

DEPOMED INC  
Form 10-Q  
November 07, 2008  
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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**



☒

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008**

**OR**

☐

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

**FOR THE TRANSITION PERIOD FROM      TO**

**COMMISSION FILE NUMBER 001-13111**

**DEPOMED, INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

**CALIFORNIA**

(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

**94-3229046**

(I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

**1360 O BRIEN DRIVE**

**MENLO PARK, CALIFORNIA 94025**

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

**(650) 462-5900**

(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐  
(Do not check if a smaller reporting  
company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The number of issued and outstanding shares of the Registrant's Common Stock, no par value, as of November 6, 2008 was 51,055,453.

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**PART I FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**



## DEPOMED, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	September 30, 2008 (Unaudited)	December 31, 2007 (1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,120	\$ 14,374
Marketable securities	71,332	39,091
Accounts receivable	3,612	3,390
Unbilled accounts receivable	510	233
Inventories	3,008	3,263
Prepaid and other current assets	3,111	2,418
Total current assets	95,693	62,769
Marketable securities		16,058
Property and equipment, net	1,116	1,621
Other assets	197	197
	\$ 97,006	\$ 80,645
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,345	\$ 1,134
Accrued compensation	1,930	1,558
Accrued clinical trial expense	844	322
Other accrued liabilities	5,129	3,322
Deferred product sales	1,437	6,489
Deferred license revenue	2,529	1,453
Other current liabilities	302	56
Current portion of long-term debt	2,621	
Total current liabilities	16,137	14,334
Deferred license revenue, non-current portion	30,376	20,763
Long-term debt, net of current portion	6,499	
Other long-term liabilities	598	28
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 outstanding at September 30, 2008 and December 31, 2007, with an aggregate liquidation preference of \$18,159	12,015	12,015
Common stock, no par value, 100,000,000 shares authorized; 48,140,927 and 47,865,529 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	170,527	168,287
Accumulated deficit	(138,965)	(134,892)
Accumulated other comprehensive (loss) gain	(181)	110
Total shareholders' equity	43,396	45,520
	\$ 97,006	\$ 80,645

(1) Derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

See accompanying notes to Condensed Consolidated Financial Statements.





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	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Revenues:				
Product sales	\$ 13,011	\$ 3,832	\$ 23,756	\$ 7,666
Royalties	516	2,546	1,060	2,625
License revenue	584	46,481	1,311	50,003
Collaborative and other revenue		1		3
Total revenues	14,111	52,860	26,127	60,297
Costs and expenses:				
Cost of sales	2,396	724	4,567	1,598
Research and development	6,998	4,724	17,748	19,425
Selling, general and administrative	5,250	8,483	16,998	21,033
Gain on termination of Esprit Pharma agreement		(5,000)		(5,000)
Gain on litigation settlement			(7,500)	
Total costs and expenses	14,644	8,931	31,813	37,056
Income (loss) from operations	(533)	43,929	(5,686)	23,241
Other income (expense):				
Interest and other income	515	638	1,871	1,504
Interest expense	(249)		(254)	
Total other income (expense)	266	638	1,617	1,504
Net income (loss) before income taxes	(267)	44,567	(4,069)	24,745
Provision for income taxes	(4)	(248)	(4)	(252)
Net income (loss)	(271)	44,319	(4,073)	24,493
Deemed dividend on preferred stock	(183)	(174)	(538)	(511)
Net income (loss) applicable to common stock shareholders	\$ (454)	\$ 44,145	\$ (4,611)	\$ 23,982
Basic net income (loss) applicable to common stock shareholders per common share	\$ (0.01)	\$ 0.93	\$ (0.10)	\$ 0.53
Diluted net income (loss) applicable to common stock shareholders per common share	\$ (0.01)	\$ 0.92	\$ (0.10)	\$ 0.52
Shares used in computing basic net income (loss) per common share	48,123,668	47,630,945	48,011,004	45,334,269
Shares used in computing diluted net income (loss) per common share	48,123,668	47,786,334	48,011,004	45,801,242

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See accompanying notes to Condensed Consolidated Financial Statements.

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## DEPOMED, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2008	2007
<b>Operating Activities</b>		
Net income (loss)	\$ (4,073)	\$ 24,493
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	890	687
Employee and director stock-based compensation	1,752	1,430
Stock-based compensation related to consultants	198	42
Changes in assets and liabilities:		
Accounts receivable	(500)	6,026
Inventories	255	632
Prepaid and other current assets	(693)	1,336
Accounts payable and other accrued liabilities	3,357	(3,440)
Accrued compensation	375	(307)
Deferred revenue	5,637	(39,593)
Net cash provided by (used in) operating activities	7,198	(8,694)
<b>Investing Activities</b>		
Purchases of property and equipment	(230)	(137)
Purchases of marketable securities	(82,758)	(38,677)
Maturities of marketable securities	54,991	21,626
Sales of marketable securities	11,159	
Net cash used in investing activities	(16,838)	(17,188)
<b>Financing Activities</b>		
Proceeds from debt issuance	9,400	
Debt issuance costs	(303)	
Proceeds from issuance of common stock	289	20,892
Net cash provided by financing activities	9,386	20,892
Net decrease in cash and cash equivalents	(254)	(4,990)
Cash and cash equivalents at beginning of period	14,374	14,574
Cash and cash equivalents at end of period	\$ 14,120	\$ 9,584

See accompanying notes to Condensed Consolidated Financial Statements.

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**DEPOMED, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***



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These unaudited condensed consolidated financial statements and the related footnote information of Depomed, Inc. (the Company or Depomed) have been prepared pursuant to the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of the Company's management, the accompanying interim unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the periods presented. The results for the interim period ended September 30, 2008 are not necessarily indicative of results to be expected for the entire year ending December 31, 2008 or future operating periods.

The balance sheet as of December 31, 2007 has been derived from the audited financial statements at that date. The balance sheet does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. For further information, refer to the financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2007 filed with the SEC.

### *Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and Depomed Development, Ltd. (DDL) through April 2007, at which time DDL was dissolved. DDL did not have any fixed assets, liabilities or employees and will not perform any further product development on behalf of Depomed or any other entity. Material intercompany accounts and transactions have been eliminated.

### *Use of Estimates*

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

### *Stock-Based Compensation*





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Effective January 1, 2006, Depomed implemented the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R)), as interpreted by SEC Staff Accounting Bulletin No. 107 (SAB 107), using the modified prospective transition method. FAS 123(R) is a revision of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (FAS 123), and supercedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). FAS 123(R) requires companies to recognize the cost of employee and director services received in exchange for awards of equity instruments, based on the grant-date fair value of those awards, in the statement of operations. Using the modified prospective transition method of FAS 123(R), Depomed began recognizing fair-value compensation expense for stock-based awards, including stock options granted and purchase rights issued under its employee purchase plan after January 1, 2006. Compensation expense for stock-based awards granted prior to implementation that were unvested and outstanding as of January 1, 2006 is recognized over the requisite service period based on the grant-date fair value of those options and awards as previously calculated under FAS 123. The compensation expense for stock-based compensation is based on the single-option approach, includes an estimate for forfeitures and is recognized over the vesting term of the options using the straight-line method. FAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Depomed estimates forfeitures based on historical experience.

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**DEPOMED, INC.**

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

*(Unaudited)*



On adoption of FAS 123(R), the Company concluded that its historical share option exercise experience did not provide a reasonable basis upon which to estimate expected term and estimated the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as illustrated by the simplified method in SAB 107. SAB 107 allowed for use of the simplified method to estimate expected term through December 31, 2007. In December 2007, the SEC issued SAB 110, which extended the ability for companies to utilize the simplified method beyond December 31, 2007 under limited circumstances. At January 1, 2008, the Company concluded again that its historical share option exercise experience did not provide a reasonable basis upon which to estimate expected term because of the Company's limited exercise history and also elected to no longer utilize the simplified method. For options granted after January 1, 2008, the Company has estimated the expected term by using the weighted average terms of a peer group of companies that grant options with similar vesting provisions. The expected term used for options granted after January 1, 2008 is 5.04 years. See Note 6 of the Notes to Condensed Consolidated Financial Statements for further information regarding Depomed's stock-based compensation expense.

### ***Revenue Recognition***

The Company recognizes revenue from the sale of its products, royalties earned, and on payments received and services performed under contractual arrangements. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable and the Company is reasonably assured of collecting the resulting receivable.

- **Product Sales:**
- **GLUMETZA®:** The Company sells GLUMETZA product to wholesalers and retail pharmacies that is subject to rights of return up to twelve months after product expiration. The Company began shipping GLUMETZA product to customers in the third quarter of 2006. Prior to the third quarter of 2008, the Company was unable to reasonably estimate expected returns of the product at the time of shipment, and therefore, deferred revenue on product shipments of GLUMETZA until the product was dispensed through patient prescriptions. The quantity of prescription units dispensed was estimated based on analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. Based on the shipment trends, prescription trends and product returns history for GLUMETZA over two years through the third quarter of 2008 and based on an analysis of return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, the Company concluded it had the information needed to reasonably estimate product returns during the third quarter of 2008. Beginning in the third quarter of 2008, the Company began recognizing revenue for GLUMETZA sales at the time of shipment to its customers. Consequently, for the quarter ended September 30, 2008, the Company recognized a one time increase of \$6.3 million in net product sales of GLUMETZA, representing product sales previously deferred, net of estimated product returns, managed care and Medicaid rebates, wholesaler and retail pharmacy discounts, chargebacks and prompt payment discounts. This change resulted in a one-time \$5.3 million reduction to net loss and decreased net loss per share by \$0.11 for the three and nine months ended September 30, 2008.



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**DEPOMED, INC.**

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

*(Unaudited)*



- **Proquin®XR:** The Company sells Proquin XR product to wholesalers and retail pharmacies that is subject to rights of return up to twelve months after product expiration. Given the Company's limited history of selling Proquin XR, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Proquin XR until the right of return no longer exists, which occurs at the earlier of the time Proquin XR units are dispensed through patient prescriptions or expiration of the right of return. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. As a result of this policy, the Company has a deferred revenue balance of \$1.4 million at September 30, 2008 related to Proquin XR product shipments that have not been recognized as revenue, which is net of wholesaler fees, retail pharmacy discounts and prompt payment discounts. The Company will recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in net revenue related to the recognition of revenue previously deferred. In addition, the costs of manufacturing and 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 products sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company's agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on earnings in the period of adjustment. The Company's product sales allowances include:

- **Managed Care Rebates** The Company offers rebates under contracts with certain managed care customers. The Company establishes an accrual equal to its estimates of future managed care rebates attributable to sales and recognizes the estimated rebates as a reduction of revenue in the same period the related revenue is recognized. The Company estimates its managed care rebates based on the terms of each agreement, estimated levels of inventory in the distribution channel, and historical and expected future utilization of our product by the managed care organization.

- **Product Returns** The Company estimates product returns on sales of GLUMETZA. The Company allows customers to return product that is within six months before and up to one year after its product expiration date. The shelf life of the 500mg GLUMETZA is currently 48 months from the date of tablet manufacture. On product launch in August 2006 and through the second quarter of 2008, the shelf life of 500mg GLUMETZA product shipped by the Company was 36 months. 1000mg GLUMETZA tablets, which became available in June 2008, currently have a shelf life of 24 months from the date of tablet manufacture. The Company estimates GLUMETZA product returns based on an analysis of return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, trends in historical returns, shipments and prescriptions and estimated channel inventory levels.

- **Wholesaler and Retail Pharmacy Discounts** The Company offers discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the



respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

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**DEPOMED, INC.**

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

*(Unaudited)*



- **Prompt Pay Discounts** - The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. Based on the Company's experience, the Company expects its customers to comply with the payment terms to earn the cash discount. The Company accounts for cash discounts by reducing accounts receivable by the full amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.
- **Medicaid Rebates** - The Company participates in Medicaid rebate programs, which provide assistance to certain eligible low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three months after the quarter in which the prescription is filled. The Company estimates and accrues Medicaid rebates based on product pricing, current rebates and changes in the level of discounts the Company offers that may affect the level of Medicaid discount, historical and estimated future percentages of our product sold to Medicaid recipients, estimated levels of inventory in the distribution channel, and third-party market data regarding prescription payor information.
- **Chargebacks** - The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity.
- **Royalties** - Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured.

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

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

The Company recognized royalties under its license agreement with Esprit Pharma (Esprit) based on Esprit's sales of Proquin XR, net of any estimated returns, discounts, rebates and chargebacks, subject to minimum annual royalties. The license agreement with Esprit was terminated in July 2007.

- License Revenue - Revenue from license arrangements is recognized when the Company has substantially completed its obligations under the terms of the arrangement and the Company's remaining involvement is inconsequential and perfunctory. If the Company has significant continuing involvement under such an arrangement, license fees are recognized over the estimated performance period. License fee payments received in excess of amounts earned are classified as deferred revenue until earned.

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**DEPOMED, INC.**

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

*(Unaudited)*



**Recently Issued Accounting Standards**

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1), which requires certain income statement presentation of transactions with third parties and of payments between parties of the collaborative arrangement, along with disclosure about the nature and purpose of the arrangement. EITF 07-1 is effective for the Company beginning January 1, 2009. The Company does not expect EITF 07-1 to have a material effect on its financial position, results of operations or cash flows.

Effective January 1, 2008, the Company adopted EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to contractual arrangements be deferred and recognized as expense in the period that the related goods are delivered or services are performed. The adoption of EITF 07-3 did not have a material impact on the Company's financial position, results of operations or cash flows.

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

The Company considers all highly liquid investments with an original maturity (at date of purchase) of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks, money market instruments and commercial paper. The Company places its cash, cash equivalents and marketable securities with high quality, U.S. financial institutions and, to date, has not experienced material losses on any of its balances. The Company records cash equivalents at amortized cost, which approximates their fair value. All marketable securities are classified as available-for-sale since these instruments are readily marketable. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive loss within shareholders' equity. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in interest and other income in the condensed consolidated statement of operations. As of September 30, 2008, the individual contractual period for all available-for-sale debt securities is less than two years.

The following table shows the gross unrealized losses and fair value of the Company's investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at September 30, 2008 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
<b>U.S. Debt Securities</b>						
U.S. government agency debt securities	\$ 4,940	\$ (10)	\$	\$	\$ 4,940	\$ (10)
U.S. corporate debt and commercial paper securities	13,040	(255)			13,040	(255)
<b>Total available-for-sale</b>	<b>\$ 17,980</b>	<b>\$ (265)</b>	<b>\$</b>	<b>\$</b>	<b>\$ 17,980</b>	<b>\$ (265)</b>

The gross unrealized losses above were caused by interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of the Company's securities. Based on the Company's review of these securities, including the assessment of the duration and severity of the unrealized losses and the Company's ability and intent to hold the investments until maturity, there were no material other-than-temporary impairments for these securities at September 30, 2008.



Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (FAS 157). FAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under FAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under FAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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**DEPOMED, INC.**

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

*(Unaudited)*



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- Level 1: Quoted prices in active markets for identical assets or liabilities.
  
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
  
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The adoption of FAS 157 did not have a material impact on the Company's financial position, results of operations or cash flows. In accordance with FAS 157, the following table represents the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of September 30, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 48			\$ 48
Commercial paper		5,449		5,449
U.S. government agency debt securities		7,200		7,200
U.S. Treasury securities		60,890		60,890
U.S. corporate debt securities		11,691		11,691
Total	\$ 48	\$ 85,230	\$	\$ 85,278

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an amendment of FASB Statement No. 115* (FAS 159), which provides a fair value option election that permits entities to irrevocably elect to measure financial assets and liabilities (except for those that are specifically scoped out of the Statement) at fair value as the initial and subsequent measurement attribute, with changes in fair value recognized in earnings as they occur. FAS 159 permits the fair value option election on an instrument-by-instrument basis at initial recognition of an asset or liability or upon an event that gives rise to a new basis of accounting for that instrument. The Company did not elect to apply the fair value option to any of its financial assets or liabilities; therefore, there has been no impact on the Company's financial position, results of operations or cash flows.

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

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

	Three Months Ended September 30, 2008	2007	Nine Months Ended September 30, 2008	2007
Weighted-average shares - basic	48,123,668	47,630,945	48,011,004	45,334,269
Effect of dilutive securities:				

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Stock options		120,599		290,949
Warrants		34,790		176,024
Weighted-average shares - diluted	48,123,668	47,786,334	48,011,004	45,801,242

For the three and nine months ended September 30, 2008, approximately 8.5 million common stock equivalent shares are not included because their effect is anti-dilutive. For the three and nine months ended September 30, 2007, approximately 7.7 million and 7.3 common stock equivalent shares are not included because their effect is anti-dilutive.

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**DEPOMED, INC.**

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

*(Unaudited)*



**NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS**

***Santarus, Inc.***

In July 2008, the Company entered into a promotion agreement with Santarus, Inc. (Santarus) granting Santarus exclusive rights to promote GLUMETZA in the United States. Santarus paid the Company a \$12 million upfront fee, and based on the achievement of specified levels of annual GLUMETZA net product sales, Santarus may be required to pay the Company additional one-time sales milestones, totaling up to \$16 million.

Santarus began promotion of GLUMETZA in October 2008. Santarus is required to meet certain minimum promotion obligations during the term of the agreement, and required to make certain minimum marketing, advertising, medical affairs and other commercial support expenditures. The Company will continue to record revenue from the sales of GLUMETZA product and, beginning in October 2008, will pay Santarus a fee ranging from 75% to 80% of the gross margin earned from net sales of GLUMETZA product in the United States.

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

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

The Company is recognizing the \$12.0 million upfront payment ratably until November 2021, which represents the estimated length of time the Company's obligations exist under the arrangement related to promotion fees it is obligated to pay Santarus. For the three months ended September 30, 2008, the Company recognized \$0.2 million in license revenue related to the amortization of the upfront payment.

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

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

The Company also receives ongoing royalty payments from Teva on sales by Teva (including IVAX) of generic Glucophage XR in the United States, which is calculated as a percentage of sales, as reported by a third-party market research company. The royalty is subject to a \$2.5 million aggregate cap. For the three and nine months ended September 30, 2008, the company recognized \$0.4 million and \$0.8 million in royalty revenue related to this arrangement, respectively.





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**DEPOMED, INC.**

**NOTES TO CONDENSED CONSOLIDATED 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 is required to pay interest on the first tranche for the first six months at an interest rate of 11.59%. Thereafter, the Company will be required to pay the principal on the first tranche, plus interest at such rate, in 30 equal monthly installments. The second tranche is interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments at an interest rate of 11.59%.

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

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

The credit facility contains affirmative and negative covenants with which the Company must comply with, and imposes restrictions with regards to additional indebtedness, liens, various fundamental changes (including mergers and acquisitions), payments, investments, transactions with affiliates, and other limitations customary in secured credit facilities. The Company was in compliance with such covenants as of September 30, 2008.

**NOTE 6. STOCK-BASED COMPENSATION**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of sales	\$ 7	\$ 6	\$ 17	\$ 16
Research and development expense	171	134	552	542
Selling, general and administrative expense	551	277	1,380	914
Total	\$ 729	\$ 417	\$ 1,949	\$ 1,472

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At September 30, 2008, Depomed had \$4.7 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 2.0 years.

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**DEPOMED, INC.**

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

*(Unaudited)*



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

Total comprehensive income (loss) for the three and nine months ended September 30, 2008 and 2007 approximates net income (loss) and includes unrealized gains and losses on marketable securities.

**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):

	September 30, 2008		December 31, 2007	
Raw materials	\$	295	\$	837
Work-in-process				419
Finished goods		2,659		1,184
Deferred costs		54		823
Total	\$	3,008	\$	3,263

At September 30, 2008, deferred costs represent the costs of Proquin XR product shipped for which recognition of revenue has been deferred. At December 31, 2007, deferred costs represented the costs of both GLUMETZA and Proquin XR product shipped for which recognition of revenue has been deferred. Beginning in the third quarter of 2008, the Company began recognizing revenue on GLUMETZA product at the time of shipment and no longer has deferred costs for GLUMETZA at September 30, 2008 (See Note 1 of the Notes to Condensed Consolidated Financial Statements for further discussion).

**NOTE 9. SHAREHOLDERS' EQUITY*****Series A Preferred Stock***

In January 2000, the Company issued 12,015 shares of Series A Preferred Stock at a price of \$1,000 per share. The Series A Preferred Stock accrued a dividend of 7% per annum, compounded semi-annually and payable in shares of Series A Preferred Stock. The Series A Preferred Stock was convertible at anytime between January 2002 and January 2006 into the Company's common stock. The original conversion price of the Series A Preferred Stock was \$12.00; however, as a result of the Company's March 2002 and October 2003 financings, the conversion price had been adjusted to \$9.51 per share. In December 2004, the Company entered into an agreement with the Series A Preferred shareholder to resolve a misunderstanding between the Company and the shareholder relating primarily to prior adjustments to the conversion price of the Series A Preferred Stock. Pursuant to the agreement, among other matters, the Company agreed to adjust the conversion price to \$7.50 per share. The Company and the shareholder also agreed to binding interpretations of certain other terms related to the Series A Preferred Stock conversion price.



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**DEPOMED, INC.**

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

**(Unaudited)**

Prior to December 2004, the amounts calculated as Series A Preferred stock dividends were accounted for as an adjustment to the conversion price following EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* (Issue No. 98-5). As a result of the modifications to the preferred stock agreement in December 2004, the Company determined that a significant modification of the agreement had been made, and, therefore, a new commitment date for accounting purposes had been established on December 10, 2004. The Company measured the difference between the carrying value of the preferred stock and the fair value of the modified preferred stock pursuant to EITF Topic No. D-42, *The Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock* and determined that the fair value of the modified security was less than the carrying value of the security prior to the modification. The Company also evaluated the effective conversion rate, after considering the reset rate of \$7.50 per share in addition to the common stock issuable upon conversion of the unpaid, accumulated dividends. The fair value of the underlying common stock on December 10, 2004 was \$5.06 per share. The Company determined that the conversion rate, after including the effect of the unpaid dividends, did not result in a beneficial conversion feature, which could have had the effect of also providing a deemed dividend to the preferred shareholder. However, an anti-dilution provision of the Series A Preferred Stock was triggered by the Company's January 2005 financing, which adjusted the conversion price of the Series A Preferred Stock to \$7.12. As a result of the adjusted conversion price and an increase in the amount of common stock issuable upon conversion of the Series A Preferred Stock due to additional accumulated dividends, the Series A Preferred Stock now contains a beneficial conversion feature subject to recognition pursuant to Issue No. 98-5.

In conjunction with the modification of the agreement, the Company issued a warrant to the Series A Preferred shareholder. The value of the warrant was considered in determining the value of the modified security. The warrant was convertible into shares of the Company's common stock during the period between January 2006 and January 2009. The conversion price of the warrant initially was \$7.12, which was equal to the Series A Preferred Stock conversion price in effect as of January 20, 2006. The conversion price of the warrant decreased by approximately 4.8% per year during the conversion period, such that the number of shares of the Company's common stock issuable upon conversion of the warrant increased by approximately 5.1% per year. The conversion of the warrant could be satisfied only by surrender of the outstanding shares of Series A Preferred Stock.

The Series A Preferred Stock accrued dividends through January 20, 2006, which is the date the warrant initially became exercisable. As a result of the issuance of the warrant, the preferred stock could be surrendered in exchange for common stock for an additional three years through January 20, 2009. As long as the Series A Preferred Stock remained outstanding, the number of shares into which the warrant could be converted increased as the conversion price of the warrant decreased resulting in additional deemed dividends on the Series A Preferred Stock. For the three and nine months ended September 30, 2008, the Company recognized Series A Preferred Stock deemed dividends of approximately \$183,000 and \$538,000, respectively, attributable to the beneficial conversion feature from the accrued dividends and decreasing warrant price.

As of September 30, 2008, there were 18,158 shares of Series A Preferred Stock outstanding with an aggregate liquidation preference of approximately \$18.2 million. The warrant was convertible into 2,913,807 shares of the Company's common stock at a conversion price of \$6.23 as of September 30, 2008.

In October 2008, the holder of the Series A Preferred Stock and warrant exercised its warrant to acquire shares of the Company's common stock by surrendering its 18,158 shares of Series A Preferred Stock in exchange for 2,914,526 shares of the Company's common stock. The warrant was exercised in accordance with its terms and without any cash payment to the company, and together with surrender of the Series A Preferred

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Stock, was convertible into the Company's common stock at a conversion price of \$6.23 per share on the date of exercise.

### *Option Exercises*

During the three and nine months ended September 30, 2008, employees and consultants exercised options to purchase 27,667 and 30,614 shares of the Company's common stock with net proceeds to the Company of approximately \$73,000 and \$80,000.

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**DEPOMED, INC.**

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

**(Unaudited)**

***Employee Stock Purchase Plan***

In May 2008, the Company sold 84,308 shares under the ESPP. The shares were purchased at a weighted average exercise price of \$2.47 with proceeds of approximately \$0.2 million.

**NOTE 10. RELATED PARTY TRANSACTIONS**

***John W. Fara, Ph.D.***

In August 2007, John W. Fara, Ph.D. retired from his positions as President, Chief Executive Officer and Chairman of the Company. Dr. Fara continued to serve as a member of the Company's Board of Directors through the 2008 Annual Meeting. The Company entered into a consulting agreement with Dr. Fara, pursuant to which Dr. Fara will provide consulting services to the Company through December 31, 2009. From August 2007 through December 31, 2008, the Company will pay Dr. Fara \$20,833 per month for his consulting services, and will reimburse Dr. Fara for COBRA and life insurance premiums. Dr. Fara will be paid on an hourly basis for consulting services provided in 2009. For the three and nine months ended September 30, 2008, the Company incurred expense of approximately \$62,000 and \$187,000, respectively, associated with this consulting agreement.

During the period of his consultancy, Dr. Fara will continue to vest in all of his currently unvested stock options, and his vested stock options will remain exercisable. For the three and nine months ended September 30, 2008, the Company recognized approximately \$101,000 and \$173,000, respectively, in stock compensation expense associated with these awards. In the event of a change in control of the Company, as defined by the Company's 2004 Equity Incentive Plan, all of Dr. Fara's unvested options will fully vest, and any remaining monthly payments for consulting under the agreement will be accelerated.

***John F. Hamilton***

In October 2007, John F. Hamilton retired from his position as Vice President, Finance and Chief Financial Officer of the Company. The Company entered into a consulting agreement with Mr. Hamilton, pursuant to which Mr. Hamilton provided consulting services to the Company through October 10, 2008. From October 10, 2007 through October 10, 2008, the Company paid Mr. Hamilton \$25,667 per month for his consulting services. For the three and nine months ended September 30, 2008, the Company incurred expense of approximately \$77,000 and \$231,000, respectively, associated with this consulting agreement.

**NOTE 11. INCOME TAXES**

The Company adopted the provisions of FIN 48 on January 1, 2007. As of December 31, 2007 and September 30, 2008, the Company had \$2.9 million and \$3.0 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. As of the date of adoption of FIN 48, the Company did not have any accrued interest or penalties associated with unrecognized tax benefits. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

**NOTE 12. SUBSEQUENT EVENTS**

*Series A Preferred Stock*

In October 2008, the holder of the Series A Preferred Stock and related warrant exercised its warrant to acquire shares of the Company's common stock by surrendering its 18,158 shares of Series A Preferred Stock in exchange for 2,914,526 shares of the Company's common stock. The warrant was exercised in accordance with its terms and without any cash payment to the company, and together with surrender of the Series A Preferred Stock, was convertible into the Company's common stock at a conversion price of \$6.23 per share on the date of exercise. See Note 9 of the Notes to Condensed Consolidated Financial Statements for further information regarding the Series A Preferred Stock and related warrant.

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

**FORWARD-LOOKING INFORMATION**



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

- our ability to find development and commercialization partners for DM-1796 and DM-5689 (both formerly referred to as Gabapentin GR®) and other product candidates;
- results and timing of our clinical trials, including the results of our DM-1796 and DM-5689 trials;
- the commercial success and market acceptance of GLUMETZA® (metformin hydrochloride extended release tablets) in the United States;
- the efforts of Santarus, Inc. with respect to the commercialization of GLUMETZA;
- the results of our internal research and development efforts;
- acceptance and approval of regulatory filings;
- our need for, and ability to raise, additional capital;
- market acceptance of Proquin® XR (ciprofloxacin hydrochloride extended release tablets);
- the efforts of Watson Pharmaceuticals with respect to the commercialization of Proquin XR;
- 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 2004, we announced our determination to evolve from a solely product development focused company to an integrated specialty pharmaceutical company, with sales and marketing of our own products. Preliminary staffing for these activities began in 2005. In 2006 and 2007, we enhanced our internal sales and marketing capabilities through the hiring of additional sales and marketing employees and the engagement of consultants.

We have developed two commercial products. GLUMETZA® (metformin hydrochloride extended release tablets) is a once-daily treatment for adults with type 2 diabetes that we commercialize in the United States with Santarus, Inc. (Santarus). Proquin® XR (ciprofloxacin hydrochloride extended release tablets) is a once-daily treatment for uncomplicated urinary tract infections that we commercialize in the United States with Watson Pharma (Watson).

We have a three-pronged approach to product development designed to optimize the use and value of our drug delivery technologies, while managing the costs and risks associated with developing and commercializing pharmaceutical products. We develop products for our own account that are designed to compete in large growing markets and that can be highly



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differentiated from immediate release versions of the compounds upon which they are based. Second, we selectively enter into collaborative partnerships with other companies where the unique capabilities of our technology can provide superior value to a partner's compound, resulting in significantly greater value for Depomed than a traditional fee-for-service arrangement. Third, we enter into arrangements that enable our technology to be applied by other companies to a greater number of compounds than our infrastructure can support, so as to derive additional value from our technology. In the future, we plan to commercialize our proprietary products, relying on partners to cover the large primary care audiences, while maintaining co-promotion and distribution rights in order to be in a position to create our own sales force when appropriate, thereby increasing the value to us of our products, and our control over them.

Our most advanced product candidates in development are DM-1796 and DM-5689 (both formerly referred to as Gabapentin GR), extended release forms of gabapentin. We have initiated two Phase 3 trials with respect to DM-5689 for the treatment of menopausal hot flashes. We have also completed a Phase 3 clinical trial with respect to DM-1796 for the treatment of postherpetic neuralgia (PHN), and have initiated a second Phase 3 trial for the same indication. In addition, we have other product candidates in earlier stages of development.

The following table summarizes our marketed products, and our product pipeline.

## Marketed Products

Product	Indication	Status
GLUMETZA®	Type 2 diabetes	<p>Currently sold in the United States, Canada and Korea.</p> <p><i>Co-promoted in the US with Santarus beginning in October 2008.</i></p> <p><i>Canadian rights held by Biovail.</i></p> <p><i>Korean rights held by LG Life Sciences.</i></p>
Proquin® XR	Uncomplicated urinary tract infection	<p>Currently sold in the United States.</p> <p><i>Co-promoted in the US with Watson Pharma.</i></p> <p>Regulatory application approved in Sweden. <i>European rights held by Rottapharm/Madaus.</i></p>

## Product Pipeline

DM-1796	Postherpetic neuralgia	Second Phase 3 study underway.
<i>Formerly referred to as Gabapentin GR®</i>		
DM-5689	Menopausal hot flashes	

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<i>Formerly referred to as Gabapentin GR®</i>		Phase 3 studies underway (Breeze 1 and Breeze 2).
DM-3458	Gastroesophageal reflux disease	Proof of concept studies completed.
<i>Formerly referred to as Omeprazole</i>		
DM-1992	Parkinson's disease	Preclinical development ongoing.
<i>Formerly referred to as Levodopa/Carbidopa</i>		
One undisclosed compound	Confidential	Preclinical development ongoing.

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

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*Significant Developments for the Quarter Ended September 30, 2008.*

- In September 2008, we enrolled and dosed the first patient in Breeze 1, the first of two pivotal Phase 3 clinical trials in our registration program for DM-5689 for the treatment of menopausal hot flashes.
- In July 2008, we entered into a promotion agreement with Santarus, Inc. (Santarus) granting Santarus exclusive rights to promote GLUMETZA in the United States, and we received a \$12 million upfront fee from Santarus.
- In July 2008, we were awarded a modest preclinical grant by The Michael J. Fox Foundation under the foundation's Therapeutics Development Initiative 2008 Program related to our DM-1992 program.
- In July 2008, the Medical Products Agency in Sweden approved the Marketing Authorization for Proquin XR, which is licensed by Rottapharm/Madaus in Europe.
- In July 2008, we drew an additional \$5.6 million under our credit facility with General Electric Credit Company and Oxford Finance Corporation.
- Revenue for the three months ended September 30, 2008 was \$14.1 million, compared to \$52.9 million for the three months ended September 30, 2007. Revenue for the three months ended September 30, 2008 included a one-time increase of \$6.3 million in product sales related to previously deferred revenue, net of estimated product returns, contractual allowances and discounts. Revenue for the three months ended September 30, 2007 included a one-time recognition of \$48.6 million associated with the termination of our Esprit Pharma license and supply agreements.
- Operating expenses for the three months ended September 30, 2008 were \$12.2 million compared to \$8.2 million for the three months ended September 30, 2007. Operating expenses for the three months ended September 30, 2007 included a one-time gain of \$5.0 million related to the termination of our agreements with Esprit Pharma, which had the effect of reducing operating expenses for that period.
- Cash, cash equivalents and marketable securities were \$85.5 million as of September 30, 2008 compared to \$69.5 million as of December 31, 2007.

## RECENT PRODUCT DEVELOPMENTS

### MARKETED PRODUCTS

#### GLUMETZA®

Santarus, Inc. In July 2008, we entered into a promotion agreement with Santarus granting Santarus exclusive rights to promote GLUMETZA in the United States. Santarus paid us a \$12.0 million upfront fee, and based on the achievement of specified levels of annual GLUMETZA net product sales, Santarus may be required to pay us additional one-time sales milestones, totaling up to \$16.0 million.

Santarus began promotion of GLUMETZA in October 2008. Santarus is required to meet certain minimum promotion obligations during the term of the agreement, and required to make certain minimum marketing, advertising, medical affairs and other commercial support expenditures. We will continue to record revenue from the sales of GLUMETZA product and, beginning in the fourth quarter of 2008, will pay Santarus a fee ranging from 75% to 80% of the gross margin earned from net sales of GLUMETZA product in the United States.

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

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

Contract Sales Organization. In February 2008, we entered into a professional detailing services agreement with Publicis Selling Services (Publicis) pursuant to which approximately 33 part-time Publicis sales representatives detailed GLUMETZA to physicians. The arrangement with Publicis ended in September 2008.

1000mg Formulation. In December 2007, the FDA approved the 1000mg formulation for marketing in the United States. In June 2008, we began selling the 1000mg GLUMETZA.

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***Proquin® XR***

*Rottapharm/Madaus.* In November 2005, we entered into a distribution and supply agreement for Proquin XR in Europe with a privately owned specialty pharmaceutical company, Madaus S.r.l., that was acquired by Rottapharm in June 2007. Under the terms of the agreement, we granted an exclusive right to Madaus for the commercialization of Proquin XR in Europe and agreed to supply Madaus with commercial quantities of Proquin XR tablets in bulk form. In March 2006, Madaus filed a Marketing Authorization Application for Proquin XR with the Medical Products Agency in Sweden. In July 2008, the Medical Products Agency in Sweden approved the Marketing Authorization. We received a \$0.3 million advance payment from Rottapharm for supply of future product in August 2008.

***PRODUCT CANDIDATES***

***DM-1796 (formerly known as Gabapentin GR) for Postherpetic Neuralgia***



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

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

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

***DM-5689 (formerly known as Gabapentin GR) for Menopausal Hot Flashes***





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In February 2008, we announced positive results of our Phase 2 trial for DM-5689 for moderate-to-severe menopausal hot flashes.

*Phase 2 Study.* In June 2007, we randomized the first patient in a Phase 2 double-blind, placebo-controlled, multi-center trial evaluating DM-5689 for the treatment of women with moderate-to-severe menopausal hot flashes. The 124 patient study was fully enrolled in September 2007.

*Study Design.* The study included 124 menopausal women (approximately 30 per group) with recurrent, moderate to severe hot flashes and was conducted at eight sites in the United States. The total study treatment duration after screening and baseline was 13 weeks. The primary objective of the study was to investigate the relationship between blood plasma concentrations of gabapentin observed in menopausal women after administration of DM-5689 and the frequency of hot flashes in those women. The plasma concentration data (pharmacokinetics) and the hot flash frequency and severity data (pharmacodynamics) are being used to construct a PK/PD dose response model designed to identify the dosing regimen to utilize in the Phase 3 program.

In order to facilitate the generation of an optimal dose response model, patients in each of the three active treatment arms remained on a stable DM-5689 dose for five weeks at an initial dose, followed by five weeks on a stable, incrementally higher dose, as follows.

Treatment Group	Weeks 2 6	Weeks 8 12
A ( 1800mg group )	600mg PM	600mg AM + 1200mg PM
B ( 2400mg group )	600mg AM + 600mg PM	600mg AM + 1800mg PM
C ( 3000mg group )	1200mg PM	1200mg AM + 1800mg PM
D ( placebo group )	placebo	placebo

Each stable dosing regimen was preceded by a one-week titration period

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**Efficacy.** DM-5689 demonstrated a reduction in the mean frequency of moderate to severe hot flashes, and in the mean total daily severity of hot flashes, in all active treatment groups. Statistical significance relative to placebo from baseline to the end of the study was observed in the 1800mg and 2400mg treatment groups with regard to frequency, and statistical significance was observed in the 1800mg treatment group with regard to severity. The severity of hot flashes is based on a mean daily composite score, where a moderate hot flash is assigned a score of 2 and a severe hot flash is assigned a score of 3. The primary efficacy outcomes observed in the study are set forth in the table below.

Treatment Group	Mean Daily Frequency (#)		Mean Total Daily Severity Score	
	Baseline	End of treatment	Baseline	End of treatment
1800mg	10.1	2.7 (p = 0.016)	24.0	6.4 (p = 0.022)
2400mg	11.8	3.0 (p = 0.03)	29.6	7.9 (p = 0.063)
3000mg	11.4	3.9 (p = 0.229)	27.8	10.2 (p = 0.334)
placebo	10.6	5.1	26.7	12.6

**Safety.** DM-5689 was generally well tolerated in the study, with one, two, one and three patients, respectively, withdrawing due to adverse events from the placebo, 1800mg, 2400mg and 3000mg groups. The most common side effects observed in the study were headache, somnolence, dizziness and nausea. The incidence of those side effects in each of the treatment groups is set forth in the table below.

Treatment Group	Somnolence (%)	Dizziness (%)	Headache (%)	Nausea (%)
1800mg	16	10	32	16
2400mg	16	39	32	3
3000mg	16	9	25	3
placebo	3	10	10	7

**Phase 3 Registration Program.** Our Phase 3 registration program for DM-5689 in menopausal hot flashes includes two randomized, double-blind, placebo-controlled studies of approximately 540 patients per study, Breeze 1 and Breeze 2. In September 2008, we enrolled and dosed the first patient in Breeze 1, and in October 2008, we enrolled and dosed the first patient in Breeze 2. In each study, patients will be randomized into three treatment arms: (i) placebo; (ii) 1200mg of DM-5689 dosed once daily; or (iii) a total dose of 1800mg of DM-5689 dosed 600mg in the morning and 1200mg in the evening.

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

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

***OTHER RESEARCH AND DEVELOPMENT AND COLLABORATIVE PROGRAMS***

*Supernus.* In September 2006, we entered into a collaboration agreement with Supernus Pharmaceuticals, Inc. to develop through a Phase 1 study a product candidate leveraging our AcuForm drug delivery technology. The cost and ownership of the program is shared between the parties equally. The collaboration agreement includes provisions pursuant to which the parties may negotiate and enter into a definitive agreement for the further development and for commercialization, by either or both parties, of the product candidate. The feasibility phase of the collaboration was completed in April 2008 and both parties have elected not to continue to develop the product candidate.

***OTHER EVENTS***

*Patent Lawsuit Settlement.* In April 2008, we entered into a Settlement and License Agreement with Teva Pharmaceuticals USA, Inc. (collectively with its affiliates, Teva) related to the patent infringement lawsuit we filed against Teva affiliates IVAX Corporation and IVAX Pharmaceuticals, Inc. in January 2006, in which we alleged infringement of the Company's patents (US Patent Nos. 6,340,475 and 6,635,280 (the Asserted Patents)) by IVAX's extended release metformin hydrochloride tablets.

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Pursuant to the settlement Agreement: (a) the parties dismissed and released all claims associated with the litigation; (b) we received a one-time payment of \$7.5 million in April 2008; (c) we granted Teva a non-exclusive license to the Asserted Patents (including IVAX) to continue to market its generic Glucophage® XR (metformin hydrochloride extended release tablets) product in the United States under the Asserted Patents; and (d) we will receive ongoing royalty payments from Teva on sales by Teva (including IVAX) of generic Glucophage XR in the United States. The royalty is subject to a \$2.5 million aggregate cap.

Credit Facility. In June 2008, we entered into a \$15.0 million secured credit facility with General Electric Capital Corporation (GECC) and Oxford Finance Corporation (Oxford). The credit facility is described below under **LIQUIDITY AND CAPITAL RESOURCES**.

## **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. Except as described below under **Revenue Recognition** and **Stock-Based Compensation**, there have been no changes to our critical accounting policies since we filed our 2007 Annual Report on Form 10-K with the Securities and Exchange Commission on March 12, 2008. For a description of our critical accounting policies, please refer to our 2007 Annual Report on Form 10-K.

### **Revenue Recognition**

We recognize revenue from the sale of our products, license fees and royalties earned on license agreements and collaborative arrangements. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable and we are reasonably assured of collecting the resulting receivable.

We sell GLUMETZA product to wholesalers and retail pharmacies that is subject to rights of return within a period beginning six months prior to, and ending twelve months following product expiration. We began shipping GLUMETZA product to customers in the third quarter of 2006. Prior to the third quarter of 2008, we were unable to reasonably estimate expected returns of the product at the time of shipment, and therefore, deferred revenue on product shipments of GLUMETZA until the product was dispensed through patient prescriptions. The quantity of prescription units dispensed was estimated based on analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. Based on the shipment trends, prescription trends and product returns history for GLUMETZA over two years through the third quarter of 2008 and based on an analysis of return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, we concluded that we had the information needed to reasonably estimate product returns during the third quarter of 2008. Beginning in the third quarter of 2008, we began recognizing revenue for GLUMETZA sales as revenue at the time of shipment to its customers. Consequently, for the quarter ended September 30, 2008, we recognized a one time increase of \$6.3 million in net product sales of GLUMETZA, representing product sales previously deferred, net of estimated product returns, managed care and Medicaid rebates, wholesaler and retail pharmacy fees and discounts, chargebacks and prompt payment discounts. Deferred costs related to shipments of GLUMETZA previously deferred were also recognized to cost of sales. This change resulted in a one-time \$5.3 million reduction of net loss for the third quarter of 2008. Revenues from GLUMETZA product sales are recorded net of estimated product returns, managed care rebates, wholesaler and retail pharmacy fees and discounts, prompt

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payment discounts, patient support programs, chargebacks, and Medicaid rebates. These gross-to-net sales adjustments are recognized in the same period the related revenue is recognized and are based on estimates of the amounts earned or to be claimed on the related sales.

We obtained the rights back from Esprit Pharma (Esprit) to market Proquin XR product in July 2007, and began selling Proquin XR to wholesalers and retail pharmacies in October 2007. Given our limited history of selling Proquin XR, we currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, 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. We estimate 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. We have not had significant

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history estimating the number of patient prescriptions dispensed for Proquin XR. If we underestimate or overestimate patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods. We have a deferred revenue balance of \$1.4 million at September 30, 2008 related to Proquin XR product shipments that have not been recognized as revenue, which is net of wholesaler and retail pharmacy fees and discounts and prompt payment discounts. We will recognize revenue for Proquin XR upon the earlier of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred. 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 deferred revenue is recognized. Revenues from Proquin XR product sales are recorded net of estimated wholesaler and retail pharmacy fees and discounts, prompt payment discounts, chargebacks and Medicaid rebates. These gross-to-net sales adjustments are recognized in the same period the related revenue is recognized and are based on estimates of the amounts earned or to be claimed on the related sales.

We believe our estimates related to gross-to-net sales adjustments for wholesaler and retail pharmacy fees and discounts, prompt payment discounts, patient support programs and chargebacks do not have a high degree of estimation complexity or uncertainty as the related amounts are settled within a relatively short period of time. We believe that estimated product return allowances and estimated rebates for GLUMETZA require a high degree of judgment and are subject to change based on our experience and certain quantitative and qualitative factors.

Beginning in the third quarter of 2008, we began recognizing GLUMETZA product sales at time title transfers to our customer, and provide for an estimate of future product returns at that time. Based on an analysis of return rates of companies with products that have similar characteristics and similar return policies within the metformin prescription market, our historical returns, shipment trends, prescription trends and estimated distribution channel inventory levels, we develop an estimate of the quantity of product in the distribution channel which may be subject to product return. As of September 30, 2008, the Company's allowance for GLUMETZA product returns was approximately \$1.1 million.

Our rebate accruals for GLUMETZA are based on definitive contractual agreements after the dispensing of the product to a medical benefit plan participant. Rebates are accrued at the time of sale, and typically are paid out several months after the sale. We estimate rebates based on current and future patient usage, the applicable contractual rebate rate amounts, and our estimates of the quantity of product in the channel.

Our product sales allowances and related accruals are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could materially affect our results of operations or financial position. As of September 30, 2008, the Company had accruals related to product sales allowances of \$3.1 million, which includes accrued estimates of product returns, managed care rebates, wholesaler and retail pharmacy discounts and fees, patient support programs, chargebacks, and Medicaid rebates.

Revenue from license arrangements, including license fees creditable against future royalty obligations (if any), of the licensee, is recognized when an arrangement is entered into if we have substantially completed our obligations under the terms of the arrangement and our remaining involvement is inconsequential and perfunctory. If we have significant continuing involvement under such an arrangement, license fees are deferred and recognized over the estimated performance period. License fee payments received in excess of amounts earned are classified as deferred revenue until earned.

***Stock-Based Compensation***

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As of January 1, 2006, we began accounting for stock-based compensation in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R)), using the modified prospective transition method. We use the Black-Scholes option valuation model to estimate the fair value of stock options and Employee Stock Purchase Plan (ESPP) shares. The Black-Scholes model requires the input of highly subjective assumptions. The most significant assumptions are our estimates of the expected volatility and the expected term of the award. For our volatility assumption, we use the historical volatility of our common stock over the expected term of the options.

On adoption of FAS 123(R), we concluded that our historical share option exercise experience did not provide a reasonable basis upon which to estimate expected term and estimated the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as illustrated by the simplified method in SEC Staff Accounting Bulletin (SAB) No. 107 (SAB 107). SAB 107 allowed for use of the simplified method to estimate expected term through December 31, 2007, and we used the simplified method to estimate the expected term for fiscal years 2006 and 2007. In December 2007, the SEC issued SAB 110, which extended the ability for companies to utilize the simplified method beyond December 31, 2007 under limited circumstances. However, we elected to no longer utilize the simplified method

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after December 31, 2007. At January 1, 2008, we concluded again that our historical share option exercise experience did not provide a reasonable basis upon which to estimate expected term because of limited exercise history. For options granted after January 1, 2008, we have estimated the expected term by using the weighted average of a peer group of companies that grant options with similar vesting provisions. The expected term used for options granted after January 1, 2008 is 5.04 years.

As required, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value employee stock-based awards granted in future periods. FAS 123(R) requires that employee and director stock-based compensation costs be recognized over the vesting period of the award, and we have elected to use the straight-line attribution method.

FAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimated forfeitures based on historical experience. Prior to the adoption of FAS 123(R), pro forma information required under FAS 123 included forfeitures as they occurred.

**RESULTS OF OPERATIONS**





*Three and Nine Months Ended September 30, 2008 and 2007*



**Revenue**



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Product sales:				
GLUMETZA	\$ 12,923	\$ 3,832	\$ 23,494	\$ 7,666
Proquin XR	88		262	
Total product sales	13,011	3,832	23,756	7,666
Royalties:				
GLUMETZA	100	46	283	125
Proquin XR		2,500		2,500
Teva	416		777	
Total royalties	516	2,546	1,060	2,625
License revenue:				
GLUMETZA	584	364	1,311	1,996
Proquin XR		46,117		47,507
AcuForm technology				500
Total license revenue	584	46,481	1,311	50,003
Collaborative and other revenue		1		3
Total revenues	\$ 14,111	\$ 52,860	\$ 26,127	\$ 60,297

### *Product sales*

As noted above under **CRITICAL ACCOUNTING POLICIES** *Revenue Recognition*, beginning in the third quarter of 2008, we began to recognize GLUMETZA product sales at time title transfers to our customer, and provide for an estimate of future product returns at that time. This resulted in a one-time increase for the three and nine months ended September 30, 2008, of \$6.3 million in net product sales of GLUMETZA, representing product sales previously deferred, net of estimated product returns, managed care and Medicaid rebates, wholesaler and retail pharmacy fees and discounts, chargebacks and prompt payment discounts. GLUMETZA product sales also increased for the three and nine months ended September 30, 2008 as compared to the three and nine months ended September 30, 2007 from an additional year of promotional and marketing efforts related to GLUMETZA, as GLUMETZA was launched in September 2006. In October

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2007, we terminated our promotion agreement related to GLUMETZA with King and King's promotion obligations ended in December 2007. From February 2008 through September 2008, we promoted GLUMETZA through a contract sales organization, as we did not have an established sales organization. Product sales for GLUMETZA relative to its current runrate will depend on the success of our promotion partner, Santarus, who commenced promotion of GLUMETZA in October 2008.

In October 2007, we re-launched Proquin XR with Watson, and began selling to wholesalers and retail pharmacies. 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 September 30, 2008, we have a deferred revenue balance, which is classified as a liability on the consolidated balance sheet, of \$1.4 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.

***Royalties***

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.

In April 2008, we entered into a settlement and license agreement with Teva related to the patent infringement lawsuit against Teva affiliates IVAX Corporation and IVAX Pharmaceuticals, Inc. we initiated in January 2006 related to Teva's generic Glucophage XR tablets. In connection with the settlement and license agreement we may receive up to \$2.5 million in future royalties on Teva's generic Glucophage XR product in the United States. For the three and nine months ended September 30, 2008, we recognized \$0.4 and \$0.8 million, respectively, in royalty revenue related to this arrangement.

In July 2007, we terminated our license agreement with Esprit, and Esprit paid us \$2.5 million in royalties, representing a pro-rated amount of minimum royalties that would have been due to us under the original agreements.

***License revenue***

License revenue for the three and nine months ended September 30, 2008 consisted primarily of license revenue recognized from the \$25.0 million upfront license fee received from Biovail in July 2005 and from the \$12.0 million upfront fee received from Santarus in July 2008. We are recognizing the \$25.0 million upfront license fee payment from Biovail as revenue ratably until October 2021, which represents the estimated length of time our obligations exist under the arrangement related to royalties we are obligated to pay Biovail on net sales of GLUMETZA in the United States and for our obligation to use Biovail as our sole supplier of the 1000mg GLUMETZA. We are recognizing the \$12.0 million upfront payment from Santarus as revenue ratably until October 2021, which represents the estimated length of time our obligations exist under the arrangement related to promotion fees we are obligated to pay Santarus for GLUMETZA in the United States.

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License revenue for the three and nine months ended September 30, 2007 consisted primarily of revenue recognized related to our agreements with Biovail for GLUMETZA and our agreements with Esprit Pharma for Proquin XR. License revenue for the nine months ended September 30, 2007 consisted of revenue recognized related to the Biovail agreements for GLUMETZA, the Esprit Pharma agreements for Proquin XR, the LG Life Sciences agreement for GLUMETZA, and the Biovail agreement related to our AcuForm drug delivery technology.

Our license agreement with Esprit for Proquin XR provided for \$50.0 million in license fees from Esprit. We received \$30.0 million in license fees in July 2005 and an additional \$10.0 million in December 2006. The final \$10.0 million installment was paid in July 2007. The first \$40.0 million in license fees received were recognized as revenue ratably commencing on our receipt of the fees through June 2020, which represented the length of time we were obligated to manufacture Proquin XR under our Proquin XR supply agreement with Esprit. In July 2007, we and Esprit terminated the license and supply agreements, and all deferred revenue related to license fees previously received from Esprit was fully recognized as revenue in July 2007, resulting in total recognition of \$46.1 million of license revenue related to our agreements with Esprit in the third quarter of 2007.

We received a \$0.6 million upfront license fee from LG in August 2004 and a \$0.5 million milestone payment received in November 2006 with respect to LG's approval to market LG's version of GLUMETZA, Novamet GR, in the Republic of Korea. These payments were originally deferred and amortized as license revenue over the estimated length of time we were obligated to provide assistance in development and manufacturing. In January 2007, we amended our agreement with LG, granted LG a license to certain of the Company's intellectual property rights to manufacture the 500mg Novamet GR in



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exchange for royalties on net sales of Novamet GR in Korea, and removed the provisions of the original agreement providing for the supply of 500mg Novamet GR tablets by us to LG. Under the amended agreement, we no longer have continuing performance obligations to LG, and recognized the remaining \$0.9 million of previously deferred license revenue in the first quarter of 2007.

In February 2007, we received \$0.5 million from Biovail upon entering into a license and development agreement with Biovail granting Biovail an option to license our AcuForm drug delivery technology to develop and commercialize up to two pharmaceutical products. We had no continuing performance obligations under the agreement and recognized the entire upfront license fee as revenue in the first quarter of 2007.

**Cost of Sales**

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, inventory write-downs, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales. Total cost of sales for the three and nine months ended September 30, 2008, as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Cost of sales	\$ 2,396	\$ 724	\$ 4,567	\$ 1,598

Cost of sales for the three and nine months ended September 30, 2008 and 2007 relates primarily to costs associated with the sale of GLUMETZA and Proquin XR. Cost of sales increased in 2008 over 2007 primarily as a result of an increase in GLUMETZA product sales. As noted above under **CRITICAL ACCOUNTING POLICIES Revenue Recognition**, beginning in the third quarter of 2008, we began to recognize GLUMETZA product sales at time title transfers to our customer. This resulted in a one-time increase of approximately \$1.0 million in costs of sales during the three and nine months ended September 30, 2008. During the three and nine months ended September 30, 2008, cost of sales also included approximately \$0.3 million and \$0.6 million, respectively, in inventory write-downs related to slow moving Proquin XR inventory that we expect will not be sold prior to its expiration date.

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.

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Total research and development expense for the three and nine months ended September 30, 2008, as compared to the prior year, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development expense	\$ 6,998	\$ 4,724	\$ 17,748	\$ 19,425
Dollar change from prior year	2,274		(1,677)	
Percentage change from prior year	48.1%		(8.6)%	

The increase in research and development expense for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 was primarily due to higher clinical research organization expenses with the commencement of Breeze 1, the first of our two Phase 3 clinical trials for DM-5689 for the treatment of menopausal hot flashes and our ongoing second Phase 3 trial for DM-1796 for the treatment of postherpetic neuralgia.

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The decrease in research and development expense for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007 was primarily due to lower clinical research organization expenses related to our first Phase 3 clinical trial for DM-1796 for the treatment of postherpetic neuralgia, which was completed in the first half of 2007, and also due to lower headcount as a result of the implementation of a reduction in force in September 2007.

In October 2008, we enrolled and dosed the first patient in Breeze 2, our second Phase 3 clinical trial for DM-5689 for the treatment of menopausal hot flashes and expect research and development expense to increase in fourth quarter of 2008.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
DM-1796	\$ 2,238	\$ 2,544	\$ 9,426	\$ 12,653
DM-5689	2,319	842	4,559	2,778
Other projects	2,441	1,338	3,763	3,994
Total research and development expenses	\$ 6,998	\$ 4,724	\$ 17,748	\$ 19,425

## Selling, General and Administrative Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Selling, general and administrative	\$ 5,250	\$ 8,483	\$ 16,998	\$ 21,033
Dollar change from prior year	(3,233)		(4,035)	
Percentage change from prior year	(38.1)%		(19.2)%	

The decrease in selling, general and administrative expense for the three and nine months ended September 30, 2008 as compared to the three and nine months ended September 30, 2007, was primarily due to a decrease in legal expenses related to our litigation with IVAX and a decrease in promotion fee expense, as we and King terminated our promotion agreement in October 2007, and we no longer are required to pay King promotion fees related to GLUMETZA. Beginning in the fourth quarter of 2008, we are required to pay promotion fees to Santarus related to GLUMETZA and expect selling, general and administrative expense to increase in the fourth quarter of 2008.

## Gain on Litigation Settlement

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

### **Gain on Termination of Esprit Pharma Agreement**

In conjunction with the termination and assignment agreement entered into with Esprit in July 2007, we received a \$5.0 million termination payment from Esprit, which has been classified as a gain within operating income for the three and nine months ended September 30, 2007.

Table of Contents**Interest Income and Expense**

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Interest and other income	\$ 515	\$ 638	\$ 1,871	\$ 1,504
Interest expense	(249)		(254)	
Net interest income (expense)	266	638	1,617	1,504

Interest and other income decreased during the three months ended September 30, 2008 as compared to the corresponding period in 2007 as a result of lower interest rates on our investments. Interest and other income increased during the nine months ended September 30, 2008 as compared to the corresponding period in 2007 as a result of higher investment balances.

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

**LIQUIDITY AND CAPITAL RESOURCES**

(in thousands)	September 30,		December 31,	
	2008		2007	
Cash, cash equivalents and marketable securities	\$ 85,452	\$	69,523	\$

Since inception through September 30, 2008, 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 September 30, 2008, we have not sold any common stock to Azimuth under this common stock purchase agreement.

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

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We will be required to pay interest on the first tranche for the first six months at an interest rate of 11.59%. Thereafter, we will be required to pay the principal on the first tranche, plus interest at such rate, in 30 equal monthly installments. The second tranche is interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments and has an interest rate of 11.59%. As of September 30, 2008, total advances on the credit facility were \$9.4 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 September 30, 2008, 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.

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As of September 30, 2008, we have accumulated net losses of \$139.0 million. We expect to continue to incur operating losses for the remainder of 2008. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of 2009. We base this expectation on our current operating plan, which may change as a result of many factors.

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

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

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

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

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to support our operations. We have limited credit facilities and, except for the common stock purchase agreement with Azimuth, we have no other committed sources of capital. To the extent that our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds through the sale of our equity securities or from development and licensing arrangements to continue our development programs. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. If adequate funds are not available we may have to:

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

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

**Cash Flows from Operating Activities**





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Cash provided by operating activities during the nine months ended September 30, 2008 was approximately \$7.2 million, compared to cash used in operating activities of approximately \$8.7 million for the nine months ended September 30, 2007. The increase in cash provided by operating activities for the nine months ended September 30, 2008 as compared to cash used in operating activities nine months ended September 30, 2007 was primarily due to receipt of the \$12.0 million upfront payment from Santarus.

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

Net cash used in investing activities during the nine months ended September 30, 2008 was approximately \$16.8 million and consisted primarily of a net increase in marketable securities. Cash used in investing activities during the nine months ended September 30, 2007 was approximately \$17.2 million and consisted primarily of a net increase in marketable securities.

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

Cash provided by financing activities during the nine months ended September 30, 2008 was approximately \$9.4 million compared to cash provided by financing activities of approximately \$20.9 million for the same period in 2007. For the nine months ended September 30, 2008, cash provided by financing activities primarily consisted of proceeds from our credit

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facility. For the nine months ended September 30, 2007, cash provided by financing activities consisted of \$20.0 million in proceeds from our registered direct offering in April 2007 and \$0.9 million in cash proceeds from exercises of stock options and our ESPP.

**Contractual Obligations**

As of September 30, 2008, 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	\$ 1,543	\$ 3,238	\$ 549	\$ 5,330
Related party arrangements	79			79
Purchase commitments	3,679			3,679
	\$ 5,301	\$ 3,238	\$ 549	\$ 9,088

At September 30, 2008, 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 the 500mg GLUMETZA and \$0.4 million under our supply agreement with Biovail for the supply of the 1000mg GLUMETZA. We also had a non-cancelable purchase order to purchase in December 2008 approximately \$2.6 million of gabapentin, the active ingredient in both DM-1796 and DM-5689, from a third-party supplier. The amounts disclosed only represent minimum purchase requirements. Actual purchases are expected to exceed these amounts.

We have a consulting arrangement with John W. Fara, Ph.D., our former Chairman, President and Chief Executive and former member of the Company's Board of Directors and are obligated to pay Dr. Fara \$62,000 for consulting services for the remainder of 2008. We also had a consulting arrangement with John F. Hamilton, our former Vice President, Finance and Chief Financial Officer and paid Mr. Hamilton \$17,000 for consulting services through October 2008.

The contractual obligations reflected in this table exclude \$3.0 million of contingent milestone payments we may be obligated to pay in the future under our sublicense agreement with PharmaNova. These payments relate to various milestones for the product candidate under the sublicense agreement, including dosing of the first patient in any Phase 3 trial, submission to the FDA of an NDA, and FDA approval of an NDA. The above table also excludes any future royalty payments we may be required to pay on products we have licensed or any promotion fees associated with our promotion agreement with Watson.

**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, 2007.

#### ITEM 4. CONTROLS AND PROCEDURES

##### *Evaluation of Disclosure Controls and Procedures*

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

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

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*Changes in Internal Controls*

There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

In December 2007, Apotex, Inc. (Apotex) filed the Canadian equivalent of an Abbreviated New Drug Application in Canada seeking approval to market a generic version of the 500mg formulation of GLUMETZA in Canada. Apotex's regulatory filing alleges that certain of the Canadian patents that we have licensed to Biovail in connection with Biovail's commercialization of GLUMETZA in Canada are invalid and unenforceable, and that Apotex's formulation does not infringe our patents. Pursuant to the intellectual property enforcement provisions of our Canadian license agreement with Biovail for GLUMETZA, Biovail has the first right to prosecute, and pay for expenses related to, any Canadian litigation related to generic challenges to GLUMETZA. In January 2008, Biovail filed suit against Apotex in Canada in response to Apotex's regulatory filing, and we have been joined to the lawsuit as a co-plaintiff with Biovail because we are the licensor of the patents at issue in the suit. The initiation of the lawsuit automatically stays approval of Apotex's formulation for 24 months. In October 2008, the court issued a ruling requiring that Apotex present its evidence in the case by mid-January 2009, and that Biovail present its evidence by mid-April 2009. 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, 2007.

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

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

In July 2007, we announced that our drug candidate DM-1796 failed to meet the primary efficacy endpoint in a Phase 3 trial for postherpetic neuralgia (PHN). In March 2008, we initiated another Phase 3 registration trial for the product for the PHN indication. We are pursuing discussions with potential development and marketing partners related to the continued development of DM-1796 for PHN. However, we may not secure a development and marketing arrangement on terms favorable to us, or at all.

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

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. Even if these trials are successful, the approval date for the drug will not occur for at least 18 months, which means that we will not receive revenue from drug sales for a number of years, if at all.

**Our clinical trials may not demonstrate that DM-5689 for menopausal hot flashes is safe and effective. If our clinical trials of DM-5689 for menopausal hot flashes do not demonstrate safety and efficacy, or if the clinical trials are delayed or terminated, our business will be harmed.**

To gain regulatory approval from the FDA to market DM-5689 for menopausal hot flashes, our planned Phase 3 registration trials must demonstrate the safety and efficacy of the product candidate. Clinical development is a long, expensive and uncertain process and is subject to delays. The results of our Phase 2 clinical trial are not necessarily

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indicative of the results we will obtain in later clinical trials. Accordingly, future clinical trials may not demonstrate that DM-5689 is effective for menopausal hot flashes.

In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. To obtain marketing approval, we may decide, or the FDA or other regulatory authorities may require us, to pursue additional pivotal clinical or other studies. These trials could significantly delay the approval and commercialization of DM-5689 for menopausal hot flashes and would require us to commit significant additional financial resources. Even after we conduct these additional clinical trials, we may not receive regulatory approval to market the product.

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

- negative or inconclusive results;
- slow patient enrollment or 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; and
- Santarus may fail to comply with its obligations under our promotion agreement.

Any of the preceding factors could affect Santarus' commitment to the collaboration, which, in turn, could adversely affect the commercial success of GLUMETZA. Any failure to successfully commercialize GLUMETZA could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

**The development of drug candidates is inherently uncertain and we cannot be certain that any of our product candidates will be approved for marketing or, if approved, will achieve market acceptance.**

We have the following programs in clinical development: DM-1796 for neuropathic pain and DM-5689 for menopausal hot flashes. We also have other product candidates in earlier stages of development.

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

We are unable to predict whether any of these product candidates will receive regulatory clearances or be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these other product candidates receive regulatory clearance, our products may not achieve or maintain market acceptance. Also,

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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 depend on Watson Pharmaceuticals for the successful commercialization of Proquin XR in the United States.**

In July 2007, we granted Watson Pharmaceuticals co-exclusive marketing rights to Proquin XR in the United States for the urology specialty and long-term care sales channels. In September 2007, we expanded our promotion arrangement with Watson to include the ob/gyn specialty as well. As described above, we do not have a permanent commercial sales force and do not, for the foreseeable future, expect to have the resources to successfully promote Proquin XR on our own. Accordingly, we will depend on Watson to successfully promote this drug. Our prior marketing partner for Proquin XR, Esprit Pharma, was unable to successfully commercialize Proquin XR following its initial launch in November 2005. As a result, we and Esprit agreed to terminate the license in July 2007. Through the third quarter of 2008, Proquin XR product sales have been low. It is possible that Proquin XR product sales will remain relatively low, which under the provisions of the promotion agreement could lead to an early termination of the agreement. If Watson fails to successfully commercialize Proquin XR, our business, financial condition and results of operations may be materially and adversely affected.

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

Although we have the rights to promote GLUMETZA and Proquin XR through our own sales force, or through third parties, we have no sales force and limited marketing and sales staff. The success of our own promotion efforts for GLUMETZA, Proquin XR and any other product candidates that receive regulatory approval that we choose to market or co-market will require that we substantially enhance our in-house marketing and sales force with technical expertise, or make arrangements with third parties to perform these services for us. The development of the infrastructure associated with these activities involves substantial resources, and considerable attention of our management and key personnel. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to fully develop marketing and sales capabilities, or enter into arrangements with third parties, our revenues may suffer.

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

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

**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 supply and distribution agreement with Madaus, a company acquired by Rottapharm in June 2007, related to the commercialization of Proquin XR in Europe. If our international commercial partners fail to successfully commercialize products we have licensed to them, our business and future revenues may be adversely affected.

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

We entered into a \$15.0 million credit facility with Oxford Finance Corporation and General Electric Capital Corporation in June 2008. We have drawn \$9.4 million under the facility and will not make any further draws under the facility. The credit facility is secured by a pledge of all of our assets other than intellectual property, and contains a variety of

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operational covenants, including limitations on our ability to incur liens or additional debt, make dispositions, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions and transactions with affiliates, among other restrictions. Any future debt financing we enter into may involve similar or more restrictive covenants affecting our operations. Our borrowings under the credit facility or any future debt financing will need to be repaid, which creates additional financial risk for our company, particularly if our business, or prevailing financial market conditions, are not conducive to paying off or refinancing our outstanding debt obligations. Furthermore, our failure to comply with the covenants in the credit facility could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, which could have a material adverse effect on our cash position and significantly harm our business.

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

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to support our operations. We have limited credit facilities and, except for our common stock purchase agreement with Azimuth, we have no other committed sources of capital. Our late stage clinical development programs will require considerable financial resources, and we may not be successful in entering into development and marketing arrangements in which a collaborative partner will pay for the costs of those programs. To the extent that our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds through the sale of our equity securities or from development and licensing arrangements to continue our development programs. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. If adequate funds are not available we may have to:

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

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

**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 nine months ended September 30, 2008, we recorded total revenues of \$26.1 million and for the years ended December 31, 2007, 2006 and 2005, we recorded total revenue of \$65.6 million, \$9.6 million, and \$4.4 million, respectively. For the nine

months ended September 30, 2008, we incurred a net loss of \$4.1 million and for the years ended December 31, 2006 and 2005 we incurred net losses of \$39.7 million, and \$24.5 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 have 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 2008. Therefore, we expect our cumulative losses to increase. These losses, among other things, have had, and we expect that they will continue to have, an adverse impact on our total assets, shareholders' equity and working capital.

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

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

- results of clinical trials for our product candidates;
- announcements regarding development plans for our drug candidates, including DM-1796 and DM-5689;
- the degree of commercial success of GLUMETZA and Proquin XR;
- regulatory actions;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply;

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- results of litigation;
- developments concerning proprietary rights, including patents, infringement allegations and litigation matters;
- variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other contract revenues;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- market acceptance of the AcuForm technology;
- adoption of new technologies by us or our competitors;
- the introduction of new products by our competitors;
- manufacturing costs and difficulties;
- third-party reimbursement policies; and
- the status of our compliance with the provisions of the Sarbanes-Oxley Act of 2002.

As a result of these factors, our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Additionally, any significant drops in our stock price, such as the one we experienced following the announcement of our DM-1796 Phase 3 trial results in July 2008, 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 a collaboration arrangement with Patheon, Inc. related to the potential development of product candidates for third parties. We also have a development collaboration agreement with Supernus, Inc. providing for the development of a product candidate through feasibility. However, neither we nor Supernus intend to further develop the product candidate. 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.

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Our collaborative partners may also terminate their collaborative relationships with us or otherwise decide not to proceed with development and commercialization of our products.

**We may be unable to protect our intellectual property and may be liable for infringing the intellectual property of others.**

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

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.

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

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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 DM-5689, or pharmacists could seek to fill prescriptions for DM-5689 with another manufacturer's gabapentin. Although any such off-label use would violate our licensed patent, effectively monitoring compliance with our licensed patent may be difficult and costly.

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

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

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

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

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

Even when or if our products obtain regulatory approval, successful commercialization requires:

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

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

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

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

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

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- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including materials for our AcuForm technology; and
- the costs of ramping up and maintaining manufacturing operations, as necessary.

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

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

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

Our agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product candidates.

**If we are unable to obtain or maintain regulatory approval, we will be limited in our ability to commercialize our products, and our business will be harmed.**

The regulatory process is expensive and time consuming. Even after investing significant time and expenditures on clinical trials, we may not obtain regulatory approval of our product candidates. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval, and the FDA may not agree with our methods of clinical data analysis or our conclusions regarding safety and/or efficacy. Significant clinical trial delays would impair our ability to commercialize our products and could allow our competitors to bring products to market before we do. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections. Even if we receive regulatory approval, this approval may entail limitations on the indicated uses for which we can market a product.

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

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alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations, which apply to items and services reimbursed under Medicaid and other state programs, or, in some states, regardless of the payer. If we, or our collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunction, and exclusion of our products from reimbursement under government programs, as well as other regulatory actions against our product candidates, our collaborative partners or us.

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

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

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

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

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

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

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

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

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

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

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Bayer Corporation developed a once-daily ciprofloxacin product for the treatment of urinary tract infections, which is currently marketed by Schering-Plough Corporation. There are also generic versions of that product on the market. There may be other companies developing products competitive with GLUMETZA and Proquin XR of which we are unaware.

Gabapentin is currently marketed by Pfizer as Neurontin for adjunctive therapy for epileptic seizures and for postherpetic pain. Pfizer's basic U.S. patents relating to Neurontin have expired, and numerous companies have received approval to market generic versions of the immediate release product. In addition, Pfizer has developed Lyrica® (pregabalin), which has been approved for marketing in the United States and the European Union.

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

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

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

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

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

Although we have obtained clinical batches of DM-1796 and DM-5689 from a contract manufacturer, we currently have no long-term supply arrangement with respect to DM-1796 and DM-5689. Any failure to obtain clinical supplies of DM-1796 and DM-5689 could adversely affect these clinical development programs.



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

We do not have, and we do not intend to establish in the foreseeable future, internal commercial scale manufacturing capabilities. Rather, we intend to use the facilities of third parties to manufacture products for Phase 3 clinical trials and commercialization. Our dependence on third parties for the manufacture of products using the AcuForm technology may adversely affect our ability to deliver such products on a timely or competitive basis. The manufacturing processes of our third party manufacturers may be found to violate the proprietary rights of others. If we are unable to contract for a sufficient supply of required products on acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers, the market introduction and commercial sales of our products will be delayed, and our future revenue will suffer.

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**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 2008 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. Our former Chairman, President and Chief Executive Officer retired in August 2007, and our Chief Financial Officer retired in October 2007; we have not yet replaced our Chief Financial Officer on a permanent basis. We may have difficulty filling open senior scientific, financial and commercial positions. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates.

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

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or

technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or such investment. We do not know if we would be able to successfully complete any acquisitions, or whether we would be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we were to be unable to integrate any acquired businesses, products or technologies effectively, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could harm our operating results.

**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.

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**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.**

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

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

Not applicable.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

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

Not applicable.

### **ITEM 5. OTHER INFORMATION**

Not applicable.

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**ITEM 6. EXHIBITS**

(a) Exhibits

- |      |                                                                                                        |
|------|--------------------------------------------------------------------------------------------------------|
| 31.1 | Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Carl A. Pelzel   |
| 31.2 | Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Tammy L. Cameron |
| 32.1 | Certification pursuant to 18 U.S.C. Section 1350 of Carl A. Pelzel                                     |
| 32.2 | Certification pursuant to 18 U.S.C. Section 1350 of Tammy L. Cameron                                   |

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**SIGNATURES**

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

Date: November 7, 2008

DEPOMED, INC.

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

/s/ Tammy L. Cameron  
Tammy L. Cameron  
Corporate Controller  
(Interim Principal Accounting  
and Financial Officer)