

DEPOMED INC  
Form 10-Q  
November 09, 2005

**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, 2005**

**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 Securities Exchange Act of 1934 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 requirements for the past 90 days.

YES       NO

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes       No

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

The number of issued and outstanding shares of the Registrant's Common Stock, no par value, as of November 4, 2005 was 40,546,919.

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DEPOMED, INC.

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**PART I FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**DEPOMED, INC.**

**(A Development Stage Company)**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

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(Unaudited)

	September 30, 2005	December 31, 2004 (See Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 20,959,340	\$ 953,295
Marketable securities	43,881,590	17,151,544
Accounts receivable	776,282	
Inventories	621,988	
Prepaid and other current assets	546,625	442,349
Total current assets	66,785,825	18,547,188
Property and equipment, net	3,377,750	3,941,127
Other assets	228,926	380,268
	\$ 70,392,501	\$ 22,868,583
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,741,580	\$ 1,733,474
Accrued compensation	1,297,216	910,723
Accrued clinical trial expense	1,015,359	59,942
Other accrued liabilities	738,356	496,142
Capital lease obligation, current portion		32,412
Long-term debt, current portion		73,008
Deferred revenue, current portion	27,118,708	75,000
Other current liabilities	93,073	93,073
Total current liabilities	32,004,292	3,473,774
Promissory note		10,280,591
Deferred revenue, non-current portion	28,393,792	493,750
Other long-term liabilities	147,367	217,170
Commitments		
Shareholders' equity:		
Preferred stock, no par value, 5,000,000 shares authorized; Series A convertible preferred stock, 25,000 shares designated, 17,543 and 15,821 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	12,015,000	12,015,000
Common stock, no par value, 100,000,000 shares authorized; 40,472,180 and 34,691,190 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	138,856,734	117,070,946
Deferred compensation	(421,412)	(621,980)
Deficit accumulated during the development stage	(140,538,980)	(119,984,625)
Accumulated other comprehensive loss	(64,292)	(76,043)
Total shareholders' equity	9,847,050	8,403,298
	\$ 70,392,501	\$ 22,868,583

See accompanying notes to Condensed Consolidated Financial Statements.

**DEPOMED, INC.**

**(A Development Stage Company)**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**



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(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period From
	2005	2004	2005	2004	Inception (August 7, 1995) to September 30, 2005
<b>Revenue:</b>					
Collaborative agreements	\$ 776,282	\$ 51,594	\$ 1,186,000	\$ 171,319	\$ 6,150,332
Collaborative agreements with affiliates					5,101,019
License revenue	18,750	12,500	56,250	12,500	87,500
<b>Total revenue</b>	<b>795,032</b>	<b>64,094</b>	<b>1,242,250</b>	<b>183,819</b>	<b>11,338,851</b>
<b>Operating expenses:</b>					
Research and development	4,695,833	5,036,348	14,766,294	16,778,540	116,129,363
General and administrative	3,507,974	1,512,395	8,440,429	4,027,811	34,118,499
Purchase of in-process research and development					298,154
<b>Total operating expenses</b>	<b>8,203,807</b>	<b>6,548,743</b>	<b>23,206,723</b>	<b>20,806,351</b>	<b>150,546,016</b>
<b>Loss from operations</b>	<b>(7,408,775)</b>	<b>(6,484,649)</b>	<b>(21,964,473)</b>	<b>(20,622,532)</b>	<b>(139,207,165)</b>
<b>Other income (expenses):</b>					
Equity in loss of joint venture					(19,817,062)
Gain on extinguishment of debt			1,058,935		1,058,935
Gain from Bristol-Myers legal settlement					18,000,000
Interest and other income	441,949	113,116	810,920	397,772	3,205,696
Interest expense	(53)	(232,474)	(459,737)	(690,286)	(3,680,384)
<b>Total other income (expenses)</b>	<b>441,896</b>	<b>(119,358)</b>	<b>1,410,118</b>	<b>(292,514)</b>	<b>(1,232,815)</b>
<b>Net loss before income taxes</b>	<b>(6,966,879)</b>	<b>(6,604,007)</b>	<b>(20,554,355)</b>	<b>(20,915,046)</b>	<b>(140,439,980)</b>
Provision for income taxes		(99,000)		(99,000)	(99,000)
<b>Net loss</b>	<b>(6,966,879)</b>	<b>(6,703,007)</b>	<b>(20,554,355)</b>	<b>(21,014,046)</b>	<b>(140,538,980)</b>
Deemed dividend on preferred stock	(218,289)		(622,229)		(622,229)
<b>Net loss applicable to common shareholders</b>	<b>\$ (7,185,168)</b>	<b>\$ (6,703,007)</b>	<b>\$ (21,176,584)</b>	<b>\$ (21,014,046)</b>	<b>\$ (141,161,209)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.18)</b>	<b>\$ (0.19)</b>	<b>\$ (0.54)</b>	<b>\$ (0.61)</b>	
Shares used in computing basic and diluted net loss per common share	39,878,759	34,640,596	39,565,638	34,618,381	

See accompanying notes to Condensed Consolidated Financial Statements.



## DEPOMED, INC.

(A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,		Period From Inception (August 7, 1995) to September 30, 2005
	2005	2004	
<b>Operating Activities</b>			
Net loss	\$ (20,554,355)	\$ (21,014,046)	\$ (140,538,980)
Adjustments to reconcile net loss to net cash used in operating activities:			
Equity in loss of joint venture			19,817,062
Depreciation and amortization	904,642	1,065,004	5,591,657
Gain on extinguishment of debt	(1,058,935)		(1,058,935)
Accrued interest expense on notes	443,344	641,347	2,940,850
Amortization of deferred compensation	326,516	193,465	1,682,559
Stock-based compensation issued to consultants	7,360	70,615	372,333
Purchase of in-process research and development			298,154
Changes in assets and liabilities:			
Accounts receivable	(776,282)	250,777	(776,282)
Inventories	(621,988)		(621,988)
Prepaid and other current assets	(104,276)	236,456	(546,625)
Other assets	151,342		(229,084)
Accounts payable and other accrued liabilities	1,205,737	(461,726)	3,495,295
Accrued compensation	386,493	(66,548)	1,229,740
Deferred revenue	54,943,750	587,500	55,512,500
Net cash provided by (used in) operating activities	35,253,348	(18,497,156)	(52,831,744)
<b>Investing Activities</b>			
Investment in joint venture			(19,817,062)
Expenditures for property and equipment	(637,216)	(2,100,558)	(8,250,889)
Purchases of marketable securities	(43,875,834)	(21,557,673)	(130,710,674)
Maturities and sales of marketable securities	17,384,461	23,403,597	86,693,903
Net cash used in investing activities	(27,128,589)	(254,634)	(72,084,722)
<b>Financing Activities</b>			
Payments on capital lease obligations	(33,186)	(25,179)	(407,089)
Proceeds from equipment loans			1,947,006
Payments on equipment loans	(73,008)	(233,575)	(1,834,606)
Proceeds from issuance of notes payable			8,846,703
Payments on notes payable	(9,665,000)		(10,665,000)
Payments on shareholder loans payable			(294,238)
Proceeds on issuance of common stock, net of issuance costs	21,652,480	229,703	136,268,030
Proceeds on issuance of preferred stock			12,015,000
Net cash provided by (used in) financing activities	11,881,286	(29,051)	145,875,806
Net increase (decrease) in cash and cash equivalents	20,006,045	(18,780,841)	20,959,340

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Cash and cash equivalents at beginning of period		953,295		20,044,698		
Cash and cash equivalents at end of period	\$	20,959,340	\$	1,263,857	\$	20,959,340

See accompanying notes to Condensed Consolidated Financial Statements.

**DEPOMED, INC.**

**(A Development Stage Company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**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 rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with 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, 2005 are not necessarily indicative of results to be expected for the entire year ending December 31, 2005 or future operating periods.

The balance sheet at December 31, 2004 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, 2004 filed with the SEC.

As of September 30, 2005, the Company had approximately \$64,841,000 in cash, cash equivalents and marketable securities, working capital of \$34,782,000 and accumulated net losses of \$140,539,000. In the course of its development activities, the Company expects such losses to continue for at least the next two years. Management plans to continue to finance the operations with its existing capital resources, a combination of equity and debt financing and revenue from corporate alliances and technology licenses. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its development programs.

#### *Principles of Consolidation*

The consolidated financial statements for the nine months ended September 30, 2005 and 2004, include the accounts of the Company and Depomed Development, Ltd., DDL, formerly a joint venture with Elan Corporation, plc, Elan Pharma International, Ltd. and Elan International Services, Ltd. (together, Elan), which became a wholly owned subsidiary in the second quarter of 2004. On July 1, 2003, the Company consolidated DDL, a variable interest entity in which the Company is the primary beneficiary, pursuant to the Financial Accounting Standards Board (FASB) Interpretation No. 46 (FIN 46) *Consolidation of Variable Interest Entities*, an interpretation of Accounting Research Bulletin No. 51. In June 2004, the Company acquired Elan's 19.9% interest in DDL for \$50,000 and DDL became a wholly owned subsidiary of the Company. Intercompany accounts and transactions have been eliminated.

*Stock-Based Compensation*

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As permitted under Statement of Financial Accounting Standards No. 123 (FAS 123), *Accounting for Stock-Based Compensation*, the Company has elected to follow Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees* in accounting for stock-based awards to its employees and directors. Accordingly, the Company accounts for grants of stock options to its employees and directors according to the intrinsic value method and, thus, recognizes no stock-based compensation expense for options granted with exercise prices equal to or greater than the fair value of the Company's common stock on the date of grant. The Company records deferred stock-based compensation when the market of the Company's common stock exceeds the exercise price of the stock options or purchase rights on the measurement date (generally, the date of grant). Any such deferred stock-based compensation is amortized ratably over the vesting period of the individual options.

Pro forma net loss information using the fair value based method of accounting for grants of stock options to employees and directors is included in the table shown below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss applicable to common shareholders as reported	\$ (7,185,168)	\$ (6,703,007)	\$ (21,176,584)	\$ (21,014,046)
Add: Total stock-based employee compensation expense, included in the determination of net loss as reported	63,427	64,410	326,516	193,465
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards	(506,434)	(524,769)	(1,609,141)	(1,575,015)
Net loss applicable to common shareholders pro forma	\$ (7,628,175)	\$ (7,163,366)	\$ (22,459,209)	\$ (22,395,596)
Net loss per share as reported	\$ (0.18)	\$ (0.19)	\$ (0.54)	\$ (0.61)
Net loss per share pro forma	\$ (0.19)	\$ (0.21)	\$ (0.57)	\$ (0.65)

Options granted to non-employees are accounted for at fair value using the Black-Scholes Option Valuation Model in accordance with FAS 123 and Emerging Issues Task Force Consensus No. 96-18, and are subject to periodic revaluation over their vesting terms. The resulting stock-based compensation expense is recorded over the service period in which the non-employee provides services to the Company.

### *Use of Estimates*

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



*Revenue Recognition*

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 client 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. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Revenue recognized relates to research and development services rendered in connection with collaborative arrangements, the achievements of milestones under such arrangements and product licenses. Revenue related to collaborative research agreements with corporate partners is recognized as the expenses are incurred under each contract. The Company is required to perform research activities as specified in each respective agreement on a best or commercially reasonable efforts basis, and the Company is reimbursed based on the costs associated with supplies and the hours worked by employees 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.

Revenue from license arrangements, including license fees creditable against future royalty obligations (if any), of the licensee, is recognized when an arrangement is entered into if 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. Royalties on product sales are recognized upon receipt.

*Recent Accounting Pronouncements*

In December 2004, the Financial Accounting Standard Board (FASB) issued Statement No. 123R, *Share-Based Payment* (FAS 123R), which is a revision of FAS 123. FAS 123R supersedes APB No. 25 and amends Statement No. 95, *Statement of Cash Flows*. Generally, the approach in FAS 123R is similar to the approach described in FAS 123. FAS 123R requires all share-based payments to employees and directors, including grants of employee and director stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. In April 2005, the SEC adopted a new rule amending the compliance dates for FAS 123R. In accordance with the new rule, the Company will adopt FAS 123R on January 1, 2006.

FAS 123R permits public companies to adopt its requirements using one of two methods: 1) a modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS 123 for all share-based payments granted after the effective date and (b) based on the requirements of FAS 123R for all awards granted to employees and directors prior to the effective date of FAS 123R that remain unvested on the effective date; or 2) a modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under FAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company plans to adopt FAS 123R using the modified prospective method.

As permitted by FAS 123, the Company currently accounts for share-based payments to employees and directors using APB No. 25's intrinsic value method and, as such, recognizes no compensation cost for employee and director stock options where the exercise price equals the fair market value of the underlying common shares on the measurement date. Accordingly, the adoption of FAS 123R's fair value method will have a significant impact on the Company's results of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted FAS 123R in prior periods, the impact of that standard would have approximated the impact of FAS 123 as described in the disclosure of pro forma net loss and loss per share in Note 1, Summary of Significant Accounting Policies, *Stock-Based Compensation*, of the Company's condensed consolidated financial statements.

In June 2005, the FASB issued FAS No. 154, *Accounting Changes and Error Corrections* (FAS 154). FAS 154 replaces APB Opinion No. 20, *Accounting Changes* and FAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. FAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle unless it is impractical to do so. FAS 154 is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. The implementation of FAS 154 is not expected to have a material impact on the Company's financial statements.

## 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 and money market instruments. The Company places its cash and cash equivalents with high quality, U.S. financial institutions and, to date, has not experienced material losses on 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 with unrealized gains and losses included in accumulated other comprehensive income (loss) within shareholders' equity. If the fair value of a marketable security is below its carrying value due to a significant adverse event, the impairment is considered to be other-than-temporary and the security is written down to its estimated fair value. Other-than-temporary declines in fair value of all marketable securities would be charged to other expense. 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. At September 30, 2005, the individual contractual period for all available-for-sale debt securities is within 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, 2005:

U.S. Debt Securities	Less than 12 months		12 months or greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. corporate debt securities	\$ 22,079,950	\$ (33,621)	\$	\$	\$ 22,079,950	\$ (33,621)
U.S. government debt securities	7,389,405	(4,953)	7,977,520	(26,201)	15,366,925	(31,154)
Total available-for-sale	\$ 29,469,355	\$ (38,574)	\$ 7,977,520	\$ (26,201)	\$ 37,446,875	\$ (64,775)

The Company's investment in U.S. corporate debt securities consists primarily of investments in investment grade corporate bonds and notes. The Company's investment in U.S. government debt securities consists of low risk government agency bonds typically with a rating of A or higher. The unrealized losses on the Company's investments in U.S. corporate debt and U.S. government debt securities were caused by interest rate increases. Due to the fact that the decline in market value is attributable to changes in interest rates and not credit quality, that the severity and duration of the unrealized losses were not significant, and that the Company has the intent and ability to hold these instruments until such losses are recovered, which may be at maturity, the Company considers these unrealized losses to be temporary at September 30, 2005.

### 3. NET LOSS PER COMMON SHARE

Net loss per common share is computed using the weighted-average number of shares of common stock outstanding. Common stock equivalent shares based on the number of shares underlying outstanding stock options, warrants and other convertible securities and convertible loans are not included as their effect is antidilutive. As of September 30, 2005 and 2004, the total number of outstanding common stock equivalent shares excluded from the loss per share computation was 15,013,809 and 17,804,007, respectively.

### 4. COMPREHENSIVE LOSS

Total comprehensive loss for the three and nine months ended September 30, 2005 and 2004 approximates net loss and includes unrealized losses on marketable securities.

### 5. INVENTORIES

Inventories are stated at the lower of cost or market and consist of work-in-process of approximately \$327,000 and raw materials of \$295,000 used in the manufacture of the Company's Proquin® XR product.

### 6. COLLABORATIVE ARRANGEMENTS AND CONTRACTS

*Elan Corporation, plc*

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In January 2000, the Company and Elan formed Depomed Development Ltd. (DDL), a Bermuda limited liability company and joint venture, to develop products using drug delivery technologies of both Elan and Depomed, Inc. DDL was owned 80.1% by Depomed and 19.9% by Elan. In August 2002, DDL discontinued all product development activity. In September 2003, the joint venture partners amended or terminated the contracts governing the operation of DDL, which included the termination of Elan's participation in the management of DDL. In June 2004, the Company acquired Elan's 19.9% interest in DDL for \$50,000.

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Pursuant to the Company's adoption of FIN 46 on July 1, 2003, the Company consolidated the accounts of DDL as of July 1, 2003. Since September 2003, the Company has recognized 100% of DDL's operating results. For the three months and nine months ended September 30, 2005 and 2004, the Company consolidated general and administrative expense of approximately \$7,000 and \$6,000, respectively, related to DDL. DDL does not have any fixed assets, liabilities or employees and will not perform any further product development on behalf of Depomed or any other entity. The Company has not made a determination as to DDL's future.

### *Boehringer Ingelheim Pharmaceuticals, Inc.*

In April 2005, the Company entered into an agreement with Boehringer Ingelheim Pharmaceuticals, Inc. to begin feasibility studies with an undisclosed drug. Under the agreement, all research and development work with the partner's drug will be funded by the partner.

### *New River Pharmaceuticals, Inc.*

In June 2005, the Company entered into an agreement with New River Pharmaceuticals, Inc. to begin feasibility studies with up to three of New River's proprietary compounds. Under the agreement, all research and development work through Phase I clinical trials with New River's compounds will be funded by New River. New River may exercise an option to license each product candidate and advance the product into additional clinical trials, which will lead to the Company receiving milestone payments and royalties on net sales of each product.

### *Biovail Laboratories Incorporated*

In May 2002, the Company entered into a development and license agreement and amended the agreement in April 2004, granting Biovail Laboratories Incorporated (Biovail) an exclusive license in the United States and Canada to manufacture and market Glumetza. In April 2003, Biovail submitted the New Drug Application to the U.S. Food and Drug Administration (FDA) for approval. In June 2005, the FDA approved Glumetza and in July 2005, in accordance with the agreement, Biovail paid a \$25.0 million payment to the Company. The Company is in discussions with Biovail concerning this development and license agreement (see Note 9, of the Notes to Financial Statements, Subsequent Events). As the agreement may be amended, the Company does not have persuasive evidence of a final arrangement and a fixed and determinable price for its license. Therefore, the Company has deferred recognition of any portion of the \$25 million payment pending the outcome of the discussions with Biovail.

### *Esprit Pharma, Inc.*

In July 2005, the Company entered into an agreement granting Esprit Pharma, Inc. (Esprit) an exclusive license to market Proquin® XR in the U.S. (including its possessions) and Puerto Rico. The agreement provides for a license fee of \$50,000,000. In July 2005, in accordance with the agreement, the Company received upfront payments of \$30,000,000 for the license fee with remaining payments totaling \$20,000,000 due in equal installments in July 2006 and July 2007. The license fee payments actually received will be recognized ratably beginning in the fourth quarter of 2005, coincident with the first commercial shipment of Proquin XR to Esprit and ending in June 2020, which represents the estimated length of time that the Company is obligated to manufacture Proquin XR for Esprit or its licensees. In addition, the Company will receive royalties of 15% on the first \$20 million of annual sales of Proquin XR by Esprit, 17.5% on the next \$20 million of annual net sales, 20% on the next \$40 million of annual net sales and 25% on annual net sales in excess of \$80 million. The annual royalty payment is subject to a minimum

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royalty of \$4.6 million in 2006 and \$5 million in each subsequent year of the term. Esprit's royalty obligation expires upon the last to expire of Depomed's U.S. patents covering Proquin XR. Royalty payments will be recognized upon receipt. Esprit has a right of first refusal to market Proquin XR in Canada. In connection with the license agreement, the Company and Esprit also entered into a related supply agreement pursuant to which the Company will supply commercial quantities of Proquin XR to Esprit.

## **7. GAIN ON EXTINGUISHMENT OF DEBT**

In connection with the formation of DDL, Elan made a loan facility available to the Company for up to \$8,010,000 in principal to support Depomed's 80.1% share of the joint venture's research and development costs pursuant to a convertible promissory note issued by Depomed to Elan. The funding term of the loan expired in November 2002. The note had a six-year term, was due in January 2006, and bore interest at 9% per annum, compounded semi-annually, on any amounts borrowed under the facility. However, in June 2005, the Company repurchased the promissory note with an outstanding balance of \$10,724,000, including \$2,927,000 of accrued interest, for \$9,665,000 including commissions paid to a financial consultant and legal fees. A gain on the extinguishment of the debt of \$1,059,000 was recorded in other income for the second quarter.

## **8. SHAREHOLDERS' EQUITY**

*Registered Direct Public Offering*

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*In January 2005, the Company completed a registered direct public offering of 5,036,000 shares of its common stock at \$4.50 per share with net proceeds of \$21,053,000.*





*Series A Preferred Stock*

The Series A Preferred Stock accrues a dividend of 7% per annum, compounded semi-annually and payable in shares of Series A Preferred Stock. The Series A Preferred Stock is convertible at anytime between January 2002 and January 2009 into the Company's common stock (including the impact of a warrant issued to the Series A Preferred stockholder in December 2004). 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 stockholder to resolve a misunderstanding between the Company and the stockholder 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 stockholder also agreed to binding interpretations of certain other terms related to the Series A 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 stockholder. 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. For the three and nine months ended September 30, 2005, the Company recognized Series A Preferred Stock deemed dividends of approximately \$218,000 and \$622,000, respectively, attributable to the beneficial conversion feature. The Company will continue to recognize Series A Preferred Stock deemed dividends until the earlier of, the time the Series A Preferred Stock is converted to common stock or until January 2009.

As of September 30, 2005, the Series A Preferred Stock and accrued dividends were convertible into 2,497,476 shares of common stock. The aggregate liquidation preference of the Series A Preferred Stock, including accrued dividends, was \$17,782,000 as of September 30, 2005.

#### *Warrant and Option Exercises*

During the three months ended September 30, 2005, employees exercised options to purchase 56,377 shares of the Company's common stock with net proceeds to the Company of approximately \$121,000. During the nine months ended September 30, 2005, employees exercised options to purchase 74,711 shares of the Company's common stock with net proceeds to the Company of approximately \$153,000. Warrant holders exercised 926,399 warrants to purchase 619,218 shares of the Company's common stock with net proceeds to the Company of approximately \$254,000 during the three and nine months ended September 30, 2005.

#### *Stock-Based Compensation*

In July 2003, the Board of Directors approved an amendment to all stock options granted to non-employee members of the Company's Board of Directors. In the case of the death of a non-employee director, the amendment provides for the director's beneficiary to exercise the director's stock options at anytime over the remaining life of the stock option. A non-cash compensation expense related to the amended stock options will be recognized if and when a director's beneficiary benefits from this modified provision. The maximum stock-based compensation expense would be \$369,000 if all non-employee directors benefited from this provision with respect to outstanding options. During the first quarter of 2005, the Company recognized approximately \$135,000 related to these options.

#### *Shareholder Rights Plan*

On April 21, 2005, the Company adopted a shareholder rights plan, (the Rights Plan). Under the Rights Plan, the Company distributed one preferred share purchase right for each share of common stock outstanding at the close of business on May 5, 2005. If a person or group acquires 20% or more of the Company's common stock in a transaction not pre-approved by the Company's Board of Directors, each right will entitle its holder, other than the acquirer, to buy additional shares of the Company's common stock at 50% of its market value, as defined in the Rights Plan. In addition, if an unapproved party acquires more than 20% of the Company's common stock, and the Company is later acquired by the unapproved party or in a transaction in which all shareholders are not treated alike, shareholders with unexercised rights, other than the unapproved party, will be entitled to receive upon exercise of the rights, common stock of the merger party or asset buyer with a value of twice the exercise price of the rights. Each right also becomes exercisable for one one-thousandth of a share of the Company's Series RP preferred stock at the right's then current exercise price ten days after an unapproved third party makes, or announces an intention to make, a tender offer or exchange offer that, if completed, would result in the unapproved party acquiring 20% or more of the Company's common stock. The Board of Directors may redeem the rights for a nominal amount before an event that causes the rights to become exercisable. The rights will expire on April 21, 2015.



In connection with the Rights Plan, the Company designated 100,000 no par shares of preferred stock to be Series RP preferred stock. These shares, if issued, will be entitled to receive quarterly dividends and liquidation preferences. There are no shares of Series RP preferred stock issued and outstanding and the Company does not anticipate issuing any shares of Series RP preferred stock except as may be required under the Rights Plan.

*Employee Stock Purchase Plan*

In May 2005, the Company sold 51,061 shares under the Employee Stock Purchase Plan for \$3.76 per share with proceeds of \$192,000. As of September 30, 2005, the Company had 401,407 common shares reserved for issuance under the plan.

*Purchasers' Option*

In July 2002 and in conjunction with a private placement of common stock with Biovail, Biovail received a three-year option to purchase additional shares of the Company's common stock in an amount sufficient for Biovail to hold 20% of the Company's common stock following exercise of the option. In July 2005, Biovail's three-year option expired.

**9. SUBSEQUENT EVENTS**

*Biovail Laboratories Incorporated*

**In October 2005, the Company delivered a notice to Biovail outlining Biovail's material breach of the parties' 2002 license agreement, as amended, for Glumetza. The breach involves the failure of Biovail to make the first commercial sale of the 500 mg strength Glumetza within 120 days of approval in each of Canada and the U.S. as required in the license agreement, and to use diligent efforts in the marketing and selling of the 500mg strength of Glumetza. The Company is in discussions with Biovail regarding resolution of the issues raised in Depomed's notice of breach, and accordingly, has deferred recognition of any portion of the \$25 million payment received from Biovail in July 2005 pending the outcome of these discussions.**

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

**FORWARD-LOOKING INFORMATION**

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

- the timing of the commercial launch of Glumetza in the United States and Canada;
- our ongoing dispute with Biovail over our license agreement relating to Glumetza;
- market acceptance of Proquin ®XR and Glumetza;
- the efforts of Esprit with respect to the marketing of Proquin XR;
- the efforts of Biovail with respect to the marketing of Glumetza;
- results and timing of our clinical trials, including the results of Gabapentin GR trials and publication of those results;
- our ability to raise additional capital;
- our ability to obtain marketing partners for our product candidates; 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 ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS section and elsewhere in this Quarterly Report on Form 10-Q. We are not obligated to update or revise these forward-looking statements to reflect new events or circumstances.

## **ABOUT DEPOMED**

We are a specialty pharmaceutical company engaged in the development of pharmaceutical products based on our proprietary oral drug delivery technologies. The United States Food and Drug Administration, or FDA, has approved two products we have developed. We have another product candidate in Phase II clinical trials. Our primary oral drug delivery system is our patented Gastric Retention System, or the GR System. The GR System is a tablet designed to be retained in the stomach for an extended period of time while it delivers the incorporated drug or drugs on a continuous, controlled-release basis. By incorporation into the GR System, some drugs currently taken two or three times a day may be administered only once a day. We also have a product containing two different drug compounds incorporated in the GR System in preclinical development. The principal patent on our GR System covers the controlled delivery of a broad range of drugs from a gastric retained polymer matrix tablet to maximize therapeutic benefits. Our intellectual property position includes nine issued patents and twelve patent applications pending in the United States.



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In this Quarterly Report on Form 10-Q, the company, Depomed, we, us, and our, refer to Depomed, Inc.

We are developing our own proprietary products and are also developing products utilizing our GR technology in collaboration with other pharmaceutical and biotechnology companies. Regarding our collaborative programs, we apply our proprietary technology to the partner's compound and from these collaborations we generally expect we will receive research and development funding, milestone payments, license fees and royalties. For our internal development programs, we apply our proprietary technology to existing drugs and typically fund development at

least through Phase II clinical trials. Upon the completion of Phase II clinical trials, we evaluate, on a case-by-case basis, the feasibility of retaining marketing or co-marketing rights to our product candidates in the United States, taking into account such factors as the marketing and sales efforts required for each of the product candidates, the potential collaborative partners and the proposed terms of any such collaboration. If we fund development through Phase III, we will again evaluate the feasibility of retaining marketing or co-marketing rights. When we license marketing rights to a collaborative partner, we generally expect the partner to fund the completion of the clinical trials, as appropriate, and to pay us license fees, milestones and royalties on sales of the product.

*Glumetza (Metformin GR)*

In June 2004, our collaborative partner, Biovail Laboratories Incorporated, or Biovail, received approval from the FDA to market in the United States our internally developed once-daily metformin product for Type II diabetes, Metformin GR, also known as the 500mg strength version of Glumetza. In May 2005, the Therapeutic Products Directorate Canada, or TPD, issued a Notice of Compliance for 500mg and 1000mg Glumetza, which Biovail Pharmaceuticals Canada, the sales and marketing division of Biovail, intends to commercialize in Canada. In October 2005, we delivered a notice of breach to Biovail in respect of our license agreement with Biovail, related to the failure of Biovail to make the first commercial sale of the 500 mg strength Glumetza within 120 days of approval in each of Canada and the United States as required in the license agreement, and to use diligent efforts in the marketing and selling of the 500 mg strength of Glumetza. The resolution of this matter is uncertain.

*Proquin®XR (Ciprofloxacin GR )*

In July 2004, we submitted an NDA to the FDA for Proquin XR, our internally developed once-daily formulation of the antibiotic drug ciprofloxacin, for uncomplicated urinary tract infections. In May 2005, we received FDA approval to market Proquin XR in the United States. In July 2005, we entered into a license agreement with Esprit Pharma, Inc. to market and distribute Proquin XR in the United States and Puerto Rico. Under the terms of the license agreement, Esprit Pharma also has right of first refusal for the sales and marketing of Proquin XR for the Canadian market. Esprit Pharma has agreed to pay us a \$50 million license fee, of which \$30 million has been paid with an additional \$10 million due in July 2006 and the remaining \$10 million due in July 2007. Also under the agreement, Esprit will pay us 15 percent to 25 percent royalties on net sales of Proquin XR, based on escalating product sales. In November 2005, Esprit launched Proquin XR in the United States.

*Gabapentin GR*

We have developed Gabapentin GR, an extended release gabapentin product. Gabapentin is marketed by Pfizer Inc. for adjunctive therapy for epileptic seizures and postherpetic pain under the label Neurontin®. We initiated a Phase II clinical trial for Gabapentin GR in the first quarter of 2005 for the treatment of post-herpetic neuralgia. The trial was fully enrolled as of October 2005. We expect to complete the trial in the fourth quarter of 2005 and announce the results of the trial in the first quarter of 2006.

*Other Research and Development Activities*

We are developing other product candidates expected to benefit from incorporation into our drug delivery system. For example, we are collaborating with AVI BioPharma, Inc. on a project for the delivery of large molecules, such as antisense compounds, from the GR System. We have also completed preclinical studies of a combination product comprising our Glumetza (500mg) once-daily formulation of metformin with a once-daily sulfonylurea for Type II diabetes. Under our agreement with Biovail, Biovail has an exclusive option to license this product from us. We expect that a Phase I clinical trial for this product will commence only if we enter into a development and licensing agreement with Biovail or another third party.

In April 2005, we entered into an agreement with Boehringer Ingelheim Pharmaceuticals, Inc. to begin feasibility studies with an undisclosed pharmaceutical compound. Under the agreement, all research and development work with the partner's drug will be funded by the partner.

In June 2005, we entered into a development and license agreement with New River Pharmaceuticals Inc. to develop through the feasibility phase up to three proprietary New River compounds in combination with the GR System. Pursuant to the agreement, New River will fund research and development under the agreement, and New River may acquire worldwide rights to use the GR System in the product candidates for agreed-upon milestone

payments and royalties. New River has proposed an initial product candidate for development, and we are collaborating with New River on the work plan for the feasibility program.

Future clinical progress of our products depends primarily on the results of each ongoing study. There can be no assurance that a feasibility study or clinical trial will be successful or that the product will gain regulatory approval. For a more complete discussion of the risks and uncertainties associated with completing development of a potential product, see the section entitled "Additional Factors that May Affect Future Results" and elsewhere in this Form 10-Q.

In addition to research and development conducted on our own behalf and through collaborations with pharmaceutical partners, our activities since inception on August 7, 1995 have included establishing our offices and research facilities, recruiting personnel, filing patent applications, developing a business strategy and raising capital. **In the third quarter of 2005, we received \$30 million in payments from Esprit Pharma, Inc. for the license of Proquin XR and a \$25 million milestone payment from Biovail based on the FDA's approval of Glumetza. Those payments will be recognized as revenue over time. Substantially all of our prior revenue, which was received from collaborative research and feasibility arrangements, has been limited.** We intend to continue investing in the further development of our drug delivery technologies and the GR System.

We have generated a cumulative net loss of approximately \$140,539,000 for the period from inception through September 30, 2005.

### **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, other than our policy regarding revenue recognition described below, since we filed our 2004 Annual Report on Form 10-K with the Securities and Exchange Commission on March 16, 2005. For a description of our critical accounting policies other than revenue recognition, please refer to our 2004 Annual Report on Form 10-K.

#### *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 client 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. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Revenue recognized relates to research and development services rendered in connection with collaborative arrangements, the achievements of milestones under such arrangements and product licenses. Revenue related to collaborative research agreements with corporate partners is recognized as the expenses are incurred under each contract. We are required to perform research activities as specified in each respective agreement on a best or commercially reasonable efforts basis, and we are reimbursed based on the costs associated with supplies and the hours

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worked by employees 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 collectability is reasonably assured.

Revenue from license arrangements, including license fees creditable against future royalty obligations (if any), of the licensee, is recognized when an arrangement is entered into if we have substantially completed our obligations under the terms of the arrangement and our remaining involvement is inconsequential and perfunctory. If we have significant continuing involvement under such an arrangement, license fees are deferred and recognized over the estimated performance period. Royalties on product sales are recognized upon receipt.

**RESULTS OF OPERATIONS**

*Three and Nine Months Ended September 30, 2005 and 2004*



**Revenues**

Revenue for the three and nine months ended September 30, 2005 was \$795,000 and \$1,242,000 compared to \$64,000 and \$184,000 in the three and nine months ended September 30, 2004, respectively. In 2005, revenue from collaborative agreements increased due to product development services performed under our agreement with Boehringer Ingelheim Pharmaceuticals. We expect to continue work under this agreement at least through the first quarter of 2006. We expect we will begin feasibility studies and recognize revenue under our agreement with New River beginning in the first quarter of 2006. Revenue from licenses in the three and nine months ended September 30, 2005 increased to \$19,000 and \$56,000 from \$13,000 in the same periods of 2004 due to revenue recognized under our license agreement with LG Life Sciences signed in August 2004. We expect to begin to recognize revenue from the Esprit license and supply agreements beginning in the fourth quarter of 2005 and additional license fees under our agreement with LG Life Sciences of approximately \$19,000 per quarter until 2012. We are in discussions with Biovail regarding matters raised in the notice of breach we sent to Biovail related to the Glumetza license agreement and, accordingly, we have deferred recognition of any portion of the \$25 million payment received in July 2005 pending the outcome of these discussions.

**Research and Development Expense**

Research and development expense decreased to \$4,696,000 and \$14,766,000 in the three and nine months ended September 30, 2005, respectively, from \$5,036,000 and \$16,779,000 for the same periods of 2004. In the three months ended September 30, 2005 the decrease of \$341,000 was primarily due to reductions of \$1.3 million related to Proquin XR and Glumetza which were partially offset by \$1.1 million in expenses related to other projects including our Phase II clinical trial for Gabapentin GR. In the nine months ended September 30, 2005, the decrease of \$2,012,000 was due primarily to reductions of expenses related to Proquin XR and Glumetza. Since our two lead products were approved by the FDA in the second quarter of 2005 and our other product candidates are still in earlier stages of development, we believe that our research and development expenses will continue to decrease slightly during 2005.

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. Furthermore, our business strategy involves licensing certain of our drug candidates to collaborative partners. Depending upon when such collaborative arrangements are executed, the amount of costs incurred solely by us will be impacted.

#### **General and Administrative Expense**

General and administrative expense for the third quarter of 2005 and 2004 was \$3,508,000 and \$1,512,000, respectively. General and administrative expense for the nine months ended September 30, 2005 was \$8,440,000 compared to \$4,028,000 in the same period of 2004. The increase of approximately \$1,996,000 in the three-month period was due to approximately \$1,309,000 in expense primarily related to planning and organization of commercial manufacturing activities at our contract manufacturer for Proquin XR, increased consulting fees of \$284,000 primarily related to the execution of our Proquin license agreement and \$271,000 in expense related to salary bonuses accrued under the bonus plan approved by the Compensation Committee of the Board of Directors in July 2005. The increase of approximately \$4,413,000 in the nine-month periods was due to \$2,609,000 in expense related primarily to planning and organization of contract commercial manufacturing activities for Proquin XR, an increase of \$866,000 related to salary bonuses accrued under the bonus plan and \$544,000 in expenses related to Proquin XR marketing incurred prior to the licensing of Proquin XR and during the transition of marketing activities to Esprit. We expect that general and administrative expense will continue to increase in 2005 as we continue to work towards becoming an integrated organization with sales and marketing of our own products.

**Consolidated Subsidiary Expense**

In January 2000, we formed Depomed Development Limited (DDL) with Elan to develop products using drug delivery technologies and expertise of both Elan and Depomed. In August 2002, all product development activities ceased. In September 2003, the joint venture partners amended or terminated the contracts governing the operation of DDL, which included the termination of Elan's participation in the management of DDL. Pursuant to our adoption of FIN 46 on July 1, 2003, we consolidated the accounts of DDL for all subsequent periods. Since September 2003, we have been responsible for 100% of the expenses incurred by DDL. In June 2004, we acquired Elan's 19.9% interest in DDL for \$50,000.

For the three and nine months ended September 30, 2005, we consolidated approximately \$7,000 and \$6,000, respectively, of DDL expenses, which are included in general and administrative expenses in the condensed consolidated statements of operations. For the three and nine months ended September 30, 2004, we consolidated approximately \$7,000 and \$6,000, respectively, of DDL expenses. We expect to consolidate general and administrative expense of approximately \$10,000 annually related to DDL. DDL does not have any fixed assets, liabilities or employees and will not perform any further product development. We have not made a determination as to DDL's future.

### **Gain on Extinguishment of Debt**

In January 2000, Elan made available to us a convertible loan facility to assist us in funding our portion of the joint venture's losses up to a principal maximum of \$8,010,000. In June 2005, we repurchased the promissory note with a balance of \$10,724,000, including \$2,927,000 in accrued interest, for \$9,665,000 including commissions paid to a financial consultant and legal fees. A gain on the extinguishment of the debt of \$1,059,000 was recorded in the quarter ended June 30, 2005.

### **Interest and Other Income and Interest Expense**

Interest expense was approximately zero and \$232,000 for the three months ended September 30, 2005 and 2004, respectively. The decrease was due to \$219,000 in decreased interest accrued on the Elan promissory note due to the repurchase of the promissory note in June 2005 and \$13,000 in decreased interest on our equipment loan, which was fully repaid as of July 2005. For the nine months ended September 30, 2005 and 2004, interest expense decreased year over year to \$460,000 from \$690,000. The decrease of approximately \$230,000 in interest expense for the nine-month period was due to decreased interest of approximately \$198,000 on the Elan convertible loan facility and an approximate \$32,000 decrease in interest expense on our other loan and lease obligations. Interest and other income was approximately \$442,000 for the three months ended September 30, 2005 compared to \$113,000 in the same period of 2004. Interest income for the nine months ended September 30, 2005 and 2004 was \$811,000 and \$398,000, respectively. The increases, year over year, were due to higher investment balances in 2005 as a result of our receipt of license fees from Esprit and Biovail in the third quarter of 2005 and also due to higher interest rates earned on our investment portfolio. Interest and other income also included immaterial gains and losses realized on sales of our marketable securities.

### **Series A Preferred Stock and Dividends**

In January 2000, we issued 12,015 shares of Series A Preferred Stock at a price of \$1,000 per share to fund our 80.1% share of the initial capitalization of DDL. The Series A Preferred Stock accrues a dividend of 7% per annum, compounded semi-annually and payable in shares of Series A Preferred Stock. The Series A Preferred Stock and dividends are convertible at anytime between January 2002 and January 2009 into our common stock (including the impact of a warrant issued to the Series A Preferred stockholder in December 2004). The original conversion price of the Series A Preferred Stock was \$12.00. However, as a result of our March 2002 and October 2003 financings, the conversion price had been adjusted to \$9.51 per share. In December 2004, we entered into an agreement with the Series A Preferred stockholder to resolve a misunderstanding between us and the stockholder relating primarily to prior adjustments to the conversion price of the Series A Preferred Stock (the December 2004 Agreement). Pursuant to the December 2004 Agreement, among other matters, we agreed to adjust the conversion price to \$7.50 per share. We and the stockholder also agreed to binding interpretations of certain other terms related to the Series A 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 December 2004 Agreement, we determined that a significant modification of the preferred stock agreement had occurred, and, therefore, a new commitment date was established for the Series A Preferred Stock. Further, we determined that the fair value of the modified preferred stock was below the carrying value of such securities as of the date of the modification, therefore, no deemed dividend resulted from this modification. Also, we determined that although a new commitment date had been established, this change did not result in a beneficial conversion feature subject to recognition pursuant to Emerging Issues Task Force Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. 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. For the three and nine months ended September 30, 2005, we recognized Series A Preferred Stock deemed dividends of approximately \$218,000 and \$622,000, respectively, attributable to the beneficial conversion feature. We will continue to recognize Series A Preferred Stock deemed dividends until the earlier of, the time the Series A Preferred Stock is converted to common stock or January 2009.

#### Stock-Based Compensation Expense

In July 2003, our Board of Directors approved an amendment to all stock options granted to non-employee members of our Board of Directors. In the case of the death of a non-employee director, the amendment provides for the director's beneficiary to exercise the director's stock options at anytime over the remaining life of the stock option. A non-cash compensation expense related to the amended stock options will be recognized if and when a director's beneficiary benefits from this modified provision. The maximum stock-based compensation expense would be \$369,000 if all non-employee directors benefit from this provision with respect to outstanding options. In the first quarter of 2005, we recognized \$135,000 in stock-based compensation expense related to these options.

## **LIQUIDITY AND CAPITAL RESOURCES**

### **Operating Activities**



Cash provided by operating activities in the nine months ended September 30, 2005 was approximately \$35,253,000, compared to cash used in operating activities of approximately \$18,497,000 for the nine months ended September 30, 2004. During the nine months ended September 30, 2005, the cash provided by operations was due primarily to increases in deferred revenue of \$54,944,000 related to the Biovail and Esprit license payments, partially offset by the net loss. In 2004, the cash used in operations was due primarily to the net loss as adjusted for depreciation expense.

#### **Investing Activities**

Cash used in investing activities in the nine months ended September 30, 2005 totaled approximately \$27,129,000 and consisted of a \$26,491,000 net increase in marketable securities due to the investment of funds received from our license agreements and \$637,000 in purchases of laboratory and office equipment. Net cash used in investing activities in the nine months ended September 30, 2004 totaled approximately \$255,000 and consisted of \$2,101,000 in purchases of leasehold improvements and lab and office equipment which were partially offset by a \$1,846,000 net decrease in marketable securities. We expect that future capital expenditures will include additional product development and quality control laboratory equipment to maintain current Good Manufacturing Practices in our laboratories.

#### **Financing Activities**

Cash provided by financing activities in the nine months ended September 30, 2005 was approximately \$11,881,000 compared to cash used in financing activities of approximately \$29,000 for the same period of 2004. In 2005, the amount consisted primarily of \$21,053,000 of net proceeds from our registered direct public offering of 5,036,000 shares of common stock for \$4.50 per share in January 2005, \$192,000 of net proceeds from the sale of 51,061 shares of common stock under our Employee Stock Purchase Plan for \$3.76 per share and \$599,000 from

exercises of stock options and warrants during the period, which was partially offset by a \$9,665,000 payment upon the extinguishment of the Elan promissory note and \$106,000 of payments on our equipment loans and capital lease obligations. In 2004, the amount consisted of \$230,000 of net proceeds from exercises of stock options and warrants, which were partially offset by \$259,000 of payments on our equipment loans and capital lease obligations.

**Contractual Obligations**

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As of September 30, 2005, our aggregate contractual obligations for the next three years are as shown in the following table. We have no contractual obligations with maturities greater than three years.

Contractual Obligations	Total	Payments Due by Period	
		Less than 1 year	1 to 3 years
Operating leases	\$ 2,550,918	\$ 981,636	\$ 1,569,282
	\$ 2,550,918	\$ 981,636	\$ 1,569,282

### Financial Condition

As of September 30, 2005, we had approximately \$64,841,000 in cash, cash equivalents and marketable securities, working capital of \$35,889,000, and accumulated net losses of \$140,539,000. In July 2005, we received a \$25.0 million payment from Biovail for the FDA approval of Glumetza and \$30.0 million from Esprit as upfront license fees for Proquin XR. Esprit is required to pay us additional license fees totaling \$20 million, in equal installments, on July 21, 2006 and July 21, 2007. We expect to continue to incur operating losses for at least the next two years. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least June 2007. However, 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:

- results of research and development efforts;
- financial terms of definitive license agreements or other commercial agreements we enter into, if any;
- relationships with collaborative partners;
- resolution of any disputes with collaborative partners;
- 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) potential products using the GR System.

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 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 not be able 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;

curtail other operations significantly; and/or

obtain funds through entering into collaboration agreements on unattractive terms.

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

**Recently Issued Accounting Standards**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 123R, *Share-Based Payment* (FAS 123R), which is a revision of FAS 123. FAS 123R supersedes APB No. 25 and amends FAS No. 95, *Statement of Cash Flows*. Generally, the approach in FAS 123R is similar to the approach described in FAS 123. FAS 123R requires all share-based payments to employees and directors, including grants of employee and director stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. In April 2005, the Securities and Exchange Commission adopted a new rule amending the compliance dates for FAS 123R. In accordance with the new rule, we will adopt FAS 123R on January 1, 2006.

FAS 123R permits public companies to adopt its requirements using one of two methods: 1) a modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of FAS 123 for all awards granted to employees and directors prior to the effective date of FAS 123R that remain unvested on the effective date; or 2) a modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We plan to adopt FAS 123R using the modified prospective method.

As permitted by FAS 123, we currently account for share-based payments to employees and directors using APB No. 25's intrinsic value method and, as such, recognize no compensation cost for employee and director stock options where the exercise price equals the fair market value of the underlying common shares on the measurement date. Accordingly, the adoption of FAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted FAS 123R in prior periods, the impact of that standard would have approximated the impact of FAS 123 as described in the disclosure of pro forma net loss and loss per share in Note 1, Summary of Significant Accounting Policies, *Stock-Based Compensation* to our condensed consolidated financial statements.

In May 2005, the FASB issued Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154). FAS 154 replaces APB No. 20, *Accounting Changes* and FAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. FAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle unless it is impractical to do so. FAS 154 is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. The implementation of FAS 154 is not expected to have a material impact on our financial statements.

#### **ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS**

In addition to other information in this report, the following factors should be considered carefully in evaluating Depomed. We believe the following are the material risks and uncertainties we face at the present time. If any of the following risks or uncertainties actually occurs, our business, financial condition or results of operations could be materially adversely affected. See also Forward-Looking Statements.

**We are at an early stage of development and are expecting operating losses in the future.**

To date, we have had no revenues from product sales and only minimal revenues from our collaborative research and development arrangements and feasibility studies. For the nine months ended September 30, 2005, we had total revenues of \$1.2 million and for the years ended



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December 31, 2002, 2003 and 2004, we had total revenues of, \$1.7 million in 2002, \$1.0 million in 2003 and \$200,000 in 2004. For the nine months ended September 30,

2005, we incurred net losses of \$20.6 million and for the years ended December 31, 2002, 2003 and 2004, we incurred net losses of \$13.5 million in 2002, \$30.0 million in 2003 and \$26.9 million in 2004. As we continue our research and development efforts, preclinical testing and clinical trial activities, we anticipate that we will continue to incur substantial operating losses for at least the next two years. 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.

**We depend heavily on our marketing partners for the successful commercialization of our lead products, Proquin XR and Glumetza. We are involved in a dispute with our marketing partner for Glumetza.**

Our two lead products, Proquin XR and the 500 mg strength Glumetza, have been approved by the FDA. Our other product candidates are in earlier stages of clinical or preclinical development. We anticipate that in the near term our success will depend on royalties generated from sales of Proquin XR and Glumetza.

We have licensed exclusive marketing rights to Proquin XR in the United States to Esprit Pharma, Inc. Esprit launched Proquin XR in November 2005. If Esprit fails to successfully commercialize Proquin XR, our business, financial condition and results of operations will be materially and adversely affected.

We have granted to Biovail an exclusive license to Glumetza. In October 2005, we delivered a notice of breach to Biovail in respect of our license agreement with Biovail. The notice relates to the failure of Biovail to make the first commercial sale of the 500 mg strength Glumetza within 120 days of approval in each of Canada and the United States as required in the license agreement, and to use diligent efforts in the marketing and selling of the 500mg strength of Glumetza. Biovail has indicated that it is seeking a third party sublicensee to market Glumetza in the United States. However, Biovail has not informed us that it has entered into a sublicensing arrangement for Glumetza in the United States. In addition, although Biovail has informed us that it intends to launch Glumetza in Canada in the fourth quarter of 2005, that launch has not yet occurred. The resolution of this matter and the timing of the commercial launch of Glumetza in the United States are uncertain. There can be no assurance that our dispute with Biovail will be resolved in a timely manner, if at all. Any additional delay in the commercial launch of Glumetza in the United States may adversely affect our business and results of operations.

**Our product candidates are at early stages of development and may not be successful or achieve market acceptance.**

In addition to Proquin XR and Glumetza, we have other product candidates in early stages of development, and we are performing feasibility studies with other compounds in combination with the GR System for collaborative partners. All of these product candidates 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. We are unable to predict whether any of these other 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, all of our other product candidates use the GR System. If it is discovered that the GR System 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.

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

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

the timing of the commercial launch of Glumetza in the United States and Canada;

the resolution of our dispute with Biovail over our license agreement with Biovail;

the degree of commercial success of Proquin XR and Glumetza;

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 GR System;

regulatory actions;

adoption of new technologies;

developments concerning proprietary rights, including patents, infringement allegations and litigation matters;

the introduction of new products by our competitors;

manufacturing costs and difficulties;

results of clinical trials for our products;

changes in government funding;

third-party reimbursement policies; and

the status of our compliance with the provisions of the Sarbanes-Oxley Act of 2002.

**Our collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership of our intellectual property and may adversely affect the commercial success of our products.**

We currently have collaboration agreements for development of product candidates through the feasibility phase with Boehringer Ingelheim Pharmaceuticals and New River Pharmaceuticals. In addition, we have entered 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 and 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, or 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 agree to less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs.

We may not be able to enter into future collaborative arrangements on acceptable terms, which would harm our ability to commercialize our 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 GR System technologies. 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 GR System.

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 United States patents and twelve United States patent applications are pending. In

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 seeking to market formulations of gabapentin that compete with Neurontin, claiming that these formulations of gabapentin infringe Pfizer's patents. The results of this litigation could adversely impact our ability to commercialize Gabapentin GR. 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.

**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 GR System, 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 GR System has unintended or undesirable side effects; or

products 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 commercialization of our potential products, particularly Glumetza or Proquin XR, 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.**

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 licensees, 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. 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 licensees 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 insulin and materials for our GR System; 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.

**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 that could delay, limit or prevent regulatory approval. 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.**

The marketing activities of our licensees of Proquin XR and Glumetza, and our own marketing activities with respect 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 with 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 payor. 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, 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 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 licensees are unable to obtain acceptable prices or adequate reimbursement for our products from third-party payors, 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 payors 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 payors would have an adverse effect on our future revenues. Third-party payors 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 not be able to compete successfully in the pharmaceutical product and drug delivery system industries.**

Other companies that have oral drug delivery technologies competitive with the GR System include Bristol-Myers Squibb, IVAX Corporation, 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 will compete. 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 IVAX Corporation, Barr Pharmaceuticals, Inc., Mylon Laboratories, Inc. and Teva Pharmaceutical Industries, Ltd. have received FDA approval for and are selling a controlled-release metformin product. Flamel Technologies has a controlled-release metformin product in clinical trials.

Bayer Corporation has 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.

To our knowledge, we are the only company currently developing a sustained release formulation of gabapentin for the United States market.

The competitive situation with respect to Gabapentin GR is complex and uncertain given the current regulatory and intellectual property status of gabapentin, which is currently marketed by Pfizer as Neurontin for adjunctive therapy for epileptic seizures and for postherpetic pain. Pfizer's basic United States patents relating to Neurontin have expired, and at least seven companies are seeking or have received FDA approval for immediate release formulations of the drug. However, Pfizer has initiated several lawsuits against companies seeking to market formulations of gabapentin that compete with Neurontin, claiming that these formulations of gabapentin infringe Pfizer's patents. In addition, Pfizer has developed a new product, Lyrica (pregabalin), which will be marketed as an improved version of Neurontin. It received FDA approval in December 2004.

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 GR System or products using the GR System, either generally or in particular market segments. These developments could make the GR System or products using the GR System noncompetitive or obsolete.

Most of our principal competitors have substantially greater financial, 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 for manufacturing of our products. Failure by these third parties would result in lost revenue.**

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

Applicable current Good Manufacturing Practices (cGMP) requirements and other rules and regulations prescribed by foreign regulatory authorities will apply to the manufacture of products using the GR System. We will

depend on the manufacturers of products using the GR System to comply with cGMP and applicable foreign standards. Any failure by a manufacturer of products using the GR System to maintain cGMP or comply with applicable foreign standards could delay or prevent their initial or continued commercial sale of our products.

**We depend on third parties who are single source suppliers to manufacture Proquin XR. If these suppliers are unable to continue manufacturing Proquin XR, our business will be harmed.**

We are responsible for supplying commercial quantities of Proquin XR to Esprit. For the manufacturer of Proquin XR tablets, we have entered into an agreement with MOVA Pharmaceuticals, as our sole supplier. Uquifa Mexico, S.A., our supplier of the active pharmaceutical ingredient to Proquin XR, is also a sole supplier to us. We obtain the active pharmaceutical ingredient to Proquin XR on a purchase order basis only. If we are unable, for whatever reason, to obtain the active pharmaceutical ingredient or Proquin XR tablets from our contract manufacturers, we may not be able to manufacture Proquin XR in a timely manner, if at all.

**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 production and manufacture of pharmaceutical products. We have obtained product liability insurance for clinical trials currently underway and forecasted 2006 sales of our products, but:

we may not be able to obtain product liability insurance for future trials;

we may not be able to maintain product liability insurance on acceptable terms;

we may not be able to secure future coverage of the commercialization of the GR System; 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 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 John W. Fara, Ph.D., our Chairman, President and Chief Executive Officer, 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 Dr. Fara or any of our other executive officers that provide for their continued employment with us. 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 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.**

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 National 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 not be able 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 general and administrative expenses are likely to increase.

**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 do 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 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 is known for 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 4. CONTROLS AND PROCEDURES**

An evaluation was performed under the supervision and with the participation of our management, including the President and Chief Executive Officer along with the Chief 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, the Company's management, including the President and Chief Executive Officer along with the Chief Financial Officer, concluded that the Company's disclosure controls and procedures were effective.

We review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and 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.

**PART II OTHER INFORMATION**

**ITEM 6. EXHIBITS**

(a)	Exhibits	
	10.1*	Exclusive License and Marketing Agreement between the Company and Esprit Pharma, Inc. dated July 21, 2005
	31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of John W. Fara, Ph.D.
	31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of John F. Hamilton
	32.1	Certification pursuant to 18 U.S.C. Section 1350 of John W. Fara, Ph.D.
	32.2	Certification pursuant to 18 U.S.C. Section 1350 of John F. Hamilton

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\* Confidential treatment requested

**SIGNATURES**

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

Date: November 9, 2005

DEPOMED, INC.

By: /s/ John F. Hamilton  
John F. Hamilton  
Vice President and  
Chief Financial Officer  
(Authorized Officer and  
Principal Accounting  
and Financial Officer)

By: /s/ John W. Fara, Ph.D.  
John W. Fara, Ph.D.  
President, Chairman and  
Chief Executive Officer

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