DEPOMED INC Form 10-Q May 04, 2010 Table of Contents

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

**FORM 10-Q** 

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

## FOR THE QUARTERLY PERIOD ENDED March 31, 2010

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 x = No o

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

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

Large accelerated filer o

Non-accelerated filer o

Accelerated filer x

Smaller reporting company o

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

The number of issued and outstanding shares of the Registrant s Common Stock, no par value, as of April 30, 2010 was 52,370,998.

Item 1. Condensed Financial Statements:

## DEPOMED, INC.

## PART I FINANCIAL INFORMATION

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#### PART I FINANCIAL INFORMATION

# ITEM 1. CONDENSED FINANCIAL STATEMENTS

## CONDENSED BALANCE SHEETS

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

	March 31, 2010 (Unaudited)	December 31, 2009 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,424	\$ 26,821
Marketable securities	51,527	42,922
Accounts receivable	6,276	4,933
Inventories	2,760	2,565
Prepaid and other current assets	2,634	1,185
Total current assets	70,621	78,426
Marketable securities, long-term	12,524	12,016
Property and equipment, net	871	942
Other assets	197	197
	\$ 84,213	\$ 91,581
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	14,452	15,222
Deferred product sales	1,594	1,635
Deferred license revenue	11,159	11,184
Other current liabilities	425	414
Current portion of long-term debt	3,859	3,747
Total current liabilities	31,489	32,202
Deferred license revenue, non-current portion	38,660	41,306
Long-term debt, net of current portion	1,160	2,170
Other long-term liabilities	143	177
Commitments		
Shareholders equity:		
Preferred stock, no par value, 5,000,000 shares authorized; Series A convertible preferred		
stock, 25,000 shares designated, 18,158 shares issued and surrendered, and zero shares		
outstanding at March 31, 2010 and December 31, 2009		
Common stock, no par value, 100,000,000 shares authorized; 52,354,402 and 52,200,358		
shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively	188,756	187,895
Accumulated deficit	(176,029)	(172,202)
Accumulated other comprehensive gain	34	33
Total shareholders equity	34 12,761	33 15,726 91,581

(1) Derived from the audited financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2009.

See accompanying notes to Condensed Financial Statements.

## CONDENSED STATEMENTS OF OPERATIONS

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

#### (Unaudited)

	Three Months E 2010	arch 31, 2009	
Revenues:			
Product sales	\$ 12,601	\$	6,840
Royalties	88		464
License and milestone revenue	2,671		2,568
Total revenues	15,360		9,872
Costs and expenses:			
Cost of sales	1,481		1,032
Research and development expense	5,187		10,021
Selling, general and administrative expense:			
Promotion fee expense	8,879		4,544
Other selling, general and administrative expense	3,550		4,458
Total selling, general and administrative expense	12,429		9,002
Total costs and expenses	19,097		20,055
Loss from operations	(3,737)		(10,183)
Other income (expense):			
Interest and other income	94		314
Interest expense	(183)		(285)
Total other income (expense)	(89)		29
Net loss before income taxes	(3,826)		(10,154)
Provision for income taxes	(1)		(1)
Net loss	\$ (3,827)	\$	(10,155)
Basic and diluted net loss per share	\$ (0.07)	\$	(0.20)
Shares used in computing basic and diluted net loss per share	52,298,726		51,207,540

See accompanying notes to Condensed Financial Statements.

## CONDENSED STATEMENTS OF CASH FLOWS

#### (in thousands)

#### (Unaudited)

	Three Months E 2010	nded Ma	nrch 31, 2009
Operating Activities			
Net loss	\$ (3,827)	\$	(10,155)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	153		214
Stock-based compensation	545		694
Changes in assets and liabilities:			
Accounts receivable	(1,343)		(323)
Inventories	(195)		(53)
Other current assets	(1,449)		1,933
Accounts payable and other accrued liabilities	539		(309)
Accrued compensation	(1,331)		(1,478)
Deferred revenue	(2,712)		22,376
Net cash (used in) provided by operating activities	(9,620)		12,899
Investing Activities			
Purchases of property and equipment	(49)		(84)
Purchases of marketable securities	(32,546)		(63,523)
Maturities of marketable securities	20,932		32,847
Sales of marketable securities	2,490		6,010
Net cash used in investing activities	(9,173)		(24,750)
Financing Activities			
Principal payments on long-term debt	(921)		(714)
Proceeds from issuance of common stock	317		26
Net cash used in financing activities	(604)		(688)
Net decrease in cash and cash equivalents	(19,397)		(12,539)
Cash and cash equivalents at beginning of period	26,821		22,127
Cash and cash equivalents at end of period	\$ 7,424	\$	9,588

See accompanying notes to Condensed Financial Statements.

## DEPOMED, INC.

# NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

## NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Basis of Presentation** 

These unaudited Condensed Financial Statements and the related footnote information of Depomed, Inc. (the Company or Depomed) have been prepared pursuant to the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of the Company s management, the accompanying interim unaudited condensed financial statements include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the periods presented. The results for the interim period ended March 31, 2010 are not necessarily indicative of results to be expected for the entire year ending December 31, 2010 or future operating periods.

The accompanying Condensed Financial Statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2009, included in our Annual Report on Form 10-K filed with the SEC. The condensed balance sheet at December 31, 2009 has been derived from audited financial statements at that date.

#### Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

#### **Revenue Recognition**

The Company recognizes revenue from the sale of its products, royalties earned, and on payments received and services performed under contractual arrangements. Revenue arrangements with multiple elements are divided into separate units of accounting if applicable 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.

## NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

Product Sales:

• <u>GLUMETZA</u>®: The Company sells GLUMETZA® (metformin hydrochloride extended release tablets) to wholesalers and retail pharmacies subject to rights of return six months before expiration and up to twelve months after product expiration. The Company recognizes revenue for GLUMETZA sales at the time title transfers to its customers, which occurs at the time product is delivered to its customers.

Proquin®XR: The Company sells Proquin® XR (ciprofloxacin hydrochloride) to wholesalers and retail pharmacies subject to rights of return six months before expiration and up to twelve months after product expiration. Given the Company s limited history of selling Proquin XR and decreasing prescription demand for 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, 2010 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 the 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.

• Product Sales Allowances The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company s agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from the Company s estimates, the Company may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company s product sales allowances include:

• Product Returns The Company estimates product returns on sales of GLUMETZA. The Company allows customers to return product that is within six months before and up to twelve months after its product expiration date. The shelf life of the 500mg GLUMETZA is currently 48 months from the date of tablet manufacture. On product launch in August 2006 and through the second quarter of 2008, the shelf life of 500mg GLUMETZA product shipped was 36 months from the date of tablet manufacture. During March 2010, the Company began shipping 1000mg GLUMETZA with a shelf life of 36 months from the date of tablet manufacture. Prior to March 2010, the 1000mg GLUMETZA shelf life on product shipped to customers was 24 months from the date of tablet manufacture. The Company monitors actual return history on individual product lot basis since product launch, which provides it with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product, shipment and prescription trends, estimated distribution channel inventory levels, the return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, as well as consideration of the introduction of competitive products.

## NOTES TO CONDENSED FINANCIAL STATEMENTS

#### (Unaudited)

• 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 product by the managed care organization.

• Wholesaler and Retail Pharmacy Discounts The Company offers discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

• Prompt Pay Discounts - The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. Based on the Company s experience, the Company expects its customers to comply with the payment terms to earn the cash discount. The Company accounts for cash discounts by reducing accounts receivable by the full amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

• Medicaid Rebates The Company participates in Medicaid rebate programs, which provide assistance to certain eligible low-income patients based on each individual state s guidelines regarding eligibility and services. Under the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three months after the quarter in which the prescription is filled. The Company estimates and accrues Medicaid rebates based on product pricing, current rebates and changes in the level of discounts the Company offers that may affect the level of Medicaid discount, historical and estimated future percentages of product sold to Medicaid recipients and estimated levels of inventory in the distribution channel.

• Chargebacks The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from 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.

• Patient Discount Programs The Company offers loyalty card programs to patients for GLUMETZA in which patients receive certain discounts at participating retail pharmacies that are reimbursed by the Company. The Company estimates and accrues future redemptions based on historical redemption activity.

#### NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

• 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 was 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 royalty cap that was met during 2009. The royalties were 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 accrued 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. As the \$2.5 million royalty cap was met in 2009, there were no royalties under this agreement in 2010.

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 cannot reliably be estimated.

• License and Collaborative Arrangements - Revenue from license and collaborative arrangements is recognized when the Company has substantially completed its obligations under the terms of the arrangement and the Company s remaining involvement is inconsequential and perfunctory. If the Company has significant continuing involvement under such an arrangement, license and collaborative fees are recognized over the estimated performance period. The Company recognizes milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. License, milestones and collaborative fee payments received in excess of amounts earned are classified as deferred revenue until earned.

## **Recently Issued Accounting Standards**

*In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-06,* Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements (ASU 2010-06), which amends the existing fair value measurement and disclosure guidance currently included in Accounting Standards Codification Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, ASU 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about

purchases, sales, issuances and settlements on a gross basis. In addition, ASU 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. The Company expects to adopt ASU 2010-06 on January 1, 2011 and does not expect to the adoption of ASU 2010-06 to have a material effect on its financial statements.

In September 2009, the FASB issued Accounting Standards Update 2009-13 (Topic 605), *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13). ASU 2009-13 applies to multiple-deliverable revenue arrangements that are currently within the scope of the *Revenue Recognition Multiple-Element Arrangements* topic of the Codification. ASU 2009-13 provides principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated and the consideration allocated. ASU 2009-13 requires an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price. ASU 2009-13 eliminates the use of the residual method and requires an entity to allocate revenue using the relative selling price method and also significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. ASU 2009-13 should be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. The Company expects to adopt ASU 2009-13 on January 1, 2011 and does not expect the adoption of ASU 2009-13 to have a material impact on its financial statements.

# DEPOMED, INC.

# NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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

Securities classified as available-for-sale as of March 31, 2010 and December 31, 2009 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

	Amortized	Gross Unrealized	Gross Unrealize	d	
March 31, 2010	Cost	Gains	Losses		Fair Value
U.S. debt securities:					
Total included in cash and cash equivalents	\$ 4,136	\$	\$	\$	4,136
Total maturing within 1 year and included in					
marketable securities:					
U.S. corporate debt securities	3,000	1			3,001
U.S. government agency debt securities	22,025	31		(7)	22,049
U.S. Treasury securities	26,468	9			26,477
Total maturing between 1 and 2 years and included					
in marketable securities:					
U.S. government agency debt securities	6,029			(4)	6,025
U.S. Treasury securities	6,495	5		(1)	6,499
Total available-for-sale	\$ 68,153	\$ 46	\$	(12) \$	68,187

	Amortized	Gross Unrealized	Gross Unrealized	d	
December 31, 2009	Cost	Gains	Losses		Fair Value
U.S. debt securities:					
Total included in cash and cash equivalents	\$ 21,186	\$	\$	\$	21,186
Total maturing within 1 year and included in					
marketable securities:					
U.S. corporate debt securities	7,900	1			7,901
U.S. government agency debt securities	12,989	40			13,029
U.S. Treasury securities	21,988	9		(5)	21,992
Total maturing between 1 and 2 years and included					
in marketable securities:					
U.S. government agency debt securities	12,028			(12)	12,016
U.S. Treasury securities					
Total available-for-sale	\$ 79,091	\$ 50	\$	(17) \$	76,124

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks, money market instruments and commercial paper. The Company places its cash, cash equivalents and marketable securities with high quality, U.S. financial institutions and, to date, has not experienced material losses on any of its balances. All marketable securities are classified as available-for-sale since these instruments are readily marketable. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive gain or 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 of March 31, 2010, the individual contractual period for all available-for-sale debt securities is less than two years.

# DEPOMED, INC.

# NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

At March 31, 2010, the Company had thirteen securities in an unrealized loss position. The following table shows the gross unrealized losses and fair value of the Company s investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at March 31, 2010 (in thousands):

		Less than 12 months			12 months or gro	Total			
				Gross		Gross			Gross
			Un	realized	U	Inrealized		1	Unrealized
U.S. Debt Securities	Fa	ir Value	I	Losses Fai	r Value	Losses	Fair Value		Losses
U.S. Treasury securities	\$	8,990	\$	(1) \$	\$	\$	8,990	\$	(1)
U.S. government agency debt									
securities		15,065		(11)			15,065		(11)
Total available-for-sale	\$	24,055	\$	(12) \$	\$	\$	24,055	\$	(12)

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, 2010.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The Company utilizes the following fair value hierarchy based on three levels of inputs:

Level 1: Quoted prices in active markets for identical assets or liabilities.

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• Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

• Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents the Company s fair value hierarchy for its financial assets measured at fair value on a recurring basis as of March 31, 2010 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 4,136	\$ \$	\$	4,136
U.S. corporate debt securities		3,001		3,001
U.S. government agency debt securities		28,074		28,074

U.S. Treasury securities		32,976	32,976
Total	\$ 4,136 \$	64,051 \$	\$ 68,187

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, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 21,186	\$	\$	\$ 21,186
U.S. corporate debt securities		7,901		7,901
U.S. government agency debt securities		25,045		25,045
U.S. Treasury securities		21,992		21,992
Total	\$ 21,186	\$ 54,938	\$	\$ 76,124

There are no financial liabilities measured at fair value on a recurring basis as of March 31, 2010 and December 31, 2009.

# DEPOMED, INC.

# NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

#### NOTE 3. NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated based on the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per common share is calculated based on the weighted-average number of shares of common stock outstanding and other dilutive securities outstanding during the period, if dilutive. The potential dilutive shares of common stock resulting from the assumed exercise of outstanding stock options and equivalents and the assumed exercise of the warrants are determined under the treasury stock method. Shares used in the computation of net loss per common share are as follows:

	Three Months Ended March 31,						
(In thousands, except per share amounts)		2010		2009			
Numerator for basic and diluted shares::							
Net loss	\$	(3,827)	\$	(10,155)			
Denominator for basic and diluted shares:							
Weighted-average common shares outstanding		52,299		51,208			
Basic and diluted net loss per share	\$	(0.07)	\$	(0.20)			

At March 31, 2010 and 2009, the total number of outstanding common stock equivalents excluded from the loss per share computation was 5.6 million and 6.5 million, respectively.

#### NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

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

In March 2010, Abbott Products Inc. (Abbott Products) submitted a New Drug Application (NDA) for DM-1796 to the U.S. Food and Drug Administration (FDA) for the management of post-herpetic neuralgia.

Effective January 2009, 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. Abbott Products acquired the pharmaceutical business of Solvay in a transaction that closed in February 2010.

Pursuant to the agreement, Solvay 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 NDA for DM-1796 for post-herpetic neuralgia, and sales milestone payments upon reaching certain sales milestones. Abbott Products is obligated to pay the Company royalties of 14 to 20 percent of net product sales, depending on the level of product sales.

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. For the three months ended March 31, 2010, the Company recognized \$1.6 million in license revenue under the arrangement. The remaining deferred revenue balance is \$17.3 million as of March 31, 2010.

# DEPOMED, INC.

# NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

#### NOTE 5. LONG-TERM DEBT

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

The Company paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Beginning in January 2009, the Company began principal payments on the first tranche, plus interest at such rate, which will be paid in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments at an interest rate of 11.59%. Interest expense, which includes amortization of debt issuance costs, was \$0.2 million for the three months ended March 31, 2010.

As of March 31, 2010, the outstanding balance under the facility was \$5.2 million, and the unamortized portion of the debt issuance costs was approximately \$0.2 million. Future contractual principal and interest payments are as follows (in thousands):

	Р	rincipal	Interest	
Less than 1 year	\$	3,957	\$	400
1-2 years		1,209		27
Total	\$	5,166	\$	427

The Company has the right to voluntarily prepay debt outstanding 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 (ii) 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, 2010.

## DEPOMED, INC.

# NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

#### NOTE 6. STOCK-BASED COMPENSATION

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

		Three Months Ended March 31,			
	2010		2009		
Cost of sales	\$	3	\$	9	
Research and development expense		166		208	
Selling, general and administrative expense		376		477	
Total	\$	545	\$	694	

At March 31, 2010, the Company had \$2.9 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 2.4 years.

#### NOTE 7. COMPREHENSIVE LOSS

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

	Three Months Ended March 31,			
		2010		2009
Net loss	\$	(3,827)	\$	(10,155)
Unrealized gain (loss) on available-for-sale				
securities				(66)
Total comprehensive loss	\$	(3,827)	\$	(10,221)

#### NOTE 8. INVENTORIES

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

	March 31, 2010	De	cember 31, 2009
Raw materials	\$ 81	\$	49
Finished goods	2,617		2,453
Deferred costs	62		63
Total	\$ 2,760	\$	2,565

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

### DEPOMED, INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

### NOTE 9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	March 31, 2010	December 31, 2009
Accounts payable	\$ 638	\$ 709
Accrued compensation	1,072	2,404
Accrued clinical trial expense	43	221
Accrued rebates and sales discounts	3,198	4,396
Allowance for product returns	3,682	3,364
Accrued promotion fee	3,926	1,752
Other accrued liabilities	1,893	2,376
Total accounts payable and accrued liabilities	\$ 14,452	\$ 15,222

### NOTE 10. SHAREHOLDERS EQUITY

### **Option Exercises**

For the three months ended March 31, 2010, employees and consultants exercised options to purchase 154,044 shares of the Company s common stock with net proceeds to the Company of approximately \$0.3 million.

### NOTE 11. INCOME TAXES

As of December 31, 2009 and March 31, 2010, the Company had \$3.2 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.

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

FORWARD-LOOKING INFORMATION

Statements made in this Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q that are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, may and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

• regulatory filings and approval of DM-1796 for postherpetic neuralgia;

• the commercial success and market acceptance of DM-1796 if it is approved for marketing in the United States, and the efforts of Abbott Products Inc. (a wholly-owned subsididary of Abbott Laboratories, or Abbott Products) with respect to the commercialization of DM-1796;

• results and timing of our clinical trials, including the results of our Serada Phase 3 trial for menopausal hot flashes;

• the commercial success and market acceptance of Serada if we receive approval to market Serada in the United States;

• 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 ongoing litigation against Lupin Limited (Lupin) related to Lupin s abbreviated New Drug Application (ANDA) to market generic GLUMETZA in the United States;

- the results of our research and development efforts;
- submission, acceptance and approval of regulatory filings;
- our need for, and ability to raise additional capital;

• our collaborative partners compliance or non-compliance with 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. In 2009, we completed Phase 3 clinical trials for two product candidates. In October 2009, we announced that DM-1796, an extended release formulation of gabapentin for the treatment of postherpetic neuralgia that we have licensed to Abbott Products met its Phase 3 clinical trial primary endpoint with statistical significance. A New Drug Application (NDA) for DM-1796 was filed with the FDA in March 2010. Also in October 2009, we announced the results of Breeze 1 and Breeze 2, our Phase 3 clinical trials for Serada, our proprietary extended release formulation of gabapentin for the treatment of menopausal hot flashes. The higher dose formulation of Serada evaluated in the studies met five of eight co-primary endpoints across the two studies, while the lower dose formulation evaluated met four of eight co-primary endpoints. In December 2009, we met with the FDA to discuss the results of the Breeze 1 and Breeze 2 studies and any additional clinical development that may be required to obtain approval to market Serada in the United States. We expect to initiate one additional Phase 3 trial for Serada after we reach an agreement with the FDA on a Special Protocol Assessment (SPA) for the trial.

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We seek to optimize the use and value of our product candidates and drug delivery technologies in three ways. First, we are seeking to assemble a number of pharmaceutical products that can be highly differentiated from immediate release versions of the compounds upon which they are based and may be promoted together within a specialty pharmaceutical field, such as women s health care providers. Our development of Serada, and our retention of co-promotion rights within the obstetrics/gynecology field in our commercialization arrangements with Covidien, Ltd. (Covidien) and Santarus, Inc. (Santarus), are examples of this aspect of our business strategy. Second, we out-license product candidates after we have increased their value through our formulation and clinical development efforts. Our DM-1796 license and development arrangement with Abbott Products 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 and our license agreement with Merck & Co., Inc. (Merck) are examples of this strategy.

We have developed two products which have been approved by the FDA and are currently marketed. GLUMETZA is a once-daily treatment for adults with type 2 diabetes that we commercialize in the United States with Santarus. Proquin® XR (ciprofloxacin hydrochloride) is a once-daily treatment for uncomplicated urinary tract infections.

The following table summarizes our product pipeline and marketed products.

### **Product Pipeline**

Product	Indication	Status
DM-1796	Postherpetic neuralgia	Phase 3 study completed.
		New Drug Application submitted to the FDA in March 2010.
		Licensed to Abbott Products in the United States, Mexico and Canada.
SeradaTM	Menopausal hot flashes	Phase 3 studies completed (Breeze 1 and Breeze 2).
		One additional Phase 3 study (Breeze 3) expected to be initiated in Q2 or Q3 2010.
DM-3458	Gastroesophageal reflux disease	Proof of concept studies completed.
DM-1992	Parkinson s disease	Phase 1 study completed.
		Second Phase 1 study expected to be initiated in 2010.

### **Marketed Products**

Product	Indication	Status
GLUMETZA®	Type 2 diabetes	Currently sold in the United States and Canada.
		Co-promoted in the United States with Santarus.

		Canadian rights held by Biovail.
		Korean rights held by LG Life Sciences.
Proquin® XR	Uncomplicated urinary tract infection	Currently sold in the United States.
		Regulatory application approved in Sweden.
		European rights held by Rottapharm/Madaus.
		17

### Significant Developments and Highlights for the Quarter Ended March 31, 2010

• In March 2010, a NDA for DM-1796 for the treatment of postherpetic neuralgia was filed with the Food & Drug Administration (FDA) by Abbott Products.

• Revenue for the three months ended March 31, 2010 was \$15.4 million, compared to \$9.9 million for the three months ended March 31, 2009.

• Operating expenses for the three months ended March 31, 2010 were \$17.6 million, compared to \$19.0 million for the three months ended March 31, 2009.

• Cash, cash equivalents and marketable securities were \$71.5 million as of March 31, 2010, compared to \$81.8 million as of December 31, 2009.

### RECENT PRODUCT DEVELOPMENTS AND TRANSACTIONS

DM-1796 for Postherpetic Neuralgia

<u>Abbott Products Inc.</u> In November 2008, we entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) 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. Abbott Products acquired the pharmaceutical business of Solvay in a transaction that closed in February 2010.

In March 2010, Abbott Products submitted a New Drug Application (NDA) for DM-1796 to the U.S. Food and Drug Administration (FDA) for the management of postherpetic neuralgia.

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. Abbott Products will pay us royalties of 14 to 20 percent of net product sales, depending on the level of net product sales.

We remain responsible for certain other regulatory support activities through NDA approval. Abbott Products is responsible for NDA filing and has the option to develop DM-1796 in further pain indications other than PHN. If Abbott Products 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 are 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 Abbott Products in 2010. The license agreement will expire with the last to expire of our patents covering DM-1796, subject to early termination in certain circumstances.

## Serada for Menopausal Hot Flashes

<u>Phase 3 Study-Breeze 3 Clinical Trial</u>. In December 2009, the Company met with the FDA regarding Serada for the treatment of menopausal hot flashes. Based on guidance reflected in the meeting minutes, Depomed plans to conduct a single additional pivotal Phase 3 trial evaluating Serada for the treatment of menopausal hot flashes. The company expects to initiate the trial, which will be known as Breeze 3, after it reaches agreement with the FDA on a Special Protocol Assessment (SPA) for the trial.

The Breeze 3 protocol has been reviewed by the FDA under the FDA s special protocol assessment procedures. An SPA is an agreement with the FDA that a proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support a product candidate s regulatory approval. We received an initial assessment of the Breeze 3 protocol in March 2010, and resubmitted the protocol for a further assessment after modifying the protocol to address the FDA s guidance reflected in the initial assessment. On April 30, 2010, we received the FDA s further guidance on the protocol. The guidance included three minor comments related to the statistical analysis of a secondary endpoint, the Patient Global Impression of Change (PGIC). The PGIC will be used in conjunction with a responder analysis that may be required to assess the clinical meaningfulness of any reduction in the frequency of hot flashes in the active arm relative to the placebo arm. Pursuant to SPA procedures, we have requested a meeting with the FDA to reach final agreement on an SPA for Breeze 3. We will begin enrolling patients as soon as we receive FDA s agreement, which we expect to occur by early July 2010.

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

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

### 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 2009 Annual Report on Form 10-K with the Securities and Exchange Commission on March 9, 2010. For a description of our critical accounting policies, please refer to our 2009 Annual Report on Form 10-K.

### **RESULTS OF OPERATIONS**

Three Months Ended March 31, 2010 and March 31, 2009

Revenue

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

	Three Months Ended March 31, 2010 2009			
Product sales:				
GLUMETZA	\$ 12,545	\$	6,643	
Proquin XR	56		197	
Total product sales	12,601		6,840	
Royalties:				
GLUMETZA	88		36	
Teva			428	
Total royalties	88		464	
License and collaborative revenue:				
DM-1796	1,561		1,477	
GLUMETZA	626		626	
Acuform technology	458		458	
Proquin XR	26		7	
Total license and collaborative revenue	2,671		2,568	
Total revenues	\$ 15,360	\$	9,872	

### Product sales

<u>GLUMETZA</u>. The increase in GLUMETZA product sales for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009 is primarily driven by increased penetration in the metformin prescription market resulting from the promotion efforts by our promotion partner, Santarus, and price increases during 2009 and the first quarter of 2010.

Product sales for GLUMETZA relative to its current runrate will depend in part on the success of our promotion partner, Santarus, as well any price adjustments.

<u>Proquin XR</u>. 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, 2010, 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.

In February 2009, we amended our promotion agreement with Watson, pursuant to which Watson performed a specified number of details in the first quarter of 2009. The agreement with Watson terminated effective December 31, 2009, and we currently have no sales force or promotion partner promoting Proquin XR to physicians. Accordingly, we expect product sales for Proquin XR relative to its current runrate to decrease as a result of a decrease in promotional efforts.

### Royalties

<u>GLUMETZA</u>. 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.

<u>*Teva*</u>. 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 were entitled to receive up to a total of \$2.5 million in future royalties on Teva s generic Glucophage XR product in the United States. The \$2.5 million cap in royalties was met in 2009.

### License revenue

<u>DM-1796</u>. DM-1796 license revenue for the three months ended March 31, 2010 and 2009 relates to the \$25.0 million upfront payment received from Solvay, now Abbott Products, under our license agreement granting Abbott Products 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.

<u>GLUMETZA</u>. GLUMETZA license revenue for the three months ended March 31, 2010 and 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.

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 pay Santarus for GLUMETZA in the United States.

<u>Acuform Technology</u>. 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 products containing acetaminophen in combination with opiates. 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 of GLUMETZA and Proquin XR. Total cost of sales for the three months ended March 31, 2010, as compared to the prior year, was as follows (in thousands):

	Т	Three Months Ended March 31,				
	20	)10		2009		
Cost of sales	\$	1,481	\$	1,032		

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Cost of sales for the three months ended March 31, 2010 and 2009 relates primarily to costs associated with the sale of GLUMETZA and Proquin XR. Cost of sales increased in 2010 as compared to the corresponding period in 2009 primarily as a result of an increase in GLUMETZA product sales.

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, 2010, as compared to the prior year, was as follows (in thousands):

	Three Months Ended March 31,				
		2010	2009		
Research and development expense	\$	5,187	\$	10,021	
Dollar change from prior year		(4,834)			
Percentage change from prior year		(48)%			

The decrease in research and development expense for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009 was primarily due to lower clinical research organization expenses related to the completion of our DM-1796 Phase 3 and Serada Breeze 1 and Breeze 2 Phase 3 programs in October 2009.

We plan to conduct a single additional pivotal Phase 3 trial evaluating Serada for the treatment of menopausal hot flashes. The company expects to initiate the trial, which will be known as Breeze 3, by the end of July 2010. As such, we expect research and development expense to increase from levels reported for the three months ended March 31, 2010. While we expect to continue to incur significant research and development expenses resulting from the progress of Breeze 3, we expect total research and development expenses to decrease in 2010 from 2009 as a result of completion of the DM-1796 Phase 3 clinical trial during 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 the expenses associated with all other projects in our product pipeline.

	Three Months Ended March 31,					
		2010		2009		
DM-1796	\$	1,377	\$	4,081		
Serada		1,948		3,575		
Other projects		1,862		2,365		
Total research and development expenses	\$	5,187	\$	10,021		

### Selling, General and Administrative Expense

Selling, general and administrative expenses primarily consist of personnel expenses to support our administrative and operating activities, marketing and promotion expenses associated with Serada, 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,				
	2010		2009		
Selling, general and administrative expense:					
Promotion fee expense	\$ 8,879	\$	4,544		
Other selling, general and administrative expense	3,550		4,458		
Total selling, general and administrative expense	\$ 12,429	\$	9,002		
Dollar change from prior year	3,427				
Percentage change from prior year	38%				

The increase in selling, general and administrative expense was primarily due to an increase in GLUMETZA promotion fees to Santarus which was driven by an increase in GLUMETZA gross margin. The increase in promotion fee expense was partially offset by a decrease in other expenses due to lower headcount in 2010.

### **Interest Income and Expense**

	Tł	Three Months Ended March 31,							
(in thousands)	20	2010							
Interest and other income	\$	94	\$		314				
Interest expense		(183)			(285)				
Net interest income (expense)		(89)			29				

Interest and other income decreased during the three months ended March 31, 2010 as compared to the corresponding period in 2009 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

	March 31, 2010	December 31, 2009		
Cash, cash equivalents and marketable securities	\$ 71,475	\$	81,759	

Since inception through March 31, 2010, 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 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, 2010, we have not sold any common stock to Azimuth under this common stock purchase agreement.

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

We paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Thereafter we are required to pay principal on the first tranche, plus interest at such rate, in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments with an interest rate of 11.59%. As of March 31, 2010, the entire outstanding balance on the credit facility was \$5.2 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, 2010, 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, 2010, we have accumulated net losses of \$176.0 million. We expect to continue to incur operating losses for the remainder of 2010. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of 2011. 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, including arrangements we make for the commercialization of Serada, if the product is approved for marketing;

- financial terms of definitive license agreements or other commercial agreements we enter into, 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;
- commercialize any products we market;
- conduct preclinical and clinical testing; and

• manufacture (or have manufactured) and market (or have marketed) our marketed products and product candidates.

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

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

**Cash Flows from Operating Activities** 

Cash used in operating activities during the three months ended March 31, 2010 was approximately \$9.6 million, compared to cash provided by operating activities of approximately \$12.9 million for the three months ended March 31, 2009. Cash used in operating activities during the three months ended March 31, 2010 was primarily due to our net loss adjusted for movements in working capital, stock-based compensation and depreciation expense. Cash provided by operating activities for the three months March 31, 2009 was primarily as a result of the \$25.0 million upfront payment received from Solvay in February 2009, offset by a net loss for the three months ended March 31, 2009.

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

Net cash used in investing activities during the three months ended March 31, 2010 was approximately \$9.2 million and consisted primarily of a net increase in marketable securities as a result of a shift in purchasing slightly longer term securities. During the three months ended March 31, 2010, the Company purchased more securities with original maturities greater than three months as compared to the fourth quarter of 2009, where purchases of securities with original maturities under three months are classified as cash equivalents and not marketable securities. Net cash used in investing activities during the three months ended March 31, 2009 was approximately \$24.8 million and consisted primarily a net increase in marketable securities resulting from investment of the upfront payment received from Solvay in February 2009.

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

Cash used in financing activities during the three months ended March 31, 2010 was approximately \$0.6 million compared to \$0.7 million for the same period in 2009, and consisted of repayments of principal on our credit facility offset by proceeds from employee and consultant option exercises.

### **Contractual Obligations**

As of March 31, 2010, 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	\$ 1,613	1,370	\$	\$ 2,983
Long-term debt (principal)	3,957	1,209		5,166
Long-term debt (interest)	400	27		427
Purchase commitments	1,690			1,690
	\$ 7,660	\$ 2,606	\$	\$ 10,266

At March 31, 2010 we had non-cancelable purchase orders and minimum purchase obligations of approximately \$0.7 million under our manufacturing agreement with Patheon Puerto Rico, Inc. for the manufacture of 500mg GLUMETZA, and \$1.0 million under our supply agreement with Biovail for the supply of 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. The payments relate to various milestones for the product candidate under the sublicense agreement, including submission to the FDA of an NDA, and FDA approval of an NDA. The above table also excludes any future

royalty payments we may be required to pay on products we have licensed or any promotion fees associated with our promotion agreement with Santarus.

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

There have been no significant changes in our market risk compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009.

### **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 Chief Executive Officer and Vice President, Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this quarterly report. Based on that evaluation, our management, including the Company s Chief Executive Officer and Vice President, Finance, concluded that our disclosure controls and procedures were effective.

We review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. Our goal is to ensure that our senior management has timely access to all material financial and non-financial information concerning our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

### **Changes in Internal Controls**

There were no changes in our internal controls over financial reporting during the quarter ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### PART II OTHER INFORMATION

### **ITEM 1. LEGAL PROCEEDINGS**

### Depomed v. Lupin (U.S. Generic GLUMETZA Litigation)

In November 2009, we filed a lawsuit against Lupin for infringement of the patents listed in the Orange Book for the our GLUMETZA product. The lawsuit is in response to an Abbreviated New Drug Application filed by Lupin with the FDA regarding Lupin s intent to market generic versions of 500mg and 1000mg dosage strengths of GLUMETZA prior to the expiration of the four listed patents (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; and 6,723,340). The Company has commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving Lupin s ANDA for 30 months or until a district court decision that is adverse to the patents, whichever may occur earlier. An adverse outcome in this matter could substantially weaken our U.S. intellectual property.

### Biovail and Depomed v. Apotex (Canadian Generic GLUMETZA Litigation)

In December 2007, Apotex, Inc. (Apotex) filed the Canadian equivalent of an Abbreviated New Drug Application in Canada seeking approval to market a generic version of the 500mg formulation of GLUMETZA in Canada.

In February 2010, Apotex received clearance from the Minister of Health in Canada to market the generic version of the 500mg formulation of GLUMETZA. Also in February 2010, Biovail and Depomed filed a complaint in the Federal Court in Canada against Apotex for infringement of the Company s Canadian Patent No. 2,290,624.

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

### ITEM 1A. RISK FACTORS

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, 2009.

The following factors, along with those described above under MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS LIQUIDITY AND CAPITAL RESOURCES should be reviewed carefully, in conjunction with the other information contained in this Report and our financial statements. These factors, among others, could cause actual

results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-Q and presented elsewhere by our management from time to time. See Part I, Item 2 Forward-Looking Information.

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

Our license agreement with Abbott Products grants Abbott Products exclusive rights to develop and commercialize DM-1796 in the United States, Canada and Mexico for pain indications. We depend on Abbott Products to obtain regulatory approval and complete any further development of DM-1796, and to commercialize the product in the licensed territories, 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 Abbott Products may not be successful in our efforts to obtain regulatory approval of DM-1796 in a timely manner, or at all;
- Abbott Products may experience financial difficulties; or

• Abbott Products 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.

Abbott completed its acquisition of Solvay s pharmaceutical business in February 2010. Accordingly Abbott s subsidiary, Abbott Products, is now responsible for the DM-1796 license arrangement. We do not yet know whether Abbott Products will be as committed to the development and commercialization of DM-1796 as Solvay, or whether Abbott Products may sublicense some or all of its obligations under the license agreement. However, it is possible that Abbott Products s acquisition of Solvay s pharmaceutical business may adversely affect the development or commercialization of DM-1796.

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

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

We will incur significant additional expenses and will not know for at least one to two years whether the drug is safe and effective such that it could be approved for marketing. Clinical development is a long, expensive and uncertain process and is subject to delays. The positive or encouraging results of prior clinical trial are not necessarily indicative of the results we will obtain in later clinical trials. Accordingly, our additional Phase 3 trial may not demonstrate that Serada is effective for menopausal hot flashes. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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;
- Santarus may in the future choose to devote fewer resources to GLUMETZA;
- GLUMETZA may fail to achieve greater market acceptance;

• The outcome of our ongoing litigation against Lupin Limited seeking to prevent Lupin from marketing a generic version of GLUMETZA in the United States;

- Santarus may experience financial difficulties; and
- Santarus may fail to comply with its obligations under our promotion agreement.

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.

In April 2010, Santarus announced that the U.S. District Court for the District of Delaware ruled that five patents covering Santarus Zegerid® (omeprazole/sodium bicarbonate) prescription products were invalid due to obviousness. The ruling may have an adverse impact on Santarus, which may in turn have an adverse impact on Santarus commitment to GLUMETZA sales and marketing efforts.

The timing and any potential negative outcome in the ongoing patent litigation with Lupin could adversely affect our financial condition and results of operations as it could result in the introduction of generic products prior to the expiration of the patents for GLUMETZA, as well as in significant legal expenses and diversion of management time.

In November 2009, we filed a lawsuit in the United States District Court for the Northern District of California against Lupin for infringement of U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; and 6,723,340 listed in the Orange Book for GLUMETZA. The lawsuit is in response to an Abbreviated New Drug Application (ANDA) filed by Lupin with the FDA regarding Lupin s intent to market generic versions of the 500mg and 1000mg strengths of GLUMETZA prior to the expiration date of the asserted patents.

We commenced the lawsuit against Lupin within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Lupin s ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. The 30-month stay expires in May 2012. If the litigation is still ongoing after expiration of the applicable 30-month stay, the termination of the stay could result in the introduction of one or more products generic to GLUMETZA prior to resolution of the litigation.

Although we intend to vigorously defend and enforce our patent rights, we are not able to predict the timing or outcome of the litigation. The court may render its decision at any time after the filing of the post-trial briefs, which may be before or after the expiration of the 30-month stay. An adverse outcome in this litigation could result in one or more generic versions of GLUMETZA being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to maximize the value of GLUMETZA and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. Regardless of how the litigation is ultimately resolved, the litigation may be costly, time-consuming and distracting to management, which could have a material adverse effect on our business.

## 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, or pending regulatory approval: DM-1796 for neuropathic pain and Serada for menopausal hot flashes, and DM-1992 for Parkinson s. We also have other product candidates in earlier stages of development.

Our own product candidates and those of our collaborative partners are subject to the risk that any or all of them may be found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. Additionally, clinical trial results in earlier trials may not be indicative of results that will be obtained in subsequent larger trials, as was the case with the Phase 3 trial for DM-1796 for the treatment of postherpetic neuralgia that we completed in 2007, and with the Phase 3 trials evaluating Serada for menopausal hot flashes we completed in October 2009.

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 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, 2010, we recorded total revenues of \$15.4 million and for the years ended December 31, 2009, 2008 and 2007, we recorded total revenues of \$57.7 million, \$34.8 million, and \$65.6 million, respectively. For the three months ended March 31, 2010, we incurred a net loss of \$3.8 million, and for the years ended December 31, 2009 and 2008 we incurred net losses of \$22.0 million and \$15.3 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 2010. 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.

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#### 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:

- announcements and results regarding clinical trial results and plans for our drug candidates, including DM-1796 and Serada;
- filings and other regulatory actions related to DM-1796, Serada and our other product candidates;
- the degree of commercial success of GLUMETZA;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply;
- the outcome of our patent infringement litigation against Lupin for GLUMETZA;
- 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 Serada Phase 3 trial results in October 2009, could give rise to shareholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved 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 Abbott Products, Santarus and Covidien. In addition, we have in the past and may in the future enter into other collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements. Collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs.

We may be unable to enter into future collaborative arrangements on acceptable terms, which 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 have limited in-house sales and marketing resources, which we will require in order to successfully promote products through our own sales force.

If Serada or another product we develop or acquire is approved for marketing in the United States, we may choose to promote the product with our own sale force or through a contract sales organization. We also have rights to promote GLUMETZA through our own sales force, or through third parties, and we have retained co-promotion rights for certain product candidates our collaborative partners may develop. We currently have no sales force and limited marketing and sales staff. The success of our own promotion efforts for Serada, 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 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 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. As of March 31, 2010, we have \$5.2 million of principal outstanding under the facility. The credit facility is secured by a pledge of all of our assets other than intellectual property, and contains a variety of operational covenants, including limitations on our ability to incur liens or additional debt, make dispositions, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions and transactions with affiliates, among other restrictions. Any future debt financing we enter into may involve similar or more restrictive covenants affecting our operations. Our borrowings under the credit facility or any future debt financing will need to be repaid, which creates additional financial risk for our company, particularly if our business, or prevailing financial market conditions, are not conducive to paying off or refinancing our outstanding debt obligations. Furthermore, our failure to comply with the covenants in the credit facility could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, which could have a material adverse effect on our cash position and significantly harm our business.

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

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to consistently support our operations. We have limited credit facilities and, except for our common stock

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purchase agreement with Azimuth, we have no other committed sources of capital. Any additional development of Serada for menopausal hot flashes or other clinical development programs may require considerable financial resources, should we choose to invest in those programs. To the extent that our capital resources are insufficient to meet our future capital requirements, in order to continue our development programs, we will have to raise additional funds through the sale of our equity securities, through debt financing, or from development and licensing arrangements. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders equity positions. If adequate funds are not available we may have to:

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

#### The global economic downturn may adversely affect our business.

The economic downturn that has affected the global economy over the past several fiscal quarters 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.

#### 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 thirteen issued United States patents, and have fifteen patent applications pending in the United States. In addition, we are preparing patent applications relating to our expanding technology for filing in the United States and abroad. We have also applied for patents in numerous foreign countries. Some of those countries have granted our applications and other applications are still pending. Our pending patent applications may lack priority over others applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or may not provide us with competitive advantages against competing products. We also rely on trade secrets and proprietary know-how, which are difficult to protect. We seek to protect such information, in part, through entering into confidentiality agreements with employees, consultants, collaborative partners and others before such persons or entities have access to our proprietary trade secrets and know-how. These confidentiality agreements may not be effective in certain cases, due to, among other things, the lack of an adequate remedy for breach of an agreement or a finding that an agreement is unenforceable. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

Our ability to develop our technologies and to make commercial sales of products using our technologies also depends on not infringing others patents or other intellectual property rights. We are not aware of any intellectual property claims against us. However, the pharmaceutical industry has experienced extensive litigation regarding patents and other intellectual property rights. For example, Pfizer has initiated several suits against companies marketing generic gabapentin products, claiming that these products infringe Pfizer s patents. The results of this litigation could adversely impact the commercialization of pharmaceutical products that contain gabapentin as an active pharmaceutical ingredient. Also, patents issued to third parties relating to sustained release drug formulations or particular pharmaceutical compounds could in the future be asserted against us, although we believe that we do not infringe any valid claim of any patents. If claims concerning any of our products were to arise and it was determined that these products infringe a third party s proprietary rights, we could be subject to substantial damages for past infringement or be forced to stop or delay our activities with respect to any infringing product, unless we can obtain a license, or we may have to redesign our product so that it does not infringe upon others patent rights, which may not be possible or could require substantial funds or time. Such a license may not be available on acceptable terms, or at all. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which 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 continue to develop successful products, our financial position and liquidity will be adversely affected.

The drug development process is costly, time-consuming and subject to unpredictable delays and failures. Before we or others make commercial sales of products using the Acuform technology, other than 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.

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

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development and commercialization goals. These milestones may include our expectations regarding the commercial launch of our products by us or our licensees, and the commencement or completion of scientific studies and clinical trials and the submission or approval of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, or the commercial launch of products. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary considerably from our estimates depending on numerous factors, some of which are beyond our control, including:

• the efforts of our marketing partners with respect to the commercialization of our products;

• the rate of progress, costs and results of our clinical trial and research and development activities, including the extent of scheduling conflicts with participating clinicians and clinical institutions and our ability to identify and enroll patients who meet clinical trial eligibility criteria;

- our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;
- other actions by regulators;

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

- our available capital resources; and
- the costs of ramping up and maintaining manufacturing operations, as necessary.

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

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

We rely on clinical investigators and clinical sites to enroll patients and other third parties to manage our trials and to perform related data collection and analysis. However, we may be unable to control the amount and timing of resources that the clinical sites that conduct the clinical testing may devote to our clinical trials. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedule, we will be unable to complete these trials or to complete them as planned, which could delay or prevent us from obtaining regulatory approvals for our product candidates.

Our agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, clinical sites or other third parties do not carry out their 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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For example, the active ingredients in the products utilizing our Acuform delivery technology that are being developed pursuant to our collaboration with Covidien include acetaminophen in combination with opiates. In connection with concerns that consumers may inadvertently take more than the recommended daily dose of acetaminophen, potentially causing liver damage, an FDA advisory committee has recommended that prescription products containing acetaminophen in combination with prescription analgesics (including opiates) should include black box warnings and/or be removed from the market. The FDA is evaluating the recommendations and has indicated that such an evaluation will take some time. The FDA is not required to accept advisory committee recommendations. Covidien s ability or willingness to develop and market the products subject to our collaboration may be adversely affected by actions of the FDA in response to the advisory committee recommendations.

Further, with respect to our approved products, once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of approved products are also subject to ongoing regulation, 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.

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 Elan Corporation, Bristol-Myers Squibb, IVAX Corporation (a subsidiary of TEVA Pharmaceutical Industries, Ltd.), 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 Shinogi & Co., Ltd., 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.

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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. 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.

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 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 2010 sales of our products, but:

- we may be unable to obtain product liability insurance for future trials;
- we may be unable to obtain product liability insurance for future products;
- we may be unable to maintain product liability insurance on acceptable terms;
- we may be unable to secure increased coverage as the commercialization of the Acuform technology proceeds; or
- our insurance may not provide adequate protection against potential liabilities.

Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Defending a lawsuit 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. We may have difficulty filling open senior scientific, financial and commercial positions. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates.

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

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or such investment. We do not know if we would be able to successfully complete any acquisitions, or whether we would be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we were to be unable to integrate any acquired businesses, products or technologies effectively, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could harm our operating results.

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

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

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.

#### 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. RESERVED

Not applicable.

**ITEM 5. OTHER INFORMATION** 

Not applicable.

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### **ITEM 6. EXHIBITS**

(a) Exhibits	
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

SIGNATURES

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

Date: May 3, 2010

DEPOMED, INC.

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

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