tammy L. Cameron  
Tammy L. Cameron  
Vice President, Finance and Interim Principal Accounting and  
Financial Officer