

DEPOMED INC  
Form 10-Q  
November 08, 2007

**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, 2007**

**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 000-23267**

**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 or a non-accelerated filer, as defined in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

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

Yes ☐ No ☒

## Edgar Filing: DEPOMED INC - Form 10-Q

The number of issued and outstanding shares of the Registrant's Common Stock, no par value, as of November 2, 2007 was 47,764,745.

---

DEPOMED, INC.

Page

**PART I FINANCIAL INFORMATION**

Item 1. Condensed Consolidated Financial Statements:

Condensed Consolidated Balance Sheets at September 30, 2007 (unaudited) and December 31, 2006 3

Condensed Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2007 and 2006 (unaudited) 4

Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2007 and 2006 (unaudited) 5

Notes to Condensed Consolidated Financial Statements 6

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 14

Item 3. Quantitative and Qualitative Disclosure About Market Risk 25

Item 4. Controls and Procedures 25

**PART II OTHER INFORMATION**

Item 1. Legal Proceedings 26

Item 1A. Risk Factors 26

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 39

Item 3. Defaults upon Senior Securities 39

Item 4. Submission of Matters to a Vote of Security Holders 39

Item 5. Other Information 39

Item 6. Exhibits 40

Signatures 41

**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, 2007 (Unaudited)	December 31, 2006 (1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,584	\$ 14,574
Marketable securities	20,033	16,985
Accounts receivable	3,045	7,127
Unbilled accounts receivable	11	1,955
Inventories	3,851	4,483
Prepaid and other current assets	1,420	2,756
Total current assets	37,944	47,880
Marketable securities	16,229	1,999
Property and equipment, net	1,860	2,541
Other assets	197	197
	\$ 56,230	\$ 52,617
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,040	\$ 4,886
Accrued compensation	1,510	1,818
Accrued clinical trial expense	27	726
Accrued promotion fee expense	2,150	2,340
Other accrued liabilities	4,426	3,088
Deferred product sales	4,735	4,825
Deferred license revenue	1,454	4,600
Other current liabilities	56	56
Total current liabilities	15,398	22,339
Deferred license revenue, non-current portion	21,126	57,483
Other long-term liabilities	42	84
Commitments		
Shareholders' equity (deficit):		
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, 2007 and December 31, 2006, respectively, with an aggregate liquidation preference of \$18,159	12,015	12,015
Common stock, no par value, 100,000,000 shares authorized; 47,630,945 and 42,029,411 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	167,184	144,820
Accumulated deficit	(159,618)	(184,111)
Accumulated other comprehensive gain (loss)	83	(13)
Total shareholders' equity (deficit)	19,664	(27,289)
	\$ 56,230	\$ 52,617

(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, 2006.

See accompanying notes to Condensed Consolidated Financial Statements.





## DEPOMED, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenue:				
Product sales	\$ 3,832	\$	\$ 7,666	\$ 1,265
Royalties	2,546	66	2,625	495
License revenue	46,481	893	50,003	2,679
Collaborative revenue	1		3	75
Total revenues	52,860	959	60,297	4,514
Costs and expenses:				
Cost of sales	724	320	1,598	1,445
Research and development	4,724	6,436	19,425	18,888
Selling, general and administrative	8,483	7,328	21,033	16,157
Gain on termination of Esprit Pharma agreement	(5,000)		(5,000)	
Total costs and expenses	8,931	14,084	37,056	36,490
Income (loss) from operations	43,929	(13,125)	23,241	(31,976)
Interest and other income	638	492	1,504	1,673
Net income (loss) before income taxes	44,567	(12,633)	24,745	(30,303)
Provision for income taxes	(248)		(252)	
Net income (loss)	44,319	(12,633)	24,493	(30,303)
Deemed dividend on preferred stock	(174)	(165)	(511)	(500)
Net income (loss) applicable to common stock shareholders	\$ 44,145	\$ (12,798)	\$ 23,982	\$ (30,803)
Basic net income (loss) applicable to common stock shareholders per common share	\$ 0.93	\$ (0.31)	\$ 0.53	\$ (0.74)
Diluted net income (loss) applicable to common stock shareholders per common share	\$ 0.92	\$ (0.31)	\$ 0.52	\$ (0.74)
Shares used in computing basic net income (loss) per common share	47,630,945	41,776,362	45,334,269	41,382,662
Shares used in computing diluted net income (loss) per common share	47,786,334	41,776,362	45,801,242	41,382,662

See accompanying notes to Condensed Consolidated Financial Statements.

## DEPOMED, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2007	2006
<b>Operating Activities</b>		
Net income (loss)	\$ 24,493	\$ (30,303)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	687	1,069
Employee and director stock-based compensation	1,430	1,896
Stock-based compensation related to consultants	42	
Changes in assets and liabilities:		
Accounts receivable	6,026	(4,847)
Inventories	632	(1,480)
Prepaid and other current assets	1,336	(1,525)
Other assets		32
Accounts payable and other accrued liabilities	(3,440)	6,262
Accrued compensation	(307)	(62)
Royalty advances		619
Deferred revenue	(39,593)	3,063
Net cash (used in) operating activities	(8,694)	(25,276)
<b>Investing Activities</b>		
Purchases of property and equipment	(137)	(669)
Purchases of marketable securities	(38,677)	(20,072)
Maturities of marketable securities	21,626	37,240
Sales of marketable securities		1,497
Net cash (used in) provided by investing activities	(17,188)	17,996
<b>Financing Activities</b>		
Proceeds from issuance of common stock	20,892	2,463
Net cash provided by financing activities	20,892	2,463
Net (decrease) in cash and cash equivalents	(4,990)	(4,817)
Cash and cash equivalents at beginning of period	14,574	7,566
Cash and cash equivalents at end of period	\$ 9,584	\$ 2,749

See accompanying notes to Condensed Consolidated Financial Statements.



**DEPOMED, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

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

*Basis of Presentation*

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, 2007 are not necessarily indicative of results to be expected for the entire year ending December 31, 2007 or future operating periods.

The balance sheet as of December 31, 2006 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, 2006 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***





## Edgar Filing: DEPOMED INC - Form 10-Q

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. Under the modified prospective transition method of implementation, no restatement of prior periods has been made. See Note 4 of the Notes to Condensed Consolidated Financial Statements for further information regarding Depomed's stock-based compensation expense.



### ***Revenue Recognition***

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.

The Company sells GLUMETZA product to wholesalers and retail pharmacies that is subject to rights of return up to twelve months after product expiration. Given the limited sales history of GLUMETZA, 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 GLUMETZA until the right of return no longer exists, which occurs at the earlier of the time GLUMETZA 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, information obtained from wholesalers with respect to inventory levels and out-movement and retail pharmacy re-stocking activity. As a result of this policy, the Company has a deferred revenue balance of \$4.7 million at September 30, 2007 related to GLUMETZA product shipments that have not been recognized as revenue, which is net of estimated patient support program discounts, wholesaler fees, prompt payment discounts, chargebacks and Medicaid rebates. The Company will recognize revenue upon the earlier 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 GLUMETZA associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized.

Product sales revenue related to the Company's supply agreement with Esprit Pharma, Inc. (Esprit) was recognized after the expiration of a 30-day period in which Esprit was entitled to reject product that did not meet agreed-upon specifications. The supply agreement with Esprit was terminated in July 2007. See Note 6 for additional information with respect to this termination agreement.

Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured. 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 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. See Note 6 for additional information with respect to this termination agreement.

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 deferred and recognized over the estimated performance period. License fee payments received in excess of amounts earned are classified as deferred revenue until earned.

## Edgar Filing: DEPOMED INC - Form 10-Q

Collaborative revenue recognized relates to services rendered in connection with collaborative arrangements and the achievement of milestones under such arrangements. Revenue related to collaborative agreements with corporate partners is recognized as the expenses are incurred under each contract. The Company is required to perform services as specified in each respective agreement and the Company is reimbursed based on the costs incurred on each specific contract. Nonrefundable substantive milestone payments are recognized pursuant to collaborative agreements upon the achievement of specified milestones where no further obligation to perform exists under that milestone provision of the arrangement and when collectibility is reasonably assured.

**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 and cash equivalents at amortized cost, which approximates the 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 income (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, 2007, 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, 2007 (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 debt securities	\$	\$	\$	\$	\$	\$
U.S. corporate debt securities	7,983	(5)			7,983	(5)
Total available-for-sale	\$ 7,983	\$ (5)	\$	\$	\$ 7,983	\$ (5)

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 other-than-temporary impairments for these securities at September 30, 2007.

**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 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,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Weighted-average shares - basic	47,630,945	41,776,362	45,334,269	41,382,662

# Edgar Filing: DEPOMED INC - Form 10-Q

Effect of dilutive securities:

Stock options	120,599		290,949	
Warrants	34,790		176,024	
Weighted-average shares - diluted	47,786,334	41,776,362	45,801,242	41,382,662

For the three and nine months ended September 30, 2007, approximately 7.7 million and 7.3 million common stock equivalent shares are not included because their effect is anti-dilutive. For the three and nine months ended September 30, 2006, approximately 10.1 million common stock equivalent shares are not included because their effect is anti-dilutive.

**NOTE 4. STOCK-BASED COMPENSATION**

The Company adopted FAS 123(R) on January 1, 2006 as described in Note 1 of the Notes to Condensed Consolidated Financial Statements. The following table presents stock-based compensation expense recognized under FAS 123(R) for stock options and the Company's employee stock purchase program (ESPP) in the Company's condensed consolidated statements of operations (in thousands):

	<b>Three Months Ended September 30,</b>		<b>2007</b>		<b>2006</b>		<b>Nine Months Ended September 30,</b>		<b>2007</b>		<b>2006</b>	
Cost of sales	\$		6	\$	3	\$		16	\$		3	
Research and development expense			134		239			542			728	
Selling, general and administrative expense			277		437			914			1,165	
Total	\$		417	\$	679	\$		1,472	\$		1,896	

At September 30, 2007, Depomed had \$6.0 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option plans that will be recognized over an average vesting period of 2.5 years.

**NOTE 5. COMPREHENSIVE INCOME (LOSS)**

Total comprehensive income (loss) for the three and nine months ended September 30, 2007 and 2006 approximates net income (loss) and includes unrealized gains and losses on marketable securities.

**NOTE 6. COLLABORATIVE ARRANGEMENTS AND CONTRACTS*****Esprit Pharma***

In July 2005, the Company entered into an exclusive license agreement with Esprit to market and distribute ProQuin XR in the United States. The agreement was amended in July 2006. In connection with the license agreement, the Company also entered into a related supply agreement with Esprit, pursuant to which the Company supplied commercial quantities of ProQuin XR to Esprit.

The license agreement obligated Esprit to pay the Company \$50.0 million in license fees, of which \$30.0 million was paid in July 2005 and \$10.0 million was paid in December 2006. The remaining \$10.0 million was due in July 2007. The license fee payments received were scheduled to be recognized as revenue ratably until June 2020, which represented the length of time that the Company was obligated to manufacture ProQuin XR for Esprit or its licensees.

The license agreement also provided for royalty payments by Esprit to the Company of 15 percent to 25 percent of ProQuin XR net sales, based on escalating net sales and subject to certain minimum royalty amounts. Esprit's minimum royalty obligation for 2007 was \$5.0 million, and in

## Edgar Filing: DEPOMED INC - Form 10-Q

subsequent years was \$5.0 million per year, subject to annual increases in the consumer price index beginning in 2008.

In July 2007, the Company entered into a termination and assignment agreement with Esprit terminating the exclusive license agreement and related supply agreement. Upon entering into the termination and assignment agreement, the marketing and distribution rights in the United States for ProQuin XR reverted back to the Company and Esprit paid the Company \$17.5 million, representing (i) a \$10.0 million payment in respect of the final license payment that would have been due to the Company in July 2007 under the license agreement; (ii) a \$2.5 million payment in respect of a pro-rated portion of minimum royalties for 2007 under the license agreement; and (iii) a \$5.0 million termination fee. Esprit has no future royalty obligations to the Company.



As a result of termination of the license and supply agreements with Esprit, the Company no longer has continuing obligations to Esprit. Accordingly, all deferred revenue related to license fees previously received from Esprit was fully recognized as revenue in July 2007, resulting in recognition of approximately \$36.1 million of license revenue. In addition, the final \$10 million payment received in July 2007 was fully recognized as license revenue on receipt, resulting in total recognition of \$46.1 million of license revenue in the third quarter of 2007. The royalty payment of \$2.5 million was recognized as royalty revenue and the \$5.0 million termination fee has been classified as a gain within operating income in the third quarter of 2007.

#### ***Watson Pharmaceuticals***

In July 2007, the Company entered into a promotion agreement with Watson Pharmaceuticals (Watson) granting Watson a co-exclusive right to promote ProQuin XR to the urology specialty and to long-term care facilities in the United States. In September 2007, the agreement was amended to also grant Watson a co-exclusive right to promote ProQuin XR to the obstetrics/gynecology (ob/gyn) specialty. Watson is required to deliver a minimum number of annual sales detail calls and maintain a sales force of a minimum size. Watson will receive a promotion fee equal to an agreed upon portion of gross margin attributable to the urology and ob/gyn specialties and long-term care facilities above an agreed upon baseline level. The Company is responsible for the manufacture and distribution of ProQuin XR. Each party bears all of its own personnel and other costs, including marketing expenses. The term of the promotion agreement is three years, with up to two additional one-year renewal periods at the election of Watson, and subject to early termination under certain circumstances. The Company has retained the right to promote ProQuin XR to physicians outside the urology, ob/gyn and long-term care markets, either directly or through third parties. The Company re-launched ProQuin XR and Watson commenced promotion in October 2007.

#### ***LG Life Sciences***

In January 2007, the Company and LG Life Sciences amended the parties' license and distribution agreement, originally entered into in August 2004, as amended in November 2006. The amendment grants LG a license to certain of the Company's intellectual property rights to manufacture LG's version of Glumetza, Novamet GR (extended release metformin tablets), in exchange for royalties on net sales of Novamet GR in Korea, and to remove the provisions of the original agreement providing for the supply of 500mg Novamet GR tablets by the Company to LG. The Company received a \$0.6 million upfront license fee in August 2004 and a \$0.5 million milestone payment in November 2006 with respect to LG's approval to market Novamet GR in the Republic of Korea that were originally deferred and amortized as revenue over the estimated length of time the Company was obligated to provide assistance in development and manufacturing. Under the amended agreement, the Company no longer has continuing performance obligations to LG that are other than inconsequential or perfunctory and accordingly, the remaining \$0.9 million of previously deferred revenue was recognized as license revenue in the first quarter of 2007.

#### ***Biovail***

In February 2007, the Company entered into a license and development agreement with Biovail granting Biovail an option to license the AcuForm drug delivery technology to develop and commercialize up to two pharmaceutical products. Pursuant to the agreement, Biovail paid the Company an upfront fee of \$0.5 million in February 2007, and is contingently obligated to pay the Company additional fees related to the exercise of the license option, the initiation of the first Phase 3 trial for each product and upon receipt of U.S. regulatory approval for each product. The agreement also requires that Biovail make royalty payments to the Company on net commercial sales of any product developed under the agreement. As the Company has no continuing obligations to Biovail under the agreement that are other than inconsequential or perfunctory, the \$0.5 million upfront license fee was recognized as license revenue in the first quarter of 2007.

Also in February 2007, the Company amended its stock purchase agreement with Biovail originally entered into in May 2002. The amended stock purchase agreement removed Biovail's observer rights at the Company's board of directors meetings and removed the right of first negotiation in favor of Biovail with respect to acquisition transactions involving the Company.

## NOTE 7. RELATED PARTY TRANSACTIONS

### *Retirement of 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 will continue to serve as a member of the Company's Board of Directors. 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 months ended September 30, 2007, the Company incurred expense of approximately \$27,000 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 months ended September 30, 2007, the Company recognized approximately \$12,000 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.

## NOTE 8. REDUCTION IN FORCE

In September 2007, the Company reduced its workforce by 25 employees, or approximately 25% of its full-time staff, to conserve cash and align its workforce with its anticipated staffing needs. The total cost of the workforce reduction is expected to be \$672,000, which consists of cash payments for severance, medical insurance and outplacement services and was recognized as expense during the three months ended September 30, 2007. Severance expense of \$451,000 and \$221,000 was recognized in research and development expense and selling, general and administrative expense, respectively, for the three months ended September 30, 2007. The following table summarizes the severance expense activity during the three months ended September 30, 2007 (in thousands):

Severance expense accrued	\$	672
Cash payments		(392)
Accrued severance balance as of September 30, 2007	\$	280

The severance accrual as of September 30, 2007 is expected to be paid in the fourth quarter of 2007.

## NOTE 9. INVENTORIES

## Edgar Filing: DEPOMED INC - Form 10-Q

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, 2007		December 31, 2006	
Raw materials	\$	980	\$	1,343
Work-in-process		272		1,387
Finished goods		1,961		970
Deferred costs		638		783
Total	\$	3,851	\$	4,483

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

**NOTE 10. SHAREHOLDERS EQUITY (DEFICIT)**

***Registered Direct Equity Offering***

In April 2007, the Company completed a registered direct offering of 5,300,000 shares of common stock with selected institutional investors. The shares were sold at a price of approximately \$3.78 per share, with net proceeds totaling approximately \$20.0 million.

***Series A Preferred Stock***

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.

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 is 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 decreases 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 will increase by approximately 5.1% per year. The conversion of the warrant may 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 may be surrendered in exchange for common stock for an additional three years through January 20, 2009. As long as the Series A Preferred Stock remains outstanding, the number of shares into which the warrant can be converted increases as the conversion price of the warrant decreases resulting in additional deemed dividends on the Series A Preferred Stock. For the three and nine months ended September 30, 2007, the Company recognized Series A Preferred Stock deemed dividends of approximately \$0.2 and \$0.5 million, respectively, attributable to the beneficial conversion feature from the accrued dividends and decreasing warrant price. The Company will continue to recognize Series A Preferred Stock deemed dividends until the earlier of, the time the Series A Preferred Stock is surrendered or until January 2009.

As of September 30, 2007, 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 2,773,402 shares of the Company's common stock at a conversion price of \$6.55 as of September 30, 2007.

#### ***Option Exercises***

There were no options exercised by employees and consultants during the three months ended September 30, 2007. Employees and consultants exercised options to purchase 226,472 shares of the Company's common stock with net proceeds to the Company of approximately \$0.7 million during the nine months ended September 30, 2007.

#### ***Employee Stock Purchase Plan***

In May 2007, the Company sold 72,217 shares under the ESPP. The shares were purchased at a weighted average exercise price of \$3.09 with proceeds of approximately \$0.2 million.

#### **NOTE 11. INCOME TAXES**

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 10* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements. Tax positions are evaluated for recognition using a more-likely-than-not threshold, and those tax positions requiring recognition are measured as the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. FIN 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted the provisions of FIN 48 on January 1, 2007. As of January 1, 2007 and September 30, 2007, the Company had \$2.3 million and \$2.9 million of unrecognized tax benefits, which is netted against deferred tax assets and is fully offset by a valuation allowance. Upon adoption of FIN 48, no adjustment was made to the Company's liability for uncertain tax positions or the Company's beginning accumulated deficit balance. The adoption of FIN 48 did not have a material impact on the Company's financial statements, results of operations

or cash flows.

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**

### ***King Pharmaceuticals***

In October 2007, the Company terminated its promotion agreement with King Pharmaceuticals (King) related to the marketing of GLUMETZA in the United States. Pursuant to the termination agreement, King paid the Company \$29.9 million in termination and other fees, and will fulfill its GLUMETZA promotion obligations through December 31, 2007. Beginning in the fourth quarter of 2007, the Company is no longer obligated to pay King promotion fees on sales of GLUMETZA in the United States.



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

**FORWARD-LOOKING INFORMATION**



## Edgar Filing: DEPOMED INC - Form 10-Q

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, 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 obtain development and marketing partners for Gabapentin GR and other product candidates;

results and timing of our clinical trials, including the results of Gabapentin GR trials and publication of those results;

the future commercialization of GLUMETZA in the United States, and our ability to find a new marketing partner for GLUMETZA in the United States;

the success of ProQuin® XR in the United States, and the success of our collaborative arrangement with Watson Pharmaceuticals with respect to ProQuin XR;

market acceptance of GLUMETZA and ProQuin XR;

our collaborative partners' compliance or non-compliance with their obligations under our agreements with them;

our ability to raise additional capital; and

our plans to develop other product candidates.

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

### ABOUT DEPOMED

Depomed is a specialty pharmaceutical company focused on the development and commercialization of differentiated products that address large and growing markets and are based on proprietary oral drug delivery technologies. We have 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. ProQuin XR (ciprofloxacin hydrochloride extended release tablets) is a once-daily treatment for uncomplicated urinary tract infections that we jointly commercialize in the United States with Watson Pharmaceuticals.

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 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

## Edgar Filing: DEPOMED INC - Form 10-Q

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 candidate is Gabapentin GR, an extended release form of gabapentin. In July 2007, we announced that the primary endpoint of our Phase 3 clinical trial for the treatment of postherpetic neuralgia (PHN) was not achieved with statistical significance. We have also completed and announced positive results of a Phase 2 clinical trial for the treatment of diabetic peripheral neuropathy (DPN), and initiated a Phase 2 clinical trial for the treatment of menopausal hot flashes. Additionally, we have other product candidates in earlier stages of development, including a treatment for gastroesophageal reflux disease (GERD).

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

*Significant Developments for the Quarter Ended September 30, 2007*

In July 2007, we announced the results of our Phase 3 clinical trial for Gabapentin GR for the treatment of PHN. The primary endpoint in the study was not achieved with statistical significance for either active treatment regimen, as compared to placebo, over the ten-week treatment period. However, important secondary endpoints related to efficacy were achieved with statistical significance relative to placebo, and the incidence of certain adverse events associated with gabapentin was relatively low.

In July 2007, we terminated our license and supply arrangements with Esprit Pharma related to ProQuin XR, and the marketing and distribution rights in the United States for ProQuin XR were transferred back to us. We received \$17.5 million in payments pursuant to the termination agreement.

In July 2007, we entered into a promotion agreement with Watson Pharmaceuticals granting Watson a co-exclusive right to promote ProQuin XR to the urology specialty and long-term care facilities in the United States. In September 2007, we amended the agreement and additionally granted Watson a co-exclusive right to promote ProQuin XR to the ob/gyn specialty.

In August 2007, Dr. John W. Fara retired from his positions as our Chairman, President and Chief Executive Officer of the Company. Dr. Fara will continue to serve the Company as a director and a consultant.

In August 2007, Carl A. Pelzel was appointed as the Company's President and Chief Executive Officer, and Craig R. Smith, M.D., was appointed Chairman of the Board of Directors.

In August 2007, we announced the results of a Phase 2a pharmacokinetic/pharmacodynamic proof-of-concept study of patients suffering with nocturnal acid breakthrough (NAB) associated with GERD.

In September 2007, we completed patient enrollment on a Phase 2 trial for Gabapentin GR for the treatment of menopausal hot flashes.

In September 2007, we implemented a reduction in force affecting approximately one-fourth of our employees.

Revenues for the three months ended September 30, 2007 were \$52.9 million, and included \$48.6 million associated with the termination of our Esprit license and supply agreements, compared to \$1.0 million for the three months ended September 30, 2006.

Operating expenses for the three months ended September 30, 2007 were \$8.2 million and included a \$5.0 million gain on termination of our Esprit license and supply agreements, compared to operating expenses of \$13.8 million for the three months ended September 30, 2006.

Cash, cash equivalents and marketable securities were \$45.8 million as of September 30, 2007, compared to \$33.6 million as of December 31, 2006.

*Other Recent Developments*

In October 2007, John F. Hamilton retired as our Vice President, Finance and Chief Financial Officer, and Tammy L. Cameron, our Corporate Controller, was appointed as our principal accounting and financial officer on an interim basis.

In October 2007, we terminated our promotion agreement with King Pharmaceuticals related to GLUMETZA. Pursuant to the termination agreement, King paid us \$29.9 million in termination and other fees, and will fulfill its GLUMETZA promotion obligations through December 31, 2007.

## RECENT PRODUCT DEVELOPMENTS

### *MARKETED PRODUCTS*

#### *GLUMETZA*

King Pharmaceuticals. In October 2007, we terminated our promotion agreement with King related to GLUMETZA. Pursuant to the termination agreement, King paid us \$29.9 million in termination and other fees, and will fulfill its GLUMETZA promotion obligations through December 31, 2007. We have no obligation to pay King promotion fees on sales of GLUMETZA for periods after September 30, 2007. We are in discussions with potential marketing partners for GLUMETZA in the United States.

In April 2007, we submitted a prior approval supplement to the FDA covering a 1000mg tablet strength of GLUMETZA seeking approval to market the product in the United States. In August 2007, we received an approvable letter from the FDA in response to the prior approval supplement. The conditions to approval set forth in the letter relate primarily to manufacturing, and we are working with Biovail to resolve them. We expect that the conditions will be satisfied, and the 1000mg GLUMETZA to be commercially available in the second quarter of 2008.

#### *ProQuin® XR*

Esprit Pharma. In July 2007, we entered into a termination and assignment agreement with Esprit terminating the exclusive license and marketing agreement originally entered into in July 2005 and subsequently amended in July 2006, in which we previously granted Esprit ProQuin XR marketing and distribution rights in the United States. The related supply agreement entered into in July 2005 and co-promotion agreement entered into in July 2006 were also terminated.

Upon entering into the termination and assignment agreement, the marketing and distribution rights in the United States for ProQuin XR were transferred back to us and Esprit paid us \$17.5 million representing (i) a \$10.0 million payment in respect of the final license payment that would have been due to us in July 2007 under the exclusive license and marketing agreement; (ii) a \$2.5 million payment in respect to a pro-rated portion minimum royalties for 2007; and (iii) a \$5.0 million termination fee. The termination and assignment agreement removed Esprit's future minimum royalty obligations to us.

Under the termination and assignment agreement, Esprit is responsible for all returns and rebates associated with ProQuin XR product distributed by Esprit.

Watson Pharmaceuticals. In July 2007, we entered into a promotion agreement with Watson granting Watson a co-exclusive right to promote ProQuin XR to the urology specialty and long-term care facilities in the United States. In September 2007, we amended the agreement to also grant Watson a co-exclusive right to promote ProQuin XR to the ob/gyn specialty. Watson is required to deliver a minimum number of annual sales detail calls and maintain a sales force of a minimum size. Watson will receive a promotion fee equal to an agreed upon portion of gross margin attributable to the urology and ob/gyn specialties and long-term care facilities above an agreed upon baseline level. We will be responsible for the manufacture and distribution of ProQuin XR. Each party will bear all of its own personnel and other costs, including marketing expenses. The term of the Promotion Agreement is three years, subject to early termination in certain circumstances, with up to two additional one-year renewal periods at the election of Watson. We have retained the right to promote ProQuin XR to physicians outside the urology and ob/gyn specialties and long-term care markets, either directly or through third parties. We and Watson re-launched ProQuin XR in October 2007.

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., who 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. We assisted Madaus with a response to comments and questions on the Marketing Authorization Application that Madaus received in May 2007. Madaus submitted its response to the Swedish Medical Products Agency's questions and comments in August 2007. We anticipate that the Medical Products Agency will act on the response submitted by Madaus before the end of the first quarter of 2008.



***PRODUCT CANDIDATES***

***Gabapentin GR***

Postherpetic Neuralgia. In May 2006, we initiated a Phase 3 clinical trial for Gabapentin GR for the treatment of PHN. The study was a randomized, double-blind, placebo-controlled study of approximately 400 PHN patients. The study was fully enrolled in March 2007. Patients in the study were randomized into three treatment arms: placebo, a total daily dose of 1800mg of Gabapentin GR dosed once daily, and a total daily dose of 1800mg of Gabapentin GR dosed twice daily.

The primary objective of the study was to assess the efficacy of Gabapentin GR 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.

In July 2007, we announced the primary endpoint was not achieved with statistical significance for either active treatment regimen, as compared to placebo, over the ten-week treatment period. The mean reductions in average daily pain scores from baseline to end of study were 1.83 (once-daily), 1.72 (twice-daily) and 1.43 (placebo). However, statistical significance relative to placebo was achieved in each of the first seven weeks for the once-daily treatment arm and in each of the first four weeks for the twice-daily treatment arm using the "baseline observation carried forward" statistical analysis applied to the primary endpoint in the study.

The secondary endpoints of sleep interference, Clinical Global Impression of Change (CGIC), a scale used by physicians for overall assessment of patient improvement, and Patient Global Impression of Change (PGIC), a scale used by patients to report their overall assessment of change, were all statistically significant for the once-daily treatment compared to placebo over the ten week study period. Sleep interference scores were reduced by 2.01 points with Gabapentin GR compared to -1.39 with placebo ( $p=0.014$ ). Physicians reported that 48.0% of patients taking Gabapentin once-daily were very much improved or much improved compared to 27.1% of the patients who received placebo ( $p<0.001$ ), as measured by the CGIC. Similar results were observed for the PGIC in the once-daily and placebo arms ( $p=0.009$ ).

We are pursuing discussions with potential development and marketing partners for Gabapentin GR for PHN. In November 2007, we plan to submit to the FDA a special protocol assessment related to a new Phase 3 clinical trial in PHN for Gabapentin GR. Under the FDA's special protocol assessment procedures, the FDA will evaluate within 45 days certain protocols for clinical trials to assess whether they are adequate to meet scientific and regulatory requirements necessary to support an approval. We believe that obtaining the FDA's input on the details of a proposed modified protocol design before starting a further study will provide valuable guidance for the efficacy demonstration needed for an NDA filing for Gabapentin GR for the PHN indication.

Menopausal Hot Flashes. In April 2007, we commenced a Phase 2 study of Gabapentin GR for the treatment of menopausal hot flashes assessing the relationship between various doses and dosing schedules of Gabapentin GR and the safety and efficacy of the formulation of Gabapentin GR for the treatment of menopausal hot flashes. In September 2007, we completed patient enrollment in the trial and expect to report top-line data from the study in the first quarter of 2008. The study is a double-blind, placebo-controlled, multi-center trial of 124 menopausal women experiencing recurrent, moderate to severe hot flashes. The primary endpoints of the trial are the frequency and severity of hot flashes, relative to baseline. Secondary endpoints include, among others, the efficacy of Gabapentin GR relative to placebo based on changes from baseline to the end of each treatment period, average daily frequency and severity score of hot flashes and sleep quality.

#### ***Gastroesophageal Reflux Disease Program***

In 2006, we conducted a Phase 1 study of the GERD treatment omeprazole, a generic proton pump inhibitor, designed to provide us with insight into our formulation strategy for our GERD program. We have also conducted two proof-of-concept studies related to our GERD program. In the initial study, we determined that our gastric retentive omeprazole tablet can predictably deliver omeprazole approximately four hours after ingestion.

In August 2007, we announced the results of the second study. The Phase 2a pharmacokinetic/pharmacodynamic proof-of-concept study demonstrated the potential clinical advantages of the delivery of omeprazole in two evening pulses to patients suffering with nocturnal acid breakthrough, or NAB, associated with GERD.

The objective of the study was to determine if the delivery of a dose of omeprazole with dinner and a second dose four hours after dinner would reduce the incidence of NAB, which typically occurs in the late evening and early morning hours. The study was an open label crossover study that involved 16 patients with at least three months history of GERD with recurrent nighttime acid reflux while taking omeprazole or any other proton pump inhibitor. Fourteen of the 16 patients completed each of two treatment arms. In the proof-of-concept arm of the study, patients received 20 mg of omeprazole with dinner followed by a second 20 mg dose four hours later, in order to simulate a two pulse delivery mechanism. In the comparative arm of the study, patients received 40 mg of omeprazole 30 minutes before dinner.

Five patients who received the two pulses of omeprazole did not have clinically meaningful blood levels of the drug associated with the first pulse and therefore did not provide useful data for this trial, because the study objective was to evaluate a two pulse delivery of the drug. These patients received the commercially available formulation of omeprazole known as Prilosec®. It is not known why these patients did not achieve blood levels with Prilosec.

In the nine patients who did achieve blood levels from both doses of omeprazole, and thus provided useful data for the two pulse concept tested in the trial, none experienced NAB. In the 40 mg single dose treatment arm, three patients experienced NAB. All three of these patients had blood levels of omeprazole fall to undetectable levels between 2 a.m. and 3 a.m.. Results from both arms of the study therefore demonstrate the need to maintain adequate blood levels of omeprazole in order to inhibit NAB.

#### ***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 will be shared between the parties equally. We continue to participate with Supernus on this collaborative program.

#### **CRITICAL ACCOUNTING POLICIES**

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, accrued liabilities and stock-based compensation to be critical policies. There have been no changes to our critical accounting policies since we filed our 2006 Annual Report on Form 10-K with the Securities and Exchange Commission on March 16, 2007. For a description of our critical accounting policies, please refer to our 2006 Annual Report on Form 10-K.

**RESULTS OF OPERATIONS**



*Three and Nine Months Ended September 30, 2007 and 2006*





**Revenue**



## Edgar Filing: DEPOMED INC - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Product sales:				
GLUMETZA	\$ 3,832	\$	\$ 7,666	\$
ProQuin XR				1,265
Total product sales	3,832		7,666	1,265
Royalties:				
GLUMETZA	46	9	125	107
ProQuin XR	2,500	57	2,500	388
Total royalties	2,546	66	2,625	495
License revenue:				
GLUMETZA	364	382	1,996	1,146
ProQuin XR	46,117	511	47,507	1,533
AcuForm technology			500	
Total license revenue	46,481	893	50,003	2,679
Collaborative revenue	1		3	75
Total revenues	\$ 52,860	\$ 959	\$ 60,297	\$ 4,514

### *Product sales*

The GLUMETZA product that we began selling to wholesalers and retail pharmacies in September 2006 is subject to rights of return of up to twelve months after product expiration. Given the limited sales history of GLUMETZA and return privileges, we currently cannot reliably estimate expected returns of the product at the time of shipment. We defer recognition of revenue on product shipments of GLUMETZA until the right of return no longer exists, which occurs at the earlier of the time GLUMETZA units are dispensed through patient prescriptions or expiration of the right of return. We estimate the volume of prescription units dispensed by pharmacies based on an analysis of third-party information, including third-party market research data, information obtained from certain wholesalers with respect to inventory levels and out-movement and retail pharmacy re-stocking activity. For the three and nine months ended September 30, 2007, we recognized approximately \$3.8 million and \$7.7 million of product sales of GLUMETZA, respectively, which is net of estimated patient support program discounts, wholesaler fees, stocking allowances, prompt payment discounts, chargebacks and Medicaid rebates. We have deferred recognition of revenue on GLUMETZA product shipments to customers which we estimate have not been dispensed through patient prescriptions. At September 30, 2007, we have a deferred revenue balance, which is classified as a liability on the consolidated balance sheet, of \$4.7 million associated with the deferral of revenue on GLUMETZA product shipments, which is net of estimated patient support program discounts, wholesaler fees, stocking allowances, prompt payment discounts, chargebacks and Medicaid rebates.

ProQuin XR product sales in 2006 relate to our supply agreement with Esprit. We began supplying Esprit with commercial quantities of ProQuin XR in the fourth quarter of 2005, and in 2007, there were no sales pursuant to the supply agreement. We terminated the license and supply agreements in July 2007 and the marketing and distribution rights in the United States for ProQuin XR reverted back to us. In October 2007, we re-launched ProQuin XR with Watson and expect to begin recognizing product sales as revenue in the fourth quarter of 2007.

***Royalties***

In July 2007, we terminated our license agreement with Esprit that provided for royalty payments by Esprit to us on ProQuin XR net sales in the United States. Under the termination and assignment agreement related to our license and supply agreements, Esprit paid us \$2.5 million in royalties in July 2007, which was recognized as royalty revenue in the third quarter of 2007. Esprit is no longer obligated to pay us royalties on ProQuin XR sales.

GLUMETZA royalties for the three and nine months ended September 30, 2007 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. In July 2007, the royalty payable by Biovail was increased to ten percent on Canadian net sales of the 500mg GLUMETZA. We began receiving royalties from LG in the first quarter of 2007.

***License revenue***

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 due 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.

As a result of the termination of our agreements with Esprit, we no longer have continuing obligations to Esprit. Accordingly, all deferred revenue related to license fees previously received from Esprit was fully recognized as revenue in July 2007, resulting in recognition of approximately \$36.1 million of license revenue. In addition, the final \$10 million payment received in July 2007 was fully recognized as license revenue on receipt, resulting in total recognition of \$46.1 million of license revenue related to our agreements with Esprit during the third quarter of 2007.

We received \$25.0 million in GLUMETZA license fees from Biovail in July 2005. We are recognizing the \$25.0 million license fee payment as revenue ratably until February 2023, 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, should the 1000mg GLUMETZA obtain approval in the United States.

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 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 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 that are other than inconsequential or perfunctory to LG. Accordingly, the remaining \$0.9 million of previously deferred revenue was recognized as license revenue in the first quarter of 2007.

## Edgar Filing: DEPOMED INC - Form 10-Q

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 have no continuing performance obligations that are other than inconsequential or perfunctory under the agreement. Accordingly, we have 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, 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, 2007, as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>2007</b>		<b>2006</b>		<b>Nine Months Ended September 30,</b>		<b>2007</b>		<b>2006</b>	
Cost of sales	\$	724	\$	320	\$	1,598	\$	1,445				

Cost of sales for the three and nine months ended September 30, 2007 relates primarily to costs associated with the sale of GLUMETZA. Costs of sales for the three and nine months ended September 30, 2006 relates primarily to costs associated with the supply of ProQuin XR to Esprit. The costs of manufacturing associated with deferred revenue on GLUMETZA product shipments are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized.

**Research and Development Expense**

Our research and development expenses currently include costs for scientific personnel, supplies, equipment, outsourced clinical and other research activities, consultants, depreciation, facilities and utilities. The scope and magnitude of future research and development expenses cannot be predicted at this time for our product candidates in the early phases of research and development, as it is not possible to determine the nature, timing and extent of clinical trials and studies, the FDA's requirements for a particular drug and the requirements and level of participation, if any, by potential partners. As potential products proceed through the development process, each step is typically more extensive, and therefore more expensive, than the previous step. Success in development therefore, generally results in increasing expenditures until actual product launch. Total research and development expense for the three and nine months ended September 30, 2007, as compared to the prior year, was as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>2007</b>		<b>2006</b>		<b>Nine Months Ended September 30,</b>		<b>2007</b>		<b>2006</b>	
Research and development expense	\$	4,724	\$	6,436	\$	19,425	\$	18,888				
Dollar change from prior year		(1,712)				537						
Percentage change from prior year		(26.6)%				2.8%						

The decrease in research and development expense for the three months ended September 30, 2007 as compared to the three months ended September 30, 2006 was primarily due to lower outside contract service expenses related to the completion of the Phase 3 clinical trial for Gabapentin GR for the treatment of postherpetic neuralgia which was completed in the first half of 2007.

The increase in research and development expense for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006 was primarily due to higher outside contract service expenses for our clinical trial expenses related to our Phase 2 clinical trial for Gabapentin GR for the treatment of menopausal hot flashes and costs associated with our Phase 2a proof-of-concept GERD formulation studies.

## Edgar Filing: DEPOMED INC - Form 10-Q

We may decide to commence one or more additional Phase 3 trials for Gabapentin GR for the treatment of postherpetic neuralgia or menopausal hot flashes either alone or with a collaborative partner, which may result in increased research and development expense in future periods.

**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, 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,	
	2007	2006	2007	2006
Selling, general and administrative	\$ 8,483	\$ 7,328	\$ 21,033	\$ 16,157
Dollar change from prior year	1,155		4,876	
Percentage change from prior year	15.8%		30.2%	

The increase in selling, general and administrative expense for the three months ended September 30, 2007 as compared to the three months ended September 30, 2006 was primarily due to \$2.1 million in promotion fees due to King under the promotion agreement for GLUMETZA, which was launched in September 2006, offset by decreases of \$0.6 million in marketing expenses related to GLUMETZA and \$0.2 million related to stock-based compensation.

The increase in selling, general and administrative expense for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006 was primarily due to an increase of \$3.0 million in promotion fees due to King under the promotion agreement for GLUMETZA, \$0.7 million in marketing costs associated with GLUMETZA, and \$1.4 million increase in legal fees resulting from our patent infringement case against IVAX, offset by a decrease of \$0.3 million related to stock-based compensation.

We are no longer obligated to pay King promotion fees related to sales of GLUMETZA. Accordingly, selling, general and administrative expenses may decrease in the fourth quarter of 2007.

**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 months ended September 30, 2007.

**Interest and Other Income**

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Interest and other income	\$ 638	\$ 492	\$ 1,504	\$ 1,673
Dollar change from prior year	146		(169)	



## Edgar Filing: DEPOMED INC - Form 10-Q

Percentage change from prior year	29.7%	(10.1)%
-----------------------------------	-------	---------

Interest and other income increased during the three months ended September 30, 2007 as compared to the corresponding period in 2006 due to higher investment balances in the three months ended September 30, 2007 as a result of receipt of \$17.5 million from Esprit in July 2007. Interest and other income decreased during the nine months ended September 30, 2007 as compared to the corresponding periods in 2006 as a result of lower investment balances in 2007.

### LIQUIDITY AND CAPITAL RESOURCES

(in thousands)	September 30, 2007	December 31, 2006
Cash, cash equivalents and marketable securities	\$ 45,846	\$ 33,558

Since inception through September 30, 2007, we have financed our product development efforts and operations primarily from private and public sales of equity securities and receipts of upfront 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. Sales to Azimuth under the agreement, if any, will occur over a 24-month term and 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, 2007, we have not sold any common stock to Azimuth under this common stock purchase agreement.

In April 2007, we completed a registered direct offering of 5,300,000 shares of common stock with institutional investors. The shares were sold at a price of approximately \$3.78 per share, with net proceeds totaling approximately \$20.0 million.

In July 2007, Esprit paid us \$17.5 million in connection with the termination of the license and supply agreement.

In October 2007, King paid us \$29.9 million in connection with the termination of our GLUMETZA promotion agreement with King.

As of September 30, 2007, we have accumulated net losses of \$159.6 million. We expect to continue to incur operating losses in 2008. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of 2008. 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;
- results of our litigation against IVAX;
- 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**



## Edgar Filing: DEPOMED INC - Form 10-Q

Cash used in operating activities during the nine months ended September 30, 2007 was approximately \$8.7 million, compared to cash used in operating activities of approximately \$25.3 million during the nine months ended September 30, 2006. During the nine months ended September 30, 2007 cash used in operating activities was primarily due to our net income adjusted for stock-based compensation, depreciation expense and movements in working capital, including recognition of previously deferred revenue. During the nine months ended September 30, 2006 cash used in operating activities was primarily due to our net loss adjusted for stock-based compensation, depreciation expense and movements in working capital. The decrease in cash used in operating activities for the nine months ended September 30, 2007 as compared to the prior year was primarily due to receipt of the \$17.5 million in payments from Esprit on termination of the license and supply agreements for ProQuin XR.

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

Cash used in investing activities during the nine months ended September 30, 2007 was approximately \$17.2 million and consisted of a \$17.1 million net increase in marketable securities. Net cash provided by investing activities during the nine months ended September 30, 2006 was approximately \$18.0 million and consisted of an \$18.7 million net decrease in marketable securities offset by \$0.7 million in purchases of laboratory and office equipment.

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

Cash provided by financing activities during the nine months ended September 30, 2007 was approximately \$20.9 million compared to cash provided by financing activities of approximately \$2.5 million for the same period in 2006. In the nine months ended September 30, 2007, the amount 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. In the nine months ended September 30, 2006, the amount consisted primarily of cash proceeds from the exercises of warrants and stock options.

**Contractual Obligations**

As of September 30, 2007, our aggregate contractual obligations are as shown in the following table (in thousands):

	<b>Less than 1 year</b>		<b>1-3 years</b>		<b>More than 3 years</b>		<b>Total</b>
Operating leases	\$	1,374	\$	1,238	\$	9	\$ 2,621

The contractual obligations reflected in this table exclude \$3.5 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 table above 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, 2006.

**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.

*Changes in Internal Controls*

There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

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

We are involved in legal proceedings relating to some of our intellectual property rights. In January 2006, we filed a complaint against IVAX Corporation in the U.S. District Court for the Northern District of California for infringement of U.S. Patent Nos. 6,340,475 and 6,635,280, both of which we own. The patents relate to our AcuForm delivery technology. The complaint alleges infringement of our patents by IVAX's extended release metformin hydrochloride tablets. In April 2006, IVAX filed an answer and counterclaim, in which it alleged that the patents in the suit are not infringed by IVAX and are invalid and unenforceable. In December 2006, the court issued an order construing certain of the claim terms appearing in the patents. Fact and expert discovery in the case is substantially complete. In September 2007, we submitted a motion for summary judgment of infringement. In October 2007, IVAX submitted motions for summary judgment of invalidity, inequitable conduct, lack of willfulness, and for construction of a claim term appearing in the patents. A consolidated hearing on the parties' summary judgment motions is scheduled for November 20, 2007. The court has not set a trial date.

### **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, 2006.

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 recent Phase 3 trial for Gabapentin GR 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 Gabapentin GR failed to meet the primary efficacy endpoint in a Phase 3 trial for the treatment of postherpetic neuralgia (PHN). We expect that one or more additional clinical trials will be required to obtain marketing approval in the United States for the product for the PHN indication. We are pursuing discussions with potential development and marketing partners related to the continued development of Gabapentin GR for PHN. However, we may not secure a development and marketing arrangement on terms favorable to us, or at all. In that event, we must consider conducting one or more additional clinical trials alone.

We intend to submit a protocol for a Phase 3 registration trial for Gabapentin GR to the FDA for a special protocol assessment, or SPA, pursuant to which the FDA will assess whether the protocol is adequate to meet the scientific and regulatory requirements necessary to support marketing approval of Gabapentin GR for PHN. In connection with the assessment, we may decide, or the FDA may require us, to modify the protocol by, for example, changing the proposed primary endpoint, the size of the study or otherwise, which may result in a delay in the completion of the trial.

If we conduct additional trials, 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 is likely to be significantly delayed, which means that we would not receive revenue from drug sales for a number of years, if at all. If we decide to abandon the further development of Gabapentin GR for PHN, our commercial prospects may be adversely affected.

**We have terminated our promotion arrangement with King Pharmaceuticals related to GLUMETZA in the United States, and have not yet identified a new commercialization partner for the product.**

In June 2006, we entered into a promotion agreement with King Pharmaceuticals pursuant to which King promoted GLUMETZA in the United States through its sales force. In October 2007, following a strategic shift in focus by King toward its neuroscience and hospital/acute care business, we and King terminated the promotion agreement. Pursuant to the termination of the promotion agreement, we received payments from King of approximately \$29.9 million, and King will continue detailing GLUMETZA through December 31, 2007.

We are seeking a new marketing partner for GLUMETZA. However, we have not yet identified a new marketing partner and we may not succeed in entering into a marketing arrangement for GLUMETZA on favorable terms, or at all. We have not yet established a sales force, or contracted with a third party to act as our sales force, and we do not have immediate plans to do so. Accordingly, the success of GLUMETZA will depend in large part on our ability to identify and enter into a marketing arrangement with a new partner. Even if we enter into a new marketing arrangement for GLUMETZA, it may not be successful. Any failure to successfully commercialize GLUMETZA could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

**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 right to co-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 depend on Watson Pharmaceuticals for the successful commercialization of ProQuin XR in the United States.**

In July 2007, we granted Watson Pharmaceuticals the co-exclusive marketing rights to ProQuin XR in the United States for 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 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. It is possible that Watson could also have similar difficulties commercializing ProQuin XR. If Watson fails to successfully commercialize ProQuin XR, our business, financial condition and results of operations may be materially and adversely affected.

**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, who was acquired by Rottapharm in June 2007, related to the commercialization of ProQuin XR in Europe. If Biovail fails to successfully commercialize GLUMETZA in Canada and/or LG fails to successfully commercialize Novamet GR in Korea, our business and future revenues may be adversely affected.

**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: Gabapentin GR for postherpetic neuralgia, Gabapentin GR for diabetic peripheral neuropathy, Gabapentin GR for the treatment of hot flashes associated with menopause and omeprazole for the treatment of gastroesophageal reflux disease. 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 are 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 our recently completed Phase 3 trial for Gabapentin GR for the treatment of postherpetic neuralgia.

We are unable to predict whether any of these product candidates will receive regulatory clearances or be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these other product candidates receive regulatory clearance, our products may not achieve or maintain market acceptance. Also, substantially all of our product candidates use the AcuForm technology. If it is discovered that the AcuForm technology could have adverse effects or other characteristics that indicate it is unlikely to be effective as a delivery system for drugs or therapeutics, our product development efforts and our business would be significantly harmed.

**We are expecting operating losses in the future.**

To date, we have recorded limited revenues from license fees, product sales, royalties, collaborative research and development arrangements and feasibility studies. For the nine months ended September 30, 2007, we recorded total revenues of \$60.3 million, and for the years ended December 31, 2006, 2005 and 2004, we recorded total revenue of \$9.6 million, \$4.4 million and \$0.2 million, respectively. For the nine months ended September 30, 2007, we have recorded net income of \$24.5 million, and for the years ended December 31, 2006, 2005 and 2004 we incurred net losses of \$39.7 million, \$24.5 million and \$26.9 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 are expected to allow us to be profitable 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 in fiscal year 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 Gabapentin GR;
- the degree of commercial success of ProQuin XR and GLUMETZA;
- regulatory actions;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply;
- results of litigation, including our pending litigation against IVAX Corporation;
- 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 Gabapentin GR Phase 3 trial results, 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 agreement for development of product candidates through the feasibility phase with New River Pharmaceuticals, a company acquired by Shire Pharmaceuticals, Inc., and we have a collaboration arrangement with Patheon, Inc. related to the potential development of product candidates for third parties. We also have a collaboration agreement with Supernus, Inc. providing for the development of a product candidate through feasibility, with the possibility to enter into a definitive agreement providing for the further development of the product candidate, by either or both parties. 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.

Generally, our collaborative arrangements do not restrict our collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future collaborative partners may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Our collaborative partners may also terminate their collaborative relationships with us or otherwise decide not to proceed with development and commercialization of our products.

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

Our success will depend in part on our ability to obtain and maintain patent protection for our 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 nine issued patents, and have fourteen 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, we are aware that 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.

In January 2006, we filed a complaint against IVAX Corporation in federal court for infringement of two of our U.S. patents related to the AcuForm delivery technology. The complaint alleged infringement of our patents by IVAX's extended release metformin hydrochloride tablet. Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will be successful in our litigation against IVAX. If one or more of our patents is declared invalid or key claims are disallowed, the patent protection for our products and product candidates could be substantially weakened and our business and business prospects could be severely impacted.



**Our licensed patent covering the use of gabapentin to treat hot flashes associated with menopause is a method-of-use patent, which increases the risk that prescriptions for gabapentin to treat hot flashes in menopausal women could be written for, or filled with, generic gabapentin.**

We have an exclusive sublicense from PharmaNova, Inc. to a patent held by the University of Rochester to develop and commercialize in the United States a gabapentin product for the treatment of hot flashes associated with menopause. Because a method-of-use patent, such as the patent we have sublicensed from PharmaNova, covers only a specified use of a particular compound, not a particular composition of matter, we cannot prevent others from commercializing gabapentin. Accordingly, physicians could prescribe another manufacturer's gabapentin to treat hot flashes in menopausal women rather than Gabapentin GR, or pharmacists could seek to fill prescriptions for Gabapentin GR 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 we may not be able to raise additional funds.**

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 and would make it difficult for us to raise financing on favorable terms, if at all.

**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 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, or the initiation of other clinical programs. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary considerably from our estimates depending on numerous factors, some of which are beyond our control, including:

our available capital resources;

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

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

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

other actions by regulators;

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

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

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

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

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



## Edgar Filing: DEPOMED INC - Form 10-Q

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 ProQuin XR and GLUMETZA, as well as marketing activities related to any other products for which we obtain regulatory approval, will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products. The FDA regulates post-approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. For example, the federal healthcare program antikickback statute prohibits giving things of value to induce the prescribing or purchase of products that are reimbursed by federal healthcare programs, such as Medicare and Medicaid. In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Under this law, the federal government in recent years has brought claims against drug manufacturers alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations, which apply to items and services reimbursed under Medicaid and other state programs, or, in some states, regardless of the payer. If we, or our collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunction, and exclusion of our products from reimbursement under government programs, as well as other regulatory actions against our product candidates, our collaborative partners or us.

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

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



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

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

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

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

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

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

Other companies that have oral drug delivery technologies competitive with the AcuForm technology include 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.

## Edgar Filing: DEPOMED INC - Form 10-Q

Bayer Corporation developed a once-daily ciprofloxacin product for the treatment of urinary tract infections, which is currently marketed by Schering-Plough Corporation. 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 a new product, Lyrica (pregabalin), which has been approved for marketing in the U.S. 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 ProQuin XR, GLUMETZA and our other product candidates. If these suppliers are unable to manufacture ProQuin XR, GLUMETZA or our product candidates, our business will be harmed.**

We are responsible for the supply and distribution of GLUMETZA, and MOVA Pharmaceuticals, a subsidiary of Patheon, 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. If approved, Biovail will be our sole supplier for the new formulation of 1000mg 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 or active pharmaceutical ingredient from 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 MOVA Pharmaceuticals, 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 MOVA Pharmaceuticals 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 Gabapentin GR from a contract manufacturer, we currently have no long-term supply arrangement with respect to Gabapentin GR. Any failure to obtain clinical supplies of Gabapentin GR could adversely affect our Gabapentin GR clinical development programs.

**We could become subject to product liability litigation and may not have adequate insurance to cover product liability claims.**

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 2007 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.

**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.

**If we lose our key personnel or are unable to attract and retain key management and operating personnel, we may be unable to pursue our product development and commercialization efforts.**

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 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.

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

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

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

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



## Edgar Filing: DEPOMED INC - Form 10-Q

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

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

**If we sell shares of our common stock under our equity line of credit arrangement or in other future financings, existing common shareholders will experience immediate dilution and, as a result, our stock price may go down.**

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

**If we are unable to satisfy regulatory requirements relating to internal controls, our stock price could suffer.**

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of their internal control over financial reporting. At the end of each fiscal year, we must perform an evaluation of our internal control over financial reporting, include in our annual report the results of the evaluation, and have our external auditors publicly attest to such evaluation. If material weaknesses were found in our internal controls in the future, if we fail to complete future evaluations on time, or if our external auditors cannot attest to our future evaluations, we could fail to meet our regulatory reporting requirements and be subject to regulatory scrutiny and a loss of public confidence in our internal controls, which could have an adverse effect on our stock price.

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

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

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

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

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

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

- (a) Exhibits
- 10.1 Termination and Assignment Agreement, dated July 5, 2007, between the Company and Esprit Pharma
  - 10.2 (+) Amended Promotion Agreement, dated September 21, 2007, between the Company and Watson Pharmaceuticals
  - 10.3 (1) Consulting Agreement, dated August 24, 2007, between the Company and John W. Fara, Ph.D.
  - 10.4 (1) Offer Letter, dated August 24, 2007, between the Company and Carl A. Pelzel
  - 10.5 (1) Amendment No. 1 to Management Continuity Agreement, dated August 24 2007, between the Company and Carl A. Pelzel
  - 10.6 (2) Consulting Agreement, dated October 10, 2007, between the Company and John Hamilton
  - 10.7 (2) Letter Agreement, dated October 10, 2007, between the Company and John Hamilton
  - 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

---

(+) Confidential treatment requested.

- (1) Incorporated by reference to the Company's Form 8-K filed with the SEC on August 27, 2007.
- (2) Incorporated by reference to the Company's Form 8-K filed with the SEC on October 11, 2007.

**SIGNATURES**



## Edgar Filing: DEPOMED INC - Form 10-Q

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 8, 2007

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)