#### SECURITIES AND EXCHANGE COMMISSION

## **FORM 10-Q**

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2011-11-07** | Period of Report: **2011-09-30** SEC Accession No. 0001104659-11-061663

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#### **FILER**

#### **DEPOMED INC**

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## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

### **FORM 10-Q**

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

FOR THE QUARTERLY PERIOD ENDED September 30, 2011

OR

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

FOR THE TRANSITION PERIOD FROM TO

**COMMISSION FILE NUMBER 001-13111** 

#### **DEPOMED, INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

**CALIFORNIA** 

94-3229046

(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)

(I.R.S. EMPLOYER IDENTIFICATION NUMBER)

#### 1360 O' BRIEN DRIVE MENLO PARK, CALIFORNIA 94025

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

(650) 462-5900

(REGISTRANT' S TELEPHONE NUMBER, INCLUDING AREA CODE)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\boxtimes$  No  $\square$ 

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act. Large accelerated filer □ Accelerated filer ⊠ Non-accelerated filer □ Smaller reporting company □ Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ⊠ The number of issued and outstanding shares of the Registrant's Common Stock, no par value, as of November 3, 2011 was 55,400,451. **Table of Contents** DEPOMED, INC. **PAGE** PART I - FINANCIAL INFORMATION Item 1. Condensed Financial Statements: Condensed Balance Sheets at September 30, 2011 (unaudited) and December 31, 2010 Condensed Statements of Operations for the three and nine months ended September 30, 2011 and 2010 (unaudited) Condensed Statements of Cash Flows for the nine months ended September 30, 2011 and 2010 (unaudited) Notes to Condensed Financial Statements (unaudited) Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 16 Item 3. Quantitative and Qualitative Disclosure About Market Risk 29 Item 4. Controls and Procedures 29 **PART II - OTHER INFORMATION** Item 1. Legal Proceedings 30 Item 1A. Risk Factors 31 Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 43 Item 3. Defaults upon Senior Securities 43

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## PART I – FINANCIAL INFORMATION ITEM 1. CONDENSED FINANCIAL STATEMENTS

# DEPOMED, INC. CONDENSED BALANCE SHEETS (in thousands, except share amounts)

Current assets:  Cash and cash equivalents  Marketable securities  Accounts receivable  Receivables from collaborative partners Inventories  Prepaid and other current assets  Total current assets  Marketable securities, long-term  Property and equipment, net  Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities  \$ Deferred product sales	19,945 89,018 827 6,645 3,292 5,516 125,243 45,233	\$	22,526 47,825 6,094 253 1,571 1,330
Cash and cash equivalents  Marketable securities  Accounts receivable  Receivables from collaborative partners Inventories  Prepaid and other current assets  Total current assets  Marketable securities, long-term  Property and equipment, net  Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$	89,018 827 6,645 3,292 5,516 125,243	\$	47,825 6,094 253 1,571
Marketable securities Accounts receivable Receivables from collaborative partners Inventories Prepaid and other current assets Total current assets Marketable securities, long-term Property and equipment, net Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY Current liabilities: Accounts payable and accrued liabilities \$	89,018 827 6,645 3,292 5,516 125,243	\$	47,825 6,094 253 1,571
Accounts receivable Receivables from collaborative partners Inventories Prepaid and other current assets Total current assets Marketable securities, long-term Property and equipment, net Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY Current liabilities: Accounts payable and accrued liabilities \$	827 6,645 3,292 5,516 125,243		6,094 253 1,571
Receivables from collaborative partners Inventories Prepaid and other current assets Total current assets  Marketable securities, long-term Property and equipment, net Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities: Accounts payable and accrued liabilities \$	6,645 3,292 5,516 125,243		253 1,571
Inventories Prepaid and other current assets  Total current assets  Marketable securities, long-term  Property and equipment, net  Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities: Accounts payable and accrued liabilities \$	3,292 5,516 125,243	_	1,571
Prepaid and other current assets  Total current assets  Marketable securities, long-term  Property and equipment, net  Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$	5,516 125,243	_	
Total current assets  Marketable securities, long-term  Property and equipment, net  Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$	125,243		1,330
Marketable securities, long-term  Property and equipment, net  Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$			
Property and equipment, net Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities: Accounts payable and accrued liabilities \$	45,233		79,599
Other assets  LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$	,		6,537
LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$	1,140		698
LIABILITIES AND SHAREHOLDERS' EQUITY  Current liabilities:  Accounts payable and accrued liabilities \$	169		197
Current liabilities: Accounts payable and accrued liabilities \$	171,785	\$	87,031
Accounts payable and accrued liabilities \$			
Deferred product sales	25,788	\$	18,473
Defended product sures	379		1,041
Deferred license revenue	7,664		10,665
Other current liabilities	387		635
Current portion of long-term debt	_		2,170
Total current liabilities	34,218		32,984
Deferred license revenue, non-current portion	19,320		30,926
Other long-term liabilities	-		15
Commitments			
Shareholders' equity:			

Preferred stock, no par value, 5,000,000 shares authorized; Series A convertible preferred stock, 25,000 shares designated, 18,158 shares issued and surrendered, and zero shares outstanding at September 30, 2011 and December 31, 2010

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Common stock, no par value, 100,000,000 shares authorized; 55,398,067 and		
52,957,787 shares issued and outstanding at September 30, 2011 and December 31,		
2010, respectively	202,022	191,343
Accumulated deficit	(83,743)	(168,306)
Accumulated other comprehensive gain (loss)	(32)	69
Total shareholders' equity	118,247	23,106
	\$ 171,785	\$ 87,031

<sup>(1)</sup> Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

See accompanying notes to Condensed Financial Statements.

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# DEPOMED, INC. CONDENSED STATEMENTS OF OPERATIONS (in thousands, except share and per share amounts) (Unaudited)

	Thr	ee Months En	ded Se	eptember 30,	N	Nine Months Ended September 30,			
		2011		2010	2011			2010	
Revenues:									
Product sales	\$	9,205	\$	9,829	\$	40,669	\$	34,086	
Royalties		2,179		75		2,412		254	
License and collaborative revenue		5,138		10,223		77,760		25,565	
Total revenues		16,522		20,127		120,841		59,905	
Costs and expenses:									
Cost of sales		1,150		2,499		4,925		6,961	
Research and development expense		3,208		4,602		12,405		14,360	
Selling, general and administrative expense:									
Promotion fee expense		6,023		6,791		27,339		23,769	
Other selling, general and administrative expense		15,451		4,313		32,667		12,403	
Total selling, general and administrative expense		21,474		11,104		60,006		36,172	
Gain on settlement agreement		-		-		(40,000)		_	
Total costs and expenses		25,832		18,205		37,336		57,493	
Income (loss) from operations		(9,310)		1,922		83,505		2,412	
Other income (expense):									
Interest and other income		410		100		846		251	
Interest expense		(24)		(130)		(133)		(471)	

Total other income (comence)	 206	_	(20)	 712	_	(220)
Total other income (expense)	386		(30)	713		(220)
Net income (loss) before income taxes	(8,924)		1,892	84,218		2,192
Benefit from (provision for) income taxes	348		(1)	345		(4)
·			<u> </u>			<u>`</u>
Net income (loss)	\$ (8,576)	\$	1,891	\$ 84,563	\$	2,188
Basic net income (loss) per common share	\$ (0.15)	\$	0.04	\$ 1.56	\$	0.04
Diluted net income (loss) per common share	\$ (0.15)	\$	0.04	\$ 1.51	\$	0.04
Shares used in computing basic net income (loss) per						
common share	55,371,954		52,595,214	54,267,829		52,444,627
Shares used in computing diluted net income (loss) per						
common share	55,371,954		53,306,449	56,071,870		53,061,251

See accompanying notes to Condensed Financial Statements.

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# DEPOMED, INC. CONDENSED STATEMENTS OF CASH FLOWS (in thousands) (Unaudited)

	N	ine Months End	ed Sept	tember 30,
		2011		2010
Operating Activities				
Net income	\$	84,563	\$	2,188
Adjustments to reconcile net income to net cash provided by (used in) operating activities:				
Depreciation and amortization		232		331
Loss on disposal of property and equipment		_		46
Stock-based compensation		2,807		1,537
Changes in assets and liabilities:				
Accounts receivable		(1,125)		(4,337
Inventories		(1,722)		1,603
Prepaid and other assets		(4,157)		(772
Accounts payable and other accrued liabilities		6,862		1,331
Accrued compensation		189		(408
Deferred revenue		(15,268)		(4,956
Net cash provided by (used in) operating activities		72,381		(3,437
Investing Activities				
Purchases of property and equipment		(665)		(86
Purchases of marketable securities		(153,875)		(56,110
Maturities of marketable securities		41,117		47,482

Sales of marketable securities	32,832	7,485
Net cash provided by (used in) investing activities	(80,591)	(1,229)
Financing Activities		
Principal payments on long-term debt	(2,243)	(2,840)
Proceeds from issuance of common stock	7,872	910
Net cash provided by (used in) financing activities	5,629	(1,930)
Net increase (decrease) in cash and cash equivalents	(2,581)	(6,596)
Cash and cash equivalents at beginning of period	22,526	26,821
Cash and cash equivalents at end of period	\$ 19,945	\$ 20,225

See accompanying notes to Condensed Financial Statements.

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# DEPOMED, INC. NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

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

#### **Basis of Presentation**

These unaudited condensed financial statements and the related footnote information of Depomed, Inc. (the Company or Depomed) have been prepared pursuant to the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of the Company's management, the accompanying interim unaudited condensed financial statements include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the periods presented. The results for the interim period ended September 30, 2011 are not necessarily indicative of results to be expected for the entire year ending December 31, 2011 or future operating periods.

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2010, included in the Company's Annual Report on Form 10-K filed with the SEC. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date.

#### Reclassifications

Certain reclassifications have been made to the December 31, 2010 balance sheet in order to conform to the Company's current presentation. The Company has now classified receivables from collaborative partners as a separate line-item on its balance sheet, which was previously included under accounts receivable.

#### Use of Estimates

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

#### Revenue Recognition

The Company recognizes revenue from the sale of its products, royalties earned, and on payments received and services performed under contractual arrangements. Revenue arrangements with multiple elements are evaluated to determine whether the multiple elements met certain criteria for dividing the arrangement into separate units of accounting, including whether the delivered element(s) have stand-alone value to the Company's customer or licensee. Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period that we remain obligated to perform services.

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

#### Product Sales:

• <u>Glumetza</u>®: Up until August 2011, the Company distributed and recorded product sales on shipments of Glumetza® (metformin hydrochloride extended release tablets) to wholesalers and retail pharmacies. The Company and Santarus, Inc. (Santarus) entered into a commercialization agreement in August 2011, under which Depomed transferred the rights to distribute Glumetza in the United States to Santarus. Santarus commenced distribution of Glumetza in September 2011 and began recording product sales. See Note 4 for further information on the Santarus commercialization agreement.

Product distributed by Depomed up until August 2011 is subject to rights of return six months before product expiration and up to twelve months after product expiration. The Company recognized revenue for Glumetza sales at the time title transferred to its customers, which occurred at the time product was delivered to its customers.

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• Proquin® XR: Up until October 2010, the Company sold Proquin® XR (ciprofloxacin hydrochloride) to wholesalers and retail pharmacies subject to rights of return six months before product expiration and up to twelve months after product expiration. Given the Company's limited history of selling Proquin XR and declining prescription demand for Proquin XR, the Company was not able to reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Proquin XR until the right of return no longer exists, which occurs at the earlier of the time Proquin XR units are dispensed through patient prescriptions or expiration of the right of return. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. As a result of this policy, the Company has a deferred revenue balance of \$0.4 million at September 30, 2011 related to Proquin XR product shipments that have not been recognized as revenue, which is net of wholesaler fees, retail pharmacy discounts and prompt payment discounts. In addition, the costs of manufacturing Proquin XR associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

- Product Sales Allowances The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company's agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from the Company's estimates, the Company may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company's product sales allowances include:
  - Product Returns The Company estimates product returns on sales of Glumetza that were originally distributed by the Company. The Company allows customers to return product that is within six months before and up to twelve months after its product expiration date. The shelf life of the 500mg Glumetza is currently 48 months from the date of tablet manufacture. On product launch in August 2006 and through the second quarter of 2008, the shelf life of 500mg Glumetza product shipped was 36 months from the date of tablet manufacture. The shelf life of the 1000mg Glumetza is 24 to 36 months from the date of tablet manufacture. The Company monitors actual return history on individual product lot basis since product launch, which provides it with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.
  - Managed Care Rebates The Company offers rebates under contracts with certain managed care organizations. The Company establishes an accrual equal to its estimates of future managed care rebates attributable to sales and recognizes the estimated rebates as a reduction of revenue in the same period the related revenue is recognized. The Company estimates its managed care rebates based on the terms of each agreement, estimated levels of inventory in the distribution channel, and historical and expected future utilization of product by the managed care organization.
  - Wholesaler and Retail Pharmacy Discounts The Company offers discounts to certain wholesale distributors and
    retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the
    respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in
    the same period the related revenue is recognized.
  - Prompt Pay Discounts The Company offers cash discounts to its customers, generally 2% of the sales price, as
    an incentive for prompt payment. Based on the Company's experience, the Company expects its customers to
    comply with the payment terms to earn the cash discount. The Company accounts for cash discounts by reducing
    accounts receivable by the full amount and recognizes the discount as a reduction of revenue in the same period
    the related revenue is recognized.
  - Medicaid Rebates The Company participates in Medicaid rebate programs, which provide assistance to certain
    eligible low-income patients based on each individual state's guidelines regarding eligibility and services. Under
    the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three
    months after the quarter in which the prescription is filled. The Company estimates and accrues Medicaid rebates
    based on product pricing, current rebates and changes in the level of discounts the Company

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offers that may affect the level of Medicaid discount, historical and estimated future percentages of product sold to Medicaid recipients and estimated levels of inventory in the distribution channel.

- Chargebacks The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity.
- Patient Discount Programs The Company offers loyalty card programs to patients for Glumetza in which
  patients receive certain discounts at participating retail pharmacies that are reimbursed by the Company. The
  Company estimates and accrues future redemptions based on historical redemption activity.
- Royalties Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectability is reasonably assured. Under the commercialization agreement between the Company and Santarus, the Company receives royalties on net sales of Glumetza distributed by Santarus in the United States. Santarus commenced distributing and recording product sales on shipments of Glumetza in September 2011. Royalties from Santarus are recognized in the period earned as the royalty amounts can reliably be estimated and collectability is reasonably assured. See Note 4 for further information on the Santarus commercialization agreement.

Royalties received under the Company's agreements with Valeant Pharmaceuticals International, Inc. (Valeant) and LG Life Sciences (LG) are recognized when the royalty payments are received as they cannot reliably be estimated.

• License and Collaborative Arrangements - Revenue from license and collaborative arrangements is recognized when the Company has substantially completed its obligations under the terms of the arrangement and the Company's remaining involvement is inconsequential and perfunctory. If the Company has significant continuing involvement under such an arrangement, license and collaborative fees are recognized over the estimated performance period. The Company recognizes milestone payments for its research and development collaborations upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement; (2) consideration earned relates to past performance, and (3) the milestone payment is nonrefundable. A milestone is considered substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone or consistent with the increase in value to the collaboration resulting from the Company's performance, the consideration earned relates solely to past performance, and the consideration earned is reasonable relative to all of the other deliverables and payments within the arrangement. License, milestones and collaborative fee payments received in excess of amounts earned are classified as deferred revenue until earned.

#### Recently Issued Accounting Standards

In September 2009, the Financial Accounting Standards Board (FASB) revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company elected to adopt this guidance prospectively, effective for the Company's fiscal year beginning January 1, 2011. Upon adoption, the guidance did not have a material impact on the Company's financial statements and is not expected to have a material impact on the Company's future operating results.

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, the Company will have the option to report total comprehensive income, including components of net income

and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. The Company does not anticipate the adoption of this guidance will have a material impact on its financial statements.

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

Securities classified as cash and cash equivalents and available-for-sale marketable securities as of September 30, 2011 and December 31, 2010 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

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				Gross		Gross		
	A	Amortized	Un	realized	Unrealized			
September 30, 2011		Cost		Gains		Losses		air Value
Cash and cash equivalents:								
Cash	\$	5,086	\$	_	\$	_	\$	5,086
Money market funds		6,410		-		_		6,410
U. S. corporate debt securities		8,449		_		_		8,449
Total cash and cash equivalents	\$	19,945	\$	_	\$	_	\$	19,945
Available-for-sale securities:								
Total maturing within 1 year and included in marketable securities:								
U.S. corporate debt securities		44,865		3		(24)		44,844
U.S. government agency debt securities		2,997		2		_		2,999
U.S. Treasury securities		41,129		45		_		41,174
Total maturing between 1 and 2 years and								
included in marketable securities:								
U.S. corporate debt securities		19,225		6		(89)		19,142
U.S. government agency debt securities		21,061		18		(5)		21,074
U.S. Treasury securities		5,006		12		_		5,018
Total available-for-sale securities	\$	134,283	\$	86	\$	(118)	\$	134,251
Total cash, cash equivalents and marketable securities	\$	154,228	\$	86	\$	(118)	\$	154,196
	A	Amortized		Gross realized	U	Gross Inrealized		

				Gross		Gross		
	A	mortized	Unrealized			Unrealized		
December 31, 2010		Cost		Gains	Losses			Fair Value
Cash and cash equivalents:								
Cash	\$	3,913	\$	_	\$	_	\$	3,913
Money market funds		17,613		-		_		17,613
U.S. Treasury securities		1,000		_		_		1,000
Total cash and cash equivalents	\$	22,526	\$	_	\$	_	\$	22,526

#### Available-for-sale securities:

Total maturing within 1 year and included in marketable securities:

U.S. corporate debt securities	12,099	2	ļ	(2)	12,101
U.S. government agency debt securities	25,667	2		_	25,688
U.S. Treasury securities	10,015	2		_	10,036
Total maturing between 1 and 2 years and included in marketable securities:					
U.S. corporate debt securities	_	-	-	_	-
U.S. government agency debt securities	_	-	-	_	_
U.S. Treasury securities	 6,512	2	5	_	 6,537
Total available-for-sale securities	\$ 54,293	\$ 7	\$	(2)	\$ 54,362
Total cash, cash equivalents and marketable securities	\$ 76,819	\$ 7.	\$	(2)	\$ 76,888

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks, money market instruments and commercial paper. The Company places its cash, cash equivalents and marketable securities with high quality, U.S. financial institutions and, to date has not experienced material losses on any of its balances. All marketable securities are classified as available-for-sale since these instruments are readily marketable. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive gain within shareholders' equity. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in "interest and other income" in the condensed statement of operations.

At September 30, 2011, the Company had thirty-two securities in an unrealized loss position. The following table shows the gross unrealized losses and fair value of the Company's investments with unrealized losses that are not deemed to be other-than-

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temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at September 30, 2011 (in thousands):

		Less than	12 m	onths	12 months	er		To			
				Gross		G	ross				Gross
			τ	Inrealized		Unr	ealized			1	U <b>nrealized</b>
	Fa	ir Value		Losses	Fair Value	Le	osses	F	air Value		Losses
U.S. corporate debt securities	\$	45,741	\$	(113)	_		_	\$	45,741	\$	(113)
U.S. government agency debt											
securities		15,010		(5)	_		_		15,010		(5)
U.S. Treasury securities		_		_			_		_		_
Total available-for-sale	\$	60,751	\$	(118)	\$ _	\$	_	\$	60,751	\$	(118)

The gross unrealized losses above were caused by interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of the Company's securities. Based on the Company's review of these securities, including the assessment of the duration and severity of the unrealized losses and the Company's ability and intent to hold the investments until maturity, there were no material other-than-temporary impairments for these securities at September 30, 2011.

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

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

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

The following table represents the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

	Level 1	Level 2			Level 3	Total		
Money market funds	\$ 6,410	\$	_	\$	_		6,410	
U.S. corporate debt securities	_		72,435		_		72,435	
U.S. government agency debt securities	_		24,073		_		24,073	
U.S. Treasury securities	_		46,192		_		46,192	
Total	\$ 6,410	\$	142,700	\$	_	\$	149,110	

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

	Level 1		Level 2		Level 3		Total	
Money market funds	\$	17,613	\$ _	\$	_	\$	17,613	
U.S. corporate debt securities		_	12,101		_		12,101	
U.S. government agency debt securities		-	25,688		-		25,688	
U.S. Treasury securities		_	 17,573		_		17,573	
Total	\$	17,613	\$ 55,362	\$	_	\$	72,975	

There are no financial liabilities measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010.

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

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period, plus dilutive common shares for the period

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determined using the treasury-stock method. For purposes of this calculation, options to purchase stock are considered to be potential common shares and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive. Basic and diluted earnings per share are calculated as follows:

	Three Months Ended September 30, Nine Months Ended Sept					ptember 30,		
(in thousands, except for per share amounts)		2011		2010		2011		2010
Numerator:								
Net income (loss)	\$	(8,576)	\$	1,891	\$	84,563	\$	2,188
Denominator for basic net income (loss) per share		55,372		52,595		54,268		52,445
Net effect of dilutive common stock equivalents		_		711		1,804		616
Denominator for diluted net income (loss) per share:		55,372		53,306		56,072		53,061
					-			
Basic net income (loss) per share	\$	(0.15)	\$	0.04	\$	1.56	\$	0.04
Diluted net income (loss) per share	\$	(0.15)	\$	0.04	\$	1.51	\$	0.04

For the three and nine months ended September 30, 2011, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 4.9 million and 1.2 million, respectively. For the three and nine months ended September 30, 2010, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 3.0 million and 3.4 million, respectively.

#### NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

#### Santarus, Inc.

In August 2011, the Company entered into a commercialization agreement with Santarus granting Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. The commercialization agreement supersedes the previous promotion agreement between the parties originally entered into in July 2008.

Under the commercialization agreement, the Company will transition to Santarus responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs. The Company ceased shipments of Glumetza in August 2011 and Santarus began distributing and recording product sales on shipments of Glumetza in September 2011. Santarus will continue to be responsible for advertising and promotional marketing activities for Glumetza.

Santarus will be required to pay the Company royalties on net product sales of Glumetza in the United States of 26.5% in 2011; 29.5% in 2012; 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. In the event of generic entry of a Glumetza product in the United States, the parties will equally share proceeds based on a gross margin split. Santarus has the exclusive right to commercialize authorized generic versions of the Glumetza products. Santarus will not pay additional sales milestones to the Company as was required under the prior promotion agreement.

In connection with its assumption of distribution and sales responsibility of Glumetza, Santarus purchased Depomed's existing inventory of Glumetza and bulk metformin hydrochloride at cost. Depomed will be financially responsible for returns of Glumetza distributed by Depomed, up to the amount of the product returns reserve account for Glumetza product returns on the date immediately before Santarus begins distributing Glumetza. Depomed will be financially responsible for Glumetza rebates and chargebacks up to the amount of its reserve accounts for those items. Santarus will be responsible for all other Glumetza returns, rebates and chargebacks.

Pursuant to the terms of the commercialization agreement, Depomed has the option to co-promote Glumetza products to physicians other than those called on by Santarus, subject to certain limitations. Depomed will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by its called on physicians over a pre-established baseline.

Under the commercialization agreement, Depomed will continue to manage the ongoing patent infringement lawsuits against Sun Pharmaceutical Industries, Inc. (Sun) and Lupin Limited (Lupin), subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. Santarus will reimburse Depomed for 70% of its out-of-pocket costs, and Depomed will reimburse Santarus for 30% of its out-of-pocket costs related to these two existing infringement cases.

The commercialization agreement will continue in effect for so long as Santarus commercializes branded Glumetza or authorized generic products, unless terminated sooner. Subject to 60 days prior written notice to Santarus, Deponded may terminate the

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agreement if Santarus fails to meet its obligations with respect to minimum promotion and expenditure obligations and fails to cure such breach within a specified time period. Either party may terminate the agreement if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period. In addition, either party may terminate the agreement if a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed. Santarus has a voluntary right to terminate the agreement upon 120 days' written notice.

During the quarter ended September 30, 2011, Depomed distributed Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus. Santarus sold Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid Depomed a royalty equal to 26.5% of net sales.

For the three and nine months ended September 30, 2011, the Company recognized \$6.0 million and \$27.3 million, respectively, in promotion fee expense to Santarus related to sales of Glumetza by Depomed. For the three and nine months ended September 30, 2010, the Company recognized \$6.8 million and \$23.8 million, respectively, in promotion fee expense to Santarus. Promotion fee expense is classified within selling, general and administrative expense.

Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus distributing Glumetza under the commercialization agreement. There were no royalty revenue amounts from Santarus in the prior year.

The Company accounted for the transaction as a sale of a business as defined by FASB Accounting Standards Codification Topic 805, "Business Combinations". In connection with entering into the commercialization agreement with Santarus, no additional consideration was exchanged between the two parties. Accordingly, the Company did not record a gain or loss with respect to this transaction and related transfer of Glumetza manufacturing and distribution activities. As the Company will have significant continuing cash inflows with respect to receiving royalties on net sales of Glumetza by Santarus, the previously reported and future activities related to Glumetza will continue to be presented in income from continuing operations in the Company's income statement.

Pursuant to the promotion agreement originally entered into in July 2008, Santarus paid the Company a \$12.0 million upfront fee. The upfront payment received was originally being amortized as revenue ratably until October 2021, which represented the estimated length of time the Company's obligations existed under the promotion agreement related to manufacturing Glumetza and paying

Santarus promotion fees on gross margin of Glumetza. The commercialization agreement in August 2011 superseded the promotion agreement and removed the manufacturing and promotion fee obligations of the Company. The commercialization agreement includes obligations with respect to manufacturing and regulatory transition to Santarus and managing the ongoing patent infringement lawsuits against Sun and Lupin. These obligations are estimated to be completed in December 2013. Accordingly, on the effective date of the commercialization agreement, the amortization period related to remaining deferred revenue on the \$12.0 million upfront fee has been adjusted, and the remaining deferred revenue will be recognized ratably until December 2013. The Company recognized approximately \$0.6 million and \$1.0 million of license revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. For the three and nine months ended September 30, 2010, the Company recognized \$0.2 million and \$0.7 million of license revenue associated with this upfront license fee. The remaining deferred revenue balance related to this upfront payment is \$8.8 million at September 30, 2011.

#### Ventiv Commercial Services, LLC

In June 2011, the Company entered into a service agreement with Ventiv Commercial Services, LLC (Ventiv), pursuant to which in Ventiv Selling Solutions, Ventiv's outsourced sales business, will provide sales force recruiting, training, deployment and ongoing operational support to the Company to promote Gralise. The agreement provides for a sales force of 164 full-time sales representatives dedicated to the Company, all of whom are employees of Ventiv.

Under the terms of the agreement, the Company paid Ventiv an upfront implementation fee and will pay an agreed upon fixed monthly management fee of \$1.8 million, which is subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of Ventiv's monthly management fee will be subject to payment by the Company only to the extent that specified performance objectives are met. The Company will also pay certain pass-through costs of Ventiv incurred in connection with the agreement, which primarily include bonuses, travel costs and certain administrative expenses. The Company incurred \$1.6 million and \$2.5 million of expense related to Ventiv for the three and nine months ended September 30, 2011.

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The agreement will expire on the second anniversary of the date on which sales representatives hired by Ventiv are deployed. The agreement is subject to early termination under certain circumstances and may be terminated by either party upon advance notice beginning in October 2012.

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

In November 2008, the Company entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) granting Solvay exclusive rights to develop and commercialize Gralise<sup>TM</sup> (gabapentin) for pain indications in the United States, Canada and Mexico. In February 2010, Abbott Laboratories acquired the pharmaceutical business of Solvay and Abbott Products, a subsidiary of Abbott Laboratories, became responsible for the Gralise license agreement with the Company.

In March 2010, Abbott Products submitted an NDA for Gralise to the U.S. Food and Drug Administration (FDA) for the management of postherpetic neuralgia (PHN). In May 2010, the FDA accepted the NDA filing for Gralise, which triggered a \$10.0 million milestone payment from Abbott Products which Depomed received in June 2010. As the nonrefundable milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement and the milestone was related to past performance, the Company recognized the entire \$10.0 million as revenue in the second quarter of 2010.

In January 2011, Abbott Products received FDA approval of Gralise for the management of PHN, which triggered a \$48.0 million development milestone from Abbott Products to the Company, which the Company received in February 2011. As the nonrefundable

milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement and the milestone was related to past performance, the entire \$48.0 million was recognized as license revenue in the first quarter of 2011.

In March 2011, the Company entered into a settlement agreement with Abbott Laboratories which provided for (i) the immediate termination of the Gralise license agreement; (ii) the transition of Gralise back to Depomed; and (iii) a \$40.0 million payment to Depomed which the Company received in March 2011. The \$40.0 million payment was recognized as a gain within operating income in the first quarter of 2011.

Pursuant to the exclusive license agreement originally entered into in November 2008, Solvay paid the Company a \$25.0 million upfront fee in February 2009. The upfront payment received was originally being amortized as revenue ratably until January 2013, which represented the estimated length of time the Company's development and supply obligations existed under the agreement. In connection with the termination of the license agreement with Abbott Products, the Company no longer has continuing obligations to Abbott Products. Accordingly, all remaining deferred revenue related to the \$25.0 million upfront license fee previously received from Abbott Products was fully recognized as revenue in March 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

#### Boehringer Ingelheim International GMBH

In March 2011, the Company entered into a license and service agreement with Boehringer Ingelheim International GMBH (Boehringer Ingelheim) granting Boehringer Ingelheim a license to certain patents related to the Company's Acuform drug delivery technology to be used in developing fixed dose combinations of extended release metformin and proprietary Boehringer Ingelheim compounds in development for type 2 diabetes. Under the terms of the agreement, Boehringer Ingelheim was also granted a right of reference to the New Drug Application covering the Company's Glumetza product and associated data for use in potential regulatory submission processes.

In connection with the license and service agreement, the Company received an upfront payment of \$10.0 million less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million in April 2011. The Company received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

The \$10.0 million upfront fee is being amortized ratably through November 2011, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. The Company recognized approximately \$3.8 million and \$8.6 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. The remaining deferred revenue balance is \$1.4 million at September 30, 2011.

Under the terms of the agreement, the Company may receive an additional \$2.5 million upon delivery of experimental batches of prototype formulations that meet certain specification. The Company is also eligible to receive additional milestone payments based on regulatory filing and approval events, as well as royalties on worldwide net sales of products.

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Depond is responsible for providing certain initial formulation work associated with the fixed dose combination products. Work performed by the Company under the service agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon FTE rate per hour plus out-of-pocket expenses. The Company recognized approximately \$0.2 million and \$0.8 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2011, respectively.

#### Ironwood Pharmaceuticals, Inc.

In July 2011, the Company entered into a collaboration and license agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) granting Ironwood a license for worldwide rights to the Company's Acuform drug delivery technology for an undisclosed Ironwood early stage development program.

In connection with the agreement, the Company received an upfront payment of \$0.9 million which is being amortized ratably through June 2012, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. The Company recognized approximately \$0.2 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011. The remaining deferred revenue balance related to this upfront payment is \$0.7 million at September 30, 2011.

Under the terms of the agreement, the Company will assist with initial product formulation and Ironwood will be responsible for all development and commercialization of the product. The initial formulation work performed by the Company under the agreement will be reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses. The Company recognized approximately \$0.1 million of revenue associated with the reimbursement of formulation work under the agreement during the three and nine months ended September 30, 2011.

Under the terms of the agreement, the Company may receive additional payments pending achievement of certain development and regulatory milestones, as well as royalties on product sales.

#### NOTE 5. LONG-TERM DEBT

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

The Company paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Beginning in January 2009, the Company began principal payments on the first tranche, plus interest at such rate, which will be paid in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments at an interest rate of 11.59%. Interest expense, which includes amortization of debt issuance costs, was approximately \$24,000 and \$133,000 for the three and nine months ended September 30, 2011, respectively.

The credit facility was fully repaid in July 2011.

#### NOTE 6. STOCK-BASED COMPENSATION

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

	Three Months Ended September 30,					Nine Months End	Months Ended September 30,			
	2011			2010		2011		2010		
Cost of sales	\$	17	\$	8	\$	50	\$	14		
Research and development expense		155		119		465		429		
Selling, general and administrative expense		769		348		2,292		1,094		
Total	\$	941	\$	475	\$	2,807	\$	1,537		

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agreement and release with Carl A. Pelzel, the Company's former President and Chief Executive Officer. See Note 11 for further information with regards to the separation agreement and release.

At September 30, 2011, the Company had \$7.6 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants that will be recognized over an average vesting period of 2.6 years.

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

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011			2010		2011		2010
Net income (loss)	\$	(8,576)	\$	1,891	\$	84,563	\$	2,188
Unrealized gain (loss) on available-for-sale								
securities		(187)		19		(101)		66
Total comprehensive income (loss)	\$	(8,763)	\$	1,910	\$	84,462	\$	2,254

#### NOTE 8. INVENTORIES

Inventories relate to the manufacture of the Company's Gralise and Proquin XR products at September 30, 2011 and Gralise, Glumetza and Proquin XR products at December 31, 2010. In August 2011, the Company sold its Glumetza inventory, at cost, to Santarus as part of the commercialization agreement. See Note 4 for further information with regards to the Santarus commercialization agreement. Inventories are stated at the lower of cost or market and consist of the following (in thousands):

	Septen	ıber 30, 2011	December 31, 2010		
Raw materials	\$	1,273	\$	74	
Work-in-process		258		202	
Finished goods		1,746		1,254	
Deferred costs		15		41	
Total	\$	3,292	\$	1,571	

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

#### NOTE 9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	Septemb	er 30, 2011	Decer	cember 31, 2010			
Accounts payable	\$	3,380	\$	1,655			
Accrued compensation		2,827		2,638			

Accrued clinical trial expense	1,094	307
Accrued rebates and sales discounts	2,232	2,625
Allowance for product returns	9,333	5,355
Accrued promotion fee	_	2,490
Other accrued liabilities	 6,922	 3,403
Total accounts payable and accrued liabilities	\$ 25,788	\$ 18,473

#### NOTE 10. SHAREHOLDERS' EQUITY

#### **Option Exercises**

For the three and nine months ended September 30, 2011, employees and consultants exercised options to purchase 58,105 and 2,370,358 shares of the Company's common stock with net proceeds to the Company of approximately \$0.3 million and \$7.6 million, respectively.

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#### Employee Stock Purchase Plan

In May 2011, the Company sold 69,922 shares under the ESPP. The shares were purchased at a weighted average purchase price of \$4.37 per share with proceeds of approximately \$0.3 million.

#### NOTE 11. RELATED PARTY TRANSACTIONS

#### Carl A. Pelzel

In April 2011, the Company entered into a separation agreement and release with Carl A. Pelzel, the Company's former President and Chief Executive Officer. Pursuant to the separation agreement, Mr. Pelzel is being paid \$520,000, which is equivalent to one year of his base salary. Payments are being made over one year, and will be reduced dollar-for-dollar by any compensation Mr. Pelzel receives in connection with employment (or full-time consulting) by another employer (or third party). The Company is also paying Mr. Pelzel's health and dental insurance COBRA premiums for up to 18 months following his separation from the Company. The separation agreement further provides for three months' accelerated vesting of Mr. Pelzel's options to purchase the Company's common stock, and a release of claims in favor of the Company. The Company incurred a one-time severance charge of approximately \$1.0 million in the second quarter of 2011 with respect to this separation agreement, consisting of approximately \$0.4 million in stock-based compensation related to the accelerated vesting of Mr. Pelzel's awards and approximately \$0.6 million of severance expense related to future payments and health care benefits.

#### NOTE 12. INCOME TAXES

As of December 31, 2010 and September 30, 2011, the Company had \$3.4 million and \$3.5 million of unrecognized tax benefits, respectively. All tax years since inception remain open to examination by the Internal Revenue Service and the California Franchise Tax Board until such time the Company's net operating losses and credits are either utilized or expire. Interest and penalties, if any, related to unrecognized tax benefits, would be recognized as income tax expense by the Company. The Company does not have any accrued interest or penalties associated with unrecognized tax benefits. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months except as related to any new items impacting the current year operations.

#### **NOTE 13. LEASE AMENDMENTS**

In June 2011, the Company entered into amendments to its existing leases for the Company's premises located at 1330 and 1360 O' Brien Drive, Menlo Park, California, consisting of approximately 46,000 rentable square feet. The lease amendments extend the term of the existing leases for twelve months, from February 1, 2012 through January 31, 2013. All material provisions of the leases remain the same, except that the Company may not extend either of the lease terms. The lease for the Company's premises located at 1430 O' Brien Drive, consisting of approximately 9,000 rentable square feet, was not amended by the lease amendments, and has a term through January 31, 2012.

#### NOTE 14. SUBSEQUENT EVENTS

In October 2011, the Company announced the commercial availability of Gralise and began distributing Gralise to wholesalers and retail pharmacies.

### 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:

• our ability to successfully launch Gralise<sup>TM</sup> (gabapentin), our product for the management of postherpetic neuralgia that was transferred to us in March 2011 from our former licensee, Abbott Products Inc. (a wholly-owned subsidiary of Abbott Laboratories, or Abbott Products);

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- the commercial success and market acceptance of Gralise and our own efforts, or those of Ventiv or of any future commercialization partner, with respect to the commercialization of Gralise;
- discussions with the U.S. Food and Drug Administration regarding the results of Breeze 3, our Phase 3 trial evaluating Serada® for menopausal hot flashes that did not meet all primary endpoints;
- any patent infringement or other litigation that may be instituted related to Gralise or Serada under the Hatch-Waxman Act:
- the commercial success of Glumetza® (metformin hydrochloride extended-release tablets) in the United States, and the efforts of our Glumetza commercial partner, Santarus, Inc. (Santarus);
- the commercial success and market acceptance of Serada if we receive approval to market Serada in the United States;
- the results of our ongoing litigation against Lupin Limited (Lupin) and Sun Pharmaceuticals related to their respective abbreviated New Drug Applications (ANDAs) to market generic Glumetza in the United States;
- our and our collaborative partners' compliance or non-compliance with legal and regulatory requirements related to the promotion of pharmaceutical products in the United States;
- results and timing of our clinical trials;

- the results of our research and development efforts;
- submission, acceptance and approval of regulatory filings;
- our need for, and ability to raise, additional capital;
- our collaborative partners' compliance or non-compliance with obligations under our collaboration agreements; and
- our plans to develop other product candidates.

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

#### ABOUT DEPOMED

Depond is a specialty pharmaceutical company focused on the development and commercialization of differentiated products that address large and growing markets and are based on proprietary oral drug delivery technologies. We have two products approved by the U.S. Food and Drug Administration (FDA) that are currently be marketed. Gralise (gabapentin) is our once-daily tablet for the management of postherpetic neuralgia that we launched and made commercially available in October 2011. Glumetza is our once-daily treatment for adults with type 2 diabetes that is commercialized in the United States by Santarus, Inc. (Santarus).

In October 2011, we announced the results of our additional Phase 3 clinical trial known as Breeze 3 for Serada, our proprietary extended release formulation of gabapentin for the treatment of menopausal hot flashes. The formulation of Serada evaluated in the trial met three of the four pre-specified endpoints of frequency and severity at four and 12 weeks but did not meet the key secondary endpoints of frequency and severity at 24 weeks. We intend to meet with and discuss the results of our three completed Phase 3 clinical trials for Serada with the FDA. However, there can be no assurance that the FDA will determine the product candidate is sufficiently safe and effective to allow a New Drug Application to be submitted to and approved by the FDA.

We seek to optimize the use and value of our product candidates and drug delivery technologies in three ways. First, we are seeking to assemble a number of pharmaceutical products that can be highly differentiated from immediate release versions of the compounds upon which they are based and may be promoted together within a specialty pharmaceutical field, such as neurologists or women's health care providers. Our development of Serada, and our retention of co-promotion rights within the obstetrics/gynecology field in our commercialization arrangements with Covidien, Ltd. (Covidien) and Santarus, Inc. (Santarus), are examples of this aspect of our business strategy. Second, we out-license product candidates after we have increased their value through our formulation and clinical development efforts. Third, we enter into collaborative partnerships with other companies where our technology can add value to a partner's product candidate. Our license and development arrangements with Covidien, Janssen Pharmaceutica N.V. (Janssen), Boehringer Ingelheim International GMBH (Boehringer Ingelheim), and Ironwood Pharmaceuticals, Inc. (Ironwood) and our license agreement with Merck & Co., Inc. (Merck) are examples of this strategy.

The following table summarizes our product pipeline and marketed products.

#### **Product Pipeline**

Product	Indication	Status
Serada <sup>®</sup>	Menopausal hot flashes	Three Phase 3 studies completed (Breeze 1, Breeze 2, and Breeze 3).
DM-1992	Parkinson' s disease	Second Phase 1 study completed in February 2011.
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#### Commercialized Products

Product	Indication	Status
•		
Gralise <sup>TM</sup>	Postherpetic neuralgia	Currently sold in the United States. <i>Approved by the FDA in January 2011. Launched in October 2011.</i>
Glumetza®	Type 2 diabetes	Currently sold in the United States and Canada. United States rights held by Santarus. Canadian rights held by Valeant.

#### Significant Developments and Highlights for the Quarter Ended September 30, 2011

- In July 2011, we entered into a research collaboration and license agreement with Ironwood Pharmaceuticals, Inc. granting
  Ironwood a license for worldwide rights to our Acuform drug delivery technology for an undisclosed Ironwood early stage
  development program.
- In August 2011, we entered into a commercialization agreement with Santarus, Inc. pursuant to which Santarus assumed commercial, manufacturing and regulatory responsibility for the commercial activities of Glumetza.
- In September 2011, our contract sales organization, Ventiv Commercial Services, LLC, (Ventiv) hired 164 sales representatives to promote Gralise.
- In September 2011, we entered into a manufacturing and supply agreement with Patheon Puerto Rico, Inc. (Patheon) for the manufacture, package and supply of commercial quantities of Gralise.
- Revenue for the three months ended September 30, 2011 was \$16.5 million, compared to \$20.1 million for the three months ended September 30, 2010.
- Cash, cash equivalents and marketable securities were \$154.2 million as of September 30, 2011, compared to \$76.9 million as
  of December 31, 2010.

#### PRODUCT DEVELOPMENTS AND TRANSACTIONS

#### Gralise<sup>TM</sup> (gabapentin) tablets for the Management of Postherpetic Neuralgia

In October 2011, we launched and announced the commercial availability of Gralise.

<u>Ventiv Commercial Services, LLC.</u> In June 2011, we entered in to a service agreement with Ventiv Commercial Services, LLC (Ventiv), pursuant to which in Ventiv Selling Solutions, Ventiv's outsourced sales business, will provide us with sales force recruiting, training, deployment and ongoing operational support to the Company to promote Gralise. The agreement provides for a sales force of 164 full-time sales representatives dedicated to the Company, all of whom are employees of Ventiv, who began employment in September 2011. Members of sales management are our employees.

In October 2011, our contract sales representatives began promoting Gralise to physicians.

Under the terms of the agreement, we will incur an upfront implementation fee, and agreed upon fixed monthly management fees, which are subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of Ventiv's monthly management fee will be subject to payment by us only to the extent that specified performance objectives are met. We will also pay certain pass-through costs of Ventiv incurred in connection with the Agreement.

The agreement will expire on the second anniversary of the date on which sales representatives hired by Ventiv are deployed. The Agreement is subject to early termination under certain circumstances and may be terminated by either party upon advance notice after the first anniversary of the deployment date.

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Under the Agreement, we will provide rolling forecasts to Patheon of its requirements for the product, a portion of which will be considered a firm purchase order. We may obtain a portion of its product requirements from a second manufacturing source. The Company will be responsible for providing Patheon with the active pharmaceutical ingredient in Gralise.

The agreement will expire on May 31, 2016, subject to early termination under certain circumstances.

<u>Abbott Products.</u> In November 2008, we entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) granting Solvay exclusive rights to develop and commercialize Gralise in the United States, Canada and Mexico for pain indications. The agreement became effective in January 2009. In February 2010, Abbott Laboratories completed its acquisition of the pharmaceutical business of Solvay. Abbott Products, a subsidiary of Abbott Laboratories, assumed responsibility for the Gralise license agreement with us in connection with the acquisition.

Pursuant to the license agreement with Solvay, we received a \$25.0 million upfront fee in February 2009. In March 2010, Abbott Products submitted an NDA for Gralise to the FDA for the management of postherpetic neuralgia. In May 2010, the FDA accepted the NDA for Gralise for the management of postherpetic neuralgia, which triggered a \$10.0 million milestone payment from Abbott Products to us in June 2010.

In January 2011, the FDA approved Gralise for once-daily management of postherpetic neuralgia. The approval triggered a \$48.0 million milestone from Abbott Products to us, which we received in February 2011.

Pursuant to a settlement agreement entered into in March 2011, we and Abbott Products terminated our license agreement for Gralise. The settlement agreement provided for (i) the transition of Gralise back to Depomed and (ii) a \$40.0 million payment to Depomed which we received in March 2011. Accordingly, all remaining deferred revenue related to the \$25.0 million upfront license fee previously received from Abbott Products was fully recognized as revenue in the first quarter of 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

#### Serada® for Menopausal Hot Flashes

Serada is our extended-release formulation of gabapentin for the treatment of menopausal hot flashes. In October 2011, we announced top-line results for Breeze 3, our third Phase 3 study for Serada.

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

In August 2010, we reached agreement with the FDA regarding a Special Protocol Assessment (SPA) on the design and analysis of Breeze 3, our ongoing Phase 3 clinical trial evaluating Serada for menopausal hot flashes. An SPA is an agreement with the FDA that a

proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support a product candidate's regulatory approval. We began enrollment in Breeze 3 in August 2010 and completed enrollment in March 2011.

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

Study Results. The primary severity endpoints were achieved with statistical significance at four weeks (p < 0.001) and 12 weeks (p < 0.01). The frequency endpoint at four weeks was achieved with statistical significance (p < 0.001). The frequency endpoint at 12 weeks, as well the key secondary frequency and severity endpoints at 24 weeks, were not met.

Serada was generally well tolerated in Breeze 3. The most common adverse events were dizziness and somnolence. The incidence of dizziness in the active arm was 12.7% compared to 3.4% for the placebo arm. Somnolence was 6.0% in the active arm compared to 2.7% in the placebo arm. Withdrawals due to adverse events in the active arm were 17%, compared to 12% in the placebo arm.

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We intend to meet with and discuss the results of our three completed Phase 3 clinical trials for Serada with the FDA. However, there can be no assurance that the FDA will determine the product candidate is sufficiently safe and effective to allow a New Drug Application to be submitted to the FDA. In the event the FDA allows us to file a New Drug Application for Serada based on the results of our three completed Phase 3 clinical trials, there can be no assurance that such New Drug Application will be approved.

#### Glumetza for Type 2 Diabetes

<u>Santarus</u>. In August 2011, we entered into a commercialization agreement with Santarus granting Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. The commercialization agreement supersedes the previous promotion agreement between the parties originally entered into in July 2008.

Under the commercialization agreement, we will transition to Santarus responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs. We ceased shipments of Glumetza in August 2011 and Santarus began selling Glumetza in September 2011. Santarus will continue to be responsible for advertising and promotional marketing activities for Glumetza. In November 2011, we and Santarus entered into an assignment and assumption agreement pursuant to which Santarus assumed all of our rights and obligations under our commercial manufacturing agreement with Patheon, which provides that Patheon will serve as the sole commercial supplier of Santarus' Glumetza 500 mg prescription products in the U.S.

Santarus will be required to pay us royalties on net product sales of Glumetza in the United States of 26.5% in 2011; 29.5% in 2012; 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. In the event of generic entry of a Glumetza product in the United States, the parties will equally share proceeds based on a gross margin split. Santarus has the exclusive right to commercialize authorized generic versions of the Glumetza products. Santarus will pay no additional sales milestones to us as was originally required under the prior promotion agreement.

In connection with its assumption of distribution and sales responsibility of Glumetza, Santarus purchased our existing inventory of Glumetza and bulk metformin hydrochloride at cost. We will be financially responsible for returns of Glumetza distributed by us, up to the amount of our product returns reserve account for Glumetza product returns on the date immediately before Santarus began

distributing Glumetza. We will also be financially responsible for Glumetza rebates and chargebacks up to the amount of its reserve account for those items. Santarus will be responsible for all other Glumetza returns, rebates and chargebacks.

Pursuant to the terms of the commercialization agreement, we have the option to co-promote Glumetza products to physicians other than those called on by Santarus, subject to certain limitations. If we exercise this option, we will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by our called upon physicians over a pre-established baseline.

Under the commercialization agreement, we will continue to manage the ongoing patent infringement lawsuits against Sun Pharmaceutical Industries, Inc. (Sun) and Lupin Limited (Lupin), subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. Santarus will reimburse us for 70% of it out-of-pocket costs, and we will reimburse Santarus for 30% of its out-of-pocket costs related to these two existing infringement cases.

The commercialization agreement will continue in effect for so long as Santarus commercializes branded Glumetza or authorized generic products, unless terminated sooner. Subject to 60 days prior written notice to Santarus, we may terminate the agreement if Santarus fails to meet its obligations with respect to minimum promotion and expenditure obligations and fails to cure such breach within a specified time period. Either party may terminate the agreement if the other party fails to perform any material term of the agreement and fails to cure such breach, subject to prior written notice within a specified time period. In addition, either party may terminate the agreement if a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed. Santarus has a voluntary right to terminate the agreement upon 120 days' written notice.

During the quarter ended September 30, 2011, we sold Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus. Santarus sold Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid us a royalty equal to 26.5% of net sales.

For the three and nine months ended September 30, 2011, the Company recognized \$6.0 million and \$27.3 million, respectively, in promotion fee expense to Santarus related to sales of Glumetza by Depomed. For the three and nine months ended September 30, 2010, the Company recognized \$6.8 million and \$23.8 million, respectively, in promotion fee expense to Santarus. Promotion fee expense is classified within selling, general and administrative expense

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Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus selling Glumetza under the commercialization agreement. There were royalty revenue amounts from Santarus in the prior year.

500mg Glumetza Recall. In June 2010, we conducted a voluntary class 2 recall of fifty-two lots of 500mg Glumetza product from wholesalers due to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA) in bottles containing 500mg Glumetza tablets. In June 2010, we temporarily suspended product shipments of 500mg Glumetza product to our customers. We resumed shipments of the 500mg Glumetza to customers in January 2011. The 1000mg Glumetza product was not subject to the recall.

#### Boehringer Ingelheim

In March 2011, we entered into a license and service agreement with Boehringer Ingelheim granting Boehringer Ingelheim a license to certain patents related our Acuform drug delivery technology to be used in developing fixed dose combinations of extended release metformin and proprietary Boehringer Ingelheim compounds in development for type 2 diabetes.

In connection with the license and service agreement, we received the upfront license payment of \$10.0 million less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million in April 2011. We received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

We are also eligible to receive an additional \$2.5 million upon delivery of experimental batches of prototype formulations that meet certain specifications, and may receive additional milestone payments based on regulatory filings and approval events, as well as royalties on worldwide net sales of products.

We are responsible for providing certain initial formulation work associated with the fixed dose combination products. Services performed by us under the agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon rate, and out-of-pocket expenses will be reimbursed.

#### Ironwood Pharmaceuticals, Inc.

In July 2011, we entered into a collaboration and license agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) granting Ironwood a license for worldwide rights to our Acuform drug delivery technology for an undisclosed Ironwood early stage development program.

In connection with the research collaboration and license agreement, we received an upfront payment of \$0.9 million.

Under the terms of the agreement, we will assist with initial product formulation and Ironwood will be responsible for all development and commercialization of the product. The initial formulation work performed by the Company under the agreement will be reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses.

We may also receive additional payments pending achievement of certain development and regulatory milestones, as well as royalties on product sales.

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

In September 2010, we initiated our second pharmacokinetic-pharmacodynamic Phase 1 study for the DM-1992 program. The second Phase 1 trial in DM-1992 was a randomized, open-label crossover study that enrolled 16 patients with stable Parkinson's disease at two leading neurology centers in Russia. The objective of the study was to compare the pharmacokinetics-pharmacodynamics of two distinct twice-daily formulations of DM-1992 and a generic version of Sinemet CR sustained-release levodopa/carbidopa dosed three-times daily, as well as the safety and tolerability of the formulations. Patients in the trial received a full day's dose of each of the three treatments being studied, two doses of each DM-1992 (460mg levodopa and 150mg carbidopa per dose) twelve hours apart, and three doses of generic levodopa/carbidopa over a 12 hour period (200mg of levodopa and 50mg of carbidopa per dose). During the 24 hour period following administration of each treatment, blood samples were drawn and a standard finger tapping test was given to assess efficacy.

In February 2011, we completed the second Phase 1 study. Both formulations are projected at steady state to consistently maintain levodopa blood levels above the efficacious threshold of 300ng/mL for 24 hours, as mean levodopa blood levels after 24 hours exceeded 300ng/mL.

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#### CRITICAL ACCOUNTING POLICIES

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, accrued liabilities and stock-based compensation to be critical policies. There have been no changes to our critical accounting policies since we filed our 2010 Annual Report on Form 10-K with the Securities and Exchange Commission on March 16, 2011. For a description of our critical accounting policies, please refer to our 2010 Annual Report on Form 10-K.

#### RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2011 and 2010

#### Glumetza

In August 2011, we entered into a commercialization agreement with Santarus granting Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. The commercialization agreement supersedes the previous promotion agreement between the parties originally entered into in July 2008.

We ceased shipments of Glumetza in August 2011 and Santarus began distributing and recognizing product sales on shipments of Glumetza in September 2011. Santarus will be required to pay us royalties on net product sales of Glumetza in the United States of 26.5% in 2011; 29.5% in 2012; 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. In the event of generic entry of a Glumetza product in the United States, the parties will equally share proceeds based on a gross margin split. Santarus has the exclusive right to commercialize authorized generic versions of the Glumetza products. Santarus will pay no additional sales milestones to us as was originally required under the prior promotion agreement.

Prior to the effective date commercialization agreement, we were required to pay Santarus 75% of gross margin on Depomed sales of Glumetza under the promotion agreement.

During the quarter ended September 30, 2011, we distributed Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus. Santarus distributed Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid us a royalty equal to 26.5% of net sales.

Glumetza product sales of \$9.2 million, Glumetza cost of goods sold of \$1.0 million and promotion fee expense to Santarus of \$6.0 million during the quarter ended September 2011 represents two months in the quarter of Depomed distributing Glumetza under the prior agreement. Glumetza royalties of \$2.1 million during the third quarter of 2011 represents one month in the quarter of royalties from on Santarus' net sales of Glumetza under the new commercialization agreement. In the corresponding quarter of the prior year, Glumetza product sales were \$9.8 million, Glumetza cost of goods sold were \$2.5 million and promotion fee expense to Santarus was \$6.8 million, which represented a full quarter of Depomed selling product under the parties' promotion agreement,

Glumetza product sales of \$40.7 million, Glumetza cost of goods sold of \$3.7 million and promotion fee expense to Santarus of \$27.3 million during the nine months ended September 2011 represents eight months in 2011 of Depomed distributing Glumetza under the prior agreement. Glumetza royalties of \$2.1 million during the nine months ended September 2011 represents one month in 2011 of royalties on Santarus' net sales of Glumetza under the new commercialization agreement. In the corresponding period of the prior year, Glumetza product sales were \$34.0 million, Glumetza cost of goods sold were \$6.9 million and promotion fee expense to Santarus was \$23.8 million, which represented nine months of Depomed selling product under the parties' promotion agreement.

We accounted for the transaction as a sale of a business as defined by FASB Accounting Standards Codification Topic 805, "Business Combinations". In connection with entering into the commercialization agreement with Santarus, no additional consideration was exchanged between the two parties. Accordingly, we did not record a gain or loss with respect to this transaction and related transfer of Glumetza manufacturing and distribution activities. As we will have significant continuing cash inflows with respect to receiving royalties on net sales of Glumetza by Santarus, the previously reported and future activities related to Glumetza will be continue to presented in income from continuing operations in the Company's income statement.

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#### Revenue

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

	Thre	Three Months Ended September 30,				Nine Months Ended September 30,				
		2011		2010		2011		2010		
Product sales:						_				
Glumetza	\$	9,205	\$	9,807	\$	40,657	\$	33,976		
Proquin XR		_		22		12		110		
Total product sales		9,205		9,829		40,669		34,086		
Royalties:										
Glumetza		2,179		75		2,412		254		
Tiones and callaboration recommen										
License and collaborative revenue:				1.5(1		(0.502		14.604		
Gralise		-		1,561		60,592		14,684		
Glumetza		962		626		5,222		1,877		
Boehringer Ingelheim		3,902		_		9,368		-		
Janssen		_		6,508		2,251		6,508		
Ironwood		274		_		274		_		
Covidien		_		1,458		_		2,375		
Proquin XR (EU)		_		26		_		77		
DM-1992		_		44		53		44		
Total license and collaborative										
revenue:		5,138		10,223		77,760		25,565		
Total revenues	\$	16,522	\$	20,127	\$	120,841	\$	59,905		

#### Product sales

<u>Glumetza</u>. The decrease in Glumetza product sales in the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 was primarily due to Depomed distributing and recognizing product sales of Glumetza for only two months in the third quarter of 2011 as opposed to the full quarter in the third quarter of 2010. This change resulted from the Santarus commercialization agreement entered into in August 2011. This decrease was offset by price increases as well as the resumption of shipments of the 500mg Glumetza in 2011. We did not ship any 500mg Glumetza in the third quarter of 2010 following the recall of

500mg Glumetza in June 2010. We temporarily suspended product shipments of 500mg Glumetza in June 2010 and did not resume shipments until January 2011. The 1000mg Glumetza was not subject to the recall.

The increase in Glumetza product sales during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 is primarily due to price increases and the resumption of shipments of the 500mg Glumetza in January 2011.

As a result of the Santarus commercialization agreement entered into in August 2011, we will no longer be recognizing Glumetza product sales going forward as we have transitioned the distribution and selling efforts related to Glumetza to Santarus. We will receive royalties on Santarus' net sales of Glumetza going forward.

The Company launched Gralise in October 2011 and will begin recognizing Gralise product sales in the fourth quarter of 2011.

#### Royalties

<u>Glumetza</u>. Glumetza royalties relate to royalties we received from Santarus, Valeant Pharmaceuticals International, Inc. (Valeant), based on net sales of Glumetza in Canada and royalties we received from LG Life Sciences (LG) based on net sales of LG's version of Glumetza, Novamet GR, in Korea.

Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus distributing and recording product sales on shipments of Glumetza under the commercialization agreement. There were no royalty revenue amounts from Santarus in the prior year. We expect royalty revenue to increase on a forward basis as a result of the commercialization agreement.

#### License and collaborative revenue

<u>Gralise</u>. In January 2011, Abbott Products received FDA approval of Gralise for the management of postherpetic neuralgia, which triggered a \$48.0 million development milestone from Abbott to us, which we received in February 2011. Because the milestone was substantive in nature, achieved and based on past performance, the entire \$48.0 million was recognized as license revenue in the first quarter of 2011.

Pursuant to the exclusive license agreement originally entered into in November 2008, Solvay paid us a \$25.0 million upfront fee in February 2009. The upfront payment received was originally scheduled to be recognized as revenue ratably until January 2013,

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which represented the estimated length of time our development and supply obligations existed under the agreement. In connection with the termination of the license agreement with Abbott Products, we no longer have continuing obligations to Abbott Products. Accordingly, all remaining deferred revenue related to the \$25.0 million upfront license fee previously received from Abbott Products was fully recognized as revenue in March 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

<u>Glumetza</u>. In January 2011, we achieved the first sales milestone under the promotion agreement with Santarus related to net sales of Glumetza reaching \$50.0 million for the 13 month period ending January 31, 2011, which triggered a milestone payment of \$3.0 million, which we received in March 2011. As the milestone was achieved and related to past performance the entire \$3.0 million was recognized as milestone revenue in the first quarter of 2011.

Glumetza license revenue for the three and nine months ended September 30, 2011 and 2010 also consisted of license revenue recognized from the \$25.0 million upfront license fee received from Biovail in July 2005 and the \$12.0 million upfront fee received from Santarus in July 2008.

We are recognizing the \$25.0 million upfront license fee payment from Biovail as revenue ratably until October 2021, which represents the estimated length of time our obligations exist under the arrangement related to royalties we are obligated to pay Biovail on net sales of Glumetza in the United States and for our obligation to use Biovail as our sole supplier of the 1000mg Glumetza.

Pursuant to the promotion agreement originally entered into in July 2008, Santarus paid us a \$12.0 million upfront fee. The upfront payment received was originally being amortized as revenue ratably until October 2021, which represented the estimated length of time our obligations existed under the promotion agreement related to manufacturing Glumetza and paying Santarus promotion fees on gross margin of Glumetza. The commercialization agreement in August 2011 superseded the promotion agreement and removed our manufacturing and promotion fee obligations. The commercialization agreement includes obligations with respect to manufacturing and regulatory transition to Santarus and managing the ongoing patent infringement lawsuits against Sun and Lupin. These obligations are estimated to be completed in December 2013. Accordingly, on the effective date of the commercialization agreement, the amortization period related to remaining deferred revenue on the \$12.0 million upfront fee has been adjusted, and the remaining deferred revenue will be recognized ratably until December 2013. We recognized approximately \$0.6 million and \$1.0 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. The remaining deferred revenue balance is \$8.8 million at September 30, 2011.

<u>Boehringer Ingelheim</u>. Under our license and services agreement with Boehringer Ingelheim entered into in March 2011, Boehringer Ingelheim paid us a \$10.0 million upfront license fee which we received in April 2011, less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million. We received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

The \$10.0 million is being amortized ratably through November 2011, which is the estimated length of time we are obligated to perform formulation work under the agreements. We recognized approximately \$3.8 million and \$8.6 million of revenue associated with this upfront license fee for the three and nine months ended September 30, 2011, respectively. The remaining deferred revenue balance is \$1.4 million at September 30, 2011.

We are also responsible for providing certain initial formulation work associated with the fixed dose combination products. Work performed by us under the service agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately \$0.1 million and \$0.8 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2011.

Janssen. In August 2010, we entered into a non-exclusive license agreement with Janssen granting Janssen a license to certain patents related to our Acuform drug delivery technology to be used in developing fixed dose combinations of canagliflozin and extended release metformin. Janssen paid us a \$5.0 million upfront license fee associated with the license agreement. The \$5.0 million was amortized ratably through March 2011, which is the estimated length of time we are obligated to perform formulation work under the agreements. We recognized approximately \$1.9 million of revenue associated with this upfront license fee during the first quarter of 2011.

We also entered into a service agreement with Janssen under which we provide formulation work for Janssen and are reimbursed by Janssen on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately \$0.3 million of revenue associated with the reimbursement of formulation work under the service agreement during the first quarter of 2011.

All formulation work under the agreement was completed at March 31, 2011 and there is no remaining deferred revenue.

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Ironwood Pharmaceuticals, Inc. In July 2011, the we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to the Company's Acuform drug delivery technology for an undisclosed Ironwood early stage development program. In connection with the research collaboration and license agreement, the Company received an upfront payment of \$0.9 million which is being amortized ratably through June 2012, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. We recognized approximately \$0.2 million of revenue associated with this upfront license fee for the three and nine months ended September 30, 2011. The remaining deferred revenue balance is \$0.7 million at September 30, 2011.

Under the terms of the agreement, the Company will assist with initial product formulation and Ironwood will be responsible for all development and commercialization of the product. The initial formulation work performed by the Company under the agreement will be reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses. We recognized approximately \$0.1 million of revenue associated with the reimbursement of formulation work under the agreement during the three and nine months ended September 30, 2011.

#### **Cost of Sales**

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, inventory write-downs, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales of Glumetza, Gralise and Proquin XR. Total cost of sales for the three and nine months ended September 30, 2011, as compared to the prior year, was as follows (in thousands):

	Thre	e Months En	ded Sep	tember 30,	Nine	Months End	ed Sept	ember 30,
		2011		2010		2011		2010
Cost of sales	\$	1,150	\$	2,499	\$	4,925	\$	6,961

Cost of sales for the three months ended September 30, 2011 decreased as compared to the prior year mainly as a result of \$1.2 million in inventory write-offs for unsalable inventory related to the 500mg Glumetza recall during the three months ended September 30, 2010. Additionally, the Company only sold Glumetza for two of the three months ended September 30, 2011 as a result of the Santarus commercialization agreement. These decreases were partially offset by manufacturing and supply costs related to the Company's launch of Gralise in October 2011.

Cost of sales for the nine months ended September 30, 2011 decreased as compared to the prior year mainly as a result of \$2.6 million in inventory write-offs for unsalable inventory related to the 500mg Glumetza recall during the nine months ended September 30, 2010.

The costs of manufacturing associated with deferred revenue on Proquin XR product shipments are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

#### **Gain on Settlement with Abbott Products**

In March 2011, we entered into a settlement agreement with Abbott Products which provided for (i) the immediate termination of the parties' license agreement; (ii) the transition of Gralise back to Depomed; and (iii) a \$40.0 million payment from Abbott to us made in March 2011. The \$40.0 million payment was recognized as a gain within operating income in the first quarter of 2011.

#### Research and Development Expense

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

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Total research and development expense for the three and nine months ended September 30, 2011 as compared to the prior year, was as follows (in thousands):

	Three Months Ended September 30,					Nine Months Ended September 30,			
	2011			2010	2011			2010	
Research and development									
expense	\$	3,208	\$	4,602	\$	12,405	\$	14,360	
Dollar change from prior year		(1,394)				(1,955)			
Percentage change from prior year	(30.3)%				(13.6)%				

The decrease in research and development expense for the three and nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010 was primarily due to reductions in research and development expense for Gralise, which received FDA approval in the first quarter of 2011 partially offset by higher clinical research organization costs associated with our Breeze 3 Phase 3 clinical trial for Serada, which was completed in October 2011.

We categorize our research and development expense by project. The table below shows research and development costs for our major clinical development

	Thre	ee Months En	tember 30,	Nine Months Ended September 30,				
(In thousands)	2011		2010		2011		2010	
Serada	\$	2,519	\$	1,577	\$	8,258	\$	5,587
Gralise		_		1,132		_		3,378
Other projects		689		1,893		4,147		5,395
Total research and development								
expense	\$	3,208	\$	4,602	\$	12,405	\$	14,360

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#### Selling, General and Administrative Expense

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

	Three Months Ended September 30,				N	Nine Months Ended September 30,			
	2011		2010		2011		2010		
Selling, general and administrative expense:									
Promotion fee expense	\$	6,023	\$	6,791	\$	27,339	\$	23,769	
Other selling, general and administrative expense		15,451		4,313		32,667		12,403	
Total selling, general and administrative expense	\$	21,474	\$	11,104	\$	60,006	\$	36,172	
Dollar change from prior year		10,370				23,834			
Percentage change from prior year		93.4%	ó			65.9%	)		

The increase in selling, general and administrative expense was primarily due to increased sales and marketing costs related to the launch of Gralise including pre-launch marketing activities and costs associated with our contract sales organization. In March 2011, we received the rights to market Gralise back from Abbott and commenced pre-launch commercial activities to support the launch of Gralise. During 2011, we advanced our commercial infrastructure with the hiring of employees for our sales management and marketing organizations. In June 2011, we entered into a service agreement with Ventiv as our contract sales organization, pursuant to which Ventiv will provide 164 full-time sales representatives dedicated to promoting Gralise. The Ventiv sales representatives were hired and commenced training in September. In October, we initiated commercial sales of Gralise.

As a result of the Santarus commercialization agreement entered into in August 2011, we will no longer have promotion fee expense to Santarus going forward. However, we expect selling, general and administrative expense to increase as we incur costs associated with our contract sales organization and related marketing for Gralise.

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

	Three	Months End	ptember 30,	Nine Months Ended September 30,				
(in thousands)		2011		2010		2011		2010
Interest and other income	\$	410	\$	100	\$	846	\$	251
Interest expense		(24)		(130)		(133)		(471)
Net interest income (expense)	\$	386	\$	(30)	\$	713	\$	(220)

Interest and other income increased during the three and nine months ended September 30, 2011 as compared to the corresponding period in 2010 as a result of higher investment balances.

Interest expense relates to interest on the credit facility we entered into in June 2008 with General Electric Capital Corporation and Oxford Finance Corporation. The credit facility was fully repaid in July 2011.

#### **Benefit From Income Taxes**

The income tax benefit of \$0.3 million for the three months and nine months ended September 30, 2011 represents a tax benefit from our ability to carry back our taxable loss in the current period to offset income taxes previously paid. As a result of the enactment of the American Recovery and Reinvestment Act of 2009 in February 2009, we are able to carry back fiscal year 2011 operating losses to the extent of our taxable income for our fiscal year 2007. We received this refund in the fourth quarter of 2011. The income tax benefit for the three months and nine months ended September 30, 2011 was partially offset by state income tax expenses.

#### LIQUIDITY AND CAPITAL RESOURCES

	September 30,	December 31,
(in thousands)	2011	2010

		_	
Cash, cash equivalents and marketable securities	\$ 154,196	\$	76,888

Since inception through September 30, 2011, we have financed our product development efforts and operations primarily from private and public sales of equity securities, upfront license, milestone and termination fees from collaborative and license partners, and product sales.

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

We paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Thereafter we were required to pay principal on the first tranche, plus interest at such rate, in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments with an interest rate of 11.59%. The credit facility was fully repaid in July 2011.

As of September 30, 2011, we have accumulated net losses of \$83.7 million. We may incur operating losses for the remainder of 2011. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through at least the end of 2012. We base this expectation on our current operating plan, which may change as a result of many factors.

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

- sales of our marketed products:
- expenditures related to our commercialization of Gralise, including our contractual obligations to Ventiv and other arrangements we make for the commercialization of Gralise;
- expenditures related to our commercialization and development efforts, including arrangements we make for the commercialization of Serada, if the product is approved for marketing;
- financial terms of definitive license agreements or other commercial agreements we enter into;
- results of research and development efforts;
- changes in the focus and direction of our business strategy and/or research and development programs;
- technological advances;
- results of clinical testing, requirements of the FDA and comparable foreign regulatory agencies; and
- acquisitions or investment in complementary businesses, products or technologies.

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

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

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to support our operations. We currently do not have any other committed sources of capital. To the extent that our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds through the sale of our equity securities or from development and licensing arrangements to continue our development programs. We may be unable to raise such

additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. If adequate funds are not available we may have to:

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

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

#### **Cash Flows from Operating Activities**

Cash provided by operating activities during the nine months ended September 30, 2011 was approximately \$72.4 million, compared to cash used in operating activities of approximately \$3.4 million during the nine months ended September 30, 2010. Cash provided by operating activities during the nine months ended September 30, 2011 was primarily as a result of the \$48.0 million milestone payment and \$40 million termination fee received from Abbott Products during the first quarter of 2011. Cash used in operating activities during the nine months ended September 30, 2010 was primarily due to our net income adjusted for movements in working capital, stock-based compensation and depreciation expense.

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

Net cash used in investing activities during the nine months ended September 30, 2011 was approximately \$80.6 million and consisted of an increase in marketable securities resulting from a partial investment of the milestone payment and settlement fee received from Abbott during the first quarter of 2011. Net cash used in investing activities during the nine months ended September 30, 2010 was approximately \$1.2 million and consisted primarily of a slight net increase in marketable securities resulting from investment of the milestone payment received from Abbott (\$10.0 million) in 2010.

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

Cash provided by financing activities during the nine months ended September 30, 2011 was approximately \$5.6 million and consisted of proceeds from employee and consultant option exercises offset by repayments of principal on our credit facility. Cash used in financing activities during the nine months ended September 30, 2010 was approximately \$1.9 million and consisted of repayments of principal on our credit facility offset by proceeds from employee and consultant option exercises.

#### **Contractual Obligations**

As of September 30, 2011, our aggregate contractual obligations are as shown in the following table (in thousands):

	L	ess than					
	1 year			1-3 years	Total		
Operating leases	\$	1,717	\$	614	\$	2,331	
Related parties		303		_		303	
Contract sales organization		19,059		-		19,059	
Purchase commitments		1,522		_		1,522	

|--|

At September 30, 2011, we had non-cancelable purchase orders and minimum purchase obligations of approximately \$1.5 million under our manufacturing agreement with Patheon Puerto Rico, Inc. for the manufacture of Gralise. The amounts disclosed only represent minimum purchase requirements. Actual purchases are expected to exceed these amounts.

Pursuant to the separation agreement and release entered into with Carl A. Pelzel, our former President and Chief Executive Officer, we are obligated to pay Mr. Pelzel \$43,333 per month through April 2012.

In June 2011, we entered in to a service agreement with Ventiv, who will provide us with sales force recruiting, training, deployment and ongoing operational support to promote Gralise in the U.S. through 164 full-time sales representatives. Each month we are required to pay Ventiv a monthly fixed fee of \$1.8 million during the term of the Ventiv Agreement. We may terminate the service agreement on the one year anniversary of the deployment date of the sales representatives. We have included an estimate of our expected contractual obligations to Ventiv based upon this fee and expected one year anniversary of deployment date of the sales representatives.

The contractual obligations reflected in this table exclude \$3.0 million of contingent milestone payments we may be obligated to pay in the future under our sublicense agreement with PharmaNova related to the development of Serada. The payments relate to various milestones for the product candidate under the sublicense agreement, including submission to the FDA of an NDA, and FDA approval of an NDA. The above table also excludes any future royalty payments we may be required to pay on products we have licensed.

# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no significant changes in our market risk compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2010.

## ITEM 4. CONTROLS AND PROCEDURES

# Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President, Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of

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the end of the period covered by this quarterly report. Based on that evaluation, our management, including our Chief Executive Officer and Vice President, Finance, concluded that our disclosure controls and procedures were effective.

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

#### Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

## Depomed v. Sun Pharmaceutical (U.S. Generic Glumetza Litigation)

In June, 2011, a lawsuit was filed in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Inc., Sun Pharma Global FZE and Sun Pharmaceuticals Industries Ltd. ("Sun"), for infringement of five (5) U.S. patents listed in the Orange Book for the Glumetza product. The lawsuit is in response to an Abbreviated New Drug Application ("ANDA") filed by Sun with the FDA regarding Sun's intent to market generic versions of 500mg and 1000mg dosage strengths of Glumetza prior to the expiration of the Orange Book patents, which includes U.S. Patent Nos.: 6,340,475, 6,488,962, 6,635,280, 6,723,340 and 7,780,987. U.S. Patent No.7,736,667 is also being asserted against Sun in the lawsuit. The lawsuit commenced within the 45 days required to automatically stay, or bar, the FDA from approving Sun's ANDA for 30 months or until a district court decision that is adverse to the patents, whichever occurs earlier.

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

In November 2009, a lawsuit was filed in the United States District Court for the Northern District of California against Lupin Limited and its wholly-owned subsidiary, Lupin Pharmaceutical, Inc. ("Lupin"), for infringement of four (4) U.S. patents listed in the Orange Book for the Glumetza product. The lawsuit is in response to an Abbreviated New Drug Application ("ANDA") filed by Lupin with the FDA regarding Lupin's intent to market generic versions of 500mg and 1000mg dosage strengths of Glumetza prior to the expiration of the Orange Book, which includes U.S. Patent Nos.: 6,340,475; 6,488,962; 6,635,280; and 6,723,340. U.S. Patent No. 6,723,340 was subsequently removed from the litigation proceedings in an amended complaint. The lawsuit commenced within the 45 days required to automatically stay, or bar, the FDA from approving Lupin's ANDA for 30 months or until a district court decision that is adverse to the patents, whichever occurs earlier. Absent a court decision, the 30-month stay is expected to expire in May 2012. Lupin has prepared and filed an answer in the lawsuit, principally asserting non-infringement and invalidity of the Orange Book patents, and has also filed counterclaims. Discovery is currently underway and a hearing for claim construction, or Markman hearing, was held on January 2011, which resulted in all ten (10) claim terms at issue in the lawsuit, construed in Depomed's favor. A bench trial is currently scheduled for August 13, 2012.

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

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

In February 2010, Valeant and Depomed filed a complaint in the Federal Court in Canada against Apotex for infringement of Canadian Patent No. 2,290,624, which is owned in its entirety by Depomed.

Also, in February 2010, Apotex received clearance from the Canadian Minister of Health to market the generic version of the 500mg formulation, however, to date, Apotex has not launched the generic version of Glumetza in Canada. This litigation is currently stayed.

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

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### ITEM 1A. RISK FACTORS

The risk factors presented below amend and restate the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

The following factors, along with those described above under "MANAGEMENT' S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – LIQUIDITY AND CAPITAL RESOURCES" should be reviewed carefully, in conjunction with the other information contained in this Report and our financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-Q and presented elsewhere by our management from time to time. See "Part I, Item 2–Forward-Looking Information."

### We may not successfully commercialize Gralise, which would harm our business.

Although Gralise has been approved for marketing, our ability to generate significant revenue from Gralise requires that we successfully commercialize the product on our own or with the assistance of a collaborative co-promotion or licensing partner. We began commercial sales of Gralise in October 2011. Other than Ventiv, with whom we have contracted to provide sales force recruiting, training, deployment and operational support for this product, we do not currently have other partners assisting us with the commercialization of Gralise. We are a small organization with limited experience selling and marketing pharmaceutical products, and have had little time to build capabilities necessary to commercialize the product. We may not be able to adequately or timely build or maintain the necessary sales, marketing, manufacturing, managed markets or other capabilities on our own that are required to successfully commercialize Gralise, and we may not enter into arrangements with other collaborative partners or other third parties to perform those functions for us. Ventiv and other contract parties and partners may not perform as required under their contracts with us or as expected. Also, the establishment and maintenance of those capabilities may require us to divert capital from other intended purposes.

Given the small size of our company and the limited experience and expertise of our current staff in selling and marketing pharmaceutical products, effectively managing a significant number of collaborative partners and third-party contractors may be challenging. If our management of collaborative partners and third-party contractors is not effective, the commercial acceptance and success of Gralise may be limited and our business would be harmed.

If we enter into a collaborative co-promotion or licensing arrangement related to Gralise, some or all of the revenues we receive will depend upon the efforts of one or more third parties, which may not be successful.

## We may not be able to obtain orphan drug exclusivity for Gralise in PHN.

The FDA has granted Gralise Orphan Drug designation for the management of PHN based on the size of the PHN population and the reduced incidence of adverse events observed in Gralise clinical trials relative to the incidence of adverse events reported in the package insert for immediate release gabapentin. Subsequent to the FDA's approval of Gralise, we were informed additional submissions or evidence to demonstrate the clinical superiority of Gralise based on improved safety will be required to be provided to the FDA in order to obtain a seven-year period of orphan exclusivity in PHN. In October 2011, the FDA proposed regulations to amend its 1992 Orphan Drug regulations implementing the Orphan Drug Act. According to the FDA, the proposed amendments are intended to clarify certain provisions of the regulations and make minor improvements to address issues that have arisen since the regulations were issued. If adopted as proposed, it is possible the amendments will adversely affect our request for orphan drug exclusivity for Gralise.

If we obtain the orphan exclusivity, the FDA may not approve another application to market the same drug for the same indication until January 2018, except in very limited circumstances.

We cannot be certain that the FDA will grant Gralise orphan exclusivity in PHN. If we do not obtain orphan exclusivity for Gralise, the period of market exclusivity in the United States for Gralise may be reduced, which would adversely affect our revenues.

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

Each of our three Phase 3 trials evaluating Serada for menopausal hot flashes, including our Phase 3 trial known as Breeze 3, failed to meet all of their primary endpoints. Although we intend to meet with and discuss the results of the trials with the FDA, there can be no assurance that the FDA will determine the product candidate is sufficiently safe and effective to allow a New Drug Application to be submitted to the FDA. In the event the FDA allows us to file a New Drug Application for Serada based on the results of our three completed Phase 3 clinical trials, there can be no assurance that such New Drug Application will be approved.

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If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our products, our business will suffer.

Under the Federal Food, Drug and Cosmetics Act (FDCA), the FDA can approve an Abbreviated New Drug Application (ANDA), for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The FDCA requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the company seeking approval of a product covered by one of our patents. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. Such litigation is often time-consuming and quite costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor is found not to infringe such patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs.

In November 2009, we filed a lawsuit in the United States District Court for the Northern District of California against Lupin for infringement of U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; and 6,723,340 listed in the Orange Book for Glumetza. The lawsuit is in response to an ANDA filed by Lupin with the FDA regarding Lupin's intent to market generic versions of the 500mg and 1000mg strengths of Glumetza prior to the expiration date of the asserted patents. We commenced the lawsuit against Lupin within the applicable 45 day period required to automatically stay, or bar, the FDA from approving Lupin's ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever may occur earlier. The 30-month stay expires in May 2012. If the litigation is still ongoing after expiration of the applicable 30-month stay, the termination of the stay could result in the introduction of one or more products generic to Glumetza prior to resolution of the litigation. Any introduction of one or more products generic to Glumetza would harm our business, financial condition, results of operations and cash flows.

In June 2011, we filed a lawsuit in the United States District Court for the District of New Jersey against Sun Pharmaceutical Industries Inc., Sun Pharma Global FZE and Sun Pharmaceuticals Industries Ltd. (Sun), for infringement of the patents listed in the Orange Book for Glumetza. The lawsuit is in response to an Abbreviated New Drug Application filed by Sun with the FDA regarding Sun's intent to market generic versions of 500mg and 1000mg strengths of Glumetza prior to the expiration of the five listed U.S. patents (U.S. Patent Nos. 6,340,475; 6,488,962; 6,635,280; 6,723,340 and 7,780,987). We also are asserting U.S. Patent 7,736,667 in the lawsuit. We commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving Sun's ANDA for 30 months or until a district court decision that is adverse to the patents, whichever may occur earlier.

In December 2007, Apotex, Inc. (Apotex) filed the Canadian equivalent of an Abbreviated New Drug Application in Canada seeking approval to market a generic version of the 500mg formulation of Glumetza in Canada. In February 2010, Apotex received clearance from the Minister of Health in Canada to market the generic version of the 500mg formulation of Glumetza. However, to date, Apotex has not launched a generic version of Glumetza in Canada. Also in February 2010, the Company and Valeant filed a complaint in the Federal Court in Canada against Apotex for infringement of our Canadian Patent No. 2,290,624. If we are not able to successfully enforce our patent and prevent the launch of Apotex's product, the resulting competition would reduce our sales and revenue for Glumetza.

The filing of the Lupin and Sun ANDAs described above, Apotex's generic Glumetza, or any other ANDA or similar application in respect to any of our products could have an adverse impact on our stock price. Moreover, if the patents covering our products were not upheld in litigation or if a generic competitor is found not to infringe these patents, the resulting generic competition would have a material adverse effect on our business, results of operations, financial condition and cash flows.

## We depend heavily on Santarus, Inc. for the successful commercialization of Glumetza in the United States.

In August 2011, we entered into a commercialization agreement with Santarus, Inc. (Santarus) pursuant to which Santarus assumed broad commercial, manufacturing and regulatory responsibility for the commercialization of Glumetza. The commercialization agreement replaces the promotion agreement we entered into with Santarus in July 2008. Under the commercialization agreement, we transitioned most U.S. commercial activities relating to Glumetza to Santarus, as well as the New Drug Application for Glumetza. Santarus will pay us royalties on net sales of Glumetza and will not pay any additional sales milestones that were required under the promotion agreement. The commercialization agreement provides for a reduced minimum spend obligation. Although we have retained rights to promote Glumetza to physicians not called on by us, we do not have any immediate plans to exercise our Glumetza co-promotion rights. Accordingly, the success of the commercialization of Glumetza will depend in large part on Santarus'

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commercialization efforts. Other factors that may affect the success of our commercialization arrangement with Santarus include the following:

- Santarus may acquire or develop alternative products (as it did in the third quarter of 2010);
- Santarus may pursue higher-priority programs, or change the focus of its marketing programs;
- Santarus may in the future choose to devote fewer resources to Glumetza;
- Glumetza may fail to achieve greater market acceptance;
- the outcome of our ongoing litigation against Lupin Limited seeking to prevent Lupin from marketing a generic version of Glumetza in the United States;

- the outcome of our ongoing litigation against Sun Pharmaceuticals Industries Ltd. seeking to prevent Sun from marketing a generic version of Glumetza in the United States;
- Santarus may experience financial difficulties; and
- Santarus may fail to comply with its obligations under our commercialization agreement.

In addition to the factors described above, Santarus' business and product revenue have been adversely affected by the introduction of a generic version of its Zegerid® (omeprazole/sodium bicarbonate) prescription products in the third quarter of 2010. Any of the preceding factors could affect Santarus' commitment to the collaboration, which, in turn, could adversely affect the commercial success of Glumetza. Any failure by Santarus to successfully commercialize Glumetza could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Our drug candidate DM-1992 for Parkinson's is in clinical development. We also have other product candidates in earlier stages of development.

Our own product candidates and those of our collaborative partners are subject to the risk that any or all of them may be found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. Additionally, clinical trial results in earlier trials may not be indicative of results that will be obtained in subsequent larger trials, as was the case with the Phase 3 trial for Gralise for the management of postherpetic neuralgia that we completed in 2007, and with the Phase 3 trials evaluating Serada for menopausal hot flashes we completed in October 2011.

Clinical development is a long, expensive and uncertain process and is subject to delays. Positive or encouraging results of prior clinical trial are not necessarily indicative of the results we will obtain in later clinical trials. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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

- negative or inconclusive results;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- FDA inspections of our clinical operations; and
- real or perceived lack of effectiveness or safety of the product candidate.

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We are unable to predict whether any of our product candidates will receive regulatory clearances or be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these other product candidates receive regulatory

clearance, our products may not achieve or maintain market acceptance. Also, substantially all of our product candidates use the Acuform technology. If it is discovered that the Acuform technology could have adverse effects or other characteristics that indicate it is unlikely to be effective as a delivery system for drugs or therapeutics, our product development efforts and our business could be significantly harmed.

# We may incur operating losses in the future.

To date, we have recorded revenues from license fees, product sales, royalties, collaborative research and development arrangements and feasibility studies. For the nine months ended September 30, 2011, we recorded total revenues of \$120.8 million and for the years ended December 31, 2010, 2009 and 2008, we recorded total revenues of \$80.8 million, \$57.7 million, and \$34.8 million, respectively. Collaborative milestones and settlement fees received from Abbott Products, Janssen and Merck resulted in the Company reaching profitability for the nine months ended September 30, 2011 and the year ended December 31, 2010. For the years ended December 31, 2009 and 2008, we incurred net losses of \$22.0 million and \$15.3 million, respectively. We may incur operating losses for the remainder of 2011. Any such losses may have an adverse impact on our total assets, shareholders' equity and working capital.

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

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

- the degree of commercial success of Gralise;
- our efforts to secure a commercialization partner for Gralise;
- announcements and results regarding clinical trial results and plans for our drug candidates;
- filings and other regulatory actions related to our product candidates;
- developments concerning proprietary rights, including patents, infringement allegations and litigation matters;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- the degree of commercial success of Glumetza;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply, or other manufacture or supply difficulties;
- the outcome of our patent infringement litigation against Lupin and Sun for Glumetza;
- variations in revenues obtained from collaborative agreements, including milestone payments, royalties, license fees and other contract revenues;
- market acceptance of the Acuform technology;
- adoption of new technologies by us or our competitors;
- the introduction of new products by our competitors;

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- the status of our compliance with laws and regulations applicable to the commercialization of pharmaceutical products;
- any limitations to access to physician prescription data, which may make our marketing efforts more effective;
- manufacturing costs;
- third-party reimbursement policies; and
- the status of our compliance with the provisions of the Sarbanes-Oxley Act of 2002.

As a result of these factors, our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Additionally, any significant drops in our stock price, such as the ones we experienced following the announcement of our Serada Phase 3 trial results in October 2009 and October 2011, could give rise to shareholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved in our favor.

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

We currently have collaboration or license arrangements with Santarus, Covidien, Merck, Janssen, Boehringer Ingelheim, PharmaNova and Ironwood. In addition, we have in the past and may in the future enter into other collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements.

Collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs.

We may be unable to enter into future collaborative arrangements on acceptable terms, which could harm our ability to develop and commercialize our current and potential future products. Further, even if we do enter into collaboration arrangements, it is possible that our collaborative partners may not choose to develop and commercialize products using the Acuform technology. Other factors relating to collaborations that may adversely affect the commercial success of our products include:

- any parallel development by a collaborative partner of competitive technologies or products;
- arrangements with collaborative partners that limit or preclude us from developing products or technologies;
- premature termination of a collaboration agreement; or

 failure by a collaborative partner to devote sufficient resources to the development and commercial sales of products using the Acuform technology.

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

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

Our existing capital resources may not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to consistently support our operations. We currently do not have any committed sources of capital. To the extent that our capital resources are insufficient to meet our future capital requirements, in order to continue our development programs, we will have to raise additional funds through the sale of our equity securities, through debt financing, or from development and licensing arrangements. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. If adequate funds are not available we may have to:

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

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

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

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

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purpose of determining the priority of inventions in connection with our patent applications or other parties' patent applications. Adverse determinations in litigation or interference proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities to third parties. If we need but cannot obtain a license, we may be prevented from marketing the affected product.

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

We have an exclusive sublicense from PharmaNova, Inc. to a patent held by the University of Rochester to develop and commercialize in the United States a gabapentin product for the treatment of hot flashes associated with menopause. Because a method-of-use patent, such as the patent we have sublicensed from PharmaNova, covers only a specified use of a particular compound, not a particular composition of matter, we cannot prevent others from commercializing gabapentin for other indications for use. Accordingly, physicians can already prescribe another manufacturer's gabapentin to treat hot flashes in menopausal women, or pharmacists could in the future seek to fill prescriptions for Serada with another manufacturer's gabapentin. Although any such "off-label" use could violate our licensed patent, effectively monitoring compliance with our licensed patent and enforcing our patent rights against individual physicians and pharmacies may be ineffective, impractical, difficult and costly. Such competition would reduce sales of Serada and our revenues which could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development and commercialization goals. These milestones may include our expectations regarding the commercial launch of our products by us or our licensees, and the commencement or completion of scientific studies and clinical trials and the submission or approval of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, or the commercial launch of

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products. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary considerably from our estimates depending on numerous factors, some of which are beyond our control, including:

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

- our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;
- other actions by regulators;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including materials for our Acuform technology;
- · our available capital resources; and
- the costs of ramping up and maintaining manufacturing operations, as necessary.

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

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

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

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

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

The regulatory process is expensive and time consuming. Even after investing significant time and expenditures on clinical trials, we may not obtain regulatory approval of our product candidates. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval, and the FDA may not agree with our methods of clinical data analysis or our conclusions regarding safety and/or efficacy. Significant clinical trial delays could 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.

For example, the active ingredients in the products utilizing our Acuform delivery technology that are being developed pursuant to our collaboration with Covidien include acetaminophen in combination with opiates. In connection with concerns that consumers may inadvertently take more than the recommended daily dose of acetaminophen, potentially causing liver damage, an FDA advisory committee has recommended that prescription products containing acetaminophen in combination with prescription analgesics

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(including opiates) should include black box warnings and/or be removed from the market. The FDA is evaluating the recommendations and has indicated that such an evaluation will take some time. The FDA is not required to accept advisory committee recommendations. Covidien's ability or willingness to develop and market the products subject to our collaboration may be adversely affected by actions of the FDA in response to the advisory committee recommendations.

Further, with respect to our approved products, once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of approved products are also subject to ongoing regulation and inspection, including compliance with FDA regulations governing current Good Manufacturing Practices (cGMP). The FDCA, the Controlled Substances Act and other federal and foreign statutes and regulations govern and influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. The failure to comply with these regulations can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, non-renewal of marketing applications or criminal prosecution.

We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns could result in labeling changes, recalls, market withdrawals or other regulatory actions. Recalls may be issued at our discretion or at the discretion of the FDA or other empowered regulatory agencies. For example, in June 2010, we instituted a voluntary class 2 recall of 52 lots of our 500mg Glumetza product after chemical traces of 2,4,6-tribromoanisole or TBA were found in the product bottle. We cannot be certain that the FDA will determine that we adequately addressed the matters that led to this recall or that the FDA will not seek to impose fines or sanctions against us as a result of this recall. Any such fines or sanctions could adversely affect our financial condition and results of operations.

#### We are subject to risks associated with NDAs submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act.

The products we develop generally are or will be submitted for approval under Section 505(b)(2) of the FDCA which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For instance, the NDA for Gralise relies on the FDA's prior approval of Neurontin® (gabapentin), the immediate release formulation of gabapentin initially approved by the FDA. An NDA for Serada would also rely in part on the FDA's prior approval of Neurontin®.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to includes certifications, known as "Paragraph IV certifications," that certify any patents listed in the FDA's Orange Book publication in respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and require us to file such submissions under

Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

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

All marketing activities associated with Gralise and Glumetza, as well as marketing activities related to any other products for which we obtain regulatory approval, will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products. The FDA regulates post-approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. For example, the federal healthcare program anti-kickback 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

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

## We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.

Companies may not promote drugs for "off-label" uses – that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG, the FDA, and DOJ allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. If the OIG or the FDA takes the position that we are not in compliance with such requirements, and, if such non-compliance is proven, we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

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

To market any of our products outside of the United States, we and our collaborative partners, including Janssen, Merck, Boehringer Ingelheim, Ironwood and Madaus, are subject to numerous and varying foreign regulatory requirements, implemented by foreign health authorities, governing the design and conduct of human clinical trials and marketing approval for drug products. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from

that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country, nor does the approval by foreign health authorities ensure approval by the FDA.

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

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

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

If reimbursement is not available for our products or product candidates, demand for these products may be limited. Further, any delay in receiving approval for reimbursement from third-party payers could have an adverse effect on our future revenues. Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty

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exists as to the reimbursement status of newly approved healthcare products, including pharmaceuticals. Our products may not be considered cost effective, and adequate third-party reimbursement may be unavailable to enable us to maintain price levels sufficient to realize an acceptable return on our investment.

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

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

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

Bristol-Myers Squibb is currently marketing a sustained release formulation of metformin, Glucophage XR, with which Glumetza competes. The limited license that Bristol-Myers Squibb obtained from us under our November 2002 settlement agreement extends to certain current and internally-developed future compounds, which may increase the likelihood that we will face competition from Bristol-Myers Squibb in the future on products in addition to Glumetza. Several other companies, including Barr Pharmaceuticals, Inc.,

Mylan Laboratories, Inc. and Teva Pharmaceutical Industries, Ltd. have received FDA approval for and are selling an extended-release metformin product. There may be other companies developing products competitive with Glumetza of which we are unaware.

Gabapentin is currently marketed by Pfizer as Neurontin® for adjunctive therapy for epileptic seizures and for postherpetic pain. Pfizer's basic U.S. patents relating to Neurontin have expired, and numerous companies have received approval to market generic versions of the immediate release product. Pfizer has also developed Lyrica® (pregabalin), which has been approved for marketing in the United States for postherpetic pain, fibromyalgia, diabetic nerve pain and for adjunctive therapy for epileptic seizures. In April 2011, GlaxoSmithKline and Xenoport, Inc.'s Horizant<sup>TM</sup> (gabapentin enacarbil extended-release tablets) received FDA approval in the United States for restless leg syndrome. There may be other companies developing products competitive with Gralise of which we are unaware.

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

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

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

Patheon is our sole supplier for Gralise pursuant to a manufacturing and supply agreement we entered into with Patheon in September 2011 and our sole supplier of Serada. Any failure to obtain Gralise tablets from Patheon, active pharmaceutical ingredient from suppliers, or excipient suppliers, could adversely affect our operating results.

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

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## A successful product liability claim against us could materially harm our business.

Our business involves exposure to potential product liability risks that are inherent in the development and production of pharmaceutical products. We have obtained product liability insurance for clinical trials currently underway and forecasted 2011 sales of our products, but:

- we may be unable to obtain product liability insurance for future trials;
- we may be unable to obtain product liability insurance for future products;

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

Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business. If third parties were to bring a successful product liability claim or series of claims against us for uninsured liabilities or in excess of insured liability limits, our business, financial condition and results of operations could be materially harmed.

Our success is dependent in large part upon the continued services of our CEO and senior management with whom we do not have employment agreements.

Our success is dependent in large part upon the continued services of our President and Chief Executive Officer, James A. Schoeneck, and other members of our executive management team, and on our ability to attract and retain key management and operating personnel. We do not have agreements with Mr. Schoeneck or any of our other executive officers that provide for their continued employment with us. We may have difficulty filling open senior scientific, financial and commercial positions. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates.

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

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

## We have implemented certain anti-takeover provisions.

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

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

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

Changing laws, regulations and standards relating to corporate governance, public disclosure and compliance practices, including the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating uncertainty for companies such as ours in understanding and complying with these laws, regulations and standards. As a result of this uncertainty and other factors, devoting the necessary resources to comply with evolving corporate governance and public disclosure standards has resulted in and may in the future result in increased general and administrative expenses and a diversion of management time and attention to compliance activities. We also expect these developments to increase our legal compliance and financial reporting costs. In addition, these developments may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. Moreover, we may be unable to comply with these new rules and regulations on a timely basis.

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

If we sell shares of our common stock in future financings, existing common shareholders will experience immediate dilution and, as a result, our stock price may go down.

As capital raising opportunities present themselves, we may enter into financing arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common shareholders will experience dilution and this dilution will be greater if we find it necessary to sell securities at a discount to prevailing market prices.

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

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

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

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

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

Not applicable.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not	ann	licable.
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# ITEM 4. RESERVED

Not applicable.

## ITEM 5. OTHER INFORMATION

Not applicable.

# **ITEM 6. EXHIBITS**

(a)	Exhibits	
	10.1*	Commercial Manufacturing Services Agreement dated September 2, 2011 between the Company and Patheon
		Puerto Rico, Inc.
	10.2*	Commercialization Agreement dated August 22, 2011 between the Company and Santarus, Inc.
	31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of James A. Schoeneck
	31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Tammy L. Cameron
	32.1	Certification pursuant to 18 U.S.C. Section 1350 of James A. Schoeneck
	32.2	Certification pursuant to 18 U.S.C. Section 1350 of Tammy L. Cameron
	101	Interactive Data Files pursuant to Rule 405 of Regulation S-T
*	* Confident	tial Treatment Requested

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# **SIGNATURES**

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

Date: November 7, 2011 DEPOMED, INC.

/s/ James A. Schoeneck

James A. Schoeneck

President and Chief Executive Officer

/s/ Tammy L. Cameron

Tammy L. Cameron Vice President, Finance

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CERTAIN MATERIAL (INDICATED BY [\*\*\*]) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Patheon Puerto Rico, Inc. and Depomed, Inc.

#### COMMERCIAL MANUFACTURING SERVICES AGREEMENT

THIS COMMERCIAL MANUFACTURING SERVICES AGREEMENT, including all schedules attached hereto (collectively, the "Agreement") is effective as of June 1, 2011 (the "Effective Date"), by and between Patheon Puerto Rico, Inc. ("Patheon"), a corporation organized under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Villa Blanca Industrial Park, State Road No. 1, Km. 34.8, Jose Garrido Avenue, Caguas, Puerto Rico 00725 and at State Road 670, Km 2.7, State Road 670 Km 2.7, Manatí, Puerto Rico 00674, and Depomed, Inc. ("Depomed"), a corporation organized under the laws of the State of California, having its principal place of business at 1360 O' Brien Drive, Menlo Park, California 94025. Patheon and Depomed each is referred to herein as a "Party" and collectively as the "Parties."

# WITNESSETH:

WHEREAS, Patheon is in the business of providing contract manufacturing services to the pharmaceutical industry and desires to provide such services to Depomed;

WHEREAS, Depomed desires to engage Patheon to provide certain of such services; and

WHEREAS, Patheon and Depomed have agreed upon a contract pursuant to which Patheon would provide manufacturing and packaging services for the Product (as hereinafter defined) for Depomed pursuant to the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the foregoing premises, which are hereby incorporated as a substantive part of this Agreement, and in consideration of the performance of the mutual covenants and promises herein contained, Patheon and Depomed, intending to be legally bound, agree as follows:

#### **ARTICLE 1 – DEFINITIONS**

The following terms not defined elsewhere in this Agreement have the following respective meanings. Terms defined in plural shall include the singular and vice-versa.

"Act" means the *Federal Food, Drug, and Cosmetic Act*, together with all regulations promulgated thereunder, including without limitation cGMPs, in each case as amended from time to time.

"Active Pharmaceutical Ingredient" or "API" means the substance having the name of gabapentin.

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"Affiliates" means, with respect to either Party, all corporations or other business entities that, directly or indirectly, are controlled by, control or are under the common control with that Party. For this purpose, the meaning of the word "control" shall mean having the ability substantially to direct the affairs or management of an entity, including, but not be limited to, ownership of more than fifty percent (50%) of the voting shares or interest of such corporation or other business entity.

"Annual Volume" means that volume of Product to be manufactured in any Year of this Agreement, as set forth in Schedule B.

"API Credit Value" means the value to be attributed to the API for certain purposes of this Agreement, as set forth in Schedule E.

"<u>Applicable Laws</u>" means all laws, statutes, ordinances, regulations, rules, judgments, decrees or orders of any Authority, including, but not limited to, the Act and cGMPs, to the extent applicable to the subject matter of, or the performance by, the Parties of their respective obligations under this Agreement.

"<u>Authority</u>" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, including, but not limited to, the FDA.

"Batch" means a batch of the Product.

"<u>Batch Records</u>" means the executed manufacturing instructions, batch production records, the executed packaging order, the analytical testing results and any other manufacturing related document, such as deviation or investigation reports.

"Bill-Back Items" means the expenses for all third party supplier fees for the purchase of columns, standards, tooling RFID tags and supporting equipment, and other project specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Materials or subject to the Capital Expenditure and Equipment Agreement. Bill-Back Items will be charged to Depomed at Patheon's cost plus a [\*\*\*] handling fee.

"Business Day" means any day other than a Saturday, Sunday or public holiday in the USA.

"Certificate of Analysis" means documented test results, in written form, executed by an authorized responsible person employed by Patheon, that demonstrate compliance of Product to the Specifications.

"cGMPs" means current and applicable good manufacturing practice requirements established in 21 C.F.R. Parts 210 and 211, as amended from time to time, and other applicable FDA policies, guidelines, and advisory opinions, in effect at the time a Batch of Product is manufactured.

"Conforming" or "Conformity," with respect to Product, means Product (a) that was manufactured, packaged and labeled in accordance with cGMPs, other Applicable Laws, the Master Batch Record, applicable standard operating procedures of Patheon, the Packaging Instructions, and

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any other directions or protocols agreed upon by the Parties, in writing (b) for which the associated Lot Documentation Package has been provided to Depomed, along with any other documentation required hereunder to be provided to Depomed by such time, and (c) that, at the time of Delivery, conforms to the Specifications.

"Control" or "Controlled" means, with respect to a Party's rights to Intellectual Property, that the Party owns or has a license to such Intellectual Property and has the ability to grant to the other Party a license to such Intellectual Property, as provided for herein, without violating the terms of any agreement or other arrangement with any third party existing at the time such Party would be first required hereunder to grant the other Party such license.

"<u>Dedicated Equipment</u>" means the Dedicated Equipment set forth in Exhibit A of the Capital Expenditure and Equipment Agreement attached hereto as Schedule D, as it may be amended from time to time by the Parties, pursuant to its terms.

"<u>Depomed Intellectual Property</u>" means any and all Intellectual Property Controlled by Depomed or its Affiliates that is necessary or useful to perform the Manufacturing Services, or that covers the Product, including but not limited to the composition of matter of the Product and methods of using, manufacturing, and/or administering the Product.

"<u>Deliver</u>" or "<u>Delivery</u>," with respect to Product, means delivery by Patheon to a common carrier, as provided in Section 2.2.1.

"Equipment" means the Dedicated Equipment and the Non-Dedicated Equipment.

"FDA" means the United States Food and Drug Administration.

"<u>Intellectual Property</u>" means all intellectual property rights, including, without limitation, patents, patent applications, formulae, trademarks, trade names, Inventions, works of authorship, copyrights, industrial designs, and registrations and applications for registration of any of the foregoing.

"Invention" means any information, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable.

"Latent Defect," (a) with respect to the Product, means a defect that results in the Product's being Nonconforming, which was not discoverable, through a commercially reasonable inspection conducted in accordance with Section 5.3 and was not known to Depomed at the time it accepted such Product, and (b) with respect to API, means API that failed, at the time of receipt by Patheon, to conform to the specifications therefor or to, which failure was not discoverable through an inspection of the API in accordance with such specifications and agreed upon test methods and was not known to Patheon at the time it was used to manufacture Product.

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"Lot Documentation Package" has the meaning given in Section 2.1(c)(ii).

"Manufacturing Services" means the process validation, manufacturing, quality control, quality assurance, stability testing, packaging, and related services to be performed under this Agreement with respect to the Product.

- "Master Batch Record" or "MBR" means the master batch record most recently upon by the Parties, in writing, that describes how the Product is to be manufactured.
- "<u>Materials</u>" means all materials and components, other than API, that are necessary for the manufacture or packaging of Product, including but not limited to excipients and other raw materials, labels and packaging components.
- "Maximum Credit Value" means the maximum value of API that may be credited by Patheon under this Agreement as set forth in Section 5.6.5 and Schedule E.
- "Minimum Run Quantity" means the minimum number of Batches to be produced during the same cycle of manufacturing as set forth in Schedule B.
- "NDA" means the New Drug Application for the Product to be submitted to the FDA by Depomed, including any amendments and supplements thereto.
  - "Nonconforming," or "Nonconformity," with respect to Product, means Product that is not Conforming.
- "Non-Dedicated Equipment" means the Non-Dedicated Equipment, as set forth in Exhibit A of the Capital Expenditure and Equipment Agreement as of the Effective Date and at any time during the term of the Agreement pursuant to any amendment of Exhibit A implemented pursuant to Section 6.5.
- "Packaging Instructions" means instructions for the packaging of Product agreed upon by the Parties as provided in Section 2.1(f) and Schedule B.
- "Patheon Facility" means the Patheon manufacturing facility located at Villa Blanca Industrial Park, State Road No. 1, Km. 34.8, Jose Garrido Avenue, Caguas, Puerto Rico 00725 (the "Caguas Facility"), and at State Road 670, Km 2.7, State Road 670 Km 2.7, Manatí, Puerto Rico 00674 (the "Manati Facility"), or any other facility operated by Patheon and agreed upon by the Parties, pursuant to Section 3.6.
- "Patheon Intellectual Property" means any and all Intellectual Property Controlled by Patheon or its Affiliates that is necessary or useful to perform the Manufacturing Services or that otherwise covers the Product, including but not limited to the composition of matter of the Product, or a method of using, manufacturing, or administering the Product.

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- "Post-Validation Product" means Product manufactured following Patheon's validation of its scaled-up manufacturing process, as described in Section 2.1(a).
- "Product" means the finished pharmaceutical product known as GRALISE (gabapentin) for PHN, in a formulation and at a dosage, which is the subject of Investigational New Drug application No. 71, 439 and NDA No. 22-544. For clarity, the Product may be supplied under this Agreement in bulk tablet form or packaged and labeled for use commercially, as samples or as otherwise agreed by the Parties in writing, and in accordance with the applicable Purchase Order.

"Purchase Order" means a numbered, written order for the Product that states the quantity, packaging configuration, and requested delivery date(s) for such Product, and any other facts necessary to ensure the timely and correct manufacture, packaging, labeling, and shipment of the Product so ordered.

"Quality Agreement" means the quality agreement attached hereto as Schedule C.

"Recall" means any (a) action by Depomed, its Affiliates or its authorized licensees or Marketing Partner(s) to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, any recall, field correction, or voluntary withdrawal of Product from the market); (b) action, request, directive or order by any Authority to detain or destroy, or conduct a recall, field correction, or voluntary withdrawal with respect to any Product or to distribute a "Dear Doctor" letter or its equivalent, regarding use of the Product; or (c) action by Depomed, its Affiliates or licensees to refrain from selling or shipping quantities of the Product to third parties which would have been subject to a recall, field correction, or voluntary withdrawal if sold or shipped.

"Specifications means the specifications for the Product, its packaging and its labeling, including those attached hereto as Schedule A and those added thereto by mutual written agreement of the Parties during the term of this Agreement. Schedule A may be amended from time to time as required and as authorized, in writing, by Depomed.

"Territory" means the USA, each of its territories, districts and possessions and the commonwealth of Puerto Rico.

"Third Party Rights" has the meaning given in Section 8.3.

"USA" means the United States of America.

"<u>Validation Product</u>" means Product manufactured prior to Patheon's completion of process validation, as described in Section 2.1(a).

"Year" means a calendar year.

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#### ARTICLE 2 – MANUFACTURING SERVICES AND RESPONSIBILITIES

- **2.1** <u>Manufacturing Services</u>. Patheon will perform the Manufacturing Services for Depomed, at the Patheon Facility. Such Manufacturing Services shall include the following.
  - (a) <u>Process Validation</u>. Patheon will validate the current Product manufacturing process according to cGMPs, as agreed upon and detailed in the Process Validation Proposal (Patheon proposal number DPM-CCG1-11-0410-R1 and Depomed Purchase Orders 10927 and 10936).
  - (b) <u>Product Manufacture</u>. Patheon will manufacture Product for purposes of supplying Product to Depomed, for commercial and other lawful use in the Territory, in accordance with the terms and conditions herein. All manufactured Product must meet specifications and criteria as set forth in the process validation protocol.
  - (c) Quality Control and Quality Assurance.

- (i) Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release for shipment to Depomed will be the responsibility of Patheon's quality assurance group. (Subject to Patheon's obligations under this Agreement, Depomed will be responsible for the release of Product to the market.) Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures, which are subject to Depomed audit review.
- (ii) Each time Patheon releases a Batch, and prior to shipment of the Batch, Patheon shall provide Depomed with the Certificate of Analysis and certificate of compliance for the Batch, including, but not limited, to a statement that the Batch has been manufactured and tested in accordance with cGMPs and Applicable Laws and conforms to the Specifications, and any deviation reports (collectively, the "Lot Documentation Package"). Patheon shall retain ownership of the (A) Batch Records, including, but not limited to, batch production, lot packaging, equipment set-up control and operating parameters records, data printouts, and raw material data, and (B) laboratory notebooks prepared by Patheon, shall be the exclusive property of Patheon; provided that Patheon hereby grants Depomed a perpetual, fully paid-up, royalty-free, worldwide, irrevocable, unencumbered right and license to use, and to grant to third parties the right to use, the foregoing in connection with the development, manufacture, testing, seeking of regulatory approval, and commercialization of Product. Notwithstanding anything to the contrary herein, the Parties agree that any and all specific Product related information contained in such documents (the "Product Information") shall be the sole property of Depomed, subject only to a limited right by Patheon to use the Product Information to provide the Manufacturing Services in accordance with the terms and conditions herein. To the extent that any rights in the Product Information do not automatically vest in Depomed by the terms of this Agreement, Patheon hereby irrevocably and unconditionally assigns and agrees to

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- assign to Depomed all of Patheon's rights, title, and interest in and to such Product Information, including any Intellectual Property therein.
- (d) <u>Supply of Materials</u>. Patheon shall supply all Materials, at Patheon's expense. Patheon shall purchase the Materials from vendors that have been pre-approved by Depomed, in writing, and shall not change any vendors of packaging components or excipient materials without prior written approval from Depomed. Patheon shall be responsible for sampling, inspecting, testing and releasing Materials, in accordance with the terms and conditions of this Agreement.
- (e) Stability Testing. Patheon will conduct stability testing of the Product, for separately-charged fees, in accordance with a written scope of work, which is minimally defined in the stability commitment per the applicable NDA to be agreed upon by the Parties at a future date, and which shall be made subject to the terms and conditions of this Agreement. Patheon will not make any changes to such testing protocols without prior written approval from Depomed. If a confirmed stability test failure occurs, Patheon will notify Depomed within one (1) Business Day, after which Patheon and Depomed will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including, but not limited to, which Party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with cGMPs or other Applicable Laws, or to supply Product that is Conforming. Patheon will give Depomed all stability test data and results, at Depomed's request.

- (f) Packaging. Patheon will package the Product as set out in the Specifications. Depomed will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Batch shipped. The batch numbers and expiration dates will be affixed on the Product and on each shipping carton of Product, as outlined in the Specifications and as required by cGMPs. Depomed may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Product. Depomed will be responsible for submitting such changes to Authorities responsible for the approval of the Product. Depomed also will be responsible for the cost of labelling obsolescence when changes are made. Patheon's name will not appear on the Product or its labeling or packaging, except to the extent (i) required by Applicable Laws or (ii) agreed upon by the Parties, in writing.
- (g) <u>Bill Back Items</u>. Patheon shall obtain Depomed's written approval before ordering any Bill-Back Item. Depomed shall reimburse Patheon for the actual cost of Bill-Back Items, plus a [\*\*\*] handling fee.
- (h) <u>Product Rejection for Specification Failure</u>. Internal process specifications will be defined and agreed upon by the Parties, in writing. If Patheon manufactures Product in accordance with such agreed-upon process specifications, and a Batch or portion of a Batch does not meet the Specifications, Patheon will immediately notify Depomed and Depomed and Patheon shall meet and discuss in good faith to correct apparent Product deficiencies at Patheon's expense.

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(i) Transfer to Manati Facility. Patheon shall be responsible for the transfer of the Product manufacturing process from the Caguas Facility to the Manati Facility. Depomed will be responsible for completing all required Product-related regulatory filings. Patheon will manufacture Product at the Caguas Facility until such transfer to the Manati Facility is complete, all regulatory approvals or clearances required to market Product manufactured at the Manati Facility have been obtained, and all of Depomed's Product requirements will be met by Product manufactured at the Manati Facility. The parties will work in good faith to expedite the transfer process.

Notwithstanding any other provision of this Agreement (or the Capital Expenditure and Equipment Agreement or the Quality Agreement) to the contrary, any and all expenses associated with the transfer contemplated this Section 2.1(i) shall be borne by Patheon.

## 2.2 API Supply.

2.2.1 <u>Timing and Method of Delivery</u>. At least [\*\*\*] days before (a) the scheduled production date, in the case of Validation Product, and (b) the start of each calendar month, in the case of Post-Validation Product, Depomed will deliver to the Patheon Facility, DDP (Incoterms 2010), free of charge, API in such quantities as Depomed reasonably believes are sufficient to enable Patheon to manufacture the required quantities of Product. Each shipment of API shall be accompanied by a certificate of analysis from the API manufacturer confirming the identity, purity, and compliance with specifications covering such API that have been approved by Depomed, in writing. Patheon shall verify the quantity of each batch of API received and will release the batch based on tests of conformance detailed in the specifications for the API.

## 2.2.2 Failure of Timely Delivery.

(a) If the API required for Product manufacture is not received within the applicable time-period provided in section 2.2.1, Patheon may delay the shipment of such Product as necessary as a result of the delay, such delay not to exceed the number of days of the delay in receipt of the API, and if Patheon is unable to manufacture the Product in time to meet such revised shipment date, due to

prior third-party production commitments, Patheon may further delay such shipment for a period of time sufficient to enable Patheon to fulfill such prior third-party commitments, and the Parties shall agree, in writing, on a revised shipment date.

- (b) The failure of Depomed to supply API shall not give rise to a right to terminate this Agreement or to any cause of action by Patheon, but shall stand as sufficient justification of Patheon's inability to Deliver Product, as set forth in Section 2.2.1., without any further consequences to Patheon, to the extent such inability to Deliver is a direct result of such failure to supply API by Depomed.
- **2.2.3** Patheon's Responsibility for API; Title. API received from Depomed will be held by Patheon, on behalf of Depomed. Title to the API, all work in progress to manufacture the Product, and all Product in possession or under the control or responsibility of Patheon, shall at all times remain in Depomed and, to the extent such rights do not automatically vest in Depomed by the nature of this Agreement, Patheon hereby assigns to Depomed all such rights; provided, however, Patheon shall be liable for any loss or damage caused directly or indirectly by Patheon due to Patheon's negligence,

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willful misconduct, or breach of this Agreement subject to Section 8.2 and to Section 5.6 in the case of API.

Except as set forth in Section 5.6, Patheon shall use the API only to perform Manufacturing Services and for no other purpose.

### ARTICLE 3 - FORECASTS AND ORDERS FOR PRODUCT

## 3.1 [\*\*\*] Month Forecasts.

- 3.1.1 <u>Initial Forecast.</u> Within one (1) month after the Effective Date, Depomed will give Patheon a non-binding, initial, [\*\*\*] forecast of the quantity of Product (i.e., the number of tablets and, where applicable, bottles in which they will be contained) that Depomed expects to order during the following [\*\*\*]. Such initial forecast will be updated by Depomed (i) on or before the date on which Depomed files the NDA and (ii) within [\*\*\*] prior to the expected grant of approval of the NDA by the FDA.
- 3.1.2 Rolling Monthly Forecast. Contemporaneously with the first delivery of a Purchase Order under Section 3.4, Depomed will give Patheon a non-binding, [\*\*\*] rolling forecast of the quantity of Product that Depomed expects to order during the following [\*\*\*] (the "Forecast"). The Forecast will be updated by Depomed on or before the fifteenth day of each month thereafter, so that it covers each subsequent [\*\*\*] time-period. Depomed will update the Forecast on a more frequent basis if it determines that the quantity of Product it will require in the following months has changed by more than [\*\*\*] from that provided in most recently updated Forecast.
- **3.2** [\*\*\*] Year Forecast. On or before the [\*\*\*] during the term of this Agreement, Depomed will give Patheon a written, non-binding [\*\*\*] forecast of the quantity of Product that Depomed expects to order during such [\*\*\*].

## 3.3 Firm Orders.

- **3.3.1** For First Shipment of Post-Validation Product.
- (a) Except as otherwise contemplated by Section 3.3(d), at least [\*\*\*] before the anticipated start of manufacture of Post-Validation Product, Depomed will update the Forecast for the first [\*\*\*] of such Post-Validation Product manufacture. Subject to

subsection (b), below, the [\*\*\*] of such updated Forecast will constitute a firm order (the "First Firm Order") by Depomed to purchase and by Patheon to manufacture and Deliver the quantity of Product that is the subject of the First Firm Order, in accordance with the terms and conditions herein. Notwithstanding the foregoing provisions of this Section 3.3(a), Product subject to Depomed purchase orders [\*\*\*] lots of Gralise <sup>M</sup> 300mg and [\*\*\*] lots of Gralise <sup>M</sup> 600mg will be delivered not later than [\*\*\*] for bulk product and [\*\*\*] for Bottled Product and [\*\*\*] lot of Gralise <sup>M</sup> 300mg and [\*\*\*] lots of Gralise <sup>M</sup> 600mg will be Delivered not later than [\*\*\*].

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- (b) If the manufacturing has not started Depomed may cancel any or all of the First Firm Order upon delivery of notice of cancellation to Patheon, (i) at no cost to Depomed, if such notice is delivered not later than [\*\*\*] before the scheduled delivery date of the Product covered by the First Firm Order, or (ii) at a cost of [\*\*\*] per cancelled Batch, if such notice is delivered not later than [\*\*\*], but less than [\*\*\*] before such scheduled delivery date. The Parties agree that such payment will be considered liquidated damages for Patheon's loss of manufacturing and will not be considered a penalty. If Depomed so cancels any part of the First Firm Order, the Forecast (and the First Firm Order) will be adjusted accordingly, at such time.
- (c) <u>Firm Orders Thereafter</u>. After the Initial Manufacturing Month, on a rolling basis during the term of this Agreement, and on or before the [\*\*\*] day of each month, Depomed will issue an updated [\*\*\*] forecast that starts with the next calendar month. The first [\*\*\*] of that updated forecast will constitute a firm written order in the form of a purchase order or otherwise ("**Firm Order**") by Depomed to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products on a date not less than [\*\*\*] following the date that the Firm Order is submitted.
- **3.3.2** For Subsequent Shipments. Upon Delivery of Product pursuant to the First Firm Order and thereafter, Patheon will use commercially reasonable efforts to supply Depomed up to [\*\*\*] of the total quantity of Product forecasted for such [\*\*\*] period (the "Maximum Firm Order").

## 3.4 Purchase Orders.

**3.4.1** For Validation Product. Deponded has already submitted Purchase Order(s) for Validation Product. Patheon shall Deliver all such Validation Product so ordered by Deponded within the time frames requested in such Purchase Orders, in accordance with the terms and conditions of this Agreement.

#### **3.4.2** For Post-Validation Commercial Product.

(a) Except as set forth in Section 3.3 with respect to the First Firm Order, Depomed will provide Patheon with each Purchase Order for Post-Validation Product not less than [\*\*\*] prior to the delivery date requested in such Purchase Order. Patheon shall supply all quantities of Product covered by such the Purchase Order and will use commercially reasonable efforts to supply any amounts of Product ordered in excess of the Firm Order. Within [\*\*\*] days after receipt of each such Purchase Order, Patheon shall provide Depomed with written confirmation of the Purchase Order and shall notify Depomed of Patheon's requirements for API to manufacture and package the Product to be supplied pursuant to such Purchase Order. In addition, Patheon shall notify Depomed of the corresponding needs for API for each month of the Firm Orders.

# 3.5 Reliance by Patheon.

**3.5.1** Deponded understands and acknowledges that Patheon will rely on the Maximum Firm Orders and Forecasts in ordering Materials sufficient to meet the Purchase Orders. In addition, Deponded understands that, to ensure an orderly supply of the

Materials, Patheon may want to purchase the Materials in sufficient volumes to meet the production requirements for Product during the ensuing

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[\*\*\*] of the Forecast or to meet the production requirements of any longer period agreed to by Patheon and Depomed, in writing. Accordingly, Depomed authorizes Patheon to purchase Materials sufficient for it to supply all Product forecasted for the [\*\*\*] of the most recent Forecast given by Depomed under Section 3.1. Patheon may make other purchases of Materials to meet anticipated manufacturing requirements, based on forecasts for longer periods, if agreed to in writing by the Parties. Depomed has authorized Patheon to order Materials for any launch quantities of Product requested by Depomed. If Materials ordered by Patheon to meet Depomed's Purchase Orders issued in accordance with Section 3.4.2 or as permitted under this Section 3.5.1 are not included in Product manufactured prior to their expiration dates through no fault of Patheon, then Depomed will pay to Patheon all costs incurred by Patheon for the purchase and handling of such Materials. Patheon shall promptly notify Depomed of the identity of any Materials that have been purchased in accordance with this Section 3.5 and that have expired or become obsolete, and any costs to be charged to Depomed therefor, in accordance with this Section 3.5. Reimbursement of such costs by Depomed shall be due, where applicable, within [\*\*\*] after its receipt of Patheon's reconciliation report and calculation of such costs prepared in accordance with Section 5.6. Patheon shall provide pricing information sufficient to show the costs of such Materials, where reimbursement is requested by Patheon.

- 3.5.2 If Depomed fails to take possession or to arrange for the delivery or destruction of any (a) Materials for which Depomed has paid Patheon's costs pursuant to Section 3.5.1 or (b) Product, within [\*\*\*] after such payment for Materials or manufacture of such Product, then, upon at least [\*\*\*] written notice to Depomed, (i) Patheon will destroy such Materials and will charge Depomed for its reasonable costs of such destruction, and (ii) Depomed will pay Patheon [\*\*\*] per pallet for Product that does not contain controlled substances or require refrigeration or [\*\*\*] per pallet for Product that contains controlled substances or requires refrigeration, per month thereafter, for storing such Product. Patheon may ship Product held by it longer than [\*\*\*] to Depomed, at Depomed's reasonable expense, on [\*\*\*] written notice to Depomed.
- 3.6 Second Source. The Parties acknowledge that Depomed may obtain Product from one or more third parties during the term of this Agreement and that Depomed shall be entitled, at any time, in its discretion, to qualify a second source for manufacturing Product. Depomed shall give Patheon notice at the time of initiation of qualification of a Second source. If Depomed appoints a third party as a second-source-supplier of Product, (a) Patheon shall, at Depomed's expense, provide reasonable assistance to enable the establishment of such second source, including without limitation, providing any and all documents necessary or useful in connection therewith to Depomed, and (b) [\*\*\*]. Notwithstanding the foregoing, Patheon shall notify Depomed promptly upon determining that it will not, for any reason, Deliver in any [\*\*\*] period, Conforming Product in quantities of at least [\*\*\*] of the quantities of Product ordered by Depomed during such [\*\*\*] period in accordance with Section 3.4, and, in addition to any other rights Depomed may have, if Patheon so notifies Depomed, or if Patheon otherwise fails to Deliver such quantities of Product in such [\*\*\*] period, the requirement that [\*\*\*], as provided in the preceding sentence shall not apply.

## **ARTICLE 4 - PRODUCT DELIVERY**

**4.1 Shipment Authorization**. Deposed will determine when Product released by Patheon will be shipped, following its review of the relevant Lot Documentation Package provided in accordance with

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Section 2.1(c)(ii). Patheon shall not Deliver the Product until Depomed has authorized its Delivery, in writing.

4.2 Manner of Delivery. Promptly upon receipt of Depomed's authorization for the Delivery of Product, in accordance with Section 4.1, Patheon shall have the Product shipped to Depomed or its designee, as indicated on the relevant Purchase Order, FCA (Incoterms 2010), the Patheon Facility, unless the Parties have agreed otherwise, in writing. Patheon will, in accordance with Depomed's instructions and as agent for Depomed, (a) arrange for shipping to be paid by Depomed and (b) at Depomed's expense, obtain any official authorization necessary to export the Product for Delivery. Depomed will arrange for insurance and will select the freight carrier used by Patheon to ship the Product and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Product will be transported in accordance with Depomed's written shipping instructions.

#### ARTICLE 5- QUALITY

- **5.1 Quality Control**. Patheon shall ensure that all Product supplied to Depomed is Conforming and that Depomed timely receives all documentation required hereunder in connection therewith. In addition, Patheon and Depomed shall comply with their respective obligations under the Quality Agreement.
- **Deviations**. Patheon will diligently track all deviations associated with the Product. Patheon shall be responsible for investigating, resolving, and documenting deviations from Batch Records, cGMPs and Specifications and reporting such matters to Depomed promptly and regularly. Patheon will notify Depomed of any Significant Deviations (as defined below) within [\*\*\*] of occurrence, according to standard operating procedures pre-approved in writing by Depomed. Patheon shall ensure that appropriate investigations are conducted in accordance with such standard operating procedures. Patheon shall provide quality assurance approval for all investigations and corrective and preventive action plans, all of which shall be shared in advance with Depomed and shall be subject to the written approval of Depomed, which shall not be unreasonably withheld. For purposes of this Agreement "Significant Deviation" means any deviation that (a) has an immediate or probable wide-ranging impact on a cGMP product, process or system in any facility where activities are conducted pursuant to this Agreement, (b) could result in significant Product safety or efficacy risk (e.g., sterility failure or data integrity issues), (c) would require notification to an Authority, or (d) would otherwise be considered by a reasonable quality assurance professional to be significant.

# 5.3 **Product Rejection**.

### **5.3.1** Timing and Notice.

(a) Except with respect to Product with a Latent Defect, Deponded shall have (i) [\*\*\*] from the date on which Deponded or its designee received a Batch or (ii) [\*\*\*] from the date on which Deponded received the complete Lot Documentation Package for such Batch, whichever is earlier, to reject all or part of such Batch because it is Nonconforming.

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(b) Depomed shall have [\*\*\*] following the date of discovery of a Latent Defect in the Product to reject such Product, provided, however, that Depomed may not reject any Product or make a claim that it is Nonconforming more than [\*\*\*] after the Product's expiration date.

- (c) A Product rejection shall be made effective by Depomed or its designee giving Patheon a written notice (a "**Deficiency Notice**"), within the time period permitted under Section 5.3.1(a) or (b), as applicable, which specifies the manner in which the Product is Nonconforming. Should Depomed or its designee fail to provide Patheon with a Deficiency Notice for Product within the applicable time period, such Product shall be deemed to have been accepted.
- **5.3.2** Defect Due to API. If any rejected Product failed, at the time of Delivery, to meet the Specifications, due to a Latent Defect in the API used to manufacture it, Patheon shall be entitled to the Production Fees for such Product and the costs of any tests reasonably employed by Patheon to determine the defect in the API.
- **5.3.3** Remediation of Rejected Product. Upon rejection of any Batch, Depomed or its designee may require, at its option, rework in accordance with procedures spelled out in the NDA, destruction, or replacement of the Batch. Costs associated with such rework, destruction or replacement shall be borne by Patheon, if the Batch was Nonconforming.
- **5.3.4** Payment Adjustments. If Depomed rejects Product pursuant to Section 5.3.1 before the date on which payment therefor is due pursuant to Sections 6.1 and 6.2, Depomed may withhold payment for that Product. If Depomed timely rejects Nonconforming Product after payment therefor has been made, Depomed shall be entitled to recoup all costs incurred in connection therewith, including the amount paid to Patheon therefor, as well as all associated shipping costs borne by Depomed within [\*\*\*] of rejection. Such recoupment shall be made, at Depomed's election: (a) by Patheon's issuing a prompt refund or (b) by Depomed's offsetting such amount against the payment of future invoices for Product. Payments for all Product that Depomed rejects but that is later agreed or determined pursuant to Section 5.4 to be Conforming shall be paid to Patheon within [\*\*\*] following the later of the date on which such determination is made or, if applicable, the date such determination is relayed to Depomed.
- **Disputes Regarding Conformity**. If Patheon and Depomed fail to agree on whether any rejected Product is Nonconforming, upon request by either Party, samples of such Product and any relevant documentation shall be submitted to an independent testing laboratory that is compliant with FDA regulations and guidelines, or, if the dispute relates to another item of compliance with the Specifications, an independent expert of recognized repute within the United States pharmaceutical industry, as applicable (the "**Laboratory**"), agreed upon by the Parties, in writing (such agreement not to be unreasonably withheld or delayed by either Party). The determination of the Laboratory shall be final and binding upon the Parties. The fees and expenses of the Laboratory shall be paid by the Party against which the determination is made. Patheon shall not destroy any rejected Product as to which there exists a dispute, until such dispute has been resolved.

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Access to the Patheon Facility by Depomed Representatives. Upon reasonable advance notice, Patheon shall permit Depomed representatives to enter the Patheon Facility during regular business hours for the purpose of making quality control inspections of (a) the facilities used in the manufacture of Product and (b) the Equipment, during the period it is used in connection therewith. Any such Depomed representatives shall be advised of the confidentiality obligations of Article 7 and shall follow such security and facility access procedures as are reasonably designated by Patheon in advance of such inspections. Patheon may require that, at all times at the Patheon Facility, Depomed representative be accompanied by a Patheon representative and that Depomed representatives not enter areas of the facility used in production of the Product at times other than when production is occurring, to ensure the protection of Patheon's or a third party's confidential information.

#### 5.6 API Yield Calculation.

**5.6.1** Monthly Reporting. Patheon shall provide Depomed with a monthly inventory report, within [\*\*\*] Business Days after the end of each month, of the API held by Patheon, which shall be substantially in the form of the inventory report form annexed hereto as Schedule F. The report shall contain the following information for such month:

"Quantity Received," which shall mean the total quantity of API in Patheon's possession that complies with the specifications for the API when received at the Patheon Facility.

"Quantity Dispensed," which shall mean the total quantity of API dispensed at the Patheon Facility during the applicable month. The Quantity Dispensed is calculated by adding the Quantity Received to the existing inventory of API that complied with the specifications for API upon receipt by Patheon and is held at the beginning of the applicable month, less the inventory of API that is held by Patheon at the end of such month. The Quantity Dispensed shall only include API received and dispensed in connection with the manufacture of Product and shall not include any API (a) that must be retained by Patheon as samples, pursuant to this Agreement, the Quality Agreement or Applicable Laws, (b) contained in Product that must be retained as samples pursuant to this Agreement, the Quality Agreement or Applicable Laws, (c) used in connection with testing, by or on behalf of Patheon or Depomed, in the performance of this Agreement or the Quality Agreement (if applicable) and (d) dispensed at Depomed's request in connection with technical transfer activities or development activities during the applicable period, including, without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period and required in the performance of this Agreement, the Quality Agreement or pursuant to Applicable Laws.

"Quantity Converted," which shall mean the total quantity of API contained in Product produced with the Quantity Dispensed and delivered to Depomed, other than Product that was rejected, recalled or returned in accordance with Section 5.3, as a result of a failure by Patheon to provide Manufacturing Services and/or Product in accordance with this Agreement or the Quality Agreement.

**5.6.2** <u>Annual Reconciliation Reports</u>. Within [\*\*\*] after the end of each Year, Patheon shall prepare a report of the annual reconciliation of API, in accordance with the reconciliation report form

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annexed hereto as Schedule G, including the calculation of the "**Actual Annual Yield**" or "**AAY**" of Product from API during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Product delivered and is calculated as follows:

Quantity Converted during the x 100%

<u>Year</u>

Quantity Dispensed during the

Year

**5.6.3** Shortfall Calculation. If the Actual Annual Yield falls below [\*\*\*] (the "<u>Target Yield</u>") in a Year, then the shortfall for such Year (the "<u>Shortfall</u>") shall be determined based on the following calculation:

[Target Yield – AAY] \* API Credit Value \* Quantity Dispensed (in kilograms)

The Shortfall shall be disclosed by Patheon on a reconciliation report prepared in the form annexed hereto as Schedule G.

- 5.6.4 <u>Credit to Depomed for Shortfalls.</u> If there is a Shortfall for a Product, then Patheon shall credit Depomed's account for the amount of any such Shortfall not later than [\*\*\*] after the end of the Year in which the Shortfall occurred. Each credit under this Section shall be summarized on the reconciliation report prepared in the form annexed hereto as Schedule G and shall be made in accordance with Section 5.6.3. Upon expiration or termination of this Agreement any remaining credit amount owing under this Section shall be reimbursed to Depomed by payment thereof to Depomed.
- **5.6.5** <u>Maximum Credit.</u> Patheon's liability for API calculated in accordance with this Section 5.6 for any Product in a Year shall not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule E.

#### ARTICLE 6 - PRODUCTION FEES AND PAYMENT

**Production Fees.** Deponded shall pay Patheon for manufacturing Product, in accordance with the tiered Production Fees for the Product for the first Year as listed in Schedule B ("**Production Fees**"), subject to any adjustments made pursuant to Sections 6.3 and 6.4 or as otherwise agreed to by the Parties, in writing. The costs of [\*\*\*] are not included and shall be established in a separate agreement between the Parties.

### 6.2 **Invoices**.

**6.2.1** For Delivered Product. Patheon shall invoice Depomed for the Production Fees on or after the date on which Patheon has delivered the subject Product, pursuant to Article 4, and, except for disputed amounts, Depomed will pay all invoices within [\*\*\*] days of the date of the invoice. Interest on past due, undisputed amounts will accrue from the date due until the date as payment is made, at a rate equal to the prime rate, as reported by Citibank, New York, New York, on the date such payment was due to be paid; provided, however, that in no event shall such rate exceed the maximum legal

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annual interest rate. If Depomed disagrees for any reason with the amount of any invoice submitted by Patheon, Depomed shall notify Patheon of such disagreement within [\*\*\*] days after receipt of such invoice, and the Parties shall promptly attempt to resolve the difference. Any portion of such invoiced amount that is not in dispute shall be paid within [\*\*\*] days of the date of the invoice.

- **6.2.2** For Product Ordered But Not Shipped. In the event that any Product manufactured in accordance with Depomed's orders cannot be recommended for release by Patheon for a period of [\*\*\*] days following completion of manufacturing, and such delay arises from cause(s) which have been established to be other than the negligence or willful misconduct of Patheon, or Patheon's failure to fully comply with the manufacturing protocols, cGMPs or the terms of this Agreement, Patheon may, upon the expiration of such [\*\*\*] day period, invoice Depomed for the applicable Production Fees, and such invoice shall be due according to Section 6.2.1.
- **6.3** Price Adjustments. After the first Year of the Agreement, Patheon may adjust the Production Fees, [\*\*\*] as follows:
- **6.3.1** Manufacturing Costs. Patheon may adjust the Production Fees for inflation, based upon the preliminary number for any increase in the Producer Price Index for Pharmaceutical Preparation Manufacturing (pcu325412325412) published by the United States Department of Labor, Bureau of Labor Statistics in August of the preceding Year, compared to the final number for the same month of the Year prior to that, unless the Parties otherwise agree in writing. On or about [\*\*\*] of each Year, Patheon will give Depomed a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Production Fees for the next Year.

- 6.3.2 <u>Materials Costs</u>. If Patheon incurs an increase in Materials costs during a Year, it may increase the Production Fees for the next Year to the extent necessary to pass through the additional Materials costs; provided that, prior to November 1st of the Year in which Patheon's Materials costs increased, Patheon notifies Depomed thereof and gives Depomed information about the increase in its Materials costs which will be applied to the calculation of the Production Fees for the next Year sufficient to reasonably demonstrate that the increase is justified. Any information provided by Patheon to Depomed pursuant to this Section 6.3.2 that is subject to obligations of confidentiality between Patheon and its suppliers shall be deemed Confidential Information of Patheon, and subject to the provisions of Article 7.
- 6.3.3 Pricing Basis. Depomed acknowledges that the Production Fees in any Year are quoted based upon the Minimum Run Quantity and the price tiers specified in Schedule B. If at any time during the term of this Agreement Depomed does not order the specified Minimum Run Quantity changes or the minimum Annual Volume in the lowest tier in a given Year, then Patheon shall be entitled to request an adjustment to the Production Fees with respect to the Product to reflect the increased costs that Patheon will incur as a result of the reduced volumes, and such adjustment shall be effective upon Depomed's written consent. To the extent that the Production Fee has been previously adjusted pursuant to this Section 6.3.3 to reflect reduced volumes, the adjustment provided for shall operate based on the fees attributed to such Product at the time the last of such adjustments were made, including any other applicable price adjustments in accordance with this Article 6.

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6.4 Extraordinary Increases in Cost of Materials. If, at any time, market conditions result in Patheon's cost of Materials being materially greater than normally forecasted increases, then Patheon will be entitled to an adjustment to the Production Fees for any affected Product to compensate it for the increased Materials costs. Changes materially greater than normally forecasted increases will have occurred if (a) the cost of a Material increases by [\*\*\*] of the cost for that Material upon which the most recent fee quote was based (b) the aggregate cost of all Materials required to manufacture Product increases by [\*\*\*] of the aggregate cost of all Materials required to manufacture Product upon which the most recent fee quote was based. If Materials costs have been previously adjusted to reflect an increase in the cost of one or more Materials, the adjustments set out in (a) and (b), above will operate based on the last cost adjustment for the Materials.

Production Fees revised under this Section 6.4 shall be effective for any Product delivered on or after the first day of the month following Depomed's receipt of the revised Schedule B, in accordance with Section 6.6.

Adjustments Due to Technical Changes. Depomed will inform Patheon in writing of any changes required to the Specifications. Amendments to the Specifications or the Quality Agreement requested by either party will only be implemented following a technical and cost review by Patheon and are subject to Depomed and Patheon reaching agreement on Production Fees changes required because of the amendment. Amendments to the Specifications or Quality Agreement, or any change of the Patheon Facility (including without limitation the location thereof) requested by Patheon will only be implemented following the written approval of Depomed, such approval not to be unreasonably withheld. Any change in the manufacturing process by Patheon (such as changes in Materials testing, quality controls, equipment, facilities, or manufacture and/or packaging methods) shall be subject to Depomed's prior written approval. If Depomed accepts a proposed Production Fees change, the proposed change in the Specifications will be implemented, and the Production Fees change will become effective only for those orders of Product manufactured under the revised Specifications. In addition, Depomed agrees to purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory to be used for manufacturing Product under the formerly applicable Specifications and purchased or maintained by Patheon in order to fill Purchase Orders or under Section 3.4 if the Inventory can no longer be used under the revised Specifications. Open orders for Materials no longer required under any revised Specifications that were

placed by Patheon with suppliers in order to fill Purchase Orders or under Section 3.4 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Depomed.

Notices of Adjustment. For a Production Fees adjustment under Sections 6.3, 6.4, and/or 6.5, Patheon will deliver to Depomed a revised Schedule B and budgetary pricing information, adjusted Materials costs or other documents reasonably sufficient to demonstrate that a Production Fees adjustment is justified. Any information provided by Patheon to Depomed pursuant to this Section 6.6 that is subject to obligations of confidentiality between Patheon and its suppliers shall be deemed Confidential Information of Patheon, and subject to the provisions of Article 7. Notwithstanding Sections 6.3, 6.4, and/or 6.5, Patheon shall use commercially reasonable efforts to minimize or avoid, where possible, any increases in the Production Fees.

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**Currency: Taxes**. Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the USA. Patheon shall be responsible for and shall pay any applicable sales, use, excise or similar taxes, including value added taxes and customs duties due on the importation of Product and arising from purchases made by Depomed under this Agreement.

#### ARTICLE 7 - CONFIDENTIAL INFORMATION

- **Confidentiality.** Any information or data (a) disclosed by or on behalf of one Party to the other Party regarding such Party's formulations, plans, programs, plants, process, technical materials, products, production requirements, standard specifications, costs, equipment, operations, procedures, instructions or customers, or (b) generated by Patheon for Depomed pursuant to this Agreement, is collectedly referred to as "**Confidential Information**."). Confidential Information described in subsection (a) shall be the sole property of the disclosing Party. Confidential Information described in subsection (b) shall be the sole property of Depomed. Each Party shall treat the other Party's Confidential Information in the same protective manner as it treats its own Confidential Information, but in no event with less than reasonable care. Except as provided herein, during the term of this Agreement and, for information not considered a trade secret under Applicable Law, for a period of five (5) years thereafter or, for information considered a trade secret under Applicable Law, neither Party shall use, disclose to others, or permit its employees or agents to use or disclose to others, the other Party's Confidential Information. For the avoidance of doubt, manufacturing processes, analytical methods used in the manufacture of Product, and test results shall be the Confidential Information of Depomed.
- **7.2 Exclusions**. Section 7.1 shall not prevent either Party from using or disclosing to others information described in Section 7.1(a):
- (a) that is known to the receiving Party at the time it is disclosed by or obtained from the disclosing Party, which knowledge can be established by competent evidence;
- (b) that is in the public domain at the time of disclosure hereunder, or through no fault of the receiving Party becomes available to the public;
- (c) that lawfully becomes available to the receiving Party from a source other than the disclosing Party with the legal right to disclose it;

- (d) that a Party can prove, by written records made prior to the date of disclosure hereunder, was independently developed by persons not engaged in activities hereunder and without regard to any information described in Section 7.1(a) conveyed hereunder or arising in connection herewith;
- (e) that is required by Applicable Laws, court order or a order of a judicial or administrative agency of competent jurisdiction to be disclosed, after maximum practicable notice by the receiving Party to the disclosing Party, provided that in each case the receiving Party shall use its best efforts to limit such disclosure and maintain the confidentiality of such information to the extent reasonably possible;

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- (f) to its Affiliates, potential or actual investment bankers, investors, lenders, or acquirers, and, solely as to Depomed, its potential or actual collaborators and/or licensees; provided, however, that the receiving Party shall remain responsible for any failure by any of the foregoing recipients of Confidential Information pursuant to this Section 7.2(f), to treat such Confidential Information as required under this Article 7.
- **Obligations Upon Termination**. Upon termination of this Agreement, if requested, a Party shall deliver to the other Party all notes, drawings, blueprints, manuals, letters, notebooks, reports and other materials in its possession or under its control, that contain or constitute Confidential Information of the other Party, including all copies thereof, except that (a) one copy may be maintained by the non-owning Party, in the files of its counsel, for the sole purpose of ensuring compliance with the continuing confidentiality obligations under this Agreement, and (b) Patheon may keep copies of those records described in Section 7.1(b) to the extent and for the time period that they are required to be kept pursuant to Applicable Laws.
- **Access Restriction**. Each Party shall restrict access to the other Party's Confidential Information to as few as practicable of its employees and agents, each of whom shall be directly connected with the performance or receipt of the services or Product hereunder.
- **7.5** Equitable Relief. Each Party acknowledges and agrees that disclosure, distribution, use or any other handling of the other Party's Confidential Information contrary to the terms of this Agreement may cause irreparable harm to the owner, for which damages at law may not provide an adequate remedy. The Parties agree that the provisions of this Article 7 may be specifically enforced, in addition to any and all other remedies available at law or in equity.

#### ARTICLE 8 - LIMITATION OF LIABILITY; INDEMNIFICATION; INSURANCE

8.1 Consequential Damages. EXCEPT AS SET FORTH IN THIS SECTION 8.1, UNDER NO CIRCUMSTANCES WHATSOEVER WILL EITHER PARTY BE LIABLE, UNDER THIS AGREEMENT, TO THE OTHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR (A) ANY (DIRECT OR INDIRECT) LOSS OF PROFITS, OF PRODUCTION, OF ANTICIPATED SAVINGS, OF BUSINESS, OR GOODWILL OR (B) ANY OTHER LIABILITY, DAMAGE, COSTS, OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF THESE DAMAGES.

#### 8.2 Limitations of Liability.

8.2.1 <u>For API</u>. Except as expressly set forth in Section 5.6, under no circumstances will Patheon be responsible for any loss or damage to API. Patheon's maximum responsibility for loss or damage to API will not exceed the Maximum Credit Value set forth in Schedule E

8.2.2 <u>Patheon's Maximum Liability</u>. Excluding any liability arising under Section 8.3, Patheon's maximum liability to Depond in any Year, under this Agreement, for any reason whatsoever will not exceed [\*\*\*] of revenues up to a cap of [\*\*\*].

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- **8.3** Indemnification by Patheon. Patheon agrees to defend, indemnify, and hold Depomed, its officers, employees, and agents (collectively, the "Depomed Indemnitees") harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) (collectively, "Losses") resulting from, or relating to any claim of infringement or alleged infringement of any Intellectual Property, including but not limited to patent rights of any third party ("Third Party Rights") as a result of the conduct of the Manufacturing Services (except for claims directly related to the API or any Depomedowned technology transferred by Depomed to Patheon pursuant to this Agreement) or any claim of personal injury or property damage, to the extent that the injury or damage is the result of (a) a failure by Patheon to provide Conforming Product, or (b) any other breach of this Agreement by Patheon, including, without limitation, any representation or warranty contained herein, except to the extent that the injury or damage is due to the gross negligence or wilful misconduct of any Depomed Indemnitee or a breach of this Agreement by Depomed.
- **8.4** Indemnification by Depomed. Depomed agrees to defend, indemnify, and hold Patheon, its officers, employees, and agents (collectively, the "Patheon Indemnitees") harmless against any and all Losses resulting from, or relating to any claim of infringement or alleged infringement of any Third Party Rights relating to the API or any Depomed-owned technology transferred by Depomed to Patheon pursuant to this Agreement, or any claim of personal injury or property damage, to the extent that the injury or damage is the result of a breach of this Agreement by Depomed, including, without limitation, any representation or warranty contained herein, except to the extent that the Loss is due to the gross negligence or wilful misconduct of any Patheon Indemnitee.
- **8.5** Indemnification Procedures. If a Party learns of any Loss for which it could seek indemnity under this Article 8, such party shall: (a) promptly notify the other Party of the Loss and of whether such indemnity is sought; (b) use commercially reasonable efforts to mitigate the effects of the Loss; (c) reasonably cooperate with the indemnifying Party in the defense of the Loss.
- 8.6 Insurance. During the term of this Agreement, each Party shall maintain adequate product liability insurance. During the term of this Agreement, Patheon and Depomed shall each maintain comprehensive general liability insurance, including product liability. At the time of first commercial sale of Product manufactured pursuant to this Agreement, the insurance afforded by the Parties shall be primary insurance with minimum limits of [\*\*\*] per occurrence and an annual aggregate amount of [\*\*\*]. Such insurance shall not be cancelled or modified without providing the other Party at least thirty (30) days prior written notice. If requested each Party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. If a Party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such Party, then such Party shall forthwith notify the other Party in writing and the Parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

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#### ARTICLE 9 - RECALLS AND PRODUCT CLAIMS

- **Recalls.** In the event of a Recall, each of the Parties hereby agrees to cooperate to take all appropriate corrective actions, including without limitation providing to the other Party copies of all relevant correspondence, notices, and similar documentation. Each Party shall notify the other Party if such Party (a) determines that an event, incident, or circumstance has occurred which may result in the need for a Recall of the Product or (b) becomes aware that an Authority is threatening or has initiated an action to remove the Product from the market or to require the distribution of a "Dear Doctor" letter, or its equivalent, regarding use of the Product. Depomed, its Affiliate or licensee, as applicable, shall be responsible for conducting any Recall of the Product, whether voluntary or involuntary, or taking such other remedial action required by Applicable Laws or agreed to by the Parties. At the request of Depomed, its Affiliate or licensee, as applicable, Patheon shall assist with respect to any such Recall or remedial action, and will provide to Depomed or a Depomed-authorized requestor all information requested, in connection with Patheon's or its Affiliates' dealings with Authorities in connection with such Recall.
- **Recall Coordination**. All coordination of any Recall involving Product shall be handled by Depomed, its Affiliate or licensee, as applicable, but Patheon shall reasonably cooperate with such Party in accomplishing any of the foregoing actions.
- **Recall Records**. Each of the Parties shall maintain complete and accurate Recall records of all the Product sold by it for such periods as may be required by Applicable Law, but in no event less than three (3) years after the date of the Recall. Each Party shall promptly notify the other by telephone, with a written confirmation within 24 hours, of any information which might affect the marketability, safety or effectiveness of the Product and/or which might result in the Recall or seizure of the Product. Upon receiving any such notice or upon any such discovery, each Party shall cease and desist from further shipments of such Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take other corrective action, if any, shall be made and implemented solely by Depomed.
- **9.4** <u>Disputes Regarding the Conformity of Recalled Product</u>. Any disputes, as between Patheon and Depomed, with respect to the quality of the Product shall be handled according to the provisions stated in Section 5.4.
- **9.5 Product Returns**. Deponded will have the responsibility for handling customer returns of the Product. Patheon will give Deponde any assistance that Deponde may reasonably require to handle the returns.

#### 9.6 Responsibilities with Respect to Recalled Product

9.6.1 Patheon's Responsibilities. In the event that a Recall results from the manufacture, packaging, storage, testing or handling of the Product by Patheon, and such Recall is due to Patheon's failure to provide the Manufacturing Services in accordance with cGMPs or other Applicable Laws, or to have supplied Conforming Product, as determined by a Laboratory pursuant to Section 5.4 or otherwise agreed upon in writing by the Parties, Patheon shall be responsible for documented out-of-pocket expenses of such Recall and shall use its commercially reasonable efforts to replace Recalled

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Product with new Product, contingent upon the receipt from Depomed of all API required for the manufacture of such replacement Product, for which Patheon shall reimburse Depomed, subject to the limitation on liability for lost API set forth in Article 8, which will be captured and calculated in the API Yield under Section 5.6. In the event that Patheon is unable to replace the Recalled Product (except where this inability results from a failure to receive the required API), then upon request by Depomed, Patheon shall reimburse Depomed promptly for the Production Fees paid to Patheon with respect to the Recalled Product. In all other circumstances, costs and expenses associated with a Recall shall be Depomed's responsibility. For purposes of this Agreement, the expenses of Recalls shall

include, without limitation, the expenses of notification and destruction or return of the Recalled Product, and Depomed's costs for the Product Recalled. Marketing and advertising expenses associated with the goodwill of the Product subject to the Recall shall not be included as an expense of Recall and shall, in all instances, be borne by Depomed.

- 9.6.2 <u>Limitations on Patheon's Responsibilities</u>. Patheon will have no obligation pursuant to Section 9.6.2 above to the extent the Recall results from (a) deficiencies in the Specifications, the safety, efficacy, or marketability of the Product, or any distribution thereof following its Delivery, (b) a defect in a Material that was not reasonably discoverable by Patheon using the test methods set forth in the specifications for such Material, the Specifications or otherwise in this Agreement, (c) Latent Defect in the API unknown to Patheon at the time of Delivery of the Product at issue, (d) actions of third parties occurring after the Product is Delivered, (e) packaging design or labelling defects or omissions for which Patheon has Patheon has no responsibility, or (f) is due to any breach by Depomed of its obligations under this Agreement.
- Product pursuant to FDA procedure, rules or guidelines, but will notify Patheon, in writing, prior to doing so. Unless it is inconsistent with FDA procedures, rules or guidelines, Depomed will not dispose of any Nonconforming, returned or Recalled Product for which it intends to assert a claim against Patheon, without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Depomed to return the Product to Patheon. Patheon will bear the cost of disposition of any Product returned, or Recalled Product for which it bears responsibility under Section 9.6.1. In all other circumstances, Depomed will bear the cost of disposition, including all Production Fees charged for Nonconforming, defective, returned, or Recalled Product.
- **Healthcare Provider or Patient Questions and Complaints**. Depomed will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Depomed's customers, healthcare providers or patients will be promptly referred to Depomed. Patheon will cooperate as reasonably required to allow Depomed to determine the cause of and resolve any questions or complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Depomed all agreed upon information that will enable Depomed to respond properly to questions or complaints about the Product as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to Deliver Conforming Product, all costs incurred under this Section 9.8 will be borne by Depomed.

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# ARTICLE 10 - RECORDS AND AUDITS; COOPERATION

10.1 Records and Retained Samples. During the term of this Agreement, Patheon shall (a) prepare and maintain Batch Records and (b) retain samples, properly stored, from each lot or Batch supplied by Patheon hereunder, sufficient to perform each quality control test specified in the Specifications at least twice. Depomed agrees to provide for such purpose all the information, processes, analytical methods, testing procedures, and any other information reasonably requested by Patheon and in the possession of Depomed necessary for manufacturing the Product in accordance with cGMPs. Patheon agrees to provide Depomed upon release and delivery of the Product, copies of the analytical testing data such as Certificate of Analysis. Patheon agrees to provide Depomed with copies of its executed batch production records and related documents. Such records shall be available for audit by Depomed and its designees, as well as FDA and foreign regulatory agencies, upon request. Patheon shall store the manufacture and analysis documentation for each Batch for the shelf life of the Batch and for two (2) years thereafter. Patheon will keep records of the manufacture, testing, and shipping of the Product and shall retain samples of the Product, as necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving product complaints and other similar issues. Copies of the records and samples will be retained for a period of three (3) years following the date of Product expiry, or longer if required by law, at which time Depomed will be contacted concerning the delivery and destruction of the documents and/or samples of Product.

- **10.2 Quarterly Review**. Each Party shall forthwith upon the Effective Date appoint one of its employees to be a relationship manager responsible for liaison between the Parties. The relationship managers shall meet not less than quarterly, whether in person, by means of video conference, telephone, or such other agreed upon means of communication, to review the current status of the business relationship and manage any issues that have arisen.
- **Reporting**. Patheon shall provide Depomed with a monthly inventory report, within four (4) Business Days after the end of each month, of the Materials, API, and Product then held by Patheon, and any work in progress as of such time.
- Authorities. Subject to Section 12.3, each Party may communicate with any Authority regarding the Product if, in the opinion of that Party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, Patheon will permit Depomed to accompany and take part in any such communications with the agency, and to receive copies of all such communications from the agency.
- **10.5 Records Inspection**. Deponded may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.
- 10.6 <u>Access to Facility</u>. Patheon will give Depomed reasonable access, at mutually agreeable times, to the areas of the Facility in which the Product is manufactured, stored, handled and/or shipped, to permit Depomed to verify that the Manufacturing Services are being performed in accordance with cGMPs and other Applicable Laws and that Product is Conforming. But, with the exception of "for-cause" audits (i.e., audits conducted to investigate alleged non-compliance with the Specifications,

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cGMPs, or other Applicable Laws), Depomed will be limited each Year to [\*\*\*] hereunder, lasting no more than [\*\*\*] days, and involving no more than [\*\*\*] auditors. Depomed may request additional such audits, audit days and/or auditors, subject to payment to Patheon of a fee of [\*\*\*] for each additional audit day, and [\*\*\*] per audit-day for each additional auditor. The right of access set forth in this Section 10.6 will not include a right to access or inspect Patheon's financial records.

- 10.7 <u>Notification of Regulatory Inspections</u>. Patheon will notify Depomed within one Business Day of any inspections by any governmental agency specifically involving the Product or a general systems-based audit relating to Patheon's conduct of the Manufacturing Services. Patheon will also notify Depomed of receipt of any form 483's or warning letters or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Product.
- **Reports**. Patheon will supply to Depomed, on an annual basis, all Product data in its control, including release test results, complaint test results, and all data regarding investigations (relating to manufacturing, testing, and storage). At Depomed's request, Patheon will provide a copy of any annual Product review report to Depomed at no additional cost. Any additional report requested by Depomed beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and Depomed.

# **ARTICLE 11 – TERM AND TERMINATION**

**11.1 Term**. Subject to the termination provisions of Section 11.3, the initial term of this Agreement shall commence on the Effective Date and shall end on May 31, 2016 ("**Initial Term**"). Thereafter, this Agreement shall be automatically renewed for an

additional term of two (2) years unless one Party gives notice to terminate eighteen (18) months prior to the expiration of the Initial Term or any extension thereof.

# 11.2 Early Termination by Depomed.

- (a) At any time after a period of two (2) years from the Effective Date, Depomed may terminate this Agreement upon one hundred and eighty (180) days written notice to Patheon, if it or its affiliates intend to no longer order Manufacturing Services for a Product due to the Product's discontinuance in the market.
- (b) If Depomed or its affiliates subsequently elect to resume commercializing the Product, Depomed shall so notify Patheon in writing, and this Agreement shall once again take effect between the Parties, and the Parties shall meet in good faith to determine the procedure to follow in order for Depomed to resume the purchase of Product from Patheon and Patheon resume the supply of Product to Depomed.
- **11.3 Termination**. This Agreement may be terminated under the conditions stated herein:
- (a) by either Party for material breach of this Agreement by the other Party, if such other Party either fails to cure any such breach within ninety (90) days after it receives a written notice of

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such breach from the non-breaching Party, or, if such breach cannot be reasonably cured within such ninety (90) day period.

- (b) by Depomed for material breach of the Quality Agreement by Patheon, if Patheon either fails to cure any such breach within ninety (90) days after it receives a written notice of such breach from Depomed, or, if such breach cannot be reasonably cured within such ninety (90) day period.
- (c) by either Party, immediately upon written notice to the other Party, if the other Party is declared insolvent or bankrupt by a court of competent jurisdiction, or a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other Party, or the other Party makes or executes any assignment for the benefit of creditors.
- (d) by Depomed, immediately, by giving Patheon written notice of such termination as a result of any debarment, whether actual or threatened, or any conviction which could result in debarment, whether it does so in fact or not; provided that if such circumstance relates to an individual, Patheon may avoid such termination by the immediate removal of such person from all tasks performed pursuant to this Agreement and replacement of such person by another qualified person.

# 11.4 <u>Effects of Termination</u>.

- **11.4.1** Upon expiration or termination of this Agreement for any reason:
- (a) Patheon shall furnish to Depomed a complete inventory of all stock on hand of work-in-progress for the manufacture of the Product and Product. Unless otherwise agreed to between the Parties, all stock on hand as of the effective date of termination of this Agreement shall be dealt with promptly as follows:

- (i) Product manufactured and packaged pursuant to Purchase Orders from Depomed shall be delivered by Patheon to Depomed, whereupon Depomed shall pay Patheon therefor in accordance with the terms hereof and Depomed shall take delivery of such products;
- (ii) Work-in-progress commenced by Patheon against Purchase Orders from Depomed shall be completed by Patheon, whereupon Depomed shall pay Patheon therefor in accordance with the terms hereof; and
- (iii) Materials not necessary to complete work-in-progress commenced under Section 11.4(a)(ii) but having been ordered or purchased by Patheon in accordance with Depomed's then current [\*\*\*] rolling forecast shall be disposed of by Patheon or returned to Depomed at Depomed's option and expense. If Patheon terminates this Agreement under Section 11.3, Depomed shall reimburse Patheon for Patheon's actual cost of such Materials purchased by Patheon in order to fulfill Depomed's then current [\*\*\*] rolling forecast. If Depomed terminates this Agreement under Section 11.3(a), (b), or (d), Patheon shall bear the costs of disposal of Materials and Active Pharmaceutical Ingredient, the cost of such Materials purchased by Patheon in order to fulfill Depomed's then current [\*\*\*] rolling forecast, and any fees charged to Patheon for the termination of such supply contracts for

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Materials which Patheon can only use for the manufacture of Product. Any credit balance owed to Depomed after application to amounts due to Patheon shall be promptly paid to Depomed.

- (b) Patheon will promptly transfer to Depomed any and all tooling purchased by Patheon to perform activities under this Agreement for which Depomed has remitted payment to Patheon, that is then in the possession of Patheon; provided that the cost of removing and moving any and all such tooling to a location designated by Depomed shall be borne by Depomed.
- (c) Depomed will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within fifteen (15) Business Days, all of Depomed's Materials, Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, Equipment or other moveable property owned by Depomed, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Depomed Property**"). If Depomed fails to remove Depomed Property within thirty (30) days following the completion, termination, or expiration of the Agreement Depomed will pay Patheon [\*\*\*] per pallet, per month, one pallet minimum thereafter for storing Depomed Property and will assume any third party storage charges invoiced to Patheon regarding Depomed Property. Patheon will invoice Depomed for the storage charges as set forth in Section 6.2 of this Agreement.
- (d) Depomed acknowledges that no Competitor of Patheon will be permitted access to the Facility (a "Competitor of Patheon" shall mean any company engaged in providing manufacturing services to pharmaceutical or biotechnology companies on a fee-for-service basis that is not also engaged in the development and/or commercialization of Product as a licensee or distributor of Depomed); and
  - (e) Patheon will return to Depomed all unused API (with shipping and related expenses, if any, to be borne by Depomed).
- 11.4.2 Patheon hereby grants to Depomed, effective as of the effective date of termination, a worldwide, transferable, sublicenseable, fully paid-up, irrevocable non-exclusive license, under the Patheon Intellectual Property, to manufacture Product or products based on or derived from the Product, including without limitation to perform manufacturing, quality control, quality assurance, stability testing, packaging, and related services with respect to the Product or products based on or derived from the Product. Patheon will promptly transfer to Depomed, in a commercially reasonable manner and at Depomed's sole expense, all

information, materials and technology then in its possession or control that is necessary or reasonably useful to enable Depomed, its Affiliates, licensees or contractors to practice the foregoing license, including without limitation transferring to Depomed all related know-how. Patheon will provide, at Depomed's sole expense, reasonable assistance, including training and education, to enable Depomed or its designee to manufacture any and all Product. Until all transfer tasks described above are completed and Depomed's new manufacturer and new manufacturing site have been qualified, Patheon will continue to perform Manufacturing Services under this Agreement as requested by and at the direction of Depomed.

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11.5 <u>No Discharge of Obligations</u>. Termination of this Agreement for any reason shall not discharge either Party's liability for obligations incurred hereunder or under the Capital Expenditure Agreement or for payments due there under.

#### **ARTICLE 12 - REGULATORY MATTERS**

- **Regulatory Filings**. Depomed will have the sole responsibility for preparing and filing all documents with all regulatory authorities and taking any other actions that may be required for the receipt and/or maintenance of regulatory authority approval for the Product, including without limitation filing the NDA, and making adverse drug reaction reports and annual reports to regulatory authorities. Patheon shall use commercially reasonable efforts to assist Depomed in complying with any arising requirements of the FDA and any other regulatory authorities. Patheon agrees to comply with all reasonable commitments made in such regulatory filings, including the NDA and any supplements thereto, regarding Patheon's manufacturing responsibilities as provided herein, provided that Patheon is notified of any such responsibilities that differ in scope from those set forth herein and is given an opportunity to review such commitments with sufficient time prior to their being included in the submitted document by Depomed and provided they are not inconsistent with the then-applicable Specifications. Any incremental costs as a result of the above are subject to the price adjustments as provided in Section 6.3. Patheon shall be responsible, at its expense, for obtaining and maintaining all licenses and approvals necessary for it to manufacture Product pursuant to this Agreement.
- **Compliance**. Deponded shall be responsible for compliance of the Specifications (including but not limited to the text and accuracy of any labeling required by Deponde) with FDA standards. Patheon shall be responsible for compliance of the manufacturing, processing, packaging procedures and testing procedures with FDA standards, including without limitation those pertaining to cGMPs. Each Party will provide reasonable assistance to the other, at no charge, if necessary to respond to FDA audits, inspections, inquiries, or requests concerning the Product. Deponded employees present at the Patheon Facility shall at all times adhere to safety regulations, cGMPs and work schedule generally applicable to Patheon's own employees, provided that such Deponded employees are notified of the same.

#### 12.3 Adverse Events Reporting and Product Information Requests.

- **12.3.1** Adverse Reaction Reporting. During the term of this Agreement, Patheon shall immediately but in any case within twenty-four (24) hours notify Depomed, by facsimile or telephone, of any adverse drug experience involving the Product that any employee or agent of Patheon becomes aware of.
- **12.3.2** Product Information Requests. Information concerning any complaints, inquiries, and/or drug information requests from consumers, physicians, or other third parties regarding the Product shall be communicated in writing to Depomed within twenty-four (24) hours of Patheon's receipt of the information and/or inquiry. Depomed shall respond to such complaints and inquiries, if necessary, in accordance with its usual and customary procedures.

- **12.3.3** Governmental Reports. Deponded shall be responsible for filing with the FDA any required adverse reaction reports that it receives directly from third parties and any adverse reaction reports that it receives through Patheon.
- 12.4 <u>Cooperation</u>. The Parties expect that any information concerning the Product required by the FDA will be submitted by Depomed. If Patheon is required to submit to the FDA any information concerning the Product as part of a FDA inspection or audit in connection with the manufacture of the Product, Depomed will provide to Patheon such documentation, data and other information as Patheon may require for submission to the FDA. Depomed shall also provide, if required by the FDA, information concerning its quality control procedures and marketing of the Product and any other information reasonably requested by FDA. Depomed shall provide its reasonable cooperation and consultation to Patheon in addressing any issue raised by FDA concerning manufacture of the Product.

#### ARTICLE 13 – INTELLECTUAL PROPERTY

13.1 <u>Trademarks and Labeling</u>. Patheon shall affix labeling to the Product as specified in the Specifications. Any such labeling shall bear one or more trademarks to be designated by Depomed, in a form and manner pre-approved in writing by Depomed. Nothing contained herein shall give Patheon any right to use any Depomed trademark except as expressly permitted herein, and Patheon shall not obtain any right, title, or interest in any Depomed trademark by virtue of this Agreement or its performance of services hereunder.

## 13.2 <u>Inventions</u>.

- 13.2.1 <u>Background Technology</u>. Each Party agrees and acknowledges that, except as expressly granted under this Agreement, such Party shall acquire no rights of any kind whatsoever with respect to any Intellectual Property of the other Party existing as of the Effective Date.
- 13.2.2 <u>License</u>. For the term of this Agreement, Depomed hereby grants Patheon a non-exclusive, paid-up, royalty-free, non-transferable, non-sublicenseable license to Depomed's Intellectual Property that is delivered from Depomed to Patheon hereunder, specifically for use in the performance by Patheon of the Manufacturing Services.

# 13.2.3 Inventions.

(a) All Inventions, and Intellectual Property therein, identified, generated or derived, in whole or in part, by Patheon, Depomed, or their respective employees or independent contractors engaged in manufacturing Product pursuant to this Agreement, in the course of performing the Manufacturing Services, that are specific to, based on, derived from or related to the development, manufacture, use or sale of the Product, or components or formulations of the Product, shall be the sole property of Depomed.

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(b) All Inventions, and Intellectual Property therein, identified, generated or derived, in whole or in part, by Patheon, Depomed, or their respective employees or independent contractors engaged in manufacturing Product pursuant to this Agreement, in

the course of performing the Manufacturing Services, that are not specific to, based on, derived from or related to the development, manufacture, use or sale of the Product, or components or formulations of the Product, and that have applications to manufacturing processes or formulation development of drug products or drug delivery systems generally (the "Broader Intellectual Property Rights") shall be the sole property of Patheon. Patheon hereby grants Depomed a non-exclusive, paid-up, royalty-free, worldwide, sublicenseable, transferable license, under the Broader Intellectual Property Rights and the Patheon Intellectual Property, to manufacture, use, sell, offer for sale, and import any product containing API or any derivatives thereof.

- (c) Inventorship of Inventions identified, generated or derived, in whole or in part, by Patheon, Depomed, or their respective employees or independent contractors, shall be determined in accordance with U.S. patent laws. Except as otherwise provided in Sections 13.2.3(a) and 13.2.3(b), (i) any and all Inventions, and all intellectual property rights therein, identified, generated or derived, in whole or in part, by Depomed, or its respective employees or independent contractors, shall be solely owned by Depomed, (ii) any and all Inventions, and all intellectual property rights therein, identified, generated or derived, in whole or in part, by Patheon, or its respective employees or independent contractors, shall be solely owned by Patheon, and (iii) any and all Inventions, and all intellectual property rights therein, identified, generated or derived, in whole or in part, jointly by Depomed and Patheon, or employees or independent contractors of each of Depomed and Patheon, shall be jointly owned by the Parties such that each Party has an undivided one-half (1/2) interest, without a duty of accounting to the other Party, in and to such Joint Invention. In the event that a jurisdiction requires consent of co-owners for one co-owner to grant license rights under or otherwise exploit jointly owned intellectual property, each of the Parties hereby consents to such license grant under or exploitation of such intellectual property by the other Party without a requirement of accounting.
- Inventions and Intellectual Property therein. Without additional consideration, each Party hereby assigns to the other Party such of its right, title and interest in and to any Inventions, patent and patent applications claiming them, and all other Intellectual Property therein, and shall require its employees or independent contractors engaged in manufacturing Product pursuant to this Agreement to so assign to the other Party such of their right, title and interest in and to the foregoing, as is necessary to effectuate the allocation of ownership of Inventions and Intellectual Property therein as set forth in this Section 13.2.3. Each Party shall, and shall cause its employees or independent contractors engaged in manufacturing Product pursuant to this Agreement to, cooperate with the other Party and take all reasonable actions and execute and deliver all necessary documents, including without limitation, any agreements, declarations, legal instruments, documents of assignment or conveyance, and other documents as may be reasonably required to perfect the other Party's right, title and interest in and to Inventions, patent and patent applications claiming them, and all other Intellectual Property therein as set forth in this Section 13.2.3. Each Party shall also include provisions in its relevant agreements with third parties that effect the intent of this Section 13.2.3.

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13.3 Intellectual Property; No Implied Rights. Subject to Section 13.2.3, all Depomed Intellectual Property shall be owned by Depomed and all Patheon Intellectual Property shall be owned by Patheon. Neither Party has, nor shall it acquire, any interest in any of the other Party's Intellectual Property except as expressly set forth in this Agreement or unless otherwise expressly agreed to in writing. Except as expressly set forth herein, nothing in this Agreement is intended to transfer or license any right, title or interest in or to either Party's Inventions or background technology. Neither Party shall use any Intellectual Property of the other Party, except as expressly set forth in this Agreement or specifically authorized by the other Party or as required for the performance of its obligations under this Agreement.

ARTICLE 14 – RELATIONSHIP OF PARTIES

- **14.1 Independent Contractors.** It is not the intent of the Parties to form any partnership or joint venture. Each Party shall, in relation to its obligations hereunder, act as an independent contractor, and nothing in this Agreement shall be construed to give such Party the power or authority to act for, bind or commit the other Party in any way whatsoever.
- **Public Statements.** Patheon and Depomed each agree not to disclose the terms of this Agreement in any public statements, whether oral or written, including but not limited to shareholder reports, communications with stock market analysts, statements to other customers or prospective customers, press releases or other communications with the media, or prospectuses, without the other Party's prior written consent, which shall not be unreasonably withheld or delayed, or as required by Applicable Laws or rules of a securities exchange. If possible, each Party shall give the other at least five (5) days advance written notice of a disclosure required by Applicable Laws or rules of a securities exchange and will cooperate with the other Party to minimize the scope and content of such disclosure.

#### **ARTICLE 15 – WARRANTIES**

- **15.1 Patheon's Warranty**. Patheon hereby represents and warrants as follows:
  - **15.1.1** The Product shall conform with the Specifications as set out in Schedule A at the time of Delivery;
- **15.1.2** Patheon shall comply in all material respects with Applicable Laws. For purposes of this Section 15.1, and without limiting the foregoing sentence, any failure to comply with any Applicable Laws that exposes Depomed to any sanction or liability, or prevents Depomed from using the Product as intended, shall be deemed to be a material non-compliance;
- 15.1.3 Patheon shall maintain all required governmental permits, licenses, orders, applications and approvals regarding the manufacturing of the Product, and Patheon shall manufacture Product in accordance with all such permits, licenses, orders, applications and approvals. Any expenses incurred to obtain special permits for Product that Patheon would not have to acquire absent this Agreement will be reimbursed by Depomed;

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- **15.1.4** Product shall, at the time it is shipped to Depomed (i) not be adulterated or misbranded within the meaning of the Act, or within the meaning of any Applicable Laws in the Territory and (ii) not be articles that may not, under the Act or any other Law, be introduced into interstate commerce:
- **15.1.5** To Patheon's knowledge, there are no actions or other legal proceedings, concerning the infringement of Third Party Rights relating to the performance of the Manufacturing Services by Patheon under this Agreement;
- 15.1.6 Patheon has full authority to enter into this Agreement, that it has no reason to believe that its performance under this Agreement will infringe any Third Party Rights and that nothing contained in any other agreement prohibits or restricts Patheon from entering into any part of this Agreement; and
- 15.1.7 Patheon represents that, as of the Effective Date and continuously during the term of this Agreement, it and its employees, Affiliates, and agents have never been (i) debarred or (ii) convicted of a crime for which a person could be debarred under Section 335(a) or 335(b) of the Act. Patheon represents that it has never been and, to the best of its knowledge after due inquiry, none of its employees, Affiliates, or agents has ever been (i) threatened to be debarred, (ii) indicted for a crime or (iii) otherwise engaged in conduct for which a person can be debarred under Section 335(a) or 335(b) of the Act. Patheon agrees that it will promptly notify Depomed in the event of any such debarment, conviction, threat, or indictment.

- **15.2 Depomed's Warranty**. Depomed hereby represents and warrants as follows:
- 15.2.1 The Active Pharmaceutical Ingredient shall, to the best of Depomed's knowledge, at the time it is shipped to Patheon, (i) not be adulterated or misbranded within the meaning of the Act or within the meaning of any other Applicable Laws in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, (ii) not be articles that may not, under the Act or any other Applicable Law, be introduced into interstate commerce, and (iii) comply with its specifications as provided by Depomed;
- **15.2.2** As of the time that any Product produced hereunder is sold to a third party, Depomed will own all rights to the Product trademarks, and the Product labeling will meet regulatory requirements;
  - **15.2.3** Depomed may lawfully disclose the Specifications to Patheon;
- **15.2.4** To Depomed's knowledge, there are no actions or other legal proceedings against Depomed in the Territory, concerning the infringement of Third Party Rights directed to the Product Specification(s), the API or the Materials, or the sale, or use of the Product in the Territory, which is made in accordance with the Specifications.
  - **15.2.5 15.2.6** The Specifications are consistent with the NDA;
  - **15.2.7** The Specifications conform to all applicable cGMPs

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- **15.2.8** Deposed has full authority to enter into this Agreement and nothing contained in any other agreement prohibits or restricts Deposed from entering into any part of this Agreement; and
- **15.2.10** All material safety data sheets, Active Pharmaceutical Ingredient or any data supplied by Depomed to Patheon are accurate to the best of Depomed's knowledge. The Parties understand that Patheon will not do analysis to verify the accuracy of such Depomed supplied data.
- 15.3 No Implied Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, PATHEON AND DEPOMED MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

#### **ARTICLE 16 – ASSIGNMENT**

Except as set forth in this Article 16, this Agreement, and all rights and obligations hereunder, are personal to the Parties and shall not be assigned in whole or in part by a Party to any other person or company without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, Patheon and Depomed shall be entitled to assign this Agreement to an Affiliate whose performance is guaranteed by the assigning Party or to a Party which is the successor to, or the assignee of, all or substantially all of Depomed's or Patheon's pharmaceutical business; provided, however, that any such successor or assignee has agreed in writing to assume all of the assigning Party obligations under this Agreement. Any assignee of a Party hereunder must be qualified to perform the assigning Party's obligations and (a) hall have a financial condition at

the time of assignment at least comparable to that of the assigning Party as of the Effective Date, and (b) shall neither have been debarred by the FDA nor otherwise made subject to an order of the FDA or a court of competent jurisdiction which would prevent it from performing the obligations of the assigning Party hereunder. In the event of any assignment pursuant to the provisions of this Article 16, the assigning Party shall have no further obligations hereunder except (i) to the extent the same has accrued prior to such assignment or (ii) pursuant to the guarantee obligation set forth above. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respective successors and permitted assigns. Patheon may terminate this Agreement upon six months prior written notice if Depomed assigns under this Article 16 this Agreement to any Competitor of Patheon (as defined in Section 11.4.1(d)).

#### ARTICLE 17 – DISPUTE RESOLUTION

#### 17.1 Exclusive Dispute Resolution Mechanism

In the event that the Parties cannot reach agreement on a matter arising out of or in connection with this Agreement (including without limitation matters relating to either Party's rights and/or obligations hereunder and/or regarding the construction, interpretation and enforceability of such agreements), the procedures set forth in this Article 17 shall be the exclusive mechanism for resolving any dispute,

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controversy, or claim (collectively, "**Disputes**") between the Parties that may arise from time to time that cannot be resolved through good faith negotiation between the Parties.

- **Resolution by Executive Officers**. In the event of any Dispute between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party may, by written notice to the other Party, refer such Dispute to the other Party for attempted resolution by good faith negotiation within thirty (30) days after such notice is received. Such Disputes shall be referred to the senior executives of each of the Parties for attempted resolution. In the event that any Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Section 17.3 and, if applicable, Section 17.4.
- 17.3 <u>Mediation</u>. Any dispute that has not been resolved within [\*\*\*] after being referred to the senior executives pursuant to Section 17.2 shall be referred to mediation before a mediator that is mutually acceptable to the Parties. Such mediation shall be conducted as soon as practicable, but in no event more than [\*\*\*] after referral to mediation.
- **17.4 Arbitration**. Any Dispute that is not resolved pursuant to Section 17.3 shall be exclusively and finally resolved by binding arbitration pursuant to this Section 17.4.
- 17.4.1 Any such arbitration shall be conducted in New York, New York, United States of America, unless otherwise agreed to by the Parties in writing. Each and any arbitration shall be administered by the American Arbitration Association (the "AAA"), and shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association (the "Rules"), as such Rules may be amended from time to time, or modified by this Section 16.4 or by agreement of the Parties. The Parties will be entitled to conduct discovery as provided in the U.S. Federal Rules of Civil Procedure and the local rules of the U.S. District Court for the Southern District of New York, provided, however, that the Parties will conduct all discovery expeditiously within the time limit set

by the arbitrator(s), it being the intent that discovery be permitted to the extent necessary to introduce all salient facts. At any applicable hearing, the Parties may present testimony (either by live witness or deposition) and documentary evidence and have the right to be represented by counsel. The U.S. Federal Rules of Evidence will apply to any and all matters submitted to final and binding arbitration under this Agreement.

17.4.2 Within ten (10) days after receipt of an arbitration notice from a Party, the Parties shall attempt in good faith to agree on a single neutral arbitrator with relevant industry experience to conduct such arbitration. If the Parties do not agree on a single neutral arbitrator within ten (10) days after receipt of an arbitration notice, each Party shall select one (1) arbitrator and the two (2) Party-selected arbitrators shall select a third arbitrator with relevant industry experience to constitute a panel of three (3) arbitrators to conduct the arbitration in accordance with the Rules. In the event that only one of the Parties selects an arbitrator, then such arbitrator shall be entitled to act as the sole arbitrator to resolve the Dispute or any and all unresolved issues subject to such arbitration. Each and every

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arbitrator of the arbitration panel conducting the arbitration must and shall agree to render an opinion within thirty (30) days after the final hearing before the panel.

- 17.4.3 The decision or award of the arbitrator(s) shall be final, binding, and incontestable and may be used as a basis for judgment thereon in any jurisdiction. The arbitrator(s) shall, upon the request of any Party, issue a written opinion of the findings of fact and conclusions of law and shall deliver a copy to each of the Parties. Each Party shall bear its own costs and attorney's fees, and the Parties shall equally bear the fees, costs, and expenses of the arbitrator(s) and the arbitration proceedings; provided, however, that the arbitrator(s) may exercise discretion to award costs, including attorney's fees, to the prevailing Party. Without limiting any other remedies that may be available under Applicable Laws, the arbitrator(s) shall have no authority to award provisional remedies of any nature whatsoever, or punitive, special, consequential, or any other similar form of damages.
- **Preliminary Injunctions**. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction or other equitable remedy from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.
- **Patent Disputes.** Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent Rights in a country within the Territory shall be determined in a court or other Governmental Authority of competent jurisdiction under the applicable patent laws of such country.
- 17.7 <u>Confidentiality</u>. All proceedings and decisions of the arbitrator(s) shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 7.

# **ARTICLE 18 – FORCE MAJEURE**

Neither Party shall be liable to the other for default or delay in the performance of its obligations under this Agreement, if such default or delay shall be caused directly or indirectly by accident, fire, flood, riot, war, weather, act of God, embargo, strike, failure or delay of usual sources of supply of materials, or delay of carriers or governmental orders or regulations, or complete or partial shutdown of plant by any of the foregoing causes or other causes beyond its reasonable control, provided the same are not due to the negligence or willful misconduct of such Party and provided further that any such default ("Force Majeure Event"), delay or failure shall be remedied by such Party as soon as possible after the removal of the cause of such default, failure or delay. Obligations to pay amounts

due under this Agreement shall not be subject to the aforestated excuses. If due to a Force Majeure Event Patheon is unable to supply Depomed with the Product for a period exceeding ninety (90) days then Depomed shall have the right to terminate this Agreement without further cost and with immediate effect and upon written notice to Patheon. At the end of the first sixty (60) days during the persistence of the Force Majeure Event Patheon shall reasonably determine whether it will be able to resume supplying Product at the end of such ninety (90) days period and notify Depomed in writing of such assessment. If Patheon has concluded that it will be unable to resume supplying Product at the end of such period, Depomed shall have the right to terminate this Agreement upon

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thirty (30) days written notice to Patheon without further cost. Patheon will provide reasonable assistance during the technology transfer for the Product upon termination due to force majeure.

#### **ARTICLE 19 - NOTICES**

Unless otherwise provided herein, any notice required or permitted to be given hereunder or any proposal for any modification of this Agreement (hereinafter collectively referred to as the "Correspondence") shall be faxed, mailed by overnight mail, mailed by certified mail, postage prepaid, or delivered by hand to the Party or the individual to whom such Correspondence is required or permitted to be given hereunder. If mailed, any such Correspondence shall be deemed to have been given five (5) Business Days from the date mailed, as evidenced by the postmark at the point of mailing. If delivered by hand or fax, any such Correspondence shall be deemed to have been given when received by the Party to whom such Correspondence is given, as evidenced by written and dated receipt of the receiving Party.

All correspondence to Patheon shall be addressed as follows:

Patheon Puerto Rico, Inc. State Road 670 Km 2.7 Manatí, PR 00674

Attention: Legal Department Telecopier No.: (787) 621-2525

Email address: joanna.bocanegra@patheon.com

With a copy to:
Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention:
Telecopier No.:
Email address:

All correspondence to Depomed shall be addressed as follows:

Depomed, Inc. 1360 O' Brien Drive Menlo Park, California 94025 Attention: Vice President, General Counsel

Facsimile: (650) 462-9993

Either Party may change the address to which any correspondence to it is to be addressed by notification to the other Party as provided herein.

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## ARTICLE 20 - SECTIONS; HEADINGS; INTERPRETATION

The division of this Agreement into Articles, Sections, Subsections, and Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "this Agreement," "hereof", "herein," "and hereunder" and similar expressions refer to this Agreement and not to any particular part, Section or Schedule of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

#### **ARTICLE 21 – SEVERABILITY**

Should any part or provision of this Agreement be held unenforceable or in conflict with Applicable Law, the invalid or unenforceable part or provision shall be replaced with a provision that accomplishes, to the extent possible, the original business purpose of such part or provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the Parties.

#### **ARTICLE 22 – WAIVER**

No failure on the part of either Party to exercise, and no delay in exercising, any right, privilege or power hereunder shall operate as a waiver or relinquishment of the provision giving rise thereto; nor shall any single or partial exercise by either Party of any right, privilege or power hereunder preclude any other further exercise thereof, or the exercise of any other right, privilege or power.

#### ARTICLE 23 – SURVIVAL

The provisions of Articles 1, 6 (for the period set forth therein), 8, 9 (for the period set forth therein), and 15 through 27 and Sections 2.6 (last two sentences only), 7.1 through 7.5, 10.4, 10.5, 11.1, 11.2, 11.4, 12.2.1, 12.2.3, 12.3, 13.1, and 14.3 shall survive the termination or expiration of this Agreement. [to be revised]

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## **ARTICLE 24 - ENTIRE AGREEMENT**

This Agreement, together with the Schedules hereto, which are incorporated herein by reference, constitute the entire Agreement between the Parties with respect to the subject matter hereof, and no statement or other agreements, oral or written, made prior to or at the signing hereof shall vary or modify the written terms hereof, and neither Party shall claim any modification or rescission of any provision hereof unless such modification or rescission is in writing and signed by the other Party. No terms, provisions or conditions of any purchase order or other business form or written authorization used by Depomed or Patheon will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement, regardless of any failure of Depomed or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement, states that it is intended to modify this Agreement, and is signed by both Parties.

#### ARTICLE 25 - NO THIRD PARTY BENEFIT OR RIGHT

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

#### ARTICLE 26 – USE OF DEPOMED' S NAME

Patheon will not make any use of Depomed's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Depomed in its sole discretion. Despite this, Depomed agrees that Patheon may include Depomed's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

#### **ARTICLE 27 – EXECUTION IN COUNTERPARTS**

This Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

#### **ARTICLE 28 – GOVERNING LAW**

This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, without regard to principles of conflicts of law that would result in the application of the laws of any other jurisdiction.

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

PATHEON PUERTO RICO, INC. DEPOMED, INC.

By: /s/ Francisco R. Negron □ By: /s/ James Schoeneck
Name: Francisco R. Negron □ Name: James Schoeneck

Title: VP Operations P.R. Title: CEO

LIST OF SCHEDULES

- 1. SCHEDULE A SPECIFICATIONS
- 2. SCHEDULE B MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRODUCTION FEES
- 3. SCHEDULE C QUALITY AGREEMENT
- 4. SCHEDULE D CAPITAL EXPENDITURE AND EQUIPMENT AGREEMENT
- 5. SCHEDULE E API, API CREDIT VALUE, AND MAXIMUM CREDIT VALUE
- 6. SCHEDULE F QUARTERLY API INVENTORY REPORT
- 7. SCHEDULE G REPORT OF ANNUAL API INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL YIELD
- 8. SCHEDULE H STABILITY TESTING SERVICES AND PRICING

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# Schedule A SPECIFICATIONS

[\*\*\*]

# Redacted 121 pages

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# Schedule B MINIMUM RUN QUANTITY, ANNUAL VOLUME, AND PRODUCTION FEES FOR PROPOSAL C-CGC-16206-R3

# Gabapentin ER 300mg Tablets (PHN) - Bottle SKU

Bottle SKU		30' s	
Tier (# of tablets)	[***]	[***]	[***]
Run Qty (bottles)	[***]	[***]	[***]
Mfg Run Qty (batches)	[***]	[***]	[***]
Pkg Run Qty (batches)	[***]	[***]	[***]
Price per bottle (USD)	[***]	[***]	[***]

# Gabapentin ER 300 mg Tablets (PHN) - Bulk Packaging

Tier (# of tablets)	[***]	[***]	[***]
Run Qty (1,000' s tablets)	[***]	[***]	[***]
Min. Mfg Run Qty (batches)	[***]	[***]	[***]
Min. Bulk Pkg Run Qty (batches)	[***]	[***]	[***]
Price per 1,000 Bulk Tablets (USD)	[***]	[***]	[***]

#### Gabapentin ER 600 mg Tablets (PHN) - Bottle SKU's

Tier (# of tablets)		[***]			[***]			[***]			[***]	
Bottle SKU	19' s	90' s	300' s	19' s	90' s	300' s	19' s	90' s	300' s	19' s	90' s	300' s
Run Qty (bottles)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Min. Mfg Run Qty												
(batches)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Min. Pkg Run Qty												
(batches)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Price per Bottle												
(USD)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

# Gabapentin ER 600 mg Tablets (PHN)- Bulk Packaging

Tier (# of tablets)	[***]	[***]	[***]	[***]
Run Qty (1,000' s tablets)	[***]	[***]	[***]	[***]
Min. Mfg Run Qty (batches)	[***]	[***]	[***]	[***]
Min. Bulk Pkg Run Qty (batches)	[***]	[***]	[***]	[***]
Price per 1,000 Bulk Tablets (USD)	[***]	[***]	[***]	[***]

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# **Key Technical Assumptions**

#### 1. Manufacturing Assumptions

- 1. The manufacturing process at Patheon will closely follow the process information provided by Depomed and experience todate at the site.
- 2. The API, Gabapentin, has been categorized by Patheon as a [\*\*\*] and can be handled safely using existing equipment and facility at the site.
- 3. The core tablet weights and manufacturing batch sizes for Gabapentin Tablets, 2 strengths, proposed by Patheon are summarized in the following table. The formulation for the 2 strengths is different.

Strength	Core Weight	Batch Size	Theoretical Yield
[***]	[***]	[***]	[***]

4.	Manufacturing process involves high shear wet granulation, fluid bed drying, milling, final blending, compressing and aqueous film coating.
5.	The manufacturing equipment train will consist of the following equipment for both strengths:
	<ul> <li>[***]</li> <li>[***]</li> <li>[***]</li> <li>[***]</li> <li>[***]</li> </ul>
6.	There will be [***] granulation loads per batch for [***] strength and [***] granulation loads per batch for the [***] strength, and will be combined for final blending in the 75 cu.ft. V-Blender respectively.
7.	Aqueous film coating will be completed in [***] and [***] pan loads per batch in the 60" Vector Coater, for [***] and [***], respectively.
8.	For each strength, a different color for aqueous film coating is required.
	Confidential Information, indicated by [***] has been omitted from this filing and filed separately with the Securities and Exchange Commission.
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9.	Various manufacturing campaigns are proposed as noted in the Pricing Tables.
10.	The 2 strengths cannot be campaigned in the same manufacturing run due to the difference in formulation and excipients for each respective strength.
11.	For bulk packaging, the manufactured tablets will be packaged into [***] at approximately [***] for both [***] and [***] strength tablets.
12.	A manufacturing yield of [***] is assumed.
	Packaging Assumptions
1.	Tablets will be packaged into various bottle SKU's for both strengths on Packaging Line 6 using the following equipment train;
	Packaging Line 4 or 6  • [***]  • [***]  • [***]  • [***]  • [***]  Copyright © 2013 <a href="www.secdatabase.com">www.secdatabase.com</a> . All Rights Reserved.  Please Consider the Environment Before Printing This Document

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

2.

- [\*\*\*]
- [\*\*\*
- [\*\*\*]
- 2. The packaging configuration at launch for each respective strength will be as follows (other configurations are contemplated and may be launch by Depomed at a later date):

Bulk Product [***]	30' s Bottle [***]	90' s Bottle [***]
• [***]	• [***]	• [***]
• [***]	• [***]	• [***]
• [***]	• [***]	• [***]
	• [***]	• [***]
	• [***]	• [***]

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- 3. One common outsert is assumed for all bottle SKUs.
- 4. Various packaging campaigns are proposed in the Pricing Tables.

# 3. Testing Assumptions

- 1. Testing for raw materials, packaging components and finished product are based on the specifications and methods completed to-date at the site. Testing is based on standard USP.
- 2. Release testing includes appearance, ID, assay, related substances, dissolution, water content, uniformity of dosage units and residual solvents.
- 3. Testing cost may be subject to change based on final specifications and agreement between the two parties.

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# Schedule C QUALITY AGREEMENT

# [TO BE ATTACHED AS SOON AS PRACTICABLE]

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.

# Schedule D CAPITAL EXPENDITURE AND EQUIPMENT AGREEMENT

# CAPITAL EXPENDITURE AND EQUIPMENT AGREEMENT THIS CAPITAL EXPENDITURE AND EQUIPMENT AGREEMENT (the "Agreement") is made as of , 2011 (the "Effective Date") between

**DEPOMED, Inc.** ("**DEPOMED**" or "DEPOMED"), a corporation organized under the laws of the State of California, having its principal place of business at 1360 O' Brien Drive, Menlo Park, California 94025.

"DEPOMED")

- and -

# PATHEON PUERTO RICO, INC.,

a corporation organized under the laws of the Commonwealth of Puerto Rico, located at **State Road 670 Km. 2.7, Manati, Puerto Rico 00674** (hereinafter referred to as "**PATHEON**")

#### **BACKGROUND**

DEPOMED and PATHEON are currently negotiating the terms of a Commercial Manufacturing Services Agreement (the "MSA") under which PATHEON will perform certain manufacturing services (the "Services") related to DEPOMED for Gralise (the "Product"). In order for PATHEON to perform the Services, certain capital expenditures will be required for the purchase and installation of capital equipment and facility improvements at PATHEON's facility located at State Road 670 Km. 2.7 Manatí, Puerto Rico 00674 (the "Facility"). The purpose of this Agreement is to set out the parties' agreement and undertakings regarding such capital expenditures.

#### **AGREEMENT**

**NOW, THEREFORE,** in consideration of the rights conferred and the obligations assumed herein, and intending to be legally bound, the parties hereby agree as follows:

#### 1. Definitions

March

"DEPOMED EQUIPMENT" means the items listed in that category on Schedule A as belonging to, owned or otherwise property of DEPOMED.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.

"DEDICATED REQUIREMENTS" means the items listed in that category on Schedule A that will be used exclusively for the services covered under the MSA by and between DEPOMED and PATHEON.

"NON-DEDICATED REQUIREMENTS" means the items listed in that category on Schedule A that can be used by PATHON for services other than those covered under the MSA by and between DEPOMED and PATHEON.

# 2. Expenditures

The DEPOMED shall be responsible for the cost of the Equipment as described on Schedule A and all expenses and costs related to its installation and qualifications at the Facility.

# 3. Equipment

- (a) DEPOMED shall, at its expense, arrange to purchase (if not already owned by DEPOMED) and deliver DEPOMED EQUIPMENT to the Facility including, without limitation, all costs and expenses associated with transportation, insurance and customs clearance (if applicable).
- (b) DEPOMED shall also be responsible for all costs and expenses associated with the installation and installation qualification / operational qualification and process qualification of DEPOMED EQUIPMENT at the Facility, upon successful completion of the installation and qualification DEPOMED EQUIPMENT shall be deemed to be in good working order and shall be suitable to manufacture the Products in accordance with current Good Manufacturing Practices

# 4. PATHEON Use of Equipment and Facility Improvements

PATHEON may use the NON-DEDICATED REQUIREMENTS to manufacture products for third parties without any compensation for this use owed to DEPOMED. PATHEON will indemnify and hold DEPOMED harmless from any claims which arise out of the use of the NON-DEDICATED REQUIREMENTS subject to the MSA limitations of liablity.

# 5. Maintenance of Dedicated Requirements

(a) PATHEON will at its expense perform routine repairs, preventive maintenance, and calibration on the NON-DEDICATED REQUIREMENTS owned by DEPOMED. Repair, maintenance, and calibration costs, including the cost of spare part purchases or equipment upgrades requested by DEPOMED will be invoiced to DEPOMED at PATHEON's actual cost. PATHEON will conduct routine repairs and preventive maintenance of the DEDICATED REQUIREMETS up to a maximum of \$[\*\*\*] per year.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.

- (b) PATHEON will give DEPOMED reasonable access during normal working hours for the inspection of the DEDICATED REQUIREMENTS.
- (c) PATHEON will keep the DEDICATED REQUIREMENTS free from encumbrances, liens, and interests of third parties.
- (d) PATHEON will notify DEPOMED if any accident, loss of or damage occurs to the DEDICATED REQUIREMENTS.

#### 6. Title and Risk of Loss of the Equipment and Facility Improvements

The DEDICATED REQUIREMENTS will be owned by DEPOMED, which will be the sole legal and beneficial owner thereof. Title and risk of loss to the NON-DEDICATED REQUIREMENTS and the FACILITY IMPROVEMENTS, will be with PATHEON, which will be the sole legal and beneficial owner thereof. PATHEON will at all times keep the DEDICATED REQUIREMENTS, the NON-DEDICATED REQUIREMENTS and the FACILITY IMPROVEMENTS, insured at replacement cost, and PATHEON will replace any of these items that are lost, damaged or destroyed. PATHEON will name DEPOMED as an additional insured on an insurance policy that covers the DEDICATED REQUIREMENTS owned by DEPOMED.

#### 7. Term; Termination.

- (a) This Agreement will commence on the Effective Date and will continue in effect until the expiration or termination of the MSA, including any extensions thereof. This Agreement will terminate automatically if the parties have not executed all of the documents comprising the Amendment to the MSA by TBD unless this date is extended by written agreement of the parties.
- (b) Upon the expiration or termination of the MSA for any reason, (a) DEPOMED shall offer PATHEON the first right option to purchase the DEPOMED EQUIPMENT at fair market value, or (b) DEPOMED shall remove, or arrange to remove, from the Facility at its expense all DEPOMED EQUIPMENT that is not purchased by PATHEON and DEPOMED shall repair, or arrange to repair, at its expense any damage to the Facility resulting from such removal.
- (c) **Removal of Equipment.** If this Agreement expires or is terminated for any reason: (i) DEPOMED will remove, or arrange to remove, from the Facility at its expense all DEDICATED REQUIREMENTS and any Equipment not purchased by PATHEON and will repair or arrange to repair, at its expense, any damage to the Facility resulting from this removal.

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#### 8. General

- (a) All monetary amounts are expressed in the lawful currency of the United States of America.
- (b) This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, without regard to principles of conflicts of law that would result in the application of the laws of any other jurisdiction.
- (c) This Agreement contains the entire understanding of the parties about the subject matter herein and supersedes all previous agreements (oral and written), negotiations and discussions.
- (d) The parties may modify or amend the provisions hereof only by an instrument in writing duly executed by both of the parties.

- (e) Neither party may assign or otherwise transfer its rights or obligations hereunder without the prior written consent of the other party.
- (f) This Agreement may be signed by facsimile or in two counterparts, each of which when executed and delivered or transmitted, will be considered an original and both of which together will constitute one and the same instrument.
- (g) The "Background" section of this document is expressly incorporated into the Agreement.

IN WITNESS WHEREOF the duly authorized representatives of the parties have executed this Agreement.

# DEPOMED, INC.

# PATHEON PUERTO RICO, INC.

/s/ James Schoeneck /s/ Francisco R. Negron□

Name:James SchoeneckName:Francisco R. Negron□Title:CEOTitle:VP PR OperationsDate:9/1/11Date:31-Aug-2011

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.

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# **SCHEDULE A**

Item			Depomed	Country		Client
#	Category	Item/Serial Number	Number	of Origin	Cost/Value	Investment
1	Depomed Equipment	[***]	etched "Gabapentin"	Patheon Caguas 1	[***]	[* **]
	(Dedicated)					
2	Depomed Equipment (Dedicated	[***]	0142	Patheon Caguas 1	[***]	[***]
3	Depomed Equipment (Dedicated	[***]	0143	Patheon Caguas 1	[***]	[***]
4	Depomed Equipment (Dedicated	[***]	0144	Patheon Caguas 1	[***]	[***]
5	Depomed Equipment (Dedicated	[***]	0145	Patheon Caguas 1	[***]	[***]
6	Depomed Equipment (Dedicated	[***]	0146	Patheon Caguas 1	[***]	[***]
7	Depomed Equipment (Dedicated	[***]	0147	Patheon Caguas 1	[***]	[***]

8	Depomed	[***]	0148	Patheon Caguas 1	[***]	[***]
	Equipment					
	(Dedicated					
9	Depomed	[***]	0149	Patheon Caguas 1	[***]	[***]
	Equipment					
	(Dedicated					

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10	Depomed Equipment (Dedicated	[***]	0150	Patheon Caguas 1	[***]	[***]
11	Depomed Equipment (Dedicated	[***]	etched "Gabapentin"	Patheon Caguas 1	[***]	[***]
12	Depomed Equipment (Non- Dedicated)	[***]	0140	Patheon Caguas 1	[***]	[***]
13	Depomed Equipment (Non-dedicated)	[***]	0222	Patheon Caguas 1	[***]	[***]
14	Depomed Equipment (Non-dedicated)	[***]	0221	Patheon Caguas 1	[***]	[***]
15	Depomed Equipment (Non-dedicated)	[***]	0219	Patheon Caguas 1	[***]	[***]
16	Depomed Equipment (Non-dedicated)	[***]	0220	Patheon Caguas 1	[***]	[***]
17	Depomed Equipment (Non-dedicated)	[***]	0217	Patheon Caguas 1	[***]	[***]
18	Depomed Equipment (Non-dedicated)	[***]	0218	Patheon Caguas 1	[***]	[***]

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19	Depomed Equipment (Non-dedicated)	[***]	0139	Patheon Caguas 1	[***]	[***]
20	Depomed Equipment (Non-dedicated)	[***]	0223	Patheon Caguas 1	[***]	[***]
21	Depomed Equipment (Non-dedicated)	[***]	0224	Patheon Caguas 1	[***]	
22	Depomed Equipment (Non-dedicated)	[***]	0225	Patheon Caguas I	[***]	[***]
23	Depomed Equipment (Non-dedicated)	[***]	0226	Patheon Caguas 1	[***]	
24	Depomed Equipment (Non-dedicated)	[***]	0141	Patheon Caguas 1	[***]	[***]
	Total Cost/Value				[***]	[***]

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# Schedule E API, API CREDIT VALUE, AND MAXIMUM CREDIT VALUE

# <u>API</u>

API	Supplier
	• [***]
Gabapentin HCl	
	• [***]

# **API CREDIT VALUE**

The API Credit Value for Product will be as follows:

Depomed's actual average yearly cost for the API.

		API
PRODUCT	API	CREDIT VALUE
Gralise	Gabapentin HCl	[***]

# **MAXIMUM CREDIT VALUE**

Patheon's liability for API calculated in accordance with Section 8.2.2 of the Agreement for any Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Gralise	[***] of the purchase price of Product delivered pursuant to
	Purchase Orders submitted during the last [***]

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.

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# Schedule F OUARTERLY API INVENTORY REPORT

QUARTERLY API INVENTORY REPORT				
TO:	DEPOMED, INC.			
FROM: PATHEON PUERTO RICO, INC.				
RE:	E: API monthly inventory report under Section 5.6.1			
Reporting quarter:				
API on hand at beginning of month:		kg	(A)	
API on hand at end of month:		kg	(B)	
Quantity Received during month:		kg	(C)	
Quantity Dispensed(1) during month: (A + C - B)		k	g	
Quantity Converted during month: (total API in Product produced and not rejected, recalled or returned)		kg		
Capitalized terms used in this report have the meanings given to the terms in the Agreement.				
PATHEON PUERTO RICO, INC.		DATE:		
Per: Name: Title:				

Excludes any (i) API this must be retained by Patheon as samples, (ii) API contained in Product that must be retained as samples, and (iii) API used any regulatory, stability, validation, or test batches manufactured during the Year.

# Schedule G REPORT OF ANNUAL API INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

ТО:	DEPOMED, INC.		
FROM:	PATHEON PUERTO RICO, INC.		
RE:	API annual inventory reconciliation report and calculation of Actual Annual Yield under Section		
Reporting Yea	ur ending:		
API on hand at beginning o	of Year:		kg (A)
API on hand at end of Year	:		kg (B)
Quantity Rece	rived during Year:		kg (C)
Quantity Disp (A + C - B)	ensed(2) during Year:		kg (D)
(total API in P	verted during Year: Product produced ed, recalled or returned)		kg (E)
API Credit Va	lue:	\$	/ kg (F)
Target Yield:			[***] % (G)
Actual Annual			% (H)
Reimburse An (G-H)*F*D	nount (if any)		\$
(2) F11	(i) A DI di i l l Deticore	1 (::) ADI4-i1 i	D 1 (4) (1 (* 1

(2) Excludes any (i) API this must be retained by Patheon as samples, (ii) API contained in Product that must be retained as samples, and (iii) API used any regulatory, stability, validation, or test batches manufactured during the Year.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.

Based on the foregoing reimbursement calculation Patheon will reimburse Depomed the amount of \$				
Capitalized terms used in this report have the meanings given to the t	erms in the Agreement.			
DATE:				
PATHEON PUERTO RICO, INC.				
Per:				
Name:				
Title:				
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# Schedule H STABILITY TESTING SERVICES AND PRICING

Patheon and Depomed will agree in writing on any stability testing to be performed by Patheon on the Product. Any agreement governing such testing will specify the protocols applicable to the stability testing and the fees payable by Depomed for this testing.

CERTAIN MATERIAL (INDICATED BY [\*\*\*]) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITES AND EXCHANGE COMMISSION.

#### **COMMERCIALIZATION AGREEMENT**

This COMMERCIALIZATION AGREEMENT (this "<u>Agreement</u>") is made as of August 22, 2011 (the "<u>Effective Date</u>"), by and between Depomed, Inc., a California corporation ("<u>Depomed</u>"), and Santarus, Inc., a Delaware corporation ("<u>Santarus</u>"). Each of Depomed and Santarus is referred to herein individually as a "party" and collectively as the "parties."

WHEREAS, Deponded and Santarus are parties to that certain Promotion Agreement dated as of July 21, 2008, as amended by those certain letter agreements dated July 30, 2010 and October 4, 2010 (collectively, the "Promotion Agreement"), pursuant to which Deponded engaged Santarus to promote and market the Products in the Territory (each as defined below);

WHEREAS, the parties desire to enter into this Agreement in order to expand Santarus' role in the commercialization of the Products in the Territory to include manufacturing, distribution and certain other responsibilities, and to make other related changes in the relationship between the parties, all as set forth herein; and

WHEREAS, this Agreement will supersede and replace the Promotion Agreement in its entirety.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants herein contained, the parties hereto intending to be legally bound hereby agree as follows:

# ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

- Section 1.1 "500mg Product" means the once-daily formulation of 500 mg of API that is the subject of the Product NDA.
- Section 1.2 "1000mg Product" means the once-daily formulation of 1000 mg of API that is the subject of the Product NDA.
- Section 1.3 "Act" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, et. seq., as it may be amended from time to time, and the regulations promulgated thereunder, including the Generic Drug Act.
  - Section 1.4 "Additional Rights of Reference" has the meaning provided in Section 2.5(c).
- Section 1.5 "<u>Additional Rights of Reference Agreement</u>" means the applicable agreement between Depomed and a Third Party pursuant to which Depomed grants an Additional Right of Reference.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

- Section 1.6 "Adverse Drug Experience" means any "adverse drug experience" as defined or contemplated by 21 C.F.R. 314.80 or 312.32, associated with a Product.
- Section 1.7 "Adverse Drug Experience Report" means any oral, written or electronic report of any Adverse Drug Experience transmitted to any Person.
- Section 1.8 "Advertising/Marketing/Educational Expenses" means the following Santarus expenses for directly Promoting the Products and conducting Educational Programs with respect to the Products in the Territory: (a) all out-of-pocket costs for Samples incurred as well as all out-of-pocket costs for Sample warehousing and distribution (excluding Sample costs paid or reimbursed by Depomed), (b) all out-of-pocket costs for Promotional Materials and training materials (excluding Promotional Materials and training materials costs paid or reimbursed by Depomed), (c) all out-of-pocket costs for sales training meetings to the extent attributable to the Products, (d) all out-of-pocket costs for the purchase of Prescriber Data (including any prescriber data for competitive products), (e) all out-of-pocket costs associated with market research, advisory boards, speaker programs, trade shows and "lunch and learns" and other outreach programs with respect to the Products; (f) all costs related to scientific liaisons, and national and regional account managers to the extent attributable to the Products; (g) all costs related to up to one (1) full-time equivalent dedicated product manager; (h) all Medical Affairs Expenses; and (i) all other out-of-pocket costs and expenses of Santarus for directly Promoting the Products and conducting or sponsoring Educational Programs with respect to the Products in the Territory. In the case of Product voucher, coupon, loyalty card or other co-pay assistance programs, all out-of-pocket costs of Santarus associated with such programs (other than redemption costs) shall be treated as Advertising/Marketing/ Educational Expenses; provided that Santarus shall not have the right to deduct such costs in calculating Net Sales. Notwithstanding the foregoing, (A) the costs set forth in items (f) and (g) above shall be subject to an [\*\*\*] cap during each calendar year (pro rated for any partial years) and (B) the costs set forth in item (c) above shall be subject to a [\*\*\*] cap during each calendar year (pro rated for any partial years); and such costs in excess of the caps set forth in clauses (A) and (B) shall not be treated as Advertising/Marketing/Educational Expenses.
- Section 1.9 "Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with, such first Person. For the purposes of this definition, "control" (including, with correlative meanings, the terms "controlling," "controlled by" and "under common control with"), as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of that Person, whether through the ownership of voting securities, by contract or otherwise.
  - Section 1.10 "Agreement" has the meaning set forth in the preamble to this Agreement.
- Section 1.11 "<u>Agreement Month</u>" means each calendar month during the Term (including any partial calendar month in the case of the first and last calendar months of the Term).

- Section 1.12 "<u>Agreement Quarter</u>" means the Initial Agreement Quarter, each successive period of three months during the Term after the Initial Agreement Quarter and the Final Agreement Quarter.
  - Section 1.13 "<u>Alliance Managers</u>" has the meaning set forth in Section 4.1.
  - Section 1.14 "ANDA" means Abbreviated New Drug Application.

- Section 1.15 "ANDA Settlement Distributor" means a Third Party, who, in connection with the settlement of an ANDA litigation proceeding under the Hatch-Waxman Act and Medicare Prescription Drug, Improvement and Modernization Act of 2003, has been licensed or otherwise permitted by Depomed or Santarus, as applicable (subject to Section 12.2), to sell a Generic Version of a Product in the Territory.
  - Section 1.16 "Annual Plan" has the meaning set forth in Section 5.5(a).
  - Section 1.17 "API" means metformin hydrochloride.
- Section 1.18 "Applicable Rate" means, as of a given date, the then-applicable royalty rate under Section 8.1(a) on such date.
- Section 1.19 "<u>Assigned Agreement</u>" means any of the agreements listed in Schedule 1.19 hereto. For the avoidance of doubt, Assigned Agreements exclude the Retained Contracts.
- Section 1.20 "<u>Authorized Generic</u>" means a Generic Version sold by or on behalf of a party hereto in the Territory, including by an Authorized Generic Distributor, but excluding by any ANDA Settlement Distributor.
- Section 1.21 "<u>Authorized Generic Distributor</u>" means a Third Party who has been contracted by Santarus to Commercialize a Generic Version on behalf of Santarus in the Territory, but excluding any ANDA Settlement Distributor.
- Section 1.22 "<u>Baseline Percentage</u>" means the percentage determined by dividing (a) the total number of Units of Product prescribed by Professionals on the Depomed Physician List during the two (2) complete Agreement Quarters prior to delivery by Depomed of notice of its intention to commence Promotion and Detailing of the Product in the Territory pursuant to Section 5.9, by (b) the total number of Units of Product prescribed by all Professionals during such two (2) complete Agreement Quarters, based on Prescriber Data for such two (2) complete Agreement Quarters, as such percentage may be amended pursuant to Section 5.9.
- Section 1.23 "<u>BLS</u>" means Valeant Pharmaceuticals International, Inc., successor-in-interest of Biovail Laboratories International SRL, or any Person which succeeds to the obligations of Biovail Laboratories International SRL under the BLS Agreements.

- Section 1.24 "<u>BLS Agreements</u>" means, collectively, the BLS Manufacturing Transfer Agreement and the BLS Supply Agreement. For the avoidance of doubt, the BLS Agreements exclude the BLS Canada License Agreement.
- Section 1.25 "<u>BLS Canada License Agreement</u>" means that certain Amended and Restated License Agreement (Extended Release Metformin Formulations Canada), dated as of December 13, 2005, by and between Depomed and BLS, as the same may be amended from time to time after the Effective Date in accordance with the terms of this Agreement.
- Section 1.26 "<u>BLS-Manufactured Product</u>" means, until such time, if ever, as the BLS Agreements are assigned by Depomed to, and assumed by, Santarus, any 1000mg Product (excluding Samples thereof) that BLS or the applicable Third Party has agreed to supply to Depomed or its designee under the BLS Supply Agreement.

- Section 1.27 "<u>BLS-Manufactured Samples</u>" means, until such time, if ever, as the BLS Agreements are assigned by Depomed to, and assumed by, Santarus, any Samples of 1000mg Product that BLS or the applicable Third Party has agreed to supply to Depomed or its designee under the BLS Supply Agreement.
- Section 1.28 "<u>BLS Manufacturing Transfer Agreement</u>" means that certain Manufacturing Transfer Agreement (Controlled Release Metformin Formulations USA), dated as of December 13, 2005, by and between Depomed and BLS, as amended on June 16, 2006, as the same may be amended from time to time after the Effective Date in accordance with the terms of this Agreement.
- Section 1.29 "BLS Patent Rights" means the "Patent Rights," as such term is defined in the BLS Manufacturing Transfer Agreement.
- Section 1.30 "<u>BLS Supply Agreement</u>" means that certain Supply Agreement (Extended Release Metformin Formulations U.S.A.), dated as of December 13, 2005, between Depomed and BLS, as amended on June 30, 2007, as amended from time to time after the Effective Date in accordance with the terms of this Agreement, or any successor Third Party supply agreement for the 1000mg Product.
- Section 1.31 "<u>cGMP</u>" shall mean current "Good Manufacturing Practices" as such term is defined from time to time by the FDA or other relevant Regulatory Authority having jurisdiction over the manufacture or sale of a Product pursuant to its regulations, guidelines or otherwise.
  - Section 1.32 "Chargeback Agreements" means Depomed's chargeback agreements for Products listed in Schedule 1.32.
- Section 1.33 "<u>COGS</u>" means, for a particular period, the applicable party's cost of goods sold (calculated in accordance with Section 8.4(c)) for the Products in the Territory for such period.

- Section 1.34 "<u>Combination Product</u>" means a pharmaceutical product formulation for human use containing both:
  (a) metformin or any other salt, chiral form or metabolite thereof; and (b) one or more other active pharmaceutical ingredients (each, an "Other API"), whether any such Other API is generic (*i.e.*, the composition of matter of such Other API is not covered by patent rights), proprietary to Depomed or any of its Affiliates, or proprietary to a Third Party.
- Section 1.35 "<u>Commercialize</u>," "<u>Commercialization</u>" or "<u>Commercializing</u>" means to Promote, import, distribute and sell Products in the Territory, including all activities incident thereto and contemplated by the terms of this Agreement.
- Section 1.36 "<u>Commercial Rebate Agreements</u>" means Depomed's commercial rebate agreements for Products listed in Schedule 1.36.
- Section 1.37 "<u>Confidentiality Agreement</u>" means that certain Confidentiality Agreement, dated as of May 20, 2004, between Depomed and Santarus.
- Section 1.38 "<u>Controlled</u>" means, with respect to patents, know-how or other intellectual property rights of any kind, the possession by a party of the ability to grant a license or sublicense of such rights as contemplated by this Agreement, without violating the terms of any agreement or other arrangement with any Third Party.

- Section 1.39 "<u>Co-Promotion Net Sales</u>" means, for a particular period, Net Sales for such Period, multiplied by the Depomed Percentage for such period.
  - Section 1.40 "Covered Combination Product" has the meaning set forth in Section 15.1.
- Section 1.41 "<u>Customers</u>" means Third Party wholesalers, retailer pharmacies, mail-order pharmacies, group purchasing organizations or other organizations similar to those that purchase the Products from Deponded as of the Effective Date in the Territory.
- Section 1.42 "<u>DDMAC</u>" means the FDA's Division of Drug Marketing, Advertising and Communications, or any successor Regulatory Authority performing comparable functions in the Territory.
  - Section 1.43 "<u>Depomed</u>" has the meaning set forth in the preamble to this Agreement.
- Section 1.44 "<u>Depomed Chargebacks Reserve</u>" means Depomed's GAAP reserve account for Product chargebacks under the Chargeback Agreements as of the business day preceding the First Sales Booking Date.
- Section 1.45 "<u>Depomed Commercial Rebates Reserve</u>" means Depomed's GAAP reserve account for Product rebates under the Commercial Rebate Agreements as of the business day preceding the First Sales Booking Date.
- Section 1.46 "<u>Depomed Government Rebates Reserve</u>" means Depomed's GAAP reserve account for Product rebates under the Government Rebate Agreements as of the business day preceding the First Sales Booking Date.

- Section 1.47 "<u>Depomed Patent Rights</u>" means all patents and patent applications Controlled by Depomed during the Term, which patents and patent applications (if issued) would be infringed by the Commercialization of Product (or a Generic Version) in the Territory or the Manufacture of Product (or a Generic Version) for Commercialization in the Territory. The Depomed Patent Rights include, without limitation, the BLS Patent Rights licensed to Depomed under the BLS Manufacturing Transfer Agreement.
- Section 1.48 "<u>Depomed Patient Discount Reserve</u>" means Depomed's GAAP reserve account for redemptions under the Discount Card Programs as of the business day preceding the First Sales Booking Date.
- Section 1.49 "Depomed Percentage" means, for a particular period during which Depomed is Promoting and Detailing a Product pursuant to Section 5.9, the difference of (a) the percentage determined by dividing (i) the total number of Units of Product prescribed during such period by Professionals on the Depomed Physician List, by (ii) the total number of Units of Product prescribed during such period by all Professionals, in each case based on Prescriber Data for the applicable period; minus (b) the Baseline Percentage; provided that the Depomed Percentage shall not be less than zero.
- Section 1.50 "<u>Depomed Physician List</u>" means the list of Professionals to be used in calculating Co-Promotion Net Sales and the Baseline Percentage, as such list may be amended from time to time as contemplated by this Agreement. The Depomed Physician List may not include any Professionals on the Santarus Physician List as in effect immediately prior to Santarus' receipt of the applicable Depomed Physician List pursuant to Section 5.9(a), and the average number of Professionals on the Depomed Physician List shall in no event exceed 150 Professionals per Depomed Sales Representative. For clarity, the limitations in this definition

regarding the Professionals includible on the Depomed Physician List are not intended to provide any limitation on the ability of Depomed to provide Details to any Professionals, but subject to any other limitations set forth in this Agreement.

- Section 1.51 "<u>Depomed Product Expiration Date</u>" means the expiration date of the last Product in the channel bearing Depomed's NDC Number on a Product-by-Product basis.
  - Section 1.52 "Depomed Promotional Materials" has the meaning set forth in Section 5.9(e).
- Section 1.53 "<u>Depomed Returns Reserve</u>" means Depomed's GAAP reserve account for Product returns as of the business day preceding the First Sales Booking Date.
- Section 1.54 "<u>Depomed Sales Force</u>" means the field force of Sales Representatives employed or contracted by Depomed.
- Section 1.55 "<u>Depomed Trademarks</u>" means (a) Glumetza® (the "<u>Depomed Product Trademark</u>"), (b) Acuform® (the "<u>Depomed Technology Trademark</u>"), and (c) Depomed® (the "<u>Depomed Corporate Trademark</u>"). The Depomed Trademarks are attached hereto as Schedule 1.55.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

- Section 1.56 "<u>Detail</u>" means an in-person, face-to-face sales presentation of a Product made by a Sales Representative to a Professional, including a P1 Detail or P2 Detail.
- Section 1.57 "<u>Discount Card Program</u>" means the Product discount card program described in the proposal for New York savings card program between Triple i and Depomed dated January 20, 2011 (the "<u>New York Discount Card Program</u>"), and the Product savings card program described in the Statement of Work, effective as of June 2, 2011, between Depomed and MediMedia, LLC (the "<u>Ex-New York Discount Card Program</u>").
- Section 1.58 "<u>Educational Programs</u>" means any activities undertaken with respect to the education of Professionals, pharmacists, managed care representatives or customers regarding a Product or any indication for a Product or funded by unrestricted educational grants, including educational programs and seminars and education materials.
  - Section 1.59 "<u>Effective Date</u>" has the meaning set forth in the preamble to this Agreement.
- Section 1.60 "<u>Encumbrance</u>" means any lien, pledge, security interest, right of first refusal, option, title defect, license, restriction or other adverse claim or interest or encumbrance of any kind or nature whatsoever, whether or not perfected, including any restriction on use, transfer, receipt of income or exercise of any other attribute of ownership.
  - Section 1.61 "Evaluation Period" has the meaning set forth in Section 14.1.
- Section 1.62 "<u>Executive Officers</u>" means the Chief Executive Officers of Santarus and Depomed (or, if there is no such officer, its President or other executive officer designated by the Chief Executive Officer).
  - Section 1.63 "Existing Infringement Cases" has the meaning set forth in Section 12.2(c).

- Section 1.64 "Existing Rights of Reference" shall mean the Rights of Reference to the Product NDA granted by Depomed:
- (a) to Boehringer Ingelheim International GmbH (including its successors and permitted assigns, "<u>BI</u>") under the License and Services Agreement between Depomed and BI dated March 4, 2011 (the "<u>BI Agreement</u>"), with respect to the Combination Product identified in the BI Agreement, including BI's right under the BI Agreement to extend such Rights of Reference to BI's Affiliates and Third Party contractors and contract service organizations;
- (b) to Janssen Pharmaceutica N.V. (including its successors and permitted assigns, "Janssen") under the License Agreement between Depomed and Janssen dated August 5, 2010 (the "Janssen Agreement"), with respect to the Combination Product identified in the Janssen Agreement, including Janssen's right under the Janssen Agreement to sublicense or otherwise extend such Rights of Reference to Janssen's Affiliates and sublicensees;

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- to Merck & Co., Inc. (including its successors and permitted assigns, "Merck") under the Non-Exclusive License, Covenant Not to Sue and Right of Reference Agreement between Depomed and Merck dated July 21, 2009 (the "Merck Agreement"), with respect to the Combination Product identified in the Merck Agreement, including Merck's right under the Merck Agreement to sublicense or otherwise extend such Rights of Reference to Merck's Affiliates, sublicensees and contractors;
- (d) to LG Life Sciences Ltd. (including its successors and permitted assigns, "<u>LG</u>") under the Amended License Agreement between Depomed and LG dated January 9, 2007 (the "<u>LG Agreement</u>"), with respect to Products for Commercialization in Korea, including LG's right under the LG Agreement to sublicense or otherwise extend such Rights of Reference to LG's Affiliates and permitted sublicensees; and
- (e) to BLS under the BLS Canada License Agreement, with respect to Products for Commercialization in Canada, including BLS's right under the BLS Canada License Agreement to sublicense or otherwise extend such Rights of Reference to BLS's Affiliates and sublicensees.
- Section 1.65 "Existing Rights of Reference Agreements" means the BI Agreement, the Janssen Agreement, the Merck Agreement, the LG Agreement and the BLS Canada License Agreement.
- Section 1.66 "<u>FDA</u>" means the United States Food and Drug Administration or any successor agency performing comparable functions in the Territory.
- Section 1.67 "<u>Final Agreement Quarter</u>" means the period commencing on the first day following the last full Agreement Quarter during the Term and ending on the last day of the Term.
  - Section 1.68 "First Sales Booking Date" means September 1, 2011, unless otherwise agreed by the parties.
  - Section 1.69 "Force Majeure Event" has the meaning set forth in Section 18.7.
  - Section 1.70 "GAAP" has the meaning set forth in Section 8.4(c).
  - Section 1.71 "Generic Drug Act" has the meaning set forth in Section 11.1(i).

- Section 1.72 "<u>Generic Entry</u>" with respect to a Product, means the initiation of sales to wholesale or retail customers of one or more Generic Versions of such Product (other than an Authorized Generic) in the Territory by a Third Party, including an ANDA Settlement Distributor, but excluding any Authorized Generic Distributor.
- Section 1.73 "<u>Generic Version</u>" means, with respect to a Product, any pharmaceutical product, which (a) contains the same active ingredient(s) in the same dosage(s) and dosage form as such Product, (b) is approved in reliance on, and by reference to, the Product NDA, or is approved under the Product NDA, and (c) in the case of products approved by reference to,

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rather than under, the Product NDA, has been issued a therapeutic equivalence code of AB (as such term is used in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the FDA Center for Drug Evaluation and Research or any successor publication) by the FDA with respect to such Product. For the avoidance of doubt, no Combination Product shall be considered a Generic Version with respect to any Product.

- Section 1.74 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the parties contemplated by this Agreement.
- Section 1.75 "<u>Government Rebate Agreements</u>" means Depomed's government and military rebate agreements for Products listed in Schedule 1.75.
- Section 1.76 "Gross Margin" means, for a particular period and particular Product (*i.e.*, the 500mg Product or the 1000mg Product), (A) Net Sales of such Product minus COGS for such period for such Product, plus (B) all amounts received by Santarus or any of its Affiliates from any Authorized Generic Distributor with respect to an Authorized Generic of such Product (including upfront fees, maintenance fees, royalties or other payments with respect to such Authorized Generic Distributor's sales of such Authorized Generic, and the supply price of Authorized Generic sold to such Authorized Generic Distributor), for such period minus COGS for such period for such Authorized Generic.
- Section 1.77 "Initial Agreement Quarter" means the period commencing on the Effective Date and ending on December 31, 2011.
- Section 1.78 "<u>Inventory</u>" means Depomed's inventory of finished Product (including Samples) and API for the Territory as of the First Sales Booking Date.
- Section 1.79 "<u>Legal Requirements</u>" means laws, rules and regulations of any Governmental Authority in the Territory, including, for clarity, all guidelines, policies and procedures referenced in Section 6.3 of this Agreement.
- Section 1.80 "<u>Manufacture</u>," "<u>Manufactured</u>" and "<u>Manufacturing</u>" mean all operations involved in the manufacture, receipt, incoming inspection, storage and handling of raw materials, and the manufacture, processing, purification, packaging, labeling, warehousing, quality control testing (including in-process release and stability testing), shipping and release of Products.

Section 1.81 "<u>Manufacture Transfer Date</u>" means (i) with respect to the 500mg Product, as soon as reasonably practicable after November 1, 2011, and on a date, not later than November 30, 2011, mutually agreed by the parties, unless otherwise agreed by the parties and (ii) with respect to the 1000mg Product, on a date mutually agreed by the parties.

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- Section 1.82 "<u>Medical Affairs Expenses</u>" incurred by a party means, with respect to a particular period, all out-of-pocket costs incurred by the applicable party related to the handling of medical inquiries during such period, to the extent attributable to the Product.
  - Section 1.83 "Minimum Detailing Obligations" has the meaning set forth in Section 5.1(b).
- Section 1.84 "<u>NDA</u>" means any "new drug application" (as such term is used under the Act) filed or acquired by Depomed or any Affiliate with the FDA with respect to a Product and all subsequent submissions, supplements and amendments thereto, including the Product NDA.
- Section 1.85 "<u>NDA Transfer Date</u>" means as soon as reasonably practicable after November 1, 2011, and on a date mutually agreed by the parties, which, unless otherwise agreed by the parties, shall be the same date as the Manufacture Transfer Date for the 500mg Product.
- Section 1.86 "NDC Number" means the National Drug Code, which is the 11-digit code registered by a party with the FDA with respect to a Product.
  - Section 1.87 "Negotiation Period" has the meaning set forth in Section 15.1.
- Section 1.88 "Net Sales" means, with respect to a Product, for a particular period, the gross amount invoiced on sales of such Product in the Territory recognized as gross revenue in accordance with GAAP by Santarus, its Affiliates and assigns to independent, unrelated Third Parties (excluding sales of Authorized Generics of such Product to Authorized Generic Distributors) during such period in bona fide arms' length transactions, less the following deductions, calculated to arrive at net sales in accordance with GAAP: (a) freight, insurance (but only insurance with respect to shipping the Product), and other transportation charges to the extent added to the sales price and set forth separately as such on the total amount invoiced; (b) any sales, use, value-added, excise taxes or duties or allowances on the selling price of the Product to the extent added to the sales price and set forth separately as such on the total amount invoiced; (c) chargebacks, trade, quantity and cash discounts and rebates to the extent customary in the trade, including governmental rebates; (d) allowances or credits, including allowances or credits on account of rejection, defects or returns of the Product, or because of a retroactive price reduction; (e) redemption costs associated with any voucher, coupon, loyalty card or other copay assistance programs for the Product; and (f) fees paid to wholesalers, group purchasing organizations, pharmacy benefit managers and the like based on the sale or dispensing of the Product. Net Sales shall not include a sale or transfer to an Affiliate, licensee, sublicensee or assign of Santarus or Depomed or if done for clinical, regulatory or governmental purposes where no consideration is received; but the resale by such Affiliate, licensee, sublicensee or assign of Santarus or Depomed shall be considered a sale of such Product (for clarity, excluding resales of Authorized Generic versions of such Product). For sales of Products by Depomed between the Effective Date and the First Sales Booking Date, Net Sales shall have the meaning set forth above mutatis mutandis. For purposes of clarity, it is the intent of the parties that "Net Sales" for the purposes of this Agreement shall be consistent with the GAAP net sales reported by Santarus or Depomed, as applicable, in its periodic reports with the U.S. Securities and

Confidential Information, indicated by [\*\*\*] has been omitted from this filing

Exchange Commission. For further clarity, Santarus shall not deduct from Net Sales any amounts for which Depomed bears financial responsibility under Section 9.3.

- Section 1.89 "Open Product Orders" has the meaning given in Section 11.1(m)(iv).
- Section 1.90 "Order" means any award, decision, injunction, judgment, decree, order, ruling, or verdict entered, issued, made, or rendered by any Governmental Authority or by any arbitrator.
- Section 1.91 "P1 Detail" means a Detail in which the promotional message involving a Product is presented to a Product Target in the first position and is the principal topic of discussion during the contact; provided, however, that where the term P1 Detail is used in reference to Details performed by the Depomed Sales Force, the reference herein to "Product Target" shall be replaced by "Professional."
- Section 1.92 "P2 Detail" means a Detail in which the promotional message involving a Product is presented to a Product Target in the second position and is emphasized more than any other product in the Detail, except for the product in the P1 Detail; provided, however, that where the term P2 Detail is used in reference to Details performed by the Depomed Sales Force, the reference herein to "Product Target" shall be replaced by "Professional."
- Section 1.93 "<u>Patheon</u>" means Patheon Puerto Rico, Inc. (f/k/a MOVA Pharmaceutical Corporation), or any Person which succeeds to the obligations of Patheon Puerto Rico, Inc. under the Patheon Agreement.
- Section 1.94 "<u>Patheon Agreement</u>" means that certain Commercial Manufacturing Agreement, dated as of December 19, 2006, by and between Depomed and Patheon, as amended from time to time after the Effective Date in accordance with the terms of this Agreement.
- Section 1.95 "<u>PDMA</u>" means the Prescription Drug Marketing Act, as amended, and the rules and regulations promulgated thereunder.
- Section 1.96 "Person" means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, or other entity or Governmental Authority.
- Section 1.97 "<u>Post-Marketing Development</u>" means, with respect to Product, the conduct of any phase IV clinical studies, quality of life assessments, pharmacoeconomic, label expansion or other post-marketing studies.
- Section 1.98 "<u>Prescriber Data</u>" means data provided by a Third Party which measures prescriptions filled for Products (by individual prescriber) in the Territory during a specified time period, from a source mutually agreed in writing by the parties (it being understood that each of IMS Health Incorporated and Wolters Kluwer is a source agreeable to the parties).
- Section 1.99 "<u>Pre-Transfer Period</u>" means the period beginning on the Effective Date and expiring on the Manufacture Transfer Date for the 500mg Product.

- Section 1.100 "Processing Transfer Date" means October 1, 2011.
- Section 1.101 "<u>Product(s)</u>" means the 500mg Product and/or the 1000mg Product, as applicable (including Authorized Generic versions), subject to amendment in accordance with Section 2.1(c).
- Section 1.102 "<u>Product Complaints</u>" means any report concerning the quality, purity, quantity, weight, pharmacologic activity, labeling, identity or appearance of a Product.
- Section 1.103 "<u>Product IND</u>" means Depomed's Investigational New Drug Application filed with the FDA with respect to Product, including all submissions, supplements and amendments thereto.
- Section 1.104 "<u>Product NDA</u>" means NDA No. 21-748 filed with FDA on April 27, 2004, including, without limitation, any and all amendments and supplements thereto and all written FDA communications related thereto, whether existing on the NDA Transfer Date or filed thereafter.
- Section 1.105 "<u>Product Target</u>" means a Professional categorized in deciles 3 to 10, inclusive, for total prescriptions of Glumetza®, branded metformin (including Products) or combined branded and generic metformin (including Products); in each case, based on the most recently available 6-month Prescriber Data for each such category.
- Section 1.106 "<u>Professional</u>" means a physician or other health care practitioner who is permitted by law to prescribe Products.
- Section 1.107 "<u>Promote</u>," "<u>Promotional</u>" and "<u>Promotion</u>" mean, with respect to a Product, any activities undertaken to encourage sales or use of such Product, including Details, product sampling, detail aids, drop-offs, coupons, discount cards, journal advertising, direct mail programs, direct-to-consumer advertising, convention exhibits and all other forms of marketing, advertising, public relations or promotion.
  - Section 1.108 "Promotion Agreement" has the meaning given in the Recitals.
  - Section 1.109 "Promotion Net Sales" means Net Sales multiplied by the Promotion Percentage.
- Section 1.110 "<u>Promotion Percentage</u>" means, for a particular period, 100% minus the Depomed Percentage for such period if any Co-Promotion Net Sales occur in such period.
  - Section 1.111 "Promotional Effort" has the meaning set forth in Section 5.1(a).
  - Section 1.112 "Promotional Materials" has the meaning set forth in Section 5.4(a).
- Section 1.113 "<u>Proprietary Information</u>" means any proprietary or confidential information communicated from one party to the other in connection with or relating to this Agreement, the Promotion Agreement or the Confidentiality Agreement (whether before or after

the Effective Date), which is identified as confidential or proprietary, or which the other party knows or has reason to know is confidential or proprietary, including the Technology and financial, marketing, business, technical and scientific information or data, information related to a party's compensation of its Sales Representatives, information contained within the Annual Plan, and the information described in Section 5.6, whether communicated in writing, orally or electronically. Proprietary Information shall not include information that the receiving party can show through written documentation:

- (a) at the time of disclosure, is publicly known;
- (b) after the time of disclosure, becomes part of the public domain, except by breach of an agreement between the disclosing party or any Affiliate thereof and the receiving party or any Affiliate thereof;
- (c) is or was in the possession of the receiving party or any Affiliate thereof at the time of disclosure by the disclosing party and was not acquired directly or indirectly from the disclosing party or any Affiliate thereof or from any other party under an agreement of confidentiality to the disclosing party or any Affiliate thereof; or
- (d) is or was developed by the receiving party or its Affiliates without use of or reference to the other party's Proprietary Information.
- Section 1.114 "<u>Regulatory Approval</u>" means any and all consents or other authorizations or approvals by the FDA or any other Regulatory Authority in the Territory that are required to develop, manufacture, market and sell a Product in the Territory, whether existing on the NDA Transfer Date or filed thereafter; but excluding (i) Third Party drug master files with respect to API or Products, (ii) state licenses, and (iii) any form of reimbursement approval.
- Section 1.115 "<u>Regulatory Authority</u>" means any Governmental Authority involved in granting approvals for the manufacturing, marketing, sale, reimbursement and/or pricing of pharmaceutical products.
- Section 1.116 "Regulatory Communications" means, collectively, whether existing before or after the NDA Transfer Date: (a) all written or electronic filings or submissions made with Regulatory Authorities in satisfaction of applicable regulatory and notification requirements with respect to Products in the Territory (including, without limitation, Annual Periodic Reports, Serious Adverse Drug Experience Reports, Adverse Drug Experience Reports, and filings and submissions regarding recalls); (b) all written or electronic correspondence to or from the FDA with respect to any of the foregoing; (c) minutes of any meeting between a party and the FDA regarding the Regulatory Approvals, or Manufacture or Commercialization of the Products in or for the Territory; and (d) written summaries of oral communications between a party and the FDA that would impact, or would reasonably be expected to be material to, the development, Manufacture, commercialization of the Products and/or any ROR Product.
- Section 1.117 "Regulatory Data" means: (a) all processes and analytical methodologies used in development, testing, analysis and manufacture of Products; and (b) all in vivo, clinical, pharmacology, toxicology, safety, efficacy and other scientific data and results relating to

Products; that, in each case, are either (i) contained in the Product NDA or (ii) if not contained in the Product NDA, are known to a party and required to be submitted to the FDA in support of the Product NDA.

- Section 1.118 "<u>Retained Contracts</u>" means (a) Depomed's agreements with Third Party providers of adverse drug reaction monitoring and reporting services, (b) state licenses held by Depomed, (c) Depomed's wholesaler contracts, (d) Depomed's government contracts, including the Chargeback Agreements and the Government Rebate Agreements, and (e) Depomed's agreement with ICS, Depomed's trade and sample fulfillment house.
- Section 1.119 "Rights of Reference" means rights of reference, as contemplated under, inter alia, 21 CFR §314.50, to the Product NDA.
- Section 1.120 "ROR Product" means (a) any Product or other product containing API as its sole active ingredient, in each case for development and commercialization solely outside the Territory, or (b) any Combination Product; in each case, with respect to which Depomed has granted to a Third Party any Rights of Reference to the Product NDA under an Existing Rights of Reference Agreement or an Additional Rights of Reference Agreement.
- Section 1.121 "Sales Representatives" means sales representatives employed by Santarus or Depomed, or a Third Party engaged by Santarus or Depomed, to Detail the Products, who have been trained and equipped to Detail the Products in accordance with this Agreement.
- Section 1.122 "<u>Samples</u>" means samples of a Product that are not for sale to be distributed by a party solely in connection with the performance of Details or as otherwise legally permissible under the rules, guidelines and policies applicable to any Professional.
  - Section 1.123 "Santarus" has the meaning set forth in the Preamble to this Agreement.
  - Section 1.124 "Santarus CAC" means Santarus' Copy Approval Committee.
- Section 1.125 "<u>Santarus-Manufactured Product</u>" means any Product, the responsibility for Manufacturing of which has been transferred to Santarus pursuant to Section 3.5.
- Section 1.126 "<u>Santarus-Manufactured Samples</u>" means Samples, the responsibility for Manufacturing of which has been transferred to Santarus pursuant to Section 3.5.
- Section 1.127 "Santarus Physician List" means, as of a given date, the Professionals included on Santarus Sales Force handheld devices, or in the process of being added to Santarus Sales Force handheld devices, to whom the Santarus Sales Force intends to conduct Details. The Santarus Physician List may not include any Professionals on the Depomed Physician List as of such date, and the average number of Professionals on the Santarus Physician List shall in no event exceed 350 Professionals per Santarus Sales Representative. For clarity, the limitations herein regarding the Professionals includible on the Santarus Physician List are not intended to provide any limitation on the ability of Santarus to provide Details to any Professionals. Such limitations are only for the purpose of determining the Professionals includible on the Depomed Physician List.

- Section 1.128 "<u>Santarus Sales Force</u>" means the field force of Sales Representatives employed or engaged by Santarus, including field-based sales force management such as regional and district sales managers.
- Section 1.129 "Santarus Trademarks" means the trademarks set forth on Schedule 1.129, including the "Santarus" trademark and associated design and logo.
- Section 1.130 "Serious Adverse Drug Experience" means any Adverse Drug Experience, including those subject to expedited reporting as defined in the regulations cited below, that is fatal or life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly/birth defect, or is of comparable medical significance or any other event which would constitute a "serious" Adverse Drug Experience pursuant to the terms of 21 C.F.R. 314.80 or 312.32.
- Section 1.131 "<u>Serious Adverse Drug Experience Report</u>" means any Adverse Drug Experience Report that involves a Serious Adverse Drug Experience.
- Section 1.132 "<u>Subcontracting</u>" means subcontracting or sublicensing a party's rights or obligations hereunder (a) pursuant to which a Third Party will Manufacture the Products; or (b) pursuant to which a Third Party Sales Representative is engaged to Promote the Products. "<u>Subcontractor</u>" means the Third Party with whom the Subcontracting agreement is entered into.
- Section 1.133 "<u>Technology</u>" means all pharmacological, toxicological, preclinical, clinical, technical or other information, data and analysis and know-how relating to the registration, Manufacture, use or Commercialization of a Product in the Territory and all proprietary rights relating thereto Controlled by Depomed or its Affiliates during the Term.
  - Section 1.134 "<u>Term</u>" has the meaning set forth in Section 10.1.
  - Section 1.135 "Territory" means the United States, including its territories and possessions and Puerto Rico.
  - Section 1.136 "Third Party" means any Person other than Santarus or Depomed or their respective Affiliates.
  - Section 1.137 "<u>Third Party Agreement</u>" has the meaning set forth in Section 7.5.
- Section 1.138 "<u>Transition Period</u>" means the period beginning on the Manufacture Transfer Date for the 500mg Product and expiring four (4) months thereafter.
  - Section 1.139 "<u>Transition Plan</u>" has the meaning set forth in Section 3.1.
- Section 1.140 "<u>Unit</u>" means one (1) tablet of the 1000mg Product and two (2) tablets of the 500mg Product; provided that "Unit" shall have such other meaning as the parties may negotiate in good faith in the event that either party reasonably determines that the then current definition of Unit does not equitably reflect differences in value between the 500mg Product and

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the 1000mg Product for purposes of calculating the Baseline Percentage and the Depomed Percentage.

#### **ARTICLE 2**

#### **GRANT**

# Section 2.1 Grant of Licenses; Appointment under the BLS Supply Agreement

- (a) <u>Depomed Patent Rights and Technology</u>. During the Term, subject to the terms and conditions of this Agreement (including Section 2.5, Section 2.6, Depomed's right to elect to Detail the Products as set forth in Section 5.9, and Article 8), Depomed hereby grants to Santarus and its Affiliates, and Santarus and its Affiliates hereby accept:
- (i) an exclusive, royalty-bearing right and license under the Depomed Patent Rights and Technology to Commercialize and conduct Post-Marketing Development activities with respect to the Products in the Territory, on the terms and subject to the conditions set forth herein. Such license shall be exclusive even as to Depomed solely with respect to Commercialization and Post-Marketing Development of the Products in the Territory. Depomed agrees that its and its Affiliates' right to Promote the Products is limited to the Detail rights set forth in Section 5.9.
- (ii) an exclusive, worldwide, royalty-bearing right and license under the Depomed Patent Rights (including the BLS Patent Rights to the extent Depomed's license rights thereto with respect to Manufacturing of the 1000mg Product become operative pursuant to the BLS Manufacturing Transfer Agreement) and Technology to Manufacture and have Manufactured the Products for Commercialization by or on behalf of Santarus and its Affiliates in the Territory, including by Authorized Generic Distributors, on the terms and subject to the conditions set forth herein. Such license shall be exclusive even as to Depomed solely with respect to the Manufacture of Products for Commercialization in the Territory, but shall be subject to Depomed's right to perform its obligations with respect to supply of Products pursuant to Section 7.1 prior to the applicable Manufacture Transfer Date.

For clarity, the parties agree that Santarus shall have the exclusive (even as to Depomed) right to Commercialize Generic Versions of Products in the Territory, either directly or indirectly through Authorized Generic Distributors or ANDA Settlement Distributors; *provided, however,* that Santarus shall not be permitted to ship, or permit an Authorized Generic Distributor to ship, any Authorized Generic version of a Product to wholesale or retail customers before the earlier of (1) [\*\*\*] prior to Generic Entry for such Product, or (2) the initiation of pre-booking activities, including taking orders or shipment on consignment of one or more Generic Versions of such Product (excluding any Authorized Generic) in the Territory by a Third Party, including an ANDA Settlement Distributor, but excluding any Authorized Generic Distributor. Notwithstanding the foregoing, Santarus or any Authorized Generic Distributor may, prior to the earlier of the dates specified in the preceding sentence, ship such Authorized Generic version of

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- a Product solely to wholesalers or retail distribution centers on consignment, provided that Santarus shall prohibit such wholesalers and retail distribution centers from shipping any such Authorized Generic version until the earlier of the dates specified in the preceding sentence.
- (b) <u>Depomed Trademarks</u>. During the Term, subject to the terms and conditions of this Agreement (including Section 2.1(c), Section 2.5, Section 5.8 and Depomed's right to elect to Detail the Products as set forth in Section 5.9), Depomed hereby grants to Santarus and its Affiliates, and Santarus and its Affiliates hereby accept, an exclusive, royalty-free right and license to use the Depomed Trademarks solely in connection with Commercializing the Products in the Territory, on the terms and subject to the conditions set forth herein. The foregoing license with respect to the Depomed Product Trademark shall be exclusive even as to

Depomed in the Territory, subject to Section 5.8 and Depomed's right to elect to Detail the Products as set forth in Section 5.9. The foregoing license with respect to the Depomed Technology Trademark and the Depomed Corporate Trademark shall be exclusive even as to Depomed solely with respect to the use of such Depomed Trademarks with the Products in the Territory, subject to Section 2.5, Section 5.8 and Depomed's right to elect to Detail the Products as set forth in Section 5.9.

- (c) [\*\*\*]
- (d) <u>Appointment under BLS Supply Agreement</u>. Effective as of the First Sales Booking Date and thereafter until such time (if ever) as the BLS Supply Agreement is assigned to Santarus, Santarus will be designated as Depomed's "Distributor" (as defined in the BLS Supply Agreement) under the BLS Supply Agreement to perform Depomed's distribution and "Marketing" (as defined in the BLS Manufacturing Transfer Agreement) activities with respect to the 1000mg Product.

## Section 2.2 <u>Sublicense</u>

- (a) Except pursuant to Section 18.9 or in connection with the use of Third Party Sales Representatives, Santarus shall not assign, subcontract or otherwise transfer or delegate any of its rights or obligations under Section 2.1(a)(i) with respect to Promotion of Products in the Territory without the express written consent of Depomed, which consent may be withheld by Depomed in its sole discretion.
- (b) Santarus shall have the right to grant sublicenses to, or Subcontract with, Third Parties with respect to 500mg Product Commercialization activities, other than Promotion (provided that the use of Third Party Sales Representatives is permitted); provided that all such sublicenses and subcontracts shall be consistent with the terms of this Agreement and that Santarus shall at all times be responsible and liable to Depomed for any breach of this Agreement by any such sublicensee or Subcontractor. After the Manufacture Transfer Date for the 500mg Product, Santarus shall have the right to grant sublicenses to, or Subcontract with, Third Parties with respect to Manufacturing of the 500mg Product; provided that all such sublicenses and subcontracts shall be consistent with the terms of this Agreement and that Santarus shall at all times, subject to Section 6.7, Section 7.5 (last sentence) and Section 13.2, be

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responsible and liable to Depomed for any breach of this Agreement by any such sublicensee or Subcontractor.

Commercialization activities, other than Promotion (provided that the use of Third Party Sales Representatives is permitted); provided that all such Subcontracts shall be consistent with the terms of this Agreement and that Santarus shall at all times be responsible and liable to Depomed for any breach of this Agreement by any such Subcontractor. After the Manufacture Transfer Date for the 1000mg Product, Santarus shall have the right to have the 1000mg Product Manufactured by a Third Party on Santarus' behalf solely in the event that Section 16.2 of the BLS Supply Agreement becomes operative and only to the extent permitted by said Section 16.2; provided that any Third Party supply arrangement for the 1000mg Product shall be consistent with the terms of this Agreement and that Santarus shall at all times, subject to Section 6.7, Section 7.5 (last sentence) and Section 13.2, be responsible and liable to Depomed for any breach of this Agreement by any such Subcontractor.

## Section 2.3 <u>Transfer of Product Information</u>

Depomed shall provide Santarus with the following Technology as promptly as practicable after the NDA Transfer Date (or, at Depomed's discretion, at any time and from time to time during the Pre-Transfer Period):

- (a) Copies of all Regulatory Approvals for the Products in the Territory held by Depomed and its Affiliates as of the Effective Date and through the NDA Transfer Date;
- (b) Copies of all Regulatory Communications relating to the Products between Depomed and a Regulatory Authority (or, to the extent in the possession and Control of Depomed, between a Third Party and a Regulatory Authority);
  - (c) Copies of all Regulatory Data to the extent in the possession and Control of Depomed;
- (d) Copies of current manufacturing, stability and release testing documentation in the possession and Control of Depomed for Product Manufactured for the Territory, which may include, to the extent in the possession and Control of Depomed, representative master and executed manufacturing batch records, test methods, stability protocols, stability results, manufacturing guides, conformance guides and specifications for the Products (it being understood that much of the foregoing documentation is held by Patheon, Depomed's API supplier or BLS, and that Santarus' access thereto shall be as set forth in Section 3.5; and
- (e) To the extent not included in the materials provided to Santarus pursuant to Section 2.3(a), Section 2.3(b), Section 2.3(c) or Section 2.3(d), all other reports, data and information relating to the Products reasonably requested by Santarus as necessary or useful for Santarus to exercise its rights hereunder or under applicable laws and regulations, including for the maintenance of the Product NDA.

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Depomed shall provide Santarus with updates to the Technology described in Section 2.3(b) through Section 2.3(e) throughout the Transition Period as promptly as reasonably practicable following the availability of any such update. In addition, during the Transition Period, Depomed shall provide up to an aggregate of [\*\*\*] of consultation to Santarus regarding the Technology transferred pursuant to this Section 2.3 and in performance of Depomed's obligations under the Transition Plan, which shall be allocated among Depomed's Quality, Manufacturing and Regulatory functions as requested by Santarus. Any consultation in excess of such [\*\*\*] would be provided only to the extent mutually agreed by the parties in writing.

#### Section 2.4 <u>Limitation on Metformin Promotion</u>

Except as expressly contemplated by this Agreement, neither party shall, directly or indirectly, develop, promote, market, distribute, sell or offer for sale any product containing API as the sole active ingredient in the Territory during the Term of this Agreement, other than the Products in accordance with the terms of this Agreement.

## Section 2.5 **Retention of Rights**

(a) Subject to the limitations set forth in Section 2.4, Depomed hereby expressly reserves the exclusive right to practice, and to grant licenses under, the Depomed Patent Rights and the Technology for any and all purposes, other than the Commercialization of Products in the Territory and Manufacture of Products for Commercialization in the Territory. Without limiting the generality of the foregoing, Depomed shall at all times have the exclusive right: (i) to develop and commercialize, and to grant licenses to Third Parties to develop, Manufacture and commercialize, Products outside the Territory; (ii) to Manufacture or have Manufactured Products in or outside of the Territory for development and commercialization outside the Territory; and (iii) subject to Santarus' rights under Section 15.1 with respect to Covered Combination Products, to develop, manufacture and commercialize Combination Products worldwide.

- (b) Depomed hereby expressly reserves (i) the exclusive right to use, and to grant licenses under, the Depomed Product Trademark outside the Territory; (ii) the exclusive right to use, and to grant licenses under, the Depomed Technology Trademark and the Depomed Corporate Trademark in the Territory for any purpose other than the Commercialization of Products in the Territory; and (iii) the exclusive right to use, and to grant licenses under, the Depomed Technology Trademark and the Depomed Corporate Trademark outside the Territory for any purpose.
- (c) Notwithstanding the assignment of the Product NDA pursuant to Section 3.2 and subject to the limitations set forth in Section 2.4, Depomed hereby expressly reserves the right: (i) to grant, or continue to grant, the Existing Rights of Reference; and (ii) subject to Santarus' rights under Section 15.1 with respect to Covered Combination Products, to grant additional Rights of Reference to any Third Party with respect to (1) Products or other products containing API as the sole active ingredient, in each case for development and commercialization solely outside the Territory, and/or (2) any Combination Product (in each case, "Additional Rights of Reference").

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(d) Except as expressly set forth herein, nothing contained herein shall be deemed to grant Santarus, by implication, a license or other right or interest in any patent, trademark or other similar property of Depomed or its Affiliates. Except as expressly set forth herein, nothing contained herein shall be deemed to grant Depomed, by implication, a license or other right or interest in any patent, trademark or other similar property of Santarus or its Affiliates, except as may be necessary for Depomed to Detail the Products pursuant to this Agreement in the event Depomed elects to Detail the Products in accordance with Section 5.9.

#### Section 2.6 Negative Covenants

- (a) Santarus, on behalf of itself and its Affiliates, hereby covenants not to practice, and not to permit or cause any licensee, sublicensee or other Third Party to practice, any Depomed Patent Rights or Technology, and not to use, and not to permit or cause any licensee, sublicensee or other Third Party to use, any Depomed Trademark, for any purpose other than as expressly authorized in this Agreement. Santarus, on behalf of itself and its Affiliates, hereby further covenants not to Commercialize, and not to permit or cause any licensee, sublicensee or other Third Party to Commercialize, an Authorized Generic version of a Product in the Territory, either directly or indirectly through a Third Party, until permitted under the provisions of the last paragraph of Section 2.1(a).
- (b) Depomed, on behalf of itself and its Affiliates, hereby covenants not to use, and not to permit or cause any licensee, sublicensee or other Third Party to use (i) any Depomed Product Trademark in the Territory, provided that if Depomed makes its election under Section 5.9, Depomed may use the Depomed Product Trademark in the Territory solely to Promote Products in accordance with this Agreement or (ii) any Santarus Trademark for any purpose other than as expressly authorized in this Agreement. Depomed, on behalf of itself and its Affiliates, hereby further covenants not to Commercialize, and not to permit or cause any licensee, sublicensee or other Third Party to Commercialize, a Generic Version in the Territory, either directly or indirectly through a Third Party, except for settlements mutually agreed to by Santarus and Depomed.

(c) [\*\*\*]

# ARTICLE 3 TRANSITION PLAN

## Section 3.1 Transition Plan

The parties have agreed to the transition plan (the "<u>Transition Plan</u>") attached as <u>Schedule 3.1</u>, which contains specific events and obligations to effect the shifting of regulatory, manufacturing and quality responsibilities to Santarus pursuant to the terms of this Agreement, subject to the last paragraph of Section 2.3. The parties agree to use commercially reasonable efforts to perform their respective obligations as set forth in the Transition Plan within the timelines set forth therein. The parties will discuss in good faith any changes to the Transition Plan that become required or advisable. Except as otherwise set forth in the Transition Plan or elsewhere in this Agreement, each party shall be responsible for its respective costs and expenses incurred in performing the Transition Plan.

The parties acknowledge that implementation of the Transition Plan will require the cooperation and/or consent of Third Parties as indicated therein, and, as a result, the timing of such transfer is not within the sole control of the parties.

#### Section 3.2 Transfer and Assignment of Product NDA and Product IND

Effective only as of the NDA Transfer Date, Depomed shall, and it hereby does, assign to Santarus all right, title and interest in the Product NDA, subject to the Existing Rights of Reference and any Additional Rights of Reference granted by Depomed during the Pre-Transfer Period, and the Product IND. On the NDA Transfer Date, Depomed shall submit to the FDA a letter authorizing the transfer of ownership of the Product NDA and Product IND from Depomed to Santarus. As soon as practicable after the submission of such letter, Santarus shall execute and submit to the FDA a letter, accompanied by the Product NDA and Product IND transfer letter(s) referred to in the preceding sentence, acknowledging Santarus' commitment to assume ownership of the Product NDA and Product IND. The parties shall take such additional actions, and execute and deliver, and file with the FDA, such additional documents, as are necessary to effect the transfer and assignment to Santarus of the Product NDA and Product IND contemplated by this paragraph. If there is any impediment to the assignment of the Product NDA or Product IND to Santarus, the parties shall cooperate in good faith and use commercially reasonable efforts to remove such impediment. If, notwithstanding such efforts, the parties are unable to remove such impediment, the parties shall discuss the matter in good faith and use commercially reasonable efforts to reach mutual agreement as to how to proceed. If, after assignment to Santarus of the Product NDA and Product IND, the parties mutually and reasonably agree in good faith that the Product NDA or Product IND should be assigned back to Depomed, the parties shall promptly execute and deliver such documents and take such actions as are necessary to effect such assignment back to Depomed.

## Section 3.3 **Rights of Reference**

On or promptly after the NDA Transfer Date, the parties shall cooperate in good faith, take such actions, and execute and deliver, and file with the FDA, such documents as, in each case, are necessary to ensure that the Existing Rights of Reference remain in full force and effect

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following transfer and assignment of the Product NDA and are exercisable by the grantee(s) thereof. In addition, in the event Depomed grants any Additional Rights of Reference during the Term, or in the event any grantee of Existing Rights of Reference or Additional Rights of Reference changes its corporate name, or sells or transfers its business relating to the applicable ROR Product to another

Person, Santarus shall, promptly, and in any event within five (5) business days after, Depomed's written request, file the requisite authorization letter with the FDA in order for such Additional Rights of Reference to become effective, or for such Existing Rights of Reference or Additional Rights of Reference to be updated to reflect such grantee's new corporate name or the name of the acquirer of its business relating to such ROR Product, as applicable. Santarus hereby covenants that neither it nor any of its Affiliates, nor any Third Party acting on behalf of Santarus or any of its Affiliates, will withdraw, revoke or terminate any Existing Rights of Reference or any Additional Rights of Reference without Depomed's express prior written authorization to do so. From and after the NDA Transfer Date, Santarus shall provide to Depomed copies of all Regulatory Approvals arising after the NDA Transfer Date as promptly as practicable after approval or receipt (as applicable) thereof.

# Section 3.4 **<u>Rights of Access to Data.</u>**

- (a) The parties recognize that the grantees of the Existing Rights of Reference have, and that Depomed may grant to any grantee of Additional Rights of Reference, rights of access to Regulatory Communications and Regulatory Data.
- (b) From and after the NDA Transfer Date, Santarus shall (i) provide to Depomed copies of all Regulatory Communications arising after the NDA Transfer Date between Santarus and a Regulatory Authority (or, to the extent in the possession and Control of Santarus, between a Third Party and a Regulatory Authority), and (ii) disclose to Depomed in writing all Regulatory Data arising after the NDA Transfer Date to the extent in the possession and Control of Santarus; in each case, as promptly as practicable (and in any event within ten (10) business days) after any such Regulatory Communications and Regulatory Data arise. Depomed may provide all such Regulatory Communications and Regulatory Data to the applicable Third Parties under the Existing Rights of Reference Agreements and Additional Rights of Reference Agreements as Depomed determines is reasonably necessary to comply with the Existing Rights of Reference Agreements and Additional Rights of Reference Agreements.
- (c) Deponded shall promptly (and in any event within ten (10) business days) provide to Santarus copies of all Regulatory Communications and Regulatory Data received by it from Third Parties under and to the extent not prohibited by an applicable Existing Rights of Reference Agreement or Additional Rights of Reference Agreement.

### Section 3.5 **Manufacturing Transfer**

(a) The Assigned Agreements relating to the manufacture and supply of the 500mg Product and the API (each, an "Assigned Manufacturing Agreement") shall be assigned by Depomed in their entirety to Santarus, and shall be assumed in their entirety by Santarus promptly following (but in no event later than five (5) business days following) the Manufacture Transfer Date for the 500mg Product, pursuant to an Assignment and Assumption Agreement to

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be negotiated in good faith by the parties. From and after such assignment and assumption, Santarus shall be solely responsible for Manufacturing, or having Manufactured, the 500mg Product and the API for the 500mg Product.

(b) Promptly after the Manufacture Transfer Date for the 500mg Product, Depomed shall notify each counterparty to any Assigned Manufacturing Agreement that such Assigned Manufacturing Agreement has been assigned to, and assumed by, Santarus, and shall authorize and instruct such counterparty to grant Santarus access to all technical, regulatory and other information and materials relating to the 500mg Product that are then in the possession of such counterparty in accordance with the applicable Assigned Manufacturing Agreement. Santarus shall be entitled to consult with such counterparty's technical personnel with respect to Manufacturing activities as set forth in such Assigned Manufacturing Agreement.

- (c) Promptly after the Effective Date, Depomed [\*\*\*]. Santarus will manage any transfer and validation of Manufacturing the 500mg Product at Patheon's Manati facility, [\*\*\*].
- (d) In the event the parties mutually agree for the BLS Supply Agreement or successor Third Party supplier agreement for the 1000mg Product to be assigned to Santarus, the parties will work together to obtain any necessary consent to assign the BLS Supply Agreement, and upon receipt of such consent, Depomed will assign the BLS Supply Agreement or successor agreement to Santarus. If Depomed makes such assignment, Santarus will assume the BLS Supply Agreement or successor agreement, pursuant to an Assignment and Assumption Agreement to be negotiated in good faith by the parties.
- (e) If the BLS Supply Agreement is assigned to Santarus pursuant to Section 3.5(d), then promptly after the Manufacture Transfer Date for the 1000mg Product, Depomed shall deliver a copy of the fully-executed Assignment and Assumption Agreement to BLS or such Third Party, and shall authorize and instruct BLS or such Third Party to grant Santarus access to all technical, regulatory and other information and materials relating to the 1000mg Product that are then in the possession of BLS or such Third Party in accordance with the BLS Supply Agreement or successor agreement. Santarus shall be entitled to consult with BLS's or such Third Party's technical personnel with respect to Manufacturing activities as set forth in the BLS Supply Agreement or successor agreement.

# ARTICLE 4 ALLIANCE MANAGEMENT

## Section 4.1 Alliance Managers

Each of the parties shall nominate at least one, but no more than two, representatives to serve as alliance managers under this Agreement (collectively, "Alliance Managers"), one of whom for each party shall be designated as the lead Alliance Manager for that party. The lead Alliance Manager for Santarus shall initially be Jon Hee, and the lead Alliance Manager for Depomed shall initially be Gerd Kochendoerfer. Each party may modify its Alliance Managers and lead Alliance Manager by providing written notice of the modification to the other party. Each party's Alliance Managers shall be appropriately qualified in order to perform their

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responsibilities as Alliance Managers pursuant to this Agreement. The parties acknowledge and agree that the Alliance Managers do not have the power to amend, modify or waive any of the terms or conditions of this Agreement.

#### Section 4.2 Alliance Manager Responsibilities

- (a) Except as otherwise set forth herein, the Alliance Managers shall periodically review Commercialization activities for the Products hereunder, it being understood that Santarus shall be responsible for directing such Commercialization activities. The responsibilities of the Alliance Managers shall be exercised consistent with this Agreement and shall include, but shall not be limited to:
  - (i) reviewing the Annual Plan as contemplated by Section 5.5(a);
  - (ii) if applicable, monitoring the Depomed Sales Force call plan for coordination with the Santarus

Sales Force; and

- (iii) such other functions as may be mutually agreed upon by the parties from time to time.
- (b) For the avoidance of doubt, the function of the Alliance Managers is primarily to facilitate information sharing between the parties, and therefore, without limiting the generality of the foregoing, unless separately authorized by a party in writing, the Alliance Managers shall not have any approval or decision-making authority on behalf of such party.

## Section 4.3 <u>Meetings of the Alliance Managers.</u>

Meetings of the Alliance Managers may be held from time to time upon mutual agreement by both parties' Alliance Managers; provided, however, that meetings of the Alliance Managers shall be held on at least an annual basis. If possible, the meetings shall be held in person or where appropriate, by video or telephone conference. Unless otherwise agreed, the location of any in-person meetings of the Alliance Managers shall alternate between the corporate offices of the parties. The parties shall determine the form of the meetings. Subject to appropriate confidentiality undertakings where applicable, each party shall have the right, upon written notice to the other party, to have present at meetings of the Alliance Managers additional participants (not to exceed ten (10) such participants at any meeting of the Alliance Managers without the consent of the other party). The party hosting any meeting shall propose the agenda for the meeting and appoint a secretary to the meeting who shall record the minutes of the meeting. Such minutes shall be circulated to the parties promptly following the meeting for review and comment and for unanimous ratification by both parties. Each party shall bear its own travel and related costs incurred in connection with participation of its respective Alliance Managers.

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# ARTICLE 5 PRODUCT COMMERCIALIZATION

#### Section 5.1 **Product Promotion**

- (a) Subject to applicable Legal Requirements, as well as the provisions of this Agreement, Santarus shall, during the Term until Generic Entry of any Product (subject to Section 8.3(b)), at its sole expense, use commercially reasonable efforts to Promote the Products within the Territory in accordance with the Annual Plan (the "Promotional Effort"). For purposes of the preceding sentence, Santarus' commercially reasonable efforts shall be met if Santarus is in compliance with its obligations under Section 5.1(b) and Section 5.1(c) of this Agreement. Santarus will cause the Santarus Sales Force and Santarus employees and agents acting on Santarus' behalf to comply with this Agreement and all applicable Legal Requirements in connection with the Commercialization of the Products. It is understood, and Santarus agrees, that it will be accountable for the acts or omissions of the Santarus Sales Force and its employees and agents.
- (b) During each Agreement Quarter during the Term until Generic Entry of any Product, the Santarus Sales Force shall perform a minimum of [\*\*\*] (the "Minimum Detailing Obligations"); provided, however, that one-half of the Minimum Detailing Obligations may be satisfied by [\*\*\*], counting each [\*\*\*] as equivalent to [\*\*\*]. For purposes of determining [\*\*\*] hereunder, each Product shall be deemed to be the same Product and shall be counted only once. By way of illustration, Santarus shall not have the right to count both a [\*\*\*] and a [\*\*\*]. In such case, only the [\*\*\*] shall be counted for purposes of determining compliance with the Minimum Detailing Obligations.

(c) From and after the Effective Date, except as otherwise noted in the first row below, and for the remainder of the Term until Generic Entry of any Product, Santarus shall spend at least the following amounts on Advertising/Marketing/Educational Expenses during the periods set forth below:

Period	Advertising/Marketing/Educational Expenses	
[***]	[***] percent [***] of [***] (calculated in accordance with the Promotion Agreement)	
[***]	The [***] of (a) [***] or (b) [***]	
[***] and for remainder of the Term	For each complete calendar year, the [***] of (a) [***] or (b) [***]	
until [***]		
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	and filed separately with the Securities Exchange Commission.	
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(d) The parties shall discuss in good faith whether and under what conditions any of the obligations in this Section 5.1 should be decreased with respect to periods leading up to Generic Entry and how the amount of such decrease should be shared by the parties.

### Section 5.2 **Representations to Customers**

Santarus will not make any false or misleading representations to Professionals, customers or others regarding Depomed or the Products and will not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Products that are not consistent with the applicable then-current FDA approved labeling and package insert (except to the extent permitted by Legal Requirements). Santarus agrees to undertake timely and complete corrective action for any deviations from this Section 5.2.

## Section 5.3 **Staffing: Training**

Santarus shall be solely responsible for all costs and expenses of compensating its Sales Representatives. Consistent with applicable Legal Requirements, Santarus shall pay incentive compensation to its Sales Representatives with respect to the Products in accordance with Santarus' incentive compensation plan for Santarus' other products. Santarus shall periodically provide training to each of its Sales Representatives, and shall update its training materials as appropriate.

## Section 5.4 **Promotional Materials; Educational Materials**

- (a) Santarus shall, at its own expense (which for clarity shall be included as an Advertising/Marketing/ Educational Expense hereunder), have the right to create, develop, produce or otherwise obtain, and utilize sales, promotional, advertising, marketing, educational and training materials ("Promotional Materials") to support the Promotional Effort for the Products. Such Promotional Materials may include, by way of example, detailing aids; leave behind items; journal advertising; educational programs; formulary binders; appropriate reprints and reprint carriers; product monographs; patient support kits; convention exhibit materials; direct mail; market research survey and analysis; training materials; and scripts for telemarketing and teleconferences.
- (b) Prior to any use thereof prior to the NDA Transfer Date, Santarus shall provide to Depomed for review a prototype of any Promotional Materials created by Santarus. Depomed shall notify Santarus of any objections it has to such prototype

and the basis therefor as soon as reasonably practicable, but no later than [\*\*\*] following its receipt thereof. Failure by Depomed to notify Santarus of any objections to the proposed prototype within such period shall constitute approval by Depomed. Santarus shall modify such Promotional Materials to the extent necessary to resolve any objections timely and reasonably made by Depomed to such Promotional Materials on the grounds that such Promotional Materials are inconsistent with any Legal Requirements, and shall in good faith consider any of Depomed's other objections. The final version of the Promotional Materials approved by the Santarus CAC (which shall include such modifications as are required to address concerns timely and reasonably made by Depomed on the grounds that such Promotional Materials are inconsistent with Legal Requirements) may be produced in quantity, and Santarus shall provide Depomed with the requisite number of

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copies of the final printed form in a timely manner so as to allow Depomed to satisfy its obligation to file such materials with the FDA prior to the first use of the Promotional Materials. Depomed will make such filing with the FDA within two (2) business days after the date Santarus provides Depomed with such copies of the final version of such Promotional Materials. In furtherance of the foregoing provisions of this Section 5.4(b), the parties will endeavor to cooperate to facilitate the timely and efficient review of Promotional Materials for use prior to the NDA Transfer Date and resolution of any disputes or disagreements related to such Promotional Materials, with a view to containing both parties' internal personnel resources and external costs associated with the creation, review and approval of such Promotional Materials.

(c) Santarus shall own all copyrights to all Promotional Materials that are created during the Term of this Agreement in connection with and to the extent relating to the Promotion of the Products.

#### Section 5.5 Annual Plan; Promotion Expenses

- (a) On or prior to [\*\*\*] of the preceding calendar year with respect to each calendar year during the Term beginning with the 2012 calendar year, Santarus shall develop an annual Promotional plan (the "Annual Plan") and submit the Annual Plan to Depomed's lead Alliance Manager. The Annual Plan shall set forth the manner in which Santarus anticipates it will Promote the Products during the period to which the Annual Plan relates; provided, however, that the Annual Plan may be modified from time to time as Santarus reasonably deems appropriate for the Promotion of the Products, subject where applicable to Santarus' compliance with its obligations under this Agreement, including without limitation the obligations set forth in Section 5.1. The Annual Plan shall include, at a minimum:
- (i) the anticipated number of [\*\*\*] Details (including [\*\*\*]) to be provided by the Santarus Sales Force, and the physicians targeted to receive those Details;
- (ii) product positioning, strategy and tactics with supporting advertising and promotional activity to be undertaken;
  - (iii) planned public relations activities, if any;
  - (iv) any training or sampling programs to be conducted;
  - (v) medical education programs to be conducted;
  - (vi) pricing and contracting strategies;

- (vii) managed health care strategies and tactics; and
- (viii) a budget for all costs and expenses associated with the activities to be undertaken pursuant to the Annual Plan (including the projected Advertising/Marketing/Educational Expenses).

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- (b) Santarus shall not have any obligation to incur Advertising/Marketing/Educational Expenses in excess of the minimum amounts provided in Section 5.1(c).
- Each party will bear its own operating expenses associated with Promotion of the Products by such Party, including all personnel, general and administrative and overhead costs. Santarus will bear all Santarus Sales Force expenses, and Depomed will bear all Depomed Sales Force expenses, if applicable. From and after the NDA Transfer Date, Santarus will bear all costs associated with maintaining and continuing all Regulatory Approvals of the Products in the Territory, including, subject to Section 6.6, all costs associated with Adverse Drug Experience reporting, filing annual reports in connection with the Product NDA, user fees and establishment fees associated with the Product NDA and all clinical and regulatory requirements.

#### Section 5.6 **Santarus Promotion Reports**

Within [\*\*\*] following the end of each Agreement Quarter, Santarus shall provide Depomed's lead Alliance Manager with a status report, which report will summarize Santarus' Detailing activities pursuant to this Agreement for such prior Agreement Quarter and on a calendar year-to-date basis, including: (a) the number of P1 and P2 Details made and recorded by Santarus' standard record keeping procedures; (b) the names and addresses of the Professionals called upon; (c) the percentage of Professionals Detailed who were provided with Samples; (d) the average number of such Samples delivered on each Detail; (e) Advertising/Marketing/Education Expenses for such Agreement Quarter; and (f) such other information as may be agreed upon in writing by the parties.

## Section 5.7 <u>Medical Inquiries</u>

- (a) The parties acknowledge that each may receive requests for medical information concerning the Product from members of the medical and paramedical professions and consumers regarding the Product.
- (b) From and after the NDA Transfer Date, any such requests will be referred to Santarus' medical department, and Santarus shall be solely responsible for responding to such requests in compliance with all applicable Legal Requirements and the Product NDA. Santarus shall be obligated for any costs associated with its responsibilities pursuant to this Section 5.7.

## Section 5.8 <u>Trademarks</u>

(a) Subject to this Section 5.8 and to applicable Legal Requirements, Santarus shall have the right to use the Santarus Trademarks, and include the name "Santarus" or any variation thereof in connection with its Commercialization activities and any materials related thereto. Santarus recognizes that (i) the Depomed Product Trademark is owned by BLS and licensed to Depomed pursuant to the BLS Manufacturing Transfer Agreement for the sole purpose of Marketing (as such term is defined therein) the Products in the Territory, and (ii) Depomed owns the entire right, title and interest in and to the Depomed Technology Trademark and the Depomed Corporate Trademark, as well as the domain name "GlumetzaXR.com" (the "Domain Name"); and Santarus shall not at any time, during or after

the Term, do or knowingly suffer to be done any act or thing which will in any way impair the rights of Depomed (or its Third Party licensor, as applicable) in or to the Depomed Trademarks or the Domain Name. Santarus acknowledges and agrees that it shall not acquire and shall not claim any right (except as expressly granted under Section 2.1 or Section 5.10), title or interest in or to the Depomed Trademarks or the Domain Name by virtue of the rights granted under this Agreement or through Santarus' use of the Depomed Trademarks or Domain Name, and the parties agree that, as between the parties, all goodwill and improved reputation associated with the Depomed Trademarks and Domain Name arising out of the use thereof by Santarus and its Affiliates, sublicensees and other Subcontractors shall inure to the benefit of Depomed. Santarus shall not use the Depomed Trademarks upon, in connection with, or in relation to, the Products, or any packaging, labels, containers, advertisements and other materials related thereto, except as is consistent with past practice under the Promotion Agreement or this Agreement or as otherwise authorized in writing by Depomed. Santarus shall as soon as practicable notify Depomed of any apparent infringement by a Third Party of any of the Depomed Trademarks of which Santarus becomes aware. Santarus agrees to reasonably cooperate with Depomed to enable Depomed to verify that the use by Santarus of the Depomed Trademarks is consistent with the requirements in this Agreement.

(b) During the Term, subject to the terms and conditions of this Agreement, Santarus hereby grants to Depomed a non-assignable, non-sublicensable (except to any Third Party Sales Representatives), non-exclusive, royalty-free right and license to use the Santarus Trademarks in the Territory solely in connection with Depomed's Detailing of the Products in the Territory in accordance with this Agreement in the event Depomed elects to Detail the Products as set forth in Section 5.9. Depomed recognizes that Santarus owns the entire right, title and interest in and to the Santarus Trademarks, and shall not at any time, during or after the Term, do or knowingly suffer to be done any act or thing which will in any way impair the rights of Santarus in or to the Santarus Trademarks. Depomed acknowledges and agrees that it shall not acquire and shall not claim any right (except as expressly granted under this Section 5.8(b)), title or interest in or to the Santarus Trademarks by virtue of the rights granted under this Agreement or through Depomed's use of the Santarus Trademarks, and the parties agree that all goodwill and improved reputation associated with the Santarus Trademarks arising out of the use thereof by Depomed shall inure to the benefit of Santarus. Depomed shall as soon as practicable notify Santarus of any apparent infringement by a Third Party of any of the Santarus Trademarks of which Depomed becomes aware. Depomed agrees to cooperate with Santarus to enable Santarus to verify that the use of the Santarus Trademarks is consistent with Santarus' quality standards. Compliance with this Section 5.8(b) shall be determined pursuant to the Depomed Promotional Materials review and approval procedures set forth in Section 5.9(e).

#### Section 5.9 **Election by Depomed to Detail in the Territory**

(a) Depomed may elect, at any time during the Term, to have the Depomed Sales Force Detail the Products directly to Professionals. If Depomed desires to make this election and to use the Depomed Sales Force for this purpose, it will inform Santarus at least [\*\*\*] in advance of the commencement of Details by the Depomed Sales Force and provide Santarus with the proposed Depomed Physician List, and, subject to Santarus' compliance with its obligations under this Section 5.9, Depomed shall commence its Detailing activities no later

than [\*\*\*] after the date of its notice to Santarus. During such initial [\*\*\*] period, Santarus will be entitled to review the proposed Depomed Physician List and remove any Professionals who are, as of the date of Santarus' receipt of the proposed Depomed Physician List, on the Santarus Physician List. Upon request from Depomed, Santarus shall provide reasonable access to Depomed to review Santarus' documentation supporting Santarus' removal of any Professionals from the proposed Depomed Physician List. Following creation of the initial Depomed Physician List, from time to time but not more than [\*\*\*] times per calendar year, Depomed may modify the Depomed Physician List pursuant to the procedure set forth above. Following the addition of Professionals to the Depomed Physician List, the Baseline Percentage shall be adjusted to reflect prescriptions written by any such Professionals by adding to the thencurrent Baseline Percentage the quotient obtained by dividing (x) [\*\*\*] by (y) [\*\*\*].

- (b) On annual basis, Depomed will submit to Santarus' lead Alliance Manager a call plan setting forth the Details to be performed by the Depomed Sales Force. Any Professional on the Depomed Physician List who does not receive at least [\*\*\*] (calculated in accordance with Section 5.1(b)) in each full calendar year following the commencement of Details for the Product by the Depomed Sales Force will be excluded from the Depomed Physician List in subsequent calendar years for purposes of calculating Co-Promotion Net Sales, and for purposes of calculating the Baseline Percentage.
- (c) All Details made by the Depomed Sales Force will be reported to Santarus. Such reports by Depomed will be made in the same manner as Santarus' Details under Section 5.6. Depomed shall be responsible for purchasing Prescriber Data relating to the Depomed Physician List at its sole cost and expense.
- (d) Depomed may purchase from Santarus, at Santarus' actual out-of-pocket costs of reproduction and shipment, copies of any Promotional Materials created by Santarus for use by the Depomed Sales Force, to the extent limited to Products. Upon Depomed's request, Santarus will provide to Depomed electronic copies of such Promotional Materials created by or for Santarus, which Promotional Materials may be modified for use by Depomed; provided that any modification must be approved or deemed to be approved as described in Section 5.9(e) below.
- ("Depomed Promotional Materials"). Prior to the use thereof, Depomed shall provide to Santarus a prototype of any Depomed Promotional Materials for review. Santarus shall notify Depomed of any objections it has to such prototype and the basis therefor as soon as reasonably practicable, but no later than [\*\*\*] following its receipt thereof. Failure by Santarus to notify Depomed of any objections to the proposed prototype within such period shall constitute approval by Santarus. Depomed shall modify such Depomed Promotional Materials to the extent necessary to resolve any objections made by Santarus to such Depomed Promotional Materials on the grounds that such Depomed Promotional Materials are inconsistent with the overall Product positioning and messaging for the Products or inconsistent with Legal Requirements, and shall in good faith consider any of Santarus' other objections. The final version of the Depomed Promotional Materials shall be provided to Santarus for its review and approval to confirm their consistency with the prototype approved by Santarus and the resolution

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of Santarus' objections in accordance with this Section 5.9(e), which review and approval shall occur, as soon as reasonably practicable, but no later than [\*\*\*] following its receipt by Santarus. Failure by Santarus to notify Depomed of any objections to the final version within such period shall constitute approval by Santarus. The Depomed Promotional Materials will not contain any Santarus Trademark unless such materials are approved by the Santarus CAC. From and after the NDA Transfer Date, Depomed shall provide Santarus with the requisite number of copies of the final printed form in a timely manner so as to allow Santarus to satisfy its obligation to file such materials with the FDA prior to the first use of the Depomed Promotional Materials, and Santarus shall make such filing with the FDA within [\*\*\*] of its receipt of such copies. In furtherance of the foregoing provisions of this Section 5.9(e), the parties will endeavor to

cooperate to facilitate the timely and efficient review of Depomed Promotional Materials and resolution of any disputes or disagreements related to Promotional Materials, with a view to containing both parties' internal personnel resources and external costs associated with the creation, review and approval of the Depomed Promotional Materials.

- (f) Santarus may purchase from Depomed, at Depomed's out-of-pocket costs for reproduction and shipment of such materials, copies of any Depomed Promotional Materials, to the extent limited to Products. Upon Santarus' request, Depomed will provide to Santarus electronic copies of such Depomed Promotional Materials created by or for Depomed, which Depomed Promotional Materials may be modified for use by Santarus.
- Depomed may purchase from Santarus, at Santarus' actual out-of-pocket costs of reproduction and shipment, copies of training materials developed and Controlled by Santarus related to the Products for use by Depomed in the training of the Depomed Sales Force. Depomed shall be responsible for training of the Depomed Sales Force, and may, at its own expense, develop training materials for the Depomed Sales Force in other media or forms, provided that such materials shall be subject to Santarus' review and approval or deemed approval as Depomed Promotional Materials as provided in Section 5.9(e). Depomed shall, at its own expense, train the Depomed Sales Force using such training materials, the other Promotional Materials and Depomed Training Materials and such programs as Depomed shall deem appropriate that are in compliance with Depomed's obligations hereunder. Such programs shall include training with respect to reporting Adverse Drug Experiences and technical complaints. After the initial training, Depomed shall periodically provide additional training to each Sales Representative in accordance with this Section 5.9(g).
- (h) Deponded shall be solely responsible for costs or expenses related to any activities of the Deponded Sales Force, including costs for Deponded Promotional Materials, training or training materials or the purchase from Santarus of Promotional Materials for the Deponded Sales Force.
- (i) Deponded will cause the Deponded Sales Force and Deponded employees and agents acting on Deponded's behalf to comply with this Agreement and all applicable Legal Requirements in connection with the Promotion of the Products. It is understood, and Deponded agrees, that it will be accountable for the acts or omissions of its employees and agents.

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(j) Depomed will not make any false or misleading representations to Professionals, customers or others regarding Santarus or the Products and will not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Products that are not consistent with the applicable then-current FDA approved labeling, package insert or other documentation accompanying or describing the Products. Depomed agrees to undertake timely and complete corrective action for any deviations from this Section 5.9(j).

## Section 5.10 **Product Website**

Until transfer of the Domain Name as provided herein, subject to the terms and conditions of this Agreement, Depomed hereby grants to Santarus and its Affiliates, and Santarus and its Affiliates hereby accept, an exclusive (even as to Depomed), royalty-free right and license to use the Domain Name and the registration thereof, including the trademark and service mark "glumetzaxr.com" and any intellectual property rights relating thereto, and all rights to use, access, control, modify, change or replace such content of the site associated to the Domain Name (the "Product Website"), to the extent any such trademark, service mark, or intellectual property rights exist as of the Effective Date or during the Term, solely in connection with Commercializing the Products in the Territory, on the terms and subject to the conditions set forth herein. Depomed agrees to cooperate with Santarus and to follow Santarus' reasonable instructions in order to effectuate the transfer of the Domain Name registration and the hosting provider account for the Domain Name

promptly (and in any event within 30 days) after the NDA Transfer Date. Specifically, Depomed agrees to prepare and transmit the necessary InterNic Registrant Name Change Agreement (RNCA) and or to correspond with InterNic to authorize transfer of the Domain Name, effective as of the NDA Transfer Date. Any out-of-pocket costs associated with maintaining and modifying the Product Website shall be included in the Advertising/Marketing/Educational Expenses for Santarus.

# ARTICLE 6 CLINICAL AND REGULATORY AFFAIRS; DEVELOPMENT

#### Section 6.1 **Regulatory Approvals**

Approvals for the Products that are in effect in the Territory as of the Effective Date. Depomed may, in its discretion, consult with Santarus regarding any proposed supplement, amendment or alteration to the Regulatory Approvals during the Pre-Transfer Period; provided that as the holder of the Product NDA, Depomed shall have final decision-making authority as to whether and how to supplement, amend or otherwise alter the Regulatory Approvals for the Products in the Territory during the Pre-Transfer Period. Depomed shall not have the right to, and hereby covenants that it will not, transfer or assign any Regulatory Approval for the Products to any Third Party, without Santarus' prior written consent (which Santarus may withhold in its sole discretion), except in conjunction with a permitted assignment of this Agreement made in accordance with Section 18.9.

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(b) From and after the NDA Transfer Date, Santarus shall properly maintain and keep current and active all Regulatory Approvals for the Products that are in effect in the Territory as of the Effective Date. Depomed agrees that, from and after the NDA Transfer Date and unless the parties otherwise agree, all Regulatory Approvals, applications therefor and any other submissions to a Governmental Authority in the Territory with respect to the Products shall be in the name of, and shall be owned by, Santarus. From and after the NDA Transfer Date, Santarus shall promptly prepare and file with the applicable Governmental Authorities all applications, reports and related documentation and shall pay any associated fees in order to maintain and continue all Regulatory Approvals for the Products. Santarus shall not have the right to, and hereby covenants that it will not, transfer or assign any Regulatory Approval for the Products to any Third Party, without Depomed's prior written consent (which Depomed may withhold in its sole discretion), except in conjunction with a permitted assignment of this Agreement made in accordance with Section 18.9.

#### Section 6.2 **Compliance with Regulatory Requirements**

- (a) Unless otherwise required by law or expressly required by this Agreement, subject to Section 6.1(a) and Section 6.4, during the Pre-Transfer Period, Depomed will be responsible for complying with all regulatory requirements and maintaining all contacts with Governmental Authorities with respect to the ownership of the Product NDA, including maintaining and updating of the Product NDA, the reporting of any Adverse Drug Experiences to the FDA and the filing of Promotional Materials with the FDA. In addition, Depomed will collaborate with Santarus to make such filings as are required for Santarus to Commercialize Products under Santarus NDC Numbers.
- (b) Unless otherwise required by law or expressly required by this Agreement, from and after the NDA Transfer Date, Santarus will be responsible for complying with all regulatory requirements and maintaining all contacts with Governmental Authorities with respect to the ownership of the Product NDA, including maintaining and updating of the Product NDA, the reporting of any Adverse Drug Experiences to the FDA and the filing of Promotional Materials with the FDA.

## Section 6.3 **Advertising and Promotion Compliance**

In performing its duties hereunder, each party shall, and shall cause the Santarus Sales Force or Depomed Sales Force, as applicable, and its employees and agents to, comply with all Legal Requirements, including the FDA's regulations and guidelines concerning the advertising of prescription drug products, DDMAC's promotional guidelines, the PhRMA Code on Interactions with Healthcare Providers, the Prescription Drug Marketing Act of 1987, as amended, and the rules and regulations promulgated thereunder, equal employment, non-discrimination and federal and state anti-kickback Legal Requirements, and Legal Requirements with respect to submission of false claims to governmental or private health care payors, which may be applicable to the activities (including the warehousing, handling and distribution of Samples) to be performed by such party hereunder. None of Santarus, Depomed, the Santarus Sales Force, the Depomed Sales Force and either party's employees and agents shall offer, pay, solicit or receive any remuneration to or from Professionals in order to induce referrals of or

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purchase of the Products in violation of applicable Legal Requirements, including without limitation federal or state anti-kickback Legal Requirements. The Santarus Sales Force and the Deponde Sales Force shall have been trained in compliance with applicable Legal Requirements prior to engaging in Promotion of the Products.

#### Section 6.4 Communications with Governmental Authorities

- (a) All communications with Governmental Authorities concerning the Products and arising from Depomed's ownership of the Product NDA prior to the NDA Transfer Date shall be the responsibility of Depomed. Depomed may, in its discretion, consult with Santarus regarding any such communication. Depomed shall within [\*\*\*] upon receipt of any communication from the FDA or from any other Regulatory Authority relating to the Products, forward a copy of the same to Santarus and reasonably respond to all inquiries by Santarus relating thereto. All communications with Regulatory Authorities concerning the Products and arising from Santarus' ownership of the Product NDA from and after the NDA Transfer Date shall be the responsibility of Santarus.
- From and after the NDA Transfer Date, Depomed shall not, without the consent of Santarus or unless so required by Legal Requirements, correspond or communicate with the FDA or with any other Regulatory Authority in the Territory concerning the Products, or otherwise take any action concerning any Regulatory Approval under which the Products are sold in the Territory or any application for Regulatory Approval of the Products in the Territory; provided that (i) Depomed shall have the right to communicate with the FDA or any other Regulatory Authority in the Territory regarding the Products if such communication is necessary to comply with the terms of this Agreement or any Legal Requirement or is related to Manufacturing or Commercialization activities undertaken by Depomed or the Depomed Sales Force, and (ii) BLS has the right to communicate with the FDA or any other Regulatory Authority in the Territory concerning the CMC portion of the Product NDA to the extent required under the BLS Supply Agreement. Each party shall within [\*\*\*] after receipt of any communication from the FDA or from any other Regulatory Authority in the Territory relating to the Products, forward a copy of the same to the other party and reasonably respond to all inquiries by the other party relating thereto. If a party is required by law to communicate with the FDA or with any other Regulatory Authority in the Territory relating to the Products, then such party shall so advise the other party within [\*\*\*] and provide the other party in advance with a copy of any proposed written communication with the FDA or any other Regulatory Authority in the Territory as soon as reasonably practicable after preparation. Each party shall, to the extent practicable in light of applicable Legal Requirements, have a period of at least [\*\*\*] (or such shorter period as is practicable under the circumstances) to provide comments to the other party on such communications, which comments the other party shall use commercially reasonable efforts to incorporate into its final communications to the extent such comments are reasonable and consistent with applicable Legal Requirements. Santarus acknowledges that, to the extent required by the Janssen Agreement and the BI Agreement, Depomed may provide a copy of any such proposed written

communication by Santarus to Janssen or BI, as applicable, for review and comment, provided that Santarus shall have no obligation to communicate directly with Janssen or BI, and any communications to Janssen or BI required under the Janssen Agreement or BI Agreement shall be the sole responsibility of Depomed.

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## Section 6.5 **Product Complaints**

From and after the NDA Transfer Date, Depomed shall refer any oral or written Product Complaints which it receives concerning the Products to Santarus within [\*\*\*] of its receipt thereof; provided that all complaints concerning suspected or actual Product tampering, contamination or mix-up shall be delivered within [\*\*\*] of its receipt thereof. Depomed shall not take any other action in respect of any such complaint without the consent of Santarus unless otherwise required by Legal Requirements. If requested by Santarus, Depomed will collaborate with Santarus to resolve any Product Complaints. All Product Complaints shall be directed to the attention of Santarus' customer service provider. Santarus shall provide Depomed with: (a) copies of all written Product Complaints which Santarus receives that relate to Products bearing Depomed's NDC Number; and (b) a summary of all oral Product Complaints that Santarus receives that relate to Products bearing Depomed's NDC Number; in each case within [\*\*\*] of its receipt thereof; provided that all complaints concerning suspected or actual Product tampering, contamination or mix-up that relate to Products bearing Depomed's NDC Number shall be delivered within [\*\*\*] of its receipt thereof.

#### Section 6.6 Adverse Drug Experience Reports

- (a) Each party shall notify the other: (i) of all Serious Adverse Drug Experience Reports within [\*\*\*] of the time such Serious Adverse Drug Experience Report becomes known to such party (including its employees); and (ii) of all Adverse Drug Experience Reports within [\*\*\*] of the time such Adverse Drug Experience Report becomes known to such party (including its employees).
- (b) Until the NDA Transfer Date, responsibility for maintaining the Adverse Drug Experience Report database shall be retained by Depomed at its sole expense. Depomed shall maintain the Adverse Drug Experience Report database in accordance with all applicable Legal Requirements. Until the NDA Transfer Date, Depomed shall report Adverse Drug Experience Reports, Periodic Adverse Drug Experience Reports (PADER) and Periodic Safety Update Reports (PSUR) in accordance with International Conference on Harmonization Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (ICH E2C) and 21 C.F.R. § 314.80.
- (c) From and after the NDA Transfer Date, Santarus shall be responsible for maintaining the Adverse Experience Report database at its sole expense; *provided, however*, that Depomed shall be required to reimburse Santarus for the reasonable, incremental, out-of-pocket and FTE costs incurred by Santarus directly relating to data, information, systems, communications or other interactions from or with other partners of Depomed in connection with the maintenance of such Adverse Experience Report database, to the extent such costs would not have been otherwise incurred by Santarus but for such partners. Such reimbursement by Depomed shall be made within [\*\*\*] after receipt of invoice from Santarus with supporting documentation in reasonable detail for invoiced amounts.
- (d) From and after the NDA Transfer Date, Santarus shall report Adverse Drug Experience Reports, Periodic Adverse Drug Experience Reports (PADER) and Periodic

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Safety Update Reports (PSUR) in accordance with International Conference on Harmonization Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (ICH E2C) and 21 C.F.R. § 314.80.

- (e) From and after the NDA Transfer Date, all follow-up investigations concerning Adverse Drug Experience Reports and Serious Adverse Drug Experience Reports shall be conducted by Santarus; provided that Depomed shall have the right to participate in any such investigations relating to Products sold under Depomed's NDC Number upon its request. Depomed shall provide all reasonable cooperation with any such follow-up investigation as may be requested by Santarus from time to time.
- (f) In the event that Depomed provides notice of its election to have the Depomed Sales Force Detail the Products pursuant to Section 5.9, then prior to the initiation of any Detailing of Products by Depomed pursuant to Section 5.9, the parties shall enter into a pharmacovigilance agreement that reflects the transfer and assumption described in Section 6.6(c) and is otherwise substantially in the form of the pharmacovigilance agreement executed pursuant to the Promotion Agreement.

## Section 6.7 **Recalls or Other Corrective Action**

- recall (including recall of packaging and promotion materials), market withdrawals or any other corrective action related to the Products. Depomed shall promptly consult with Santarus with respect to any such actions proposed to be taken by Depomed (and in all events prior to the taking of such actions), including all actions that are reasonably likely to result in a material adverse effect on the marketability of the Products in the Territory. At Depomed's request, Santarus shall provide assistance to Depomed in conducting such recall, market withdrawal or other corrective action (including retrieving Samples distributed by the Santarus Sales Force to Professionals). As the NDA holder, Depomed shall be responsible for all communications with the FDA with respect to any Product recall, market withdrawal or other corrective action; provided that (i) Depomed shall consult with Santarus prior to submitting any related documentation to the FDA, (ii) Depomed shall provide Santarus with copies of all communications received from or submitted to the FDA with respect to any such recall, market withdrawal or other corrective action within [\*\*\*] after receipt or submission thereof and (iii) Santarus shall be permitted to accompany Depomed and take part in any meetings or discussions with FDA with respect to any such recall, market withdrawal or other corrective action.
- (b) From and after the NDA Transfer Date, Santarus shall have final decision-making authority with respect to any recall (including recall of packaging and promotion materials), market withdrawals or any other corrective action related to the Products. At Santarus' request, Depomed shall provide assistance to Santarus in conducting such recall, market withdrawal or other corrective action as it relates to Products distributed by Depomed (including retrieving Samples distributed by the Depomed Sales Force to Professionals) or Manufactured by or on behalf of Depomed. As the NDA holder, Santarus shall be responsible for all communications with the FDA with respect to any Product recall, market withdrawal or

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other corrective action; provided that Santarus shall provide Depomed with copies of all communications received from or submitted to the FDA with respect to any such recall, market withdrawal or other corrective action within [\*\*\*] after receipt or submission thereof.

- (c) With respect to any recall, market withdrawal or corrective action with respect to Product, (i) Depomed shall be responsible for the out-of-pocket costs associated with such recall, market withdrawal or corrective action to the extent relating to Product Manufactured prior to the Effective Date, and (ii) Santarus shall be responsible for the out-of-pocket costs associated with such recall, market withdrawal or corrective action to the extent relating to Product Manufactured on or after the Effective Date. To the extent the recall, market withdrawal or corrective action relates to Product Manufactured before and after the Effective Date, the responsibility for out-of-pocket costs associated therewith shall be equitably apportioned between the parties based on the relative amount of Product affected that was Manufactured before the Effective Date and the relative amount of Product affected that was Manufactured on or after the Effective Date.
- (d) Notwithstanding Section 6.7(c) above, in the event of a recall, market withdrawal or other corrective action with respect to Product manufactured at Patheon's Caguas or Manati facilities in Puerto Rico that results from the presence of 2,4,6-tribromoanisole, or TBA, Santarus and Depomed shall share equally all out-of-pocket costs (other than Product returns) associated with such recall, market withdrawal or other corrective action that are incurred by either party, including inventory write-offs and costs and expenses associated with product liability, as adjusted for any amounts or other consideration recovered from Third Party manufacturers or other Third Parties or insurance proceeds received. With respect to Product returns arising from any recall, market withdrawal or other corrective action covered by this Section 6.7(d), the parties will work in good faith to ensure that (i) the parties share equally manufacturing costs of Product that replaces returned Product and (ii) royalties on Product distributed to replace returned Product are payable at the same rate in effect when such Product is returned.

#### Section 6.8 Assistance

Each party agrees to provide to the other all reasonable assistance and take all actions reasonably requested by the other party that are necessary to enable the other party to comply with any Legal Requirement applicable to the Products in the Territory.

# ARTICLE 7 MANUFACTURING AND SUPPLY; SALES; PRICING

#### Section 7.1 **Supply of Product Prior to the Manufacture Transfer Date**

(a) Santarus shall provide to Depomed [\*\*\*] forecasts for its purchase of Products and Samples consistent with Depomed's obligations under the BLS Supply Agreement and the Patheon Agreement, as applicable. Depomed shall promptly submit Santarus' forecasts to BLS and Patheon without any substantive change. Santarus' forecasts shall be binding to the same extent as Depomed's forecasts to BLS or Patheon are required to be binding under the BLS Supply Agreement or Patheon Agreement, respectively, such that Santarus shall place purchase

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orders to Depomed for the Products and Samples during such period as set forth in such forecast, and the remainder shall be a good faith estimate of the anticipated volumes of Product and Samples to be ordered by Santarus during such period. Depomed shall not be obligated to accept purchase orders for supply of Product or Samples in excess of the amount accepted by BLS or Patheon, as applicable. Depomed will use commercially reasonable efforts to have BLS and Patheon, as applicable, accept all purchase orders for Products and Samples submitted by Santarus.

(b) Santarus shall coordinate its purchase orders for BLS-Manufactured Product so as to transition to Santarus' NDC Numbers as soon as practicable after FDA's approval of 1000mg Product labels with Santarus' NDC Numbers, with the goal for

such transition being for BLS-Manufactured Product shipped on or before [\*\*\*]. The parties will cooperate to submit such Product labels to the FDA as soon as practicable after the Effective Date, as contemplated by the Transition Plan.

- (c) Depomed shall invoice Santarus for Product and Samples ordered and shipped after the Effective Date, at the price charged therefor by BLS pursuant to the BLS Supply Agreement or by Patheon pursuant to the Patheon Agreement, as applicable (including shipping and handling costs charged by BLS or Patheon), and Santarus shall pay each such invoice within [\*\*\*] of the receipt of invoice.
- Depomed shall promptly inform Santarus in the event that, prior to the applicable Manufacture Transfer Date, Depomed becomes aware of any matters under any Assigned Manufacturing Agreement or the BLS Agreements which would reasonably be expected to have an adverse impact on the ability of the Third Party manufacturer to supply Products or Samples in a timely manner. In each such event, and until the applicable Manufacture Transfer Date, Depomed shall provide Santarus with a reasonable opportunity to participate directly in discussions with Depomed's Third Party manufacturers of Products under the Assigned Manufacturing Agreements or with BLS, as applicable, concerning the investigation and resolution of such matters. Notwithstanding the generality of the foregoing, Depomed agrees to notify Santarus within [\*\*\*] after Depomed has become aware of any event or circumstance related to the Manufacture of the Product or Samples by any such Third Party manufacturer or by BLS that would reasonably be expected to impact the safety or efficacy of the Product or Samples or that would reasonably be expected to cause Product or Samples to be adulterated or misbranded within the meaning of the Act. Prior to the Manufacture Transfer Date, if ever, for the 1000mg Product, Depomed shall provide Santarus with a reasonable opportunity to participate directly in quality audits of BLS under the BLS Supply Agreement and shall conduct such audits as reasonably requested by Santarus consistent with the terms of the BLS Supply Agreement.
- (e) Santarus acknowledges and agrees that Product and Samples ordered by Santarus prior to the applicable Manufacture Transfer Date will be delivered from the BLS or Patheon site, as applicable, and will be shipped according to the terms for delivery in the BLS Supply Agreement or Patheon Agreement, as applicable, and that title to and risk of loss with respect to Product and Samples will pass to Santarus as set forth in the BLS Supply Agreement or Patheon Agreement, as applicable. Santarus will be responsible for procuring insurance for

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the transport of Product and Samples from the facilities of BLS and Patheon to the shipping address designated by Santarus in its purchase order.

- (f) Santarus or its designee may inspect all shipments of Products and Samples and accept or reject Product or Samples to the extent set forth in the applicable Third Party Manufacturing Agreement.
- (g) Santarus shall be responsible for securing the return and appropriate disposal of and reconciling existing Sample inventories from discontinued Santarus Sales Representatives. Upon its receipt of Samples, Santarus shall be solely responsible for accountability and compliance with the PDMA for the Santarus Sales Force, and other applicable Legal Requirements relating to such Samples or the distribution of same by the Santarus Sales Force, and shall be responsible for adherence by its Sales Representatives to such Legal Requirements.

#### Section 7.2 Sales; Pricing

- (a) As of the First Sales Booking Date, Santarus or its Affiliates shall book all sales of the Products in the Territory and shall be responsible for entering into any contracts and other arrangements with any Person regarding the sale of the Products, and for establishing and approving the form, content and terms and conditions thereof, including any discount, allowance, rebate, chargeback or other term granted therein; provided, however, that: Santarus may not sell Products as part of a bundled product without the prior written consent of Depomed. For purposes of this Section 7.2(a), a "bundled product" means Product that is sold together with at least one other pharmaceutical product for a single price or discounted price, whether sold together in the same package or merely price bundled.
- (b) Commencing on the Effective Date and during the Term, except as expressly set forth in Section 7.2(a) and Section 9.2, Santarus will have the sole authority to determine the prices of the Products sold by it and to establish its own terms and conditions of sale and pricing policies for the Products in the Territory, including price increases or decreases and the timing thereof, subject to complying as of the First Sales Booking Date and thereafter (subject to further amendment or termination by Santarus at its sole discretion) with the terms and conditions of the Assigned Agreements with group purchasing organizations, managed health care organizations or similar entities.
- (c) The parties agree that, on the Effective Date (or, if this Agreement becomes effective after 1:00 p.m., Pacific time, on the next business day), Depomed shall notify its wholesale customers of a wholesale acquisition price increase for Products, effective immediately, provided that Depomed shall be obligated to provide such notification (in the forms attached hereto as Schedule 7.2) before the issuance of the press release announcing the execution of this Agreement. [\*\*\*].

### Section 7.3 **Purchase and Sale of Inventory**

(a) As of the First Sales Booking Date, Depomed shall sell, convey and assign to Santarus, and Santarus shall purchase and acquire from Depomed, all of Depomed's right, title

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and interest in and to the Inventory, free and clear of all Encumbrances; provided, however, that, notwithstanding Santarus' payment for the API included in the Inventory that is held at Patheon as of the First Sales Booking Date ("Existing API"), Depomed shall have the right to use the Existing API solely for the purpose of having Manufactured any additional quantities of 500mg Product ordered by Santarus prior to the Manufacture Transfer Date for the 500mg Product pursuant to Section 7.1 or covered by Open Product Orders for the 500mg Product.

- (b) As consideration for the Inventory described in Section 7.3(a), Santarus shall pay to Depomed a purchase price equal to Depomed's out-of-pocket costs of such Inventory, as reasonably documented by Depomed and as set forth per bottle of finished Product and per kilogram of API on Schedule 7.3(b), net of reserves with respect to the Inventory as of the First Sales Booking Date, if any. The purchase price for the Inventory shall be paid in three equal installments, the first of which shall be received by Depomed not later than [\*\*\*], the second of which shall be received by Depomed not later than [\*\*\*] and the third of which shall be received by Depomed not later than [\*\*\*].
- (c) In order to ensure that Santarus has sufficient supply of API for orders for the 500mg Product by Santarus pursuant to Section 7.1, with Santarus' prior written approval, Depomed shall, sufficiently in advance of the Manufacture Transfer Date for the 500mg Product, order, purchase, and hold at Patheon, such additional quantity of API as is reasonably necessary for such manufacturing run(s) ("Additional API"). Depomed shall invoice Santarus for Additional API shipped, at the price charged therefor by Farmhispania, S.A. pursuant to that certain Supply Agreement between Farmhispania, S.A. and Depomed dated as of September 15,

2010 (including shipping and handling costs charged by Farmhispania, S.A.), as reasonably documented by Depomed. Santarus shall pay such invoice within [\*\*\*] of receipt of invoice. Depomed shall have the right to use the Additional API solely for the purpose of having Manufactured 500mg Product for Santarus. Effective as of the Manufacture Transfer Date for the 500mg Product, Santarus shall be responsible for having Manufactured 500 mg Product using the Additional API.

(d) Santarus shall have BLS label and package any bulk (work-in-process) 1000mg Product held by BLS under Santarus' NDC Numbers as soon as practicable after FDA's approval of 1000mg Product labels with Santarus' NDC Numbers, with the goal for such transition being on or before January 1, 2012.

### Section 7.4 **Purchase of Samples by Depomed**

- (a) This Section 7.4 shall apply only after the Manufacture Transfer Date for a particular Santarus-Manufactured Product and only in the event that Depomed elects to Detail Products in the Territory in accordance with Section 5.9.
- (b) Santarus shall provide or cause to be provided to Depomed, as ordered by Depomed hereunder, Santarus-Manufactured Samples to be distributed by Depomed solely in connection with the performance of Details or as otherwise required by the rules, guidelines and policies applicable to any Professional.

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- (c) At least [\*\*\*] prior to the beginning of each Agreement Quarter ending after Depomed's election to Detail Products in the Territory, Depomed shall submit to Santarus a written non-binding forecast by month of the number of units of Santarus-Manufactured Samples, on a Santarus-Manufactured Product-by-Santarus-Manufactured Product basis, for the [\*\*\*] period beginning with such Agreement Quarter. Such Santarus-Manufactured Sample forecast provided by Depomed shall be consistent with Santarus' Third Party Product supply agreements then in effect (the relevant provisions of which shall be provided to Depomed upon Depomed's request). Depomed shall place binding orders with Santarus for Santarus-Manufactured Samples, in a mutually agreeable format, to the same extent as Santarus is required to place binding orders for Santarus-Manufactured Samples with its Third Party suppliers.
- (d) Depomed acknowledges and agrees that Santarus-Manufactured Samples will be delivered from the Third Party supplier site, and will be shipped according to the terms for delivery in the Assigned Manufacturing Agreement or successor agreement, and that title to and risk of loss with respect to Santarus-Manufactured Samples will pass to Depomed as set forth in the Assigned Manufacturing Agreement or successor agreement. Depomed will be responsible for procuring insurance for the transport of Santarus-Manufactured Samples from the facilities of the Third Party supplier to the shipping address designated by Depomed in its purchase order. Depomed shall be responsible for distributing the Santarus-Manufactured Samples to its Sales Representatives in a timely manner. Santarus shall invoice Depomed for each shipment of Santarus-Manufactured Samples, at Santarus' out-of-pocket cost, payable within [\*\*\*] of the invoice date. Depomed shall be responsible for securing the return and appropriate disposal of and reconciling existing Sample inventories from discontinued Depomed Sales Representatives.
- (e) Santarus-Manufactured Samples supplied by Santarus to Depomed shall be used by Depomed solely in performing Details to Professionals in accordance with this Agreement. Upon its receipt of any Samples, Depomed shall be solely responsible for accountability and compliance with the PDMA for the Depomed Sales Force, and other applicable Legal Requirements relating to Samples or the distribution of same by the Depomed Sales Force, and shall be responsible for adherence by its Sales Representatives to such Legal Requirements.

- (f) All Santarus-Manufactured Samples supplied to Depomed under this Agreement with approved expiry dating of [\*\*\*] or greater will have a minimum shelf life of [\*\*\*] at time of shipment to Depomed, and all Santarus-Manufactured Samples supplied to Depomed under this Agreement with approved expiry dating of less than [\*\*\*] will be shipped to Depomed either within [\*\*\*] of the start of manufacture or with a minimum shelf life of [\*\*\*] at time of shipment to Depomed.
- (g) Deponde or its designee may inspect all shipments of Santarus-Manufactured Samples and accept or reject such Samples to the extent set forth in the applicable Assigned Manufacturing Agreement or successor agreement.

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#### Section 7.5 **Third Party Agreements**

The parties acknowledge that Depomed has certain rights and is subject to certain obligations under the BLS Agreements, the Chargeback Agreements, the Government Rebate Agreements and, prior to assignment as provided in this Agreement, the Assigned Agreements, concerning rights to, or the Manufacture or Commercialization of, Products in the Territory (the "Third Party Agreements"). Deponded shall not amend, terminate or cause to be terminated any of the Third Party Agreements without the prior written consent of Santarus. Depomed shall not assign any of the Third Party Agreements in whole or in part, except in conjunction with a permitted assignment of this Agreement pursuant to Section 18.9, and shall not delegate any of its obligations under any of the Third Party Agreements without the prior written consent of Santarus. Depomed shall not take any action, or intentionally omit to take any action, which action or omission would constitute a material breach or with or without the passage of time would enable termination by a Third Party or a material reduction or other material limitation in the rights granted by Depomed to Santarus. Depomed shall not voluntarily terminate any of the Third Party Agreements. Deponded shall not waive or otherwise excuse the performance or nonperformance of any obligations by a Third Party under the Third Party Agreements that would result in a material reduction or other material limitation in the rights granted by Depomed to Santarus, without Santarus' prior written consent. Depomed shall promptly notify Santarus upon receipt by Depomed of any notice or other correspondence from a Third Party of any actual or alleged breach under any Third Party Agreement. Santarus shall be permitted to take part in any communications with the applicable Third Party regarding any actual or alleged breach under a Third Party Agreement or other matter that could result in the termination of such agreement or any material reduction or other material limitation in Depomed's rights thereunder to the extent such termination, reduction or limitation would be reasonably expected to adversely affect Santarus' rights under this Agreement. At Santarus' reasonable request. Depomed shall promptly exercise any rights or pursue any recourse it may have under the Third Party Agreements. In the event of any failure by a Third Party supplier to timely deliver and supply Product in accordance with the terms of the applicable supply agreement, assuming each party's compliance with its obligations under this Agreement, each party's liability to the other for such failure shall be limited to the recourse that such party receives, if any, from the Third Party supplier, and any such failure on the part of the Third Party supplier shall not be a breach or default of this Agreement by such party (except to the extent that any such failure by the Third Party supplier arises directly from such party's failure to comply with its obligations, including paying amounts due, under the applicable Third Party supply agreement).

# ARTICLE 8 COMPENSATION

#### Section 8.1 Santarus Payments Prior to Generic Entry

(a) During the Term, Santarus shall pay to Depomed royalties on Promotion Net Sales according to the schedule set forth below, until Generic Entry of any Product (subject to Section 8.3(b)):

YEAR	ROYALTY %	
2011	26.5%	
2012	29.5%	
2013 and 2014	32.0%	
2015 and beyond	34.5%	

- (b) For so long as Santarus is required to pay royalties to Depomed pursuant to Section 8.1(a), in the event Depomed elects to Detail Products in the Territory pursuant to Section 5.9, Santarus shall pay to Depomed during the Term a royalty equal to 70% of Co-Promotion Net Sales.
- (c) Within [\*\*\*] following the end of each Agreement Month during which Santarus is required to pay royalties to Depomed pursuant to this Section 8.1, Santarus shall provide Depomed with a statement in a mutually agreeable format setting forth:
- (i) the aggregate number of units of Product (on a Product-by-Product basis) sold to customers in the Territory during such Agreement Month;
  - (ii) Net Sales during such Agreement Month;
  - (iii) Promotion Net Sales during such Agreement Month; and
- (iv) if applicable, Co-Promotion Net Sales during the most recent Agreement Month for which Co-Promotion Net Sales can be calculated given the lead-time required for availability of the Prescriber Data required to calculate Co-Promotion Net Sales for a given Agreement Month.
- (d) Within [\*\*\*] following the end of each Agreement Month during which Santarus is required to pay royalties to Depomed pursuant to this Section 8.1 (or, if later, within [\*\*\*] after such information becomes available to Santarus), Santarus shall provide Depomed with a statement setting forth the aggregate number of units of Product sold by Santarus, its Affiliates, Subcontractors and assigns in the Territory during such Agreement Month.
- (e) Payments required to be made by Santarus under this Section 8.1 shall be paid within [\*\*\*] after the end of the applicable Agreement Month. Statements required to be provided to Depomed under this Section 8.1 shall be emailed to such Depomed email addresses as Depomed may from time to time reasonably designate in writing.

## Section 8.2 Sales by Depomed Prior to the First Sales Booking Date.

(a) With respect to sales of Product by Depomed shipped on or after the Effective Date, Depomed shall pay to Santarus the amount determined by multiplying (x) one

minus the applicable royalty percentage set forth in Section 8.1(a), by (y) Depomed's Net Sales for the applicable Agreement Month, and then deducting its COGS for such sales.

- (b) Within [\*\*\*] following the end of each Agreement Month during which Depomed sells Product, Depomed shall provide Santarus with a statement in a mutually agreeable format setting forth:
- (i) the aggregate number of units of Product (on a Product-by-Product basis) sold to customers in the Territory during such Agreement Month;
  - (ii) Net Sales during such Agreement Month; and
  - (iii) COGS during such Agreement Month.
- (c) Deponded shall pay the applicable amounts under this Section 8.2 within [\*\*\*] after the applicable Agreement Month. Statements required to be provided by Deponde under this Section 8.2 shall be emailed to such Santarus email addresses as Santarus may from time to time reasonably designate in writing

## Section 8.3 Santarus Payments After Generic Entry

- (a) From and after Generic Entry of any Product (subject to Section 8.3(b)), Santarus shall pay to Depomed during the Term fifty percent (50%) of the Gross Margin.
- (b) On or prior to Generic Entry of the first Product, Santarus may elect by written notice to Depomed to continue to Promote one or more Products, despite Generic Entry, in accordance with the obligations under Section 5.1. In the event Santarus timely makes such election, its royalty obligations under Section 8.1(a) shall continue with respect to the Product for which Generic Entry has not occurred, and the payments under Section 8.3(a) shall not apply with respect to such Product, unless and until Santarus elects by written notice to cease Promoting Products in accordance with the obligations under Section 5.1.
- (c) Within [\*\*\*] following the end of each Agreement Month during which Santarus is required to pay Depomed pursuant to Section 8.3(a), Santarus shall provide Depomed with a statement in a mutually agreeable format setting forth:
- (i) the aggregate number of units of Product (on a Product-by-Product basis) sold to customers in the Territory during such Agreement Month;
  - (ii) Net Sales during such Agreement Month;
  - (iii) COGS during such Agreement Month;
- (iv) Amounts received from Authorized Generic Distributors with respect to an Authorized Generic of such Product during such Agreement Month; and
  - (v) Gross Margin for such Agreement Month.

- (d) Within [\*\*\*] following the end of each Agreement Month during which Santarus is required to make payments to Depomed pursuant to Section 8.3(a) (or, if later, within [\*\*\*] after such information becomes available to Santarus), Santarus shall provide Depomed with a statement setting forth the aggregate number of units of Product sold by Santarus, its Affiliates, Subcontractors and assigns in the Territory during such Agreement Month.
- (e) Payments required to be made by Santarus under this Section 8.3 shall be paid within [\*\*\*] after the end of the applicable Agreement Month. Statements required to be provided to Depomed under this Section 8.3 shall be emailed to such Depomed email addresses as Depomed may from time to time reasonably designate in writing.

#### Section 8.4 **Maintenance of Records**

- (a) Each party agrees to keep, for a period of at least three years after the date of entry (or such longer period as may be required by Legal Requirements) full and accurate records maintained in accordance with such party's accounting practices in sufficient detail to enable a Third Party to accurately calculate all payments, reports and similar obligations of a party under this Agreement. Upon thirty (30) days prior written notice, such records shall be made available by the audited party for audit by an independent certified public accounting firm designated by the other party and reasonably acceptable to the party whose records are to be examined. The auditor will only examine such books and records during business hours but not more than once each fiscal year while this Agreement remains in effect and for three years thereafter. The fees and expenses of the auditor performing such verification examination shall be borne by the party conducting the verification; provided, however, that if any verification reveals that the audited party has reported incorrectly, and the amount of such discrepancy is at least five percent (5%) of the aggregate amount that should have been reported for the period examined, then the audited party shall pay the entire amount of the fees and expenses for such verification.
- (b) Each party shall have the right, upon [\*\*\*] prior written notice, to audit all applicable records of the other party (other than records described in Section 8.3(a)) for the purpose of determining the audited party's compliance with the obligations set forth in this Agreement. The audit will be conducted during normal business hours, at convenient times. Any such audit may be conducted no more than [\*\*\*] each fiscal year. The fees and expenses of the auditing party shall be borne by such party. This right to audit shall extend throughout the term of this Agreement and for one year after expiration or termination of this Agreement.
- (c) Whenever in this Agreement a party is required to report its costs, or is entitled to receive or obligated to make a payment based on its costs, such costs (including COGS and Advertising/Marketing/Educational Expenses) shall be determined in accordance with generally accepted accounting principles as applied in the United States ("GAAP"), consistent with the terms of this Agreement. The term "out-of-pocket" costs or expenses means cost or expenses paid to Third Parties and shall not include any fixed costs or expenses, personnel costs or expenses, overhead costs or expenses, or other costs or expenses of a similar nature.

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## Section 8.5 **Payments**

Any payments required to be made by either party under this Agreement shall be made in United States dollars via wire transfer of immediately available funds to such bank account as the other party shall designate in writing prior to the date of such payment. All payments shall bear interest from the date due until paid at a rate equal to the prime rate effective for the date that payment was due plus eight percent (8%), as quoted by the Wall Street Journal, New York Edition, on the date such payment was due, or, if less, the maximum rate permitted by applicable law.

## Section 8.6 **Depomed Percentage**

If, prior to or following the commencement of Product Promotion by the Depomed Sales Force, either party reasonably determines that the Prescriber Data fails to, or is likely to fail to, reasonably accurately reflect the portion of Net Sales attributable to prescriptions written by Professionals on the Depomed Physician List (whether as a result of Professionals opting out of the American Medical Association's Physician Masterfile database or otherwise), the parties shall negotiate in good faith with respect to implementing a revised manner of measuring the portion of Net Sales attributable to prescriptions written by Professionals on the Depomed Physician List, and reflect any such modification in the definition of "Depomed Percentage" and the "Baseline Percentage." The parties shall consider in their discussions any other customary manner of determining similar information as may arise in light of Professionals opting out of the American Medical Association's Physician Masterfile database or otherwise.

## Section 8.7 <u>BLS Royalty</u>

With respect to sales of 500mg Product made in the Territory prior to the Manufacture Transfer Date for the 500mg Product, the royalty payable by Depomed to BLS pursuant to Section 4.6 of the BLS Manufacturing Transfer Agreement shall be allocated between the parties according to the royalty percentage set forth in Section 8.1(a). With respect to sales of 500mg Product made in the Territory on or after the Manufacture Transfer Date for the 500mg Product, the royalty payable by Depomed to BLS pursuant to Section 4.6 of the BLS Manufacturing Transfer Agreement shall be the sole responsibility of Depomed. In the event that as a result of this Agreement, any amounts are required to be paid by Depomed to BLS pursuant to Section 8.3 of the BLS Supply Agreement, the parties shall discuss in good faith an equitable allocation of such amounts.

# ARTICLE 9 TRANSITION MATTERS

## Section 9.1 <u>Customer Contracts and Notifications</u>

Within ten (10) days after the Effective Date, Depomed shall: (a) take all actions necessary to remove Products from its contracts with Customers and shall use commercially reasonable efforts to do so in the shortest period of time permitted thereunder, or, only to the extent mutually agreed by the parties in writing, shall terminate such contracts and relationships to the extent they pertain to Products; provided that such Product removal shall not be effective

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prior to the First Sales Booking Date; and (b) notify all of its Customers in the Territory that future orders for the Products in the Territory on or after the First Sales Booking Date shall be placed with Santarus. Any orders held by Depomed for the purchase of Products in the Territory by Customers on the Effective Date which require shipment after the First Sales Booking Date shall be passed to Santarus by Depomed. Depomed shall refer to Santarus any orders for Products that it receives in the Territory which provide for delivery after the First Sales Booking Date. From and after the First Sales Booking Date, Santarus shall be responsible for supplying Products in fulfillment of such orders.

## Section 9.2 **NDC and Labeling Transition.**

Santarus shall have the right to sell and distribute Products bearing Depomed's NDC Number and to increase the invoice price of such Products, provided that (i) [\*\*\*] (ii) Santarus shall begin selling and distributing Product with Santarus' NDC Number as soon

as practicable and commercially reasonable after selling the Inventory and Product covered by Open Product Orders, on a Product-by-Product basis.

#### Section 9.3 Rebates, Chargebacks, Discount Redemptions and Returns

- (a) <u>Depomed Reserve Documentation</u>. Within ten (10) days after the Effective Date, Depomed shall provide to Santarus Depomed's estimate of the Depomed Commercial Rebates Reserve, Depomed Government Rebates Reserve, Depomed Chargebacks Reserve, Depomed Patient Discount Reserve and the Depomed Returns Reserve, and, assuming the Effective Date were the business day immediately preceding the First Sales Booking Date, Depomed's analyses in support of each of those items. Within ten (10) days after the First Sales Booking Date, Depomed shall provide to Santarus Depomed's estimate of the Depomed Commercial Rebates Reserve, Depomed Government Rebates Reserve, Depomed Chargebacks Reserve, Depomed Patient Discount Reserve and the Depomed Returns Reserve and Depomed's analyses in support of Depomed's final determination of the Depomed Commercial Rebates Reserve, Depomed Government Rebates Reserve, Depomed Chargebacks Reserve, Depomed Patient Discount Reserve and the Depomed Returns Reserve.
- (b) General. The parties agree that: (i) Depomed will continue to process and be financially responsible for all rebates, chargebacks, patient discounts and returns prior to the First Sales Booking Date in accordance with this Agreement; (ii) on and after the First Sales Booking Date, Depomed will be financially responsible for Product rebates and chargebacks, but only up to the amount of Depomed's applicable reserve accounts for those items as of the business day immediately preceding the First Sales Booking Date (*i.e.*, up to the amount of each of the Depomed Commercial Rebates Reserve, the Depomed Government Rebates Reserve and the Depomed Chargebacks Reserve) on a first-in-first-out basis; (iii) on and after the First Sales Booking Date, Depomed will be financially responsible for Product returns attributable to Product distributed by Depomed, but, subject to Section 6.7(d), only up to the amount of the Depomed Returns Reserve; (iv) on and after the First Sales Booking Date, Santarus will be financially responsible for all Product rebates and chargebacks in excess of the amount of

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Depomed's applicable reserve accounts for those items as of the business day immediately preceding the First Sales Booking Date (*i.e.*, in excess of the amount of each of the Depomed Commercial Rebates Reserve, the Depomed Government Rebates Reserve and the Depomed Chargebacks Reserve) on a first-in-first out basis; (v) on and after the First Sales Booking Date, Santarus will be financially responsible for Product returns attributable to Product distributed by Santarus, subject to Section 6.7(d); (vi) subject to Section 6.7(d), on and after the First Sales Booking Date, Santarus will be financially responsible for Product returns attributable to Product distributed by Depomed in excess of the Depomed Returns Reserve; (vii) the parties will coordinate with the applicable vendor(s) to ensure that all redemptions under the Product Discount Card Programs are the financial responsibility of Santarus on and after the First Sales Booking Date; and (viii) the mechanics for processing of, and payments with respect to, Product rebates, chargebacks, discount card redemptions and returns will be as set forth in the remainder of this Section 9.3. For clarity, Santarus shall not deduct from Net Sales any amounts for which Depomed bears financial responsibility under this Section 9.3.

(c) Assignment of Commercial Rebate Agreements and Discount Card Programs. Effective as of the Processing Transfer Date, all Commercial Rebate Agreements shall be assigned by Depomed to Santarus, and shall be assumed by Santarus, pursuant to an Assignment and Assumption Agreement to be negotiated in good faith by the parties. Effective as of the First Sales Booking Date, (i) the New York Discount Card Program shall be assigned by Depomed to Santarus, and shall be assumed by Santarus, pursuant to an Assignment and Assumption Agreement to be negotiated in good faith by the parties and (ii) the Ex-New York Discount Card Program shall be terminated by Depomed, and Santarus shall amend its existing agreement with MediMedia, LLC to assume

responsibility for redemptions made on and after the First Sales Booking Date. In connection with the foregoing: (A) any amounts held by the applicable vendor(s) on behalf of Depomed for redemption pursuant to the Discount Card Programs will be returned to Depomed; and (B) Depomed will transfer to Santarus an amount equal to the Depomed Patient Discount Reserve.

Commercial Rebates. Prior to the Processing Transfer Date, Depomed shall process all rebates under the Commercial Rebate Agreements. From and after the Processing Transfer Date, Santarus shall process all rebates under the Commercial Rebate Agreements for Products dispensed from and after October 1, 2011, and Depomed shall continue to process all rebates under the Commercial Rebate Agreements for Products dispensed prior to October 1, 2011. On a monthly basis, each party shall report to the other in writing any Product rebates processed and paid by it for which Depomed is financially responsible pursuant to Section 9.3(b). Any Product rebates for which Depomed is financially responsible under Section 9.3(b) processed and paid by Santarus under the Commercial Rebate Agreements shall be invoiced to Depomed on a monthly basis and paid by Depomed within thirty (30) days after Depomed's receipt thereof (and Depomed shall reduce the Depomed Commercial Rebates Reserve by the amount of such invoice) until the balance in the Depomed Commercial Rebates Reserve is zero. Any Product rebates for which Santarus is financially responsible pursuant to Section 9.3(b) that are processed and paid by Depomed under the Commercial Rebate Agreements shall be invoiced to Santarus on a monthly basis and paid by Santarus within thirty (30) days after Santarus' receipt thereof. In the event there is any remaining Depomed Commercial Rebates Reserve as of April 1, 2012 (i.e., the Depomed Commercial Rebates

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Reserve as of the business day preceding the First Sales Booking Date, less any Product rebates processed against it pursuant to this Section 9.3(d)), Depomed shall remit payment to Santarus within thirty (30) days thereafter in the amount determined as follows: (i) for any remaining portion of the Depomed Commercial Rebates Reserve taken prior to the Effective Date, [\*\*\*] of such remainder and (ii) for any remaining portion of the Depomed Commercial Rebates Reserve taken from and after the Effective Date, the amount obtained by multiplying (x) [\*\*\*] by (y) [\*\*\*]. From and after determination of the amount payable to Santarus pursuant to the immediately preceding sentence, for purposes of this Agreement, the Depomed Commercial Rebates Reserve shall be zero. For clarity, Santarus shall bear financial responsibility for all rebates under commercial agreements for Products entered into by Santarus other than the Commercial Rebate Agreements.

- Products sold with a Depomed NDC Number. Santarus shall process all government rebates for Products sold with a Santarus NDC Number. On a monthly basis, Depomed shall report to Santarus in writing any Product rebates processed by it for which Depomed is financially responsible pursuant to Section 9.3(b) that are applied to the Depomed Government Rebates Reserve. All other Product rebates under the Government Rebate Agreements processed by Depomed shall be invoiced to Santarus on a monthly basis and paid within thirty (30) days after Santarus' receipt thereof. In the event there is any remaining Depomed Government Rebates Reserve as of April 1, 2013 (*i.e.*, the Depomed Government Rebates Reserve as of the business day preceding the First Sales Booking Date, less any Product rebates processed against it pursuant to this Section 9.3(e)), Depomed shall remit payment to Santarus within thirty (30) days thereafter in the amount determined as follows: (i) for any remaining portion of the Depomed Government Rebates Reserve taken prior to the Effective Date, [\*\*\*] of such remainder and (ii) for any remaining portion of the Depomed Government Rebates Reserve taken from and after the Effective Date, the amount obtained by multiplying (x) [\*\*\*] by (y) [\*\*\*]. From and after determination of the amount payable to Santarus pursuant to the immediately preceding sentence, for purposes of this Agreement, the Depomed Government Rebates Reserve shall be zero. For clarity, Santarus shall bear financial responsibility for all government rebates for Products sold under a Santarus NDC Number.
- (f) <u>Chargebacks</u>. Prior to the First Sales Booking Date, Deponded shall process all chargeback claims for Products. Beginning with the First Sales Booking Date, Santarus shall process all chargeback claims for Products. On a monthly basis,

Depomed shall report to Santarus all chargeback claims for Products, if any, for which Depomed is financially responsible pursuant to Section 9.3(b) that are processed by it under the Chargeback Agreements and applied to the Depomed Chargebacks Reserve. Any chargeback claims for Products for which Depomed is financially responsible pursuant to Section 9.3(b) that are processed by Santarus under the Chargeback Agreements shall be invoiced to Depomed on a monthly basis and paid by Depomed within thirty (30) days after Depomed's receipt thereof (and Depomed shall reduce the Depomed Chargebacks Reserve by the amount of such invoice) until the balance in the Depomed Chargebacks Reserve is zero. All other chargeback claims for Products under the Chargeback Agreements processed by Depomed shall be invoiced to Santarus on a monthly basis and paid within thirty (30) days after Santarus' receipt thereof. In the event there is any remaining Depomed Chargebacks Reserve as of April 1, 2012 (i.e., the Depomed Chargebacks

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Reserve as of the business day preceding the First Sales Booking Date, less any Product chargebacks processed against it pursuant to this Section 9.3(f)), Depomed shall remit payment to Santarus within thirty (30) days thereafter in the amount determined as follows: (i) for any remaining portion of Depomed Chargebacks Reserve taken prior to the Effective Date, [\*\*\*] of such remainder and (ii) for remaining portion of the Depomed Chargebacks Reserve taken from and after the Effective Date, the amount obtained by multiplying (x) [\*\*\*] by (y) [\*\*\*]. From and after determination of the amount payable to Santarus pursuant to the immediately preceding sentence, for purposes of this Agreement, the Depomed Chargebacks Reserve shall be zero. For clarity, Santarus shall bear financial responsibility for all chargeback claims for Products under agreements entered into by Santarus other than the Chargeback Agreements.

- (g) <u>Discount Card Redemptions</u>. From and after the First Sales Booking Date, Santarus shall be financially responsible for, and shall process, all Product discount redemptions under the New York Discount Card Program and Santarus' agreement with MediMedia, LLC for the Ex-New York Discount Card Program. Any requests for redemptions under the Discount Card Programs on or after the First Sales Booking Date shall be transferred by Depomed to Santarus.
- (h) Product Returns. On a [\*\*\*] basis, each party shall report to the other in writing any Product returns processed and paid by it, or short-paid by any Third Party to it, for which Depomed is financially responsible pursuant to Section 9.3(b). Any Product returns for which Depomed is financially responsible under Section 9.3(b) processed and paid by, or shortpaid by any Third Party to, Santarus shall be invoiced to Depomed on a [\*\*\*] basis and paid by Depomed within thirty (30) days after Depomed's receipt thereof (and Depomed shall reduce the Depomed Returns Reserve by the amount of such invoice) until the balance in the Depomed Returns Reserve is zero. Any Product returns for which Santarus is financially responsible pursuant to Section 9.3(b) that are processed and paid by, or short-paid by any Third Party to, Depomed shall be invoiced to Santarus on a [\*\*\*] basis and paid by Santarus within thirty (30) days after Santarus' receipt thereof. Financial responsibility for Product returns from any Product lots distributed by both parties will be determined on a pro rata basis. In the event there is any remaining Depomed Returns Reserve as of the first anniversary of the Depomed Product Expiration Date (as to each applicable Product) (i.e., the Depomed Returns Reserve as of the business day preceding the First Sales Booking Date, less any Product returns processed against it pursuant to this Section 9.3(h)), Deponded shall remit payment to Santarus within thirty (30) days thereafter in the amount determined as follows: (i) for any remaining portion of the Depomed Returns Reserve taken prior to the Effective Date, [\*\*\*] of such remainder and (ii) for any remaining portion of the Depomed Returns Reserve taken from and after the Effective Date, the amount obtained by multiplying (x) [\*\*\*] by (y) [\*\*\*]. From and after determination of the amount payable to Santarus pursuant to the immediately preceding sentence, for purposes of this Agreement, the Depomed Returns Reserve shall be zero for the applicable Product. Subject to the provisions of this Section 9.3(h), from and after the First Sales Booking Date. Santarus shall process all returns of Products.
- (i) <u>Review of Analyses</u>. Depomed will review with Santarus its analyses and related transactions data for the various rebate, chargeback and returns reserves covered by this Section 9.3 on each of the Effective Date and the First Sales Booking Date, and within thirty (30)

days after the end of each Agreement Month until the applicable reserve has been reduced to zero or paid to Santarus as provided above. Santarus will review with Depomed within thirty (30) days after the end of each Agreement Month amounts invoiced to Depomed by Santarus under this Section 9.3(b) and related transactions data until the applicable reserve has been reduced to zero as provided above.

## Section 9.4 **Government Pricing Information.**

- (a) With respect to Product sold by Santarus after the First Sales Booking Date that bears a Depomed NDC Number, Santarus will provide to Depomed the information reasonably requested by Depomed to permit Depomed to comply with its government price reporting obligations under Legal Requirements.
- (b) Depomed will provide Santarus with the information reasonably requested by Santarus to permit Santarus to comply with its government price reporting obligations under Legal Requirements after the transition to Santarus NDC Number.

#### Section 9.5 <u>Customer Service</u>

For the period from the Effective Date up to the First Sales Booking Date, Depomed will continue to provide all customer service at a level comparable to that which was provided prior to the Effective Date. On and from the First Sales Booking Date, through the completion of the Term, Santarus shall assume all customer service responsibility and provide all customer service required by its customers with respect to the Products. As of the First Sales Booking Date, and through the completion of the Term, all customer service requests relating to the Product coming to Depomed will be referred to Santarus to the attention of Santarus' customer service provider as designated by Santarus.

#### Section 9.6 <u>Termination of the Promotion Agreement</u>

As of the Effective Date, the Promotion Agreement shall automatically terminate and shall be superseded and replaced in its entirety by this Agreement. For clarification, all Proprietary Information of a party that was disclosed to the other party pursuant to the Promotion Agreement or the Confidentiality Agreement shall become subject to this Agreement.

# ARTICLE 10 TERM AND TERMINATION

## Section 10.1 Term

The term of this Agreement shall commence on the Effective Date and shall continue, unless terminated sooner in accordance with this Article 9, for so long as Santarus is engaging in any Commercialization activities with respect to a Product (the "Term").

#### Section 10.2 Early Termination

- (a) Deponded may terminate this Agreement, at any time after providing sixty (60) days' prior written notice, in the event that Santarus fails to meet its obligations under Section 5.1(b) and (c) with respect to minimum Promotion obligations. Notwithstanding the foregoing, Santarus shall have an opportunity to cure any such breach within ninety (90) days following written notice from Deponded provided that: (i) Santarus has complied with at least ninety percent (90%) of the aggregate obligations in effect under such Sections during the relevant time period; and (ii) no other breach of the obligations set forth in Section 5.1(b) or (c) has occurred within the prior twelve (12) month period.
- (b) Deponded shall have the right to terminate this Agreement immediately upon written notice to Santarus if Santarus or any of its Affiliates, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, or initiates any legal proceeding, challenging the validity or enforceability of any of the Deponded Patent Rights.
- (c) Santarus may terminate this Agreement for any reason upon one hundred twenty (120) days' prior written notice to Depomed, provided that, if requested by Depomed in writing during such notice period, Santarus shall, at its expense, cooperate in good faith with Depomed to facilitate the transition of regulatory, manufacturing and quality responsibilities with respect to Products back to Depomed.
- (d) Santarus may terminate this Agreement immediately upon written notice to Depomed in the event of any action taken or objection raised by any Governmental Authority that prevents Santarus from performing its obligations under this Agreement or otherwise makes such activity unlawful.

#### Section 10.3 <u>Termination for Cause</u>

Either party may terminate this Agreement, effective at any time after providing sixty (60) days written notice and an opportunity to cure during such sixty (60)-day period in the event of a material failure of the other party to comply with its material obligations contained in this Agreement. If such cure is effected within such period, such notice with respect to such termination shall be null and void.

#### Section 10.4 Termination for Bankruptcy or Force Majeure

To the extent permitted by law, each party will have the right to terminate this Agreement immediately upon notice to the other party, in the event of either of the following:

(a) The entry of an order for relief under the United States Bankruptcy Code (or any corresponding remedy under successor laws) against the other party; the filing of a petition by or against the other party under any bankruptcy, insolvency or similar law (which petition is not dismissed within sixty (60) days after filing), except Chapter 11 of the United States Bankruptcy Code or any successor statute that permits a corporation to continue its operation while protecting it from creditors; the appointment of a receiver for the other party's

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business or property; or the other party's making of a general assignment for the benefit of its creditors; or

(b) Any Force Majeure Event affecting the other party beyond the other party's control which lasts for a period of at least six (6) months and which is of sufficient intensity to interrupt or prevent the carrying out of such other party's material obligations under this Agreement during such period; provided that there shall be no such termination right in the event of a Force Majeure Event relating to Manufacturing of Product.

Notwithstanding the occurrence of any of the events specified in subsection (a) of this Section 10.4, the parties acknowledge and agree that, to the extent Section 365(n) of the United States Bankruptcy Code applies to this Agreement, the non-insolvent party may elect to retain and exercise the rights granted to it hereunder with respect to the intellectual property owned or controlled by the insolvent party.

#### Section 10.5 Force Majeure

Any Force Majeure Event of the type described in Section 18.7 affecting a party hereunder shall entitle the other party hereto, at any time after the expiry of the period of six (6) months specified therein and upon sixty (60) days written notice given after such six (6)-month period (such notice being null and void if the Force Majeure Event is discontinued during such sixty (60)-day period, in addition to the right to terminate this Agreement under Section 10.4, the right to continue the Agreement in full force and effect without modification. In no circumstances will either party be liable to the other for its inability to perform under this Agreement due to any such Force Majeure Event.

#### Section 10.6 **Effect of Termination**

- (a) No additional payment obligations arising under Article 7 hereof shall accrue after the date of expiration or termination of this Agreement; *provided, however*; that expiration or termination of this Agreement shall not relieve either party of any obligations accruing prior to such expiration or termination (including, without limitation, accrued payment obligations). Certain provisions of this Agreement by their terms continue after the expiration or termination of this Agreement, including Section 8.4, Section 8.5, Section 8.7, Section 9.3, Section 10.6, Section 11.3, Section 17.1 and Article 13, Article 14, Article 16 and Article 18. In addition, any other provisions required to interpret and enforce the parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.
- (i) any remedies which any party may then or thereafter have hereunder or at law or in equity; and (ii) a party's right to receive any payment accrued under the Agreement prior to the termination date but which became payable thereafter; and (iii) either party's right to obtain performance of any obligations provided for in this Agreement which survive termination by their terms or by a fair interpretation of this Agreement. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity or otherwise.

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- (c) Upon expiration or termination of this Agreement, all licenses granted by Depomed to Santarus pursuant to Section 2.1 shall automatically terminate and revert to Depomed.
- (d) Subject to Section 10.6(f), upon the expiration or termination of this Agreement pursuant to this Article 9, each party shall promptly transfer and return to the other party all Proprietary Information of the other party (provided that each party may keep one copy of such Proprietary Information for archival purposes only). Upon the expiration or termination of this Agreement, Santarus shall, if requested by Depomed, provide to Depomed all Promotional Materials in Santarus' possession (including electronic

files of all Promotional Materials) at Santarus' out-of-pocket cost for printing and delivering such materials; provided, however, that Santarus shall, unless otherwise requested by Depomed, destroy any printed copies of Promotional Materials bearing the Santarus Trademarks and may remove the Santarus Trademarks from electronic files of Promotional Materials.

- (e) Upon the expiration or termination of this Agreement pursuant to this Article 9, other than termination by Santarus pursuant to Section 10.3, Depomed may, but is not obligated to, purchase from Santarus, at Santarus' cost (as determined pursuant to this Agreement) all remaining Product inventory, including Samples. In the event of any purchase of inventory from Santarus pursuant to this Section 10.6(e), the parties shall negotiate in good faith as to an equitable treatment with respect to liability arising out of sales of such inventory by or on behalf of Depomed.
- (f) In the event of the expiration or termination of this Agreement, other than termination by Santarus pursuant to Section 10.3, at Depomed's sole discretion, Santarus shall, as promptly as practicable (and in any event within 60 days, unless a shorter period is specified below) after such expiration or termination perform any or all of the following (at Depomed's option): (i) upon Depomed's written request, assign to Depomed, subject to Section 18.11, any or all Assigned Agreements and/or Assigned Manufacturing Agreements and any or all other contracts with vendors to the extent such contracts are necessary for Depomed to take over responsibility for the Manufacture and Commercialization of Product in the Territory; (ii) deliver to Depomed true, correct and complete copies of all Regulatory Approvals in the Territory; (iii) transfer and assign, or cause to be transferred and assigned (and, effective upon expiration or termination, hereby does transfer and assign, or cause to be transferred and assigned), to Depomed or its designee the Product NDA (and, if applicable, any or all other Regulatory Approvals in the Territory that are then held by Santarus) and all right, title and interest in and to the Domain Name; (iv) within three (3) business days of Depomed's written request for transfer and assignment of the Product NDA (and, if applicable, other Regulatory Approvals), submit to the FDA a letter authorizing the transfer of ownership of the Product NDA and such other Regulatory Approvals (if any) from Santarus to Depomed; or (v) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record any transfer, assignment or other conveyance of rights under this Section 10.6(f) elected by Depomed to Depomed. If Depomed requests that Santarus withdraw the Product NDA, rather than transferring and assigning it to Depomed, Santarus shall do so within three (3) business days of such request.

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(g) Notwithstanding the expiration or any termination of this Agreement, Santarus shall continue to have sole financial responsibility for Product rebates, chargebacks, discount redemptions and returns as set forth in Section 9.3, for any other Product rebates, chargebacks, discount redemptions and returns with respect to Product Commercialized by or on behalf of Santarus, and, except as set forth in Section 6.7(d), for out-of-pocket costs for Product recalls, market withdrawals and other corrective actions with respect to Product Commercialized by or on behalf of Santarus; provided, however, that (i) Depomed shall not Commercialize Product under any Santarus NDC Numbers and (ii) the provisions of Section 9.3 shall continue to apply to any remaining amount of the Depomed Commercial Rebates Reserve, the Depomed Government Rebates Reserve, the Depomed Chargebacks Reserve and the Depomed Returns Reserve. For clarity, Santarus shall not be financially responsible for Product rebates, chargebacks, discount redemptions, returns or recalls with respect to Product distributed by Depomed or any Third Party from and after expiration or termination of this Agreement.

# ARTICLE 11 REPRESENTATIONS AND WARRANTIES

Section 11.1 Representations and Warranties of Depomed

Depomed hereby represents and warrants to Santarus as of the date hereof as follows:

- (a) <u>Organization</u>. Deponde (i) is a corporation duly organized, validly existing and in good standing under the laws of the state of California, and (ii) has all necessary corporate power and corporate authority to own its properties and to conduct its business, as currently conducted.
- (b) <u>Authorization</u>. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby are within the corporate power of Depomed, have been duly authorized by all necessary corporate proceedings of Depomed, and this Agreement has been duly executed and delivered by Depomed.
- (c) No Conflict. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby in accordance with all applicable terms and conditions hereof do not: (i) conflict with or result in a breach of any provision of Depomed's organizational documents; (ii) result in a material breach of any material agreement to which Depomed is party; (iii) result in a violation of any Order to which Depomed is subject; (iv) except as expressly contemplated by this Agreement, require Depomed to obtain any material approval or consent from any Governmental Authority or Third Party other than those consents and approvals which have been obtained prior to the date hereof; or (v) violate any Legal Requirement applicable to Depomed in any material respect.
- (d) <u>Enforceability</u>. This Agreement constitutes the valid and binding obligation of Depomed, enforceable against Depomed in accordance with its terms, subject to bankruptcy, reorganization, insolvency and other similar laws affecting the enforcement of creditors' rights in general and to general principles of equity (regardless of whether considered in a proceeding in equity or an action at law).

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- (e) <u>Broker</u>. Depomed has not employed any broker, finder, or agent with respect to this Agreement or the transactions contemplated hereby.
- Depomed Intellectual Property. To the knowledge of Depomed, the Manufacture and Commercialization of (f) Product in the Territory in accordance with this Agreement will not infringe any patents, trademarks or other intellectual property rights of any Third Party; provided, that Depomed makes no representation as to the Santarus Trademarks. Depomed has the right, power and authority to grant the licenses granted by it hereunder. As of the Effective Date, Schedule 11.1(f) sets forth a true, correct and complete list of all patents and patent applications Controlled by Depomed or its Affiliates as of the Effective Date, a license to which (with respect to patent applications, if patents are issued) is necessary for Santarus to Commercialize Products in the Territory or Manufacture Products for Commercialization in the Territory. All patents, trademarks and other intellectual property rights used by Depomed to Commercialize Products in the Territory or Manufacture Products for Commercialization in the Territory prior to the Effective Date are included in the Depomed Patent Rights, Depomed Trademarks and Technology licensed to Santarus hereunder. Depomed has not received any written claim or demand from any Third Party, and to the knowledge of Depomed, neither BLS nor Patheon has received any written claim or demand from any Third Party, alleging that any infringement, violation or misappropriation of such Third Party's intellectual property rights has occurred as a result of the manufacture, use, offer for sale, sale or importation of any Product in the Territory. Depond is not aware of any actual, alleged or threatened infringement, violation or misappropriation by a Third Party of any Depomed intellectual property rights covering a Product or its uses. Except for the Existing Infringement Cases, Depomed has not received any written claim or demand from any Third Party alleging invalidity or unenforceability of any of the Depomed Patent Rights.

- (g) <u>Litigation</u>. Except for the Existing Infringement Cases, there is no litigation, arbitration proceeding, governmental investigation, action or claims of any kind, pending or, to the knowledge of Depomed, threatened, by or against Depomed or any of its Affiliates relating to the Products or which would reasonably be expected to materially affect Depomed's ability to perform its obligations hereunder, or Santarus' ability to exercise its rights hereunder, nor, to Depomed's knowledge, is any litigation, arbitration proceeding, governmental investigation, action or claims of any kind, pending or, to the knowledge of Depomed, threatened, by or against BLS or Patheon or their respective Affiliates relating to the Products. Depomed is not a party to any litigation regarding any claim of product liability or damage to person (including death) or property resulting from the use or consumption of a Product in the Territory, nor has Depomed received any written communication threatening any such litigation.
- (h) <u>Documentation</u>. Deponde has made available to Santarus copies of substantially all clinical data and reports, regulatory correspondence and filings, medical information, intellectual property, manufacturing and quality information related to the Products in Deponde's possession that have been requested by Santarus in the course of Santarus' due diligence investigation of the Products.

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- (i) Generic Drug Act. Pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a, as may be amended or supplemented (the "Generic Drug Act"),
- (i) none of Depomed, its Affiliates, or any Person under its direction or control is currently debarred by the FDA under the Generic Drug Act;
- (ii) none of Depomed, its Affiliates, or any Person under its direction or control is currently using or will use in any capacity in connection with the Products any Person that is debarred by FDA under the Generic Drug Act; and
- (iii) there have been no convictions of Depomed, its Affiliates, or any Person under its direction or control for any of the types of crimes set forth in the Generic Drug Act within the five years prior to the Effective Date.
- Legal Requirements. None of Depomed, its Affiliates, or any Person under its direction or control is currently excluded from a federal or state health care program under Sections 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 as may be amended or supplemented. None of Depomed, its Affiliates, or Person under its direction or control is otherwise currently excluded from contracting with the federal government. None of Depomed, its Affiliates, or Person under its direction or control is otherwise currently excluded, suspended, or debarred from any federal or state program. Depomed shall immediately notify Santarus if, at any time during the Term, Depomed, its Affiliates, or any Person under its direction or control is convicted of an offense that would subject it or Santarus to exclusion, suspension, or debarment from any federal or state program. To Depomed's knowledge, the manufacture, use, offer for sale, sale and importation of the Products in the Territory has been in material compliance with all Legal Requirements.
- (k) Product NDA. Depomed has not committed fraud in relation to the filing or acquisition of the Product NDA or used unfair methods of competition in connection with such filing or acquisition or maintenance, including, in either case, in connection with any data supplied by Depomed to the FDA. The parties acknowledge that a breach of this representation is a material failure of a material obligation and is not subject to cure. To Depomed's knowledge, the data regarding the efficacy, safety, chemistry, manufacturing and control of the Products contained in the Product NDA and other regulatory filings submitted to the FDA in support of obtaining and maintaining marketing approval of the Products are complete and accurate in all material respects. To Depomed's knowledge, the Product NDA and other regulatory filings submitted to the FDA in support of marketing approval for the Products do

not contain any material misstatement of a material fact related to safety or efficacy nor omit to state any material fact in Depomed's possession related to safety or efficacy of the Products. Depomed has not received any written communication from FDA stating that any Post-Marketing Development activities are required by the FDA as a condition to maintenance of the Product NDA. Depomed has not received notice from any Governmental Authority (i) requiring or recommending any recall, market withdrawal or other corrective action with respect to Products, except with respect to the prior recall of the 500mg Product for the presence of TBA, or (ii) suspending or revoking, or threatening to suspend or revoke, any Regulatory Approval relating to Products; nor has BLS or Patheon notified Depomed of BLS's or Patheon's receipt of

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any such notice from any Governmental Authority relating to Products. Depomed has no plans to initiate any recall, market withdrawal or other corrective action with respect to Products.

(I) Third Party Agreements. Depomed is not in material breach of any Assigned Agreement, nor any of the BLS Agreements, and has not submitted to any Third Party any notice (written or oral) to the effect that the Third Party is in breach of any such Assigned Agreement or BLS Agreement. Depomed has not received from a Third Party any notice (written or oral) to the effect that Depomed is in breach of any Assigned Agreement or BLS Agreement. To Depomed's knowledge, (i) no Third Party counterparty to any Assigned Agreement is in breach of the applicable Assigned Agreement, and (ii) BLS is not in breach of any of the BLS Agreements. Each Assigned Agreement and BLS Agreement is legal, valid, binding, enforceable and in full force and effect in all material respects. True, correct and complete copies of the Assigned Agreements and BLS Agreements have been delivered to Santarus, including all waivers, modifications and amendments. Other than the Retained Contracts, the Assigned Agreements represent all agreements to which Depomed is a party relating to the Manufacture or Commercialization of Products in the Territory. Depomed has provided to Santarus all excerpts from the Existing Rights of Reference Agreements that contain provisions with respect to the Existing Rights of Reference or the right of access to data described in Section 3.4, and all such excerpts are true and accurate.

#### (m) Inventory.

- (i) Schedule 11.1(m) sets forth a true, complete and accurate list of the Inventory as of August 1, 2011.
- (ii) Since August 1, 2011, Depomed has not (i) materially altered its distribution practices or terms with respect to the Products, (ii) altered its activities and practices with respect to inventory levels of the Products maintained at the wholesale, chain, institutional or retail levels in any material respect, or (iii) experienced abnormally high levels of returns of the Products when compared to historical norms.
- (iii) To Depomed's knowledge, all of the Inventory (a) is good, issuable and merchantable in the ordinary course of business, and is free of any material defect or deficiency, (b) fully conforms to the specifications for the Products in the Regulatory Approvals, (c) was manufactured, packaged, labeled, held, tested and shipped in accordance with the specifications for the Products as set forth in the Regulatory Approvals, cGMPs, all other applicable laws, regulations and requirements of applicable Governmental Authorities, (d) is not adulterated or misbranded and is of suitable quality; and (e) may be introduced into interstate commerce in the Territory pursuant to the Act.
- (iv) Schedule 11.1(m) sets forth a true, complete and accurate list of all firm orders placed or deemed to have been placed for Product or API under the Assigned Manufacturing Agreements and the BLS Supply Agreement as of August 1, 2011 (collectively, "Open Product Orders").

(n) <u>Reserves</u>. Each of the Depomed Commercial Rebates Reserve, Depomed Government Rebates Reserve, Depomed Chargebacks Reserve, Depomed Patient Discount

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Reserve and the Depomed Returns Reserve are and will be as of the business day preceding the First Sales Booking Date in accordance with GAAP, consistently calculated and represent Depomed's best estimate for the applicable reserve as of the applicable date.

#### Section 11.2 Representations and Warranties of Santarus

Santarus hereby represents and warrants to Depomed as of the date hereof as follows:

- (a) <u>Organization</u>. Santarus (i) is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware, and (ii) has all necessary corporate power and corporate authority to own its properties and to conduct its business, as currently conducted.
- (b) <u>Authorization</u>. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby are within the corporate power of Santarus, have been duly authorized by all necessary corporate proceedings of Santarus, and this Agreement has been duly executed and delivered by Santarus.
- (c) <u>No Conflict</u>. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not: (i) conflict with or result in a breach of any provision of Santarus' organizational documents; (ii) result in a material breach of any material agreement to which Santarus is party; (iii) result in a violation of any Order to which Santarus is subject; (iv) require Santarus to obtain any material approval or consent from any Governmental Authority or Third Party other than those consents and approvals which have been obtained prior to the date hereof; or (v) violate any Legal Requirement applicable to Santarus in any material respect.
- (d) <u>Enforceability</u>. This Agreement constitutes the valid and binding obligation of Santarus, enforceable against Santarus in accordance with its terms, subject to bankruptcy reorganization, insolvency and other similar laws affecting the enforcement of creditors' rights in general and to general principles of equity (regardless of whether considered in a proceeding in equity or an action at law).
- (e) <u>Broker</u>. Santarus has not employed any broker or finder with respect to this Agreement or the transactions contemplated hereby.
- (f) <u>Santarus Trademarks</u>. To the knowledge of Santarus, the use of the Santarus Trademarks to Promote and sell Products in the Territory in accordance with this Agreement will not infringe any trademarks or other intellectual property rights of any Third Party.
- (g) <u>Litigation</u>. There is no litigation, arbitration proceeding, governmental investigation, action or claims of any kind, pending or, to the knowledge of Santarus, threatened, by or against Santarus or any of its Affiliates relating to the Products or which would reasonably be expected to materially affect Santarus' ability to perform its obligations hereunder.

- (h) <u>Generic Drug Act</u>. Pursuant to the Generic Drug Act,
- (i) none of Santarus, its Affiliates, or any Person under its direction or control is currently debarred by the FDA under the Generic Drug Act;
- (ii) none of Santarus, its Affiliates, or any Person under its direction or control is currently using or will use in any capacity in connection with the Products any Person that is debarred by FDA under the Generic Drug Act; and
- (iii) there have been no convictions of Santarus, its Affiliates, or any Person under its direction or control for any of the types of crimes set forth in the Generic Drug Act within the five years prior to the Effective Date.
- (i) <u>Legal Requirements</u>. None of Santarus, its Affiliates, or any Person under its direction or control is currently excluded from a federal or state health care program under Sections 1128 or 1156 of the Social Security Act, 42 U.S.C. §§ 1320a-7, 1320c-5 as may be amended or supplemented. None of Santarus, its Affiliates, or any Person under its direction or control is otherwise currently excluded from contracting with the federal government. None of Santarus, its Affiliates, or Person under its direction or control is otherwise currently excluded, suspended, or debarred from any federal or state program. Santarus shall immediately notify Depomed if, at any time during the Term, Santarus, its Affiliates, or any Person under its direction or control is convicted of an offense that would subject it or Depomed to exclusion, suspension, or debarment from any federal or state program.

#### Section 11.3 Warranty Disclaimer

EXCEPT AS EXPRESSLY PROVIDED HEREIN, EACH PARTY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE PRODUCTS, INCLUDING THE WARRANTY OF MERCHANTABILITY AND WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

# ARTICLE 12 INTELLECTUAL PROPERTY MATTERS

#### Section 12.1 **Intellectual Property Prosecution and Maintenance**

Depomed shall use commercially reasonable efforts to prosecute and maintain the Depomed intellectual property in the Territory related to any Product or its use, including the Depomed Patent Rights and the Depomed Trademarks (subject, in the case of the 1000mg Product, to BLS's rights and Depomed's obligations in respect of intellectual property under the BLS Agreements). Depomed shall make available to Santarus (or its designated counsel) copies of such patent application files and shall make available to Santarus (or its designated counsel) all office actions relating to any Product (or a proposed Generic Version thereof) wherein at least one (1) claim is directed to the Product (or a proposed Generic Version thereof) in those patent applications, and copies of material correspondence with the U.S. Patent and Trademark Office relating to such patent applications to the extent they relate to the Product (or a proposed Generic Version thereof) or its use. Santarus shall have the right to comment upon the prosecution of

such patent applications (subject, in the case of the 1000mg Product, to BLS's rights and Depomed's obligations in respect of intellectual property under the BLS Agreements). Depomed shall, in good faith, consider such comments of Santarus. In addition, Depomed shall keep Santarus reasonably informed regarding material developments relating to the prosecution, maintenance or enforcement of Depomed's intellectual property rights related to any Product inside or outside the Territory that would reasonably be expected to have a material impact on Depomed's intellectual property rights related to the Product in the Territory.

#### Section 12.2 <u>Infringement</u>

- (a) If either party shall learn of a claim or assertion that the manufacture, use or sale of a Product in the Territory infringes or otherwise violates the intellectual property rights of any Third Party or that any Third Party violates the intellectual property rights owned or Controlled by (i) Depomed in a Product and the Depomed Trademarks in the Territory or (ii) Santarus in the Santarus Trademarks, then the party becoming so informed shall promptly, but in all events within fifteen (15) days thereof, notify the other party to this Agreement of the claim or assertion. In the event either party receives a notice under Paragraph IV of the U.S. Federal Drug Price Competition and Patent Term Restoration Act of 1984, as amended, also known as the Hatch-Waxman Act, with respect to any Product, such party shall provide the other party with written notice of such Paragraph IV notice within two (2) business days (each, a "Paragraph IV Notice").
- (b) If warranted in the opinion of Depomed, after consultation with Santarus, Depomed shall have the right to take such legal action ("Enforcement Action") as is advisable in Depomed's opinion to restrain infringement of such Depomed Patent Rights related to any Product or the Depomed Trademarks in the Territory (subject, in the case of the 1000mg Product, to BLS's rights and Depomed's obligations with respect to the intellectual property under the BLS Agreements). Depomed will have the right to institute the Enforcement Action in its own name using counsel of its choice and, except as otherwise set forth in this Agreement, with the right to control the course of such Enforcement Action. Santarus shall cooperate fully with, and as reasonably requested by Depomed in any Enforcement Action, and Depomed shall reimburse Santarus for its out-of-pocket expenses incurred in providing such cooperation. Santarus may be represented by counsel of its own selection at its own expense in any Enforcement Action. Depomed shall keep Santarus reasonably informed regarding material developments relating to any Enforcement Action (including by making its outside counsel available to participate in periodic status calls); provided, however, that Depomed shall obtain Santarus' consent (which Santarus will not unreasonably withhold) in advance of (i) the grant of any license, covenant not to sue, right of reference, right of supply, other intellectual property right or other settlement in any Enforcement Action, and (ii) filing with the court or serving on any Third Party any pleadings (e.g., briefs, discovery requests and/or responses, expert reports, court filings and stipulations), the selection and engagement of expert witnesses, and any written or electronic correspondence with the opposing party or its counsel concerning substantive issues in the litigation, including positions taken with respect to fact, expert opinions and claim construction. If Depomed elects in writing not to bring or defend an Enforcement Action with respect to any Product in the Territory within ninety (90) days following a notification pursuant to Section 12.2(a) (provided that in the case of a Paragraph IV Notice, Depomed shall confirm in

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writing its election to bring such Enforcement Action no later than twenty (20) days following receipt of the Paragraph IV Notice), or if Depomed fails to bring or defend an Enforcement Action or take other reasonable action to protect the Depomed Patent Rights or the Depomed Trademarks in the Territory from such infringement, or to abate such infringement, then, subject to the terms and conditions of the BLS Manufacturing Transfer Agreement or other in-license agreement with respect to applicable Depomed Patent Rights licensed from a Third Party, if any, then, except as set forth in 0, Santarus shall have the right, at its sole discretion, to institute an Enforcement Action in its own name using counsel of its choice, at its own expense, and, except as otherwise set forth in this Agreement, with the right to control the course of such Enforcement Action (the "Santarus Step-In Rights"). Depomed shall cooperate fully with, and as reasonably requested by, Santarus in any such Enforcement Action, including joining such Enforcement Action if necessary to maintain

the Enforcement Action, and Santarus shall reimburse Depomed for its out-of-pocket expenses incurred in providing such cooperation. Depomed shall have the right to join and participate in the Enforcement Action whether or not such joinder is requested by Santarus. Santarus shall keep Depomed reasonably informed regarding material developments relating to any such Enforcement Action (including by making its outside counsel available to participate in periodic status calls); provided, however, that Santarus shall obtain Depomed's consent (which Depomed will not unreasonably withhold) in advance of (i) the grant of any license, covenant not to sue, right of reference, right of supply, other intellectual property right or other settlement in any Enforcement Action, and (ii) filing with the court or serving on any Third Party any pleadings (e.g., briefs, discovery requests and/or responses, expert reports, court filings and stipulations), the selection and engagement of expert witnesses, and any written or electronic correspondence with the opposing party or its counsel concerning substantive issues in the litigation, including positions taken with respect to fact, expert opinions and claim construction. Depomed may be represented by counsel of its own selection at its own expense in any Enforcement Action brought by Santarus pursuant to the Santarus Step-In Rights. Any recovery received by a party as a result of any Enforcement Action shall be used first to reimburse the parties for their costs and expenses (including attorneys' and professional fees) incurred in connection with such Enforcement Action (and not previously reimbursed, including any reimbursement made or required to be made to Depomed by BLS under the BLS Agreements or by any other licensor of the applicable Depomed Patent Rights or Depomed Trademarks under the terms of the respective in-license agreement, if any). Of any remaining amounts, the amount (if any) which is required to be paid to BLS pursuant to the BLS Agreements or any other licensors of the applicable Depomed Patent Rights or Depomed Trademarks under the terms of the respective in-license agreement, if any, shall then be paid to BLS or such other licensor, if any, and any amounts remaining thereafter shall be shared [\*\*\*] to Santarus and [\*\*\*] to Depomed.

(c) The parties acknowledge that as of the Effective Date, Depomed has ongoing patent infringement litigation with respect to Products against each of Sun Pharmaceutical Industries, Inc. (and Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd.) and Lupin Limited (and its subsidiary Lupin Pharmaceuticals Inc.) (the "Existing Infringement Cases"). Notwithstanding Section 12.2(b): (i) Santarus shall have the right upon written notice to Depomed to lead settlement negotiations for either or both of the Existing Infringement Cases within mutually agreed settlement parameters; (ii) Santarus shall be required to reimburse Depomed for seventy percent (70%) of its out-of-pocket costs paid for periods after

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the Effective Date in pursuing the Existing Infringement Cases; and (iii) Depomed shall be required to reimburse Santarus for thirty percent (30%) of its out-of-pocket costs paid for periods after the Effective Date in pursuing the Existing Infringement Cases; in each case, including costs and legal fees related to discovery requests. Prior to the Effective Date, Depomed has provided to Santarus a budget for Depomed's out-of-pocket costs relating to the conduct of the Existing Infringement Cases. Santarus' budget for out-of-pocket costs relating to the conduct of the Existing Infringement Cases shall be consistent with the amounts Depomed has negotiated for comparable activities in connection with the Existing Infringement Cases, and Santarus shall use commercially reasonable efforts to negotiate similar arrangements. The parties agree to use commercially reasonable efforts to conduct the Existing Infringement Cases within the budgets described above. If a party believes that it will not be able to conduct the Existing Infringement Cases within such budget, such party shall promptly notify the other party thereof, and the parties shall confer in good faith regarding the handling of costs outside of such budget and use commercially reasonable efforts to minimize such excess costs. Any modifications to the budgets shall be agreed upon in advance by the parties. Any other ANDA litigation arising after the Effective Date shall be subject to the preceding provisions of this Section 12.2(c), *mutatis mutandis*.

(d) If warranted in the opinion of Santarus, Santarus shall take such legal action as is advisable in Santarus' opinion to restrain such infringement of the Santarus Trademarks. Depomed shall cooperate fully with, and as requested by, Santarus in Santarus' attempt to restrain such infringement, and Santarus shall reimburse Depomed for its out-of-pocket expenses incurred in

providing such cooperation. Depomed may be represented by counsel of its own selection at its own expense in any suit or proceeding brought to restrain such infringement, but Santarus shall have the right to control the suit or proceeding.

# ARTICLE 13 INDEMNIFICATION; LIMITS ON LIABILITY

#### Section 13.1 **Indemnification**

Indemnification by Santarus. Subject to the parties' agreement to equally share costs relating to recalls related to TBA and associated Third Party claims pursuant to Section 6.7(d), Santarus hereby agrees to save, defend, indemnify and hold harmless Depomed, its Affiliates and their respective officers, directors, employees, consultants and agents (the "Depomed Indemnitees"), from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("Losses"), to which any Depomed Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the Post-Marketing Development, Manufacture, use, handling, storage or Commercialization of Products by or on behalf of Santarus or any of its Affiliates or Third Party licensees; (b) the gross negligence or willful misconduct of any Santarus Indemnitee (defined below); or (c) the breach by Santarus of any warranty, representation, covenant or agreement made by it in this Agreement; except, in each case, to the extent such Losses result from (w) the gross negligence or willful misconduct of any Depomed Indemnitee, (x) the breach by Depomed of any warranty, representation, covenant or agreement made by it in this Agreement, (y) the Manufacture of any

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Product by or on behalf of Depomed prior to the Effective Date or (z) any claim made by any Third Party that the manufacture (in accordance with manufacturing processes in effect as of the applicable Manufacture Transfer Date), use or sale of Products infringed or misappropriated the patent, trademark or other intellectual property rights of such Third Party, except with respect to any such claim relating to the Santarus Trademarks.

- (b) Indemnification by Depomed. Subject to the parties' agreement to equally share costs relating to recalls related to TBA and associated Third Party claims pursuant to Section 6.7(d), Depomed hereby agrees to save, defend, indemnify and hold harmless Santarus, its Affiliates and their respective officers, directors, employees, consultants and agents (the "Santarus Indemnitees"), from and against any and all Losses to which any Santarus Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, Manufacture, use, handling, storage or Commercialization of Products or Combination Products by or on behalf of Depomed or any of its Affiliates or Third Party licensees; or (b) the gross negligence or willful misconduct of any Depomed Indemnitee; (c) the breach by Depomed of any warranty, representation, covenant or agreement made by it in this Agreement; or (d) any claim made by any Third Party that the manufacture, use or sale of the Products prior to the Effective Date infringed or misappropriated the patent, trademark, or other intellectual property rights of such Third Party, except with respect to any claim relating to the Santarus Trademarks; except, in each case, to the extent such Losses result from (1) the gross negligence or willful misconduct of any Santarus Indemnitee, (2) the breach by Santarus of any warranty, representation, covenant or agreement made by it in this Agreement or (3) the Manufacture of any Product by or on behalf of Santarus after the Effective Date.
- (c) <u>Procedure</u>. In the event a Party seeks indemnification under Section 13.1(a) or Section 13.1(b), it shall inform the other party (the "<u>Indemnifying Party</u>") of a claim as soon as reasonably practicable after such party (the "<u>Indemnified Party</u>") receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Section 13.1(c) shall not relieve the Indemnifying Party of its indemnification obligation under this

Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party (except monetary damages to be satisfied in full by the Indemnifying Party) or that acknowledges fault by the Indemnified Party; in each case, without the prior written consent of the Indemnified Party.

#### Section 13.2 Consequential Damages

NEITHER SANTARUS NOR DEPOMED (WHICH FOR THE PURPOSES OF THIS Section 13.2 SHALL INCLUDE THEIR RESPECTIVE AFFILIATES, DIRECTORS,

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OFFICERS, EMPLOYEES AND AGENTS) SHALL HAVE ANY LIABILITY TO THE OTHER FOR ANY PUNITIVE DAMAGES, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES, INCLUDING LOST SALES OR LOST PROFITS, RELATING TO OR ARISING FROM THIS AGREEMENT, EVEN IF SUCH DAMAGES MAY HAVE BEEN FORESEEABLE; PROVIDED THAT SUCH LIMITATION SHALL NOT APPLY IN THE CASE OF EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER Section 13.1 OR IN THE CASE OF FRAUD OR WILLFUL MISCONDUCT.

# ARTICLE 14 CONFIDENTIALITY AND PUBLICITY

#### Section 14.1 **Proprietary Information**

Pursuant to this Agreement, a party receiving Proprietary Information from the other, directly or indirectly, will treat such Proprietary Information as confidential, will use such Proprietary Information only for the purposes of this Agreement and will not disclose, and will take all reasonable precautions to prevent the disclosure of, such Proprietary Information to (a) any of its officers, directors, managers, equity holders, employees, agents, representatives, Affiliates or consultants, except those who need to know such Proprietary Information and who are bound by a like obligation of confidentiality or (b) to Third Parties.

#### Section 14.2 **Disclosures Required by Law**

In the event the recipient party is required under applicable Legal Requirements to disclose Proprietary Information of the disclosing party to any Governmental Authority to obtain any Regulatory Approval for the Products, is required to disclose Proprietary Information in connection with bona fide legal process (including in connection with any bona fide dispute hereunder) or is required to disclose Proprietary Information under the rules of the securities exchange upon which its securities are traded, the recipient party may do so only if it limits disclosure to that purpose after giving the disclosing party prompt written notice of any instance of such a requirement in reasonable time for the disclosing party to attempt to object to or to limit such disclosure. In the event of disclosures required under applicable Legal Requirements, the recipient party shall cooperate with the disclosing party as reasonably requested thereby.

#### Section 14.3 **Publicity**

The parties have agreed upon the form and content of a joint press release to be issued by the parties promptly following the execution of this Agreement. Once such press release or any other written statement is approved for disclosure by both parties, either party may make subsequent public disclosure of the contents of such statement without the further approval of the other party. Any other publicity, news release, public comment or other public announcement, whether to the press, to stockholders, or otherwise, relating to this Agreement, shall first be reviewed and approved by both parties, except no such approval shall be required for such publicity, news release, public comment or other public announcement which, in accordance with the advice of legal counsel to the party making such disclosure, is required by law or for appropriate market disclosure; provided, however, that each party shall be entitled to refer publicly to the relationship of the parties reflected in this Agreement in a manner that is

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consistent with the joint press release issued by the parties. For clarity, any party making any announcement which is required by law will, unless prohibited by law, give the other party an opportunity to review the form and content of such announcement and comment before it is made. The parties shall work together to coordinate filings with governmental agencies, including the United States Securities and Exchange Commission, as to the contents and existence of this Agreement as the parties shall reasonably deem necessary or appropriate and each party shall provide the other party an opportunity to comment on any proposed filings, including redactions thereto.

#### Section 14.4 Survival

The provisions of this Article 13 shall survive termination of this Agreement and shall remain in effect until a date three (3) years after the Term of this Agreement.

#### **ARTICLE 15**

#### RIGHT OF FIRST NEGOTIATION FOR CERTAIN COMBINATION PRODUCTS; EXCLUSIVITY; DIVESTITURE

## Section 15.1 Right of First Negotiation

Depomed shall notify Santarus in writing in the event that Depomed desires to grant rights to a Third Party to develop or commercialize a pharmaceutical product containing metformin and another generic active pharmaceutical ingredient (i.e., an active pharmaceutical ingredient that is produced and distributed within the Territory without composition of matter patent protection for the compound) in combination with Depomed's proprietary Acuform drug delivery technology incorporated within the Products (a "Covered Combination Product"). If Santarus notifies Depomed in writing within [\*\*\*] after receipt of such notice (the "Evaluation Period") that Santarus is not interested in obtaining the applicable rights in and to the applicable Covered Combination Product (the "Covered Combination Product Rights"), or if Santarus fails to notify Depomed of Santarus' interest in obtaining the Covered Combination Product Rights, in either case prior to the expiration of the Evaluation Period, then Depomed shall have no further obligation to Santarus under this Agreement with respect to the applicable Covered Combination Product Rights with respect to the applicable Covered Combination Product. If Santarus is interested in obtaining the applicable rights, it shall so notify Depomed in writing prior to the expiration of the Evaluation Period, and upon Depomed's receipt of such notice Santarus and Depomed shall promptly commence good-faith negotiations, for a period of [\*\*\*] and such longer period as may be mutually agreed upon by the parties in writing in the event the parties have made material progress in the negotiations (the "Negotiation Period"), regarding the commercially reasonable terms of an agreement pursuant to which Santarus shall obtain the applicable rights. If Depomed and Santarus fail to enter into an agreement for the applicable rights prior to the expiration of the Negotiation Period, then Depomed shall thereafter have the right to negotiate and enter into an agreement with a Third Party granting such rights to a Third Party; provided that, for a

period of [\*\*\*], any such agreement may not be on terms and conditions materially more favorable to the Third Party than the terms and conditions last offered by Santarus prior to the termination of discussions with Depomed. The provisions of this Section 15.1 shall not apply to, and Depomed shall have no obligation to Santarus under this

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Section 15.1 in respect of, any acquisition of Depomed by a Third Party, any merger or consolidation with or involving Depomed, any acquisition by a Third Party of any material portion of the stock of Depomed, or any acquisition by a Third Party of a material portion of the assets of Depomed in addition to the Covered Combination Product.

#### Section 15.2 **Divestiture**

Neither party shall have the right to divest either or both of the Products in their entirety without the mutual agreement of the other party; provided that the foregoing shall not prohibit any acquisition of a party by a Third Party, any merger or consolidation with or involving a party, any acquisition by a Third Party of any material portion of the stock of a party, or any acquisition by a Third Party of a material portion of the assets of a party in addition to the Products. In the event the parties mutually agree in writing to divest the Products in their entirety, the resulting net proceeds (after transaction costs) will be evenly split between Depomed and Santarus.

# ARTICLE 16 NOTICES

## Section 16.1 Notices

All notices required or permitted hereunder shall be given in writing and sent by facsimile transmission (with a copy sent by first-class mail), or mailed postage prepaid by certified or registered mail (return receipt requested), or sent by a nationally recognized express courier service, or hand-delivered at the following address:

If to Depomed:

Depomed, Inc. 1360 O' Brien Drive Menlo Park, California 94025 Attention: General Counsel Fax No.: (650) 462-9991

With a copy to (which shall not constitute notice hereunder):

Cooley LLP 4401 Eastgate Mall San Diego, California 92121 Attention: Jane K. Adams Fax No.: (858) 550-6420

If to Santarus:

Santarus, Inc.
3721 Valley Centre Drive
Suite 400
San Diego, California 92130
Attention: Legal Affairs Department

Fax No.: (858) 314-5702

With a copy to (which shall not constitute notice hereunder):

Foley & Lardner LLP 3579 Valley Centre Drive, Suite 300 San Diego, California 92130 Attention: David A. Charapp

Fax No: (858) 792-6773

All notices shall be deemed made upon receipt by the addressee as evidenced by the applicable written receipt.

# ARTICLE 17 INSURANCE

#### Section 17.1 **Insurance**

During the Term and for a period of two (2) years after any expiration or termination of this Agreement, each party shall maintain (i) a commercial general liability insurance policy or policies with minimum limits of [\*\*\*] per occurrence and [\*\*\*] in the aggregate on an annual basis and (ii) a product liability insurance policy or policies with minimum limits of [\*\*\*] per occurrence and [\*\*\*] in the aggregate on an annual basis.

Upon request, each party shall provide certificates of insurance to the other evidencing the coverage specified herein. Neither party's liability to the other is in any way limited to the extent of its insurance coverage.

# ARTICLE 18 MISCELLANEOUS

## Section 18.1 Headings

The titles, headings or captions and paragraphs in this Agreement are for convenience only and do not define, limit, extend, explain or describe the scope or extent of this Agreement or any of its terms or conditions and therefore shall not be considered in the interpretation, construction or application of this Agreement.

## Section 18.2 Severability

In the event that any of the provisions or a portion of any provision of this Agreement is held to be invalid, illegal, or unenforceable by a court of competent jurisdiction or a governmental authority, such provision or portion of provision will be construed and enforced as if it had been narrowly drawn so as not to be invalid, illegal, or unenforceable, and the validity, legality, and enforceable portion of any such provision and the remaining provisions will not be adversely affected thereby.

#### Section 18.3 Entire Agreement

This Agreement, together with the schedules and exhibits hereto, all of which are incorporated by reference, contains all of the terms agreed to by the parties regarding the subject matter hereof and supersedes any prior agreements, understandings, or arrangements between them, whether oral or in writing.

#### Section 18.4 **Amendments**

This Agreement may not be amended, modified, altered, or supplemented except by means of a written agreement or other instrument executed by both of the parties hereto. No course of conduct or dealing between the parties will act as a modification or waiver of any provisions of this Agreement.

## Section 18.5 <u>Counterparts</u>

This Agreement may be executed in any number of counterparts, each of which will be deemed an original as against the party whose signature appears thereon, but all of which taken together will constitute but one and the same instrument.

#### Section 18.6 Waiver

The failure of either party to enforce or to exercise, at any time or for any period of time, any term of or any right arising pursuant to this Agreement does not constitute, and will not be construed as, a waiver of such term or right, and will in no way affect that party's right later to enforce or exercise such term or right.

#### Section 18.7 **Force Majeure**

In the event of any failure or delay in the performance by a party of any provision of this Agreement due to acts beyond the reasonable control of such party (such as, for example, fire, explosion, strike or other difficulty with workmen, shortage of transportation equipment, accident, act of God, declared or undeclared wars, acts of terrorism, or compliance with or other action taken to carry out the intent or purpose of any law or regulation, but not any failure of such party to perform under a Third Party Agreement) (a "Force Majeure Event"), then such party shall have such additional time to perform as shall be reasonably necessary under the circumstances. In the event of such failure or delay, the affected party will use its diligent efforts, consistent with sound business judgment and to the extent permitted by law, to correct

such failure or delay as expeditiously as possible. In the event that a party is unable to perform by a reason described in this Section 18.7, its obligation to perform under the affected provision of this Agreement shall be suspended during such time of nonperformance.

Neither party shall be liable hereunder to the other party nor shall be in breach for failure to perform its obligations caused by a Force Majeure Event. In the case of any such event, the affected party shall promptly, but in no event later than ten (10) days of its occurrence, notify the other party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. Furthermore, the affected party shall keep the other party informed of the efforts to resume performance. After sixty (60) days of such inability to perform, the parties agree to meet and in good faith discuss how to proceed. In the event that the affected party is prevented from performing its obligations pursuant to this Section 18.7 for a period of six (6) months, the other party shall have the right to terminate this Agreement pursuant to the provisions of Section 9.4(b).

# Section 18.8 Successors and Assigns

Subject to Section 18.9, this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns permitted under this Agreement.

#### Section 18.9 Assignment

This Agreement and the rights granted herein shall not be assignable (or otherwise transferred) by either party hereto without the prior written consent of the other party. Any attempted assignment without consent shall be void. Notwithstanding the foregoing, a party may transfer, assign or delegate its rights and obligations under this Agreement without consent to (a) an Affiliate reasonably capable of performing such party's obligations under this Agreement or (b) a successor to all or substantially all of the business or assets of the assigning party, whether by sale, merger, consolidation, acquisition, transfer, operation of law or otherwise. In connection with any assignment, or Subcontracting pursuant to which a Third Party Sales Representative is engaged to Promote the Products, of this Agreement or any of the rights granted herein pursuant to this Section 18.9, the assignor, or party Subcontracting to another, shall ensure that the assignee, or Subcontractor, represents and warrants the matters set forth in Section 11.1(i) and (j) (in substantially the same form as set forth in Section 11.1(i) and (j)), where Depomed (or one of its successors or assigns) is the assignor or Subcontracting party, or Section 11.2(h) and (i) (in substantially the same form as set forth in Section 11.2(h) and (i)), where Santarus (or one of its successors or assigns) is the assignor or Subcontracting party. In connection with any Subcontracting pursuant to which a Third Party will manufacture the Products, the party Subcontracting to another shall use its commercially reasonable efforts to cause the Subcontractor to represent and warrant the matters set forth in Section 11.1(j) and (k) (in substantially the same form as set forth in Section 11.1(j) and (k)). Neither party shall knowingly engage any Third Party appearing on the FDA's debarment list or the list of excluded individuals/entities of the Office of Inspector General of the Department of Health and Human Services to perform, or assist such party in the performance of, its obligations under this Agreement, and each party shall review each such list prior to engaging any such Third Party.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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#### Section 18.10 **Construction**

The parties acknowledge and agree that: (a) each party and its representatives have reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; and (b) the terms and provisions of this Agreement will be construed fairly as to each party hereto and not in favor of or against either party regardless of which party was generally responsible for the preparation or drafting of this Agreement. Unless the context of this Agreement otherwise requires: (i) words of any gender include

each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby," and derivative or similar words refer to this entire Agreement; (iv) the terms "Article," "Section," "Exhibit," "Schedule," or "clause" refer to the specified Article, Section, Exhibit, Schedule, or clause of this Agreement; (v) "or" is disjunctive but not necessarily exclusive; and (vi) the term "including" or "includes" means "including without limitation" or "includes without limitation." Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified.

# Section 18.11 Consents to Assignment

Notwithstanding anything to the contrary contained in this Agreement, to the extent that the transfer or assignment by Depomed of any Assigned Agreement as set forth herein would require any Third Party authorizations, approvals, consents or waivers (collectively, the "Consent"), then Depomed's obligation to transfer or assign such Assigned Agreement shall be contingent upon Depomed's receipt of such Consent. The parties shall cooperate to obtain promptly such Consent. Pending receipt of any such Consent, the parties shall use their commercially reasonable efforts to implement an alternative arrangement to permit Santarus to receive substantially similar rights and for Santarus to assume substantially similar obligations under any such Assigned Agreement as if such impediment to assignment or transfer did not exist. Depomed shall not amend, modify or terminate any Assigned Agreement that is to be assigned to Santarus under this Agreement without Santarus' prior written consent.

#### Section 18.12 Governing Law

This Agreement will be construed under and in accordance with, and governed in all respects by, the laws of the State of California, without regard to its conflicts of law principles.

#### Section 18.13 Equitable Relief

Each party acknowledges that a breach by it of the provisions of this Agreement may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other party irreparable injury and damage. By reason thereof, each party agrees that the other party is entitled to seek, in addition to any other remedies it may have under this Agreement or otherwise, preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of this Agreement by the other party; provided, however, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach. Each party agrees that the existence of any claim, demand, or cause of action of it against the other party, whether predicated upon this Agreement, or otherwise, will not constitute

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a defense to the enforcement by the other party, or its successors or assigns, of the covenants contained in this Agreement.

## Section 18.14 **Relationship Between Parties**

The parties hereto are acting and performing as independent contractors, and nothing in this Agreement creates the relationship of partnership, joint venture, sales agency, or principal and agent. Neither party is the agent of the other, and neither party may hold itself out as such to any other party.

## Section 18.15 **Cooperation**

Depomed shall (a) prepare the financial statements of the business related to the manufacturing and sale of the Products for the three year period ended December 31, 2010 and (b) prepare interim financial statements for the period prior to the Effective Date, in each case to the extent required by applicable Legal Requirements to be included in Santarus' reports and filings with the U.S. Securities and Exchange Commission ("SEC"), including in connection with the acquisition of a "significant business" pursuant to Regulation S-X of the SEC. Deponded shall commence the preparation of the financial statements promptly after the Effective Date and will use efforts similar to those used in connection with its own audited financial statements to complete such financial statements as promptly as possible to enable Santarus to comply with applicable Legal Requirements with respect to reports and filings with the SEC. Santarus shall engage Ernst & Young LLP, its independent auditors, at Santarus' sole cost and expense, to audit the financial statements of the business for the three year period ended December 31, 2010 and to render an opinion on such financial statements. Depomed will provide, if required by Santarus' independent auditors, executed representation letters, which representation letters are required to enable independent auditors to render an opinion on audited financial statements. Depomed shall request, and take all reasonable steps necessary to encourage, its auditors to cooperate with Santarus and provide all necessary consents required by the SEC and customary "comfort letters" in connection with securities offerings of Santarus and with its preparation of any financial statements or other reports pursuant to Legal Requirements, in each case the reasonable fees and expenses of Depomed's auditors shall be at Santarus' sole cost and expense. Santarus will consider in good faith with its independent auditors whether to discuss with the SEC the Legal Requirements with respect to the inclusion of such financial statements in Santarus' reports and filings.

[Signature page follows]

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in duplicate on the day and year first above written.

DEPOMED, INC.

/s/ James A. Schoeneck

By: James A. Schoeneck Its: President and CEO

SANTARUS, INC.

/s/ Gerald T. Proehl

By: Gerald T. Proehl Its: President and CEO

# COMMERCIALIZATION AGREEMENT

by and between

DEPOMED, INC.

and

SANTARUS, INC.

Dated as of August 22, 2011

# **SCHEDULES**

Schedule 1.19 – Assigned Agreements

Schedule 1.32 – Chargeback Agreements

Schedule 1.36 – Commercial Rebate Agreements

Schedule 1.55 – Depomed Trademarks

Schedule 1.75 – Government Rebate Agreements

Schedule 1.129 - Santarus Trademarks

Schedule 3.1 – Transition Plan

Schedule 7.3(b) – Out-of-Pocket Costs of Inventory

Schedule 11.1(f) – Depomed Patent Rights

Schedule 11.1(m) - Inventory and Firm Orders as of August 1, 2011

# Schedule 1.19 Assigned Agreements

- 1) [\*\*\*]
- 2) [\*\*\*]
- 3) [\*\*\*]
- 4) [\*\*\*]

5) [\*\*\* 6) [\*\*\* 7) [\*\*\*

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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#### Schedule 1.32

#### **Chargeback Agreements**

- 1) [\*\*\*]
- 2) [\*\*\*]

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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#### Schedule 1.36

# **Commercial Rebate Agreements**

- 1) [\*\*\*]
- 2) [\*\*\*]
- 3) [\*\*\*]
- 4) [\*\*\*]

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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#### Schedule 1.55

# **Depomed Trademarks**

 Mark
 Numbers

 GLUMETZA(1)
 Reg. No. 3366577

 DEPOMED
 Reg. No. 2112593

 DEPOMED (word and design mark)
 Ser. No. 78781903

 ACUFORM
 Reg. No. 3604419

G (stylized design mark) Ser. No. 78931764 (1) Owned by BLS, and licensed in the United States to Depomed for the purpose of promoting the Products. Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission. 6 Schedule 1.75 **Government Rebate Agreements** Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission. Schedule 1.129 **Santarus Trademarks** Serial/Registration Mark Numbers

# Mark Numbers SANTARUS Reg. No. 2,711,984 SANTARUS logo Reg. No. 2,896,926 Triangle logo Reg. No. 2,899,097

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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Schedule 3.1

**Transition Plan** 

[\*\*\*]

Redacted 3 pages

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# Schedule 7.2 Forms of Price Increase Notifications

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August 22, 2011

#### IMPORTANT PRODUCT PRICING INFORMATION

#### Dear Pharmaceutical Buyer:

Coinciding with this announcement, Depomed and Santarus are announcing a new commercialization agreement whereby Santarus has acquired the U.S. commercialization rights to Glumetza<sup>®</sup>. Specific communication related to trade transition plans will be coming over the next couple days.

Effective August 22, 2011 at 2:00 a.m. (Pacific Time), at Santarus' direction, Depomed is announcing a price increase on the Glumetza® family of products. All orders placed with Depomed after 2:00 a.m. (Pacific Time) on August 22, 2011 will be received on August 22, 2011 and billed at the new price.

Please find listed below the new wholesaler list prices for the affected products.

**New Wholesaler List Price** 

Product Name / Description	NDC	as of August 22, 2011
Glumetza® (metformin hydrochloride extended release tablets) <b>500 mg</b>	13913-002-13	\$ [***]
Glumetza® (metformin hydrochloride extended release tablets) 1000 mg	13913-003-16	\$ [***]

<sup>\*</sup>The unit list price does not reflect discounts, rebates, chargebacks, and other terms or distribution arrangements that may reduce actual sales price.

If you have any questions, please contact Depomed's Customer Service Department at 1-866-223-0287.

Sincerely,

Chris DeSimone Sr. Director, Managed Care & Trade Depomed, Inc. Jeff Wagner

Sr. Director, Trade Sales & Development

Santarus, Inc.

Confidential Information, indicated by [\*\*\*] has been omitted from this filing

To: Leon Nevers, Director of Pharmacy, HEB

From: Chris DeSimone, Sr. Director Managed Care & Trade, Depomed, Inc.

Date: 8/XX/2011

Re: Amended Direct supply contract price on Depomed's product Line.

We are pleased to offer the following proposal for consideration to the current contractual agreement.

				D	irect Purchase	
NDC	Description	WAC			Contract Price	
13913-002-13	Glumetza® 500mg tablets, Extended-release. 100 Count Bottle	\$	[***]	\$	[***]	
13913-003-16	Glumetza® 1000mg tablets, Extended-release. 90 Count bottle	\$	[***]	\$	[***]	

#### **Terms**

- Term of payment are 2%/30 net 31.
- HEB agrees to abide by Depomed, Inc's Returned Good policy dated 3/17/2010.

If this proposal is acceptable to you, please sign below and fax to (650) 462-9993. We appreciate the continuing support of our products and look forward to growing our business together.

Sincerely,

Chris DeSimone

Sr. Director Managed Care & Trade

Depomed, Inc.

Phone - 650.462.5900 Fax- 650.462.9993

Accep	ted and	Agreed:		

Date:

Section 1.02

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To: Bob Breetz, Director of Pharmacy, Kroger

From: Chris DeSimone, Sr. Director Managed Care & Trade, Depomed, Inc.

Date: 8/XX/2011

Re: Amended Direct supply contract price on Depomed's product Line.

We are pleased to offer the following proposal for consideration to the current contractual agreement.

					Direct Purchase
NDC	Description	Description WAC			Contract Price
13913-002-13	Glumetza® 500mg tablets, Extended-release. 100 Count Bottle	\$	[***]	\$	[***]
13913-003-16	Glumetza® 1000mg tablets, Extended-release. 90 Count bottle	\$	[***]	\$	[***]

# **Terms**

- Term of payment are 2%/30 net 31.
- Kroger agrees to abide by Depomed, Inc's Returned Good policy dated 3/17/2010.

If this proposal is acceptable to you, please sign below and fax to (650) 462-9993. We appreciate the continuing support of our products and look forward to growing our business together.

Sincerely,

Chris DeSimone

Sr. Director Managed Care & Trade

Depomed, Inc.

Phone - 650.462.5900 Fax- 650.462.9993

Accepted and Agreed:	

Date:

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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# Schedule 7.3(b)

## **Out-of-Pocket Costs of Inventory**

#### **API at Patheon:**

	Description	Lot #	KG on Hand	_	\$\$ per KG	Total Cost		
Me	etformin HCL	[***]	***	\$	[***]	\$	[***]	
Me	etformin HCL	[***]	***	] \$	[***]	\$	[***]	

Metformin HCL	[***]	[***] \$ [**	*] \$	[***]
Metformin HCL	[***]	[***] \$ [**	*] \$	[***]
		[***]	\$	[***]

#### **Finished Goods at ICS:**

					C	ost Per		
<b>Product Code</b>	Description	LotNumber	ExpDate	Qty		Bottle	Т	otal MFG Cost
11690002-13	Glumetza 500mg Tablets	[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
	<b>Total 500mg Finished Goods</b>	S		[***]			\$	[***]

Note: Inventory amounts in this schedule are as of 8/12/2011 and subject to change prior to the First Sales Booking Date

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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Schedule 7.3(b)

**Out-of-Pocket Costs of Inventory (Continued)** 

Product Code	Description Lot Number Exp Date		Qty	Cost per Bottle		Total MFG Cost		
11690003-16	Glumetza 1000mg Tablets							
	•	[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]
		[***]	[***]	[***]	\$	[***]	\$	[***]

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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Product					C	ost per	To	otal MFG
Code	Description		Lot Number Exp Date Qty			Bottle	Cost	
		[***]	[***]	[***]	\$	[		[***]

	[***]	[***]	[***]	\$ [***]	\$ [***]
	[***]	[***]	[***]	\$ [***]	\$ [***]
Total 1000mg Finished Goods			[***]		\$ [***]
	To	otal Finished Good	ls		\$ [***]
	To	otal Inventory @8-	12-2011		\$ [***]

Note: Inventory amounts in this schedule are as of 8/12/2011 and subject to change prior to the First Sales Booking Date

Confidential Information, indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities Exchange Commission.

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#### Schedule 11.1(f)

#### **Depomed Patent Rights**

#### Application

Patent No.	Issue Date	No.	Title	Patent Expiration
6,340,475	January 22, 2002	09/282,233	Extending the Duration of Drug Release	September 19, 2016
			within the Stomach During the FED Mode	
6,488,962	December 3, 2002	09/598,061	Tablet Shapes to Enhance Gastric Retention	June 20, 2020
			of Swellable Controlled-Release Oral	
			Dosage Forms	
6,635,280	October 21, 2003	10/045,823	Extending the Duration of Drug Release	September 19, 2016
			within the Stomach During the FED Mode	
6,723,340	April 20, 2004	10/029,134	Optimal Polymer Mixtures for Gastric	October 25, 2021
			Retentive Tablets	
7,780,987*	August 24, 2010	10/370,109	Controlled Release Dosage Forms	March 23, 2025
NA*	Filed July 9, 2008	12/169,852	Controlled Release Dosage Forms	-
NA*	Filed December 5, 2008	12/328,828	Controlled Release Dosage Forms	-

<sup>\*</sup>Assigned to Valeant International SRL

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# Schedule 11.1(m)

Inventory and Firm Orders as of August 12, 2011

(see Section 7.3(b) for Inventory-on-hand)

# Firm Orders with Patheon

		_	Samples		Trade	e		
Product	PO#	Month	Lots	Bottles	Lots	Bottles	]	Dollars
500mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$	[***]
500mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$	[***]
500mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$	[***]

#### Firm Orders with Valeant

		_	Samples		Trade	:	
Product	PO#	Month	Lots	Bottles	Lots	Bottles	 Dollars,
1000mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$ [***]
1000mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$ [***]
1000mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$ [***]
1000mg Glumetza	[***]	[***]	[***]	[***]	[***]	[***]	\$ [***]

Note: Inventory amounts in this schedule are as of 8/12/2011 and subject to change prior to the First Sales Booking Date

# CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, James A. Schoeneck, certify that:

- 1. I have reviewed this Quarterly Report of Depomed, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

November 7, 2011		
	By:	/s/ James A. Schoeneck James A. Schoeneck Chief Executive Officer

any fraud, whether or not material, that involves management or other employees who have a significant role in the

(b)

registrant's internal control over financial reporting.

# CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

## I, Tammy L. Cameron, certify that:

- 1. I have reviewed this Quarterly Report of Depomed, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

November 7, 2011		
	By:	/s/ Tammy L. Cameron Tammy L. Cameron Vice President, Finance

any fraud, whether or not material, that involves management or other employees who have a significant role in the

(b)

registrant's internal control over financial reporting.

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Depomed, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James A. Schoeneck, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2011

/s/ James A. Schoeneck

James A. Schoeneck

President and Chief Executive Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Depomed, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Tammy L. Cameron, Principal Accounting and Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2011

/s/ Tammy L. Cameron

Tammy L. Cameron Vice President, Finance

# CONDENSED BALANCE SHEETS (Parenthetical) (USD \$) Sep. 30, 2011 Dec. 31, 2010

(USD \$)		
Preferred stock, no par value		
Preferred stock, shares authorized	5,000,000	5,000,000
Common stock, no par value		
Common stock, shares authorized	100,000,000	100,000,000
Common stock, shares issued	55,398,067	52,957,787
Stockholders Equity	55,398,067	52,957,787
Series A convertible preferred stock		
Preferred stock, shares designated	25,000	25,000
Preferred stock, shares issued	18,158	18,158
Preferred stock shares surrendered	18,158	18,158
Preferred stock, shares outstanding	0	0

CONDENSED STATEMENTS OF	3 Mont	hs Ended	9 Months Ended		
OPERATIONS (USD \$) In Thousands, except Share data	Sep. 30, 2011	Sep. 30, 2010	Sep. 30, 2011	Sep. 30, 2010	
Revenues:					
Product sales	\$ 9,205	\$ 9,829	\$ 40,669	\$ 34,086	
Royalties	2,179	75	2,412	254	
License and collaborative revenue	5,138	10,223	77,760	25,565	
<u>Total revenues</u>	16,522	20,127	120,841	59,905	
Costs and expenses:					
<u>Cost of sales</u>	1,150	2,499	4,925	6,961	
Research and development expense	3,208	4,602	12,405	14,360	
Selling, general and administrative expense:					
<u>Promotion fee expense</u>	6,023	6,791	27,339	23,769	
Other selling, general and administrative expense	15,451	4,313	32,667	12,403	
Total selling, general and administrative expense	21,474	11,104	60,006	36,172	
Gain on settlement agreement	0	0	(40,000)	0	
<u>Total costs and expenses</u>	25,832	18,205	37,336	57,493	
Income (loss) from operations	(9,310)	1,922	83,505	2,412	
Other income (expense):					
Interest and other income	410	100	846	251	
<u>Interest expense</u>	(24)	(130)	(133)	(471)	
<u>Total other income (expense)</u>	386	(30)	713	(220)	
Net income (loss) before income taxes	(8,924)	1,892	84,218	2,192	
Benefit from (Provision for) income taxes	348	(1)	345	(4)	
Net income (loss)	\$ (8,576)	\$ 1,891	\$ 84,563	\$ 2,188	
Basic net income (loss) per common share	\$ (0.15)	\$ 0.04	\$ 1.56	\$ 0.04	
Diluted net income (loss) per common share	\$ (0.15)	\$ 0.04	\$ 1.51	\$ 0.04	
Shares used in computing basic net income (loss) per commor share	<sup>1</sup> 55,371,954	52,595,214	54,267,829	52,444,627	
Shares used in computing diluted net income (loss) per common share	55,371,954	53,306,449	56,071,870	53,061,251	

# Document and Entity 9 Months Ended

Information Sep. 30, 2011 Nov. 03, 2011

**Document and Entity Information** 

Entity Registrant Name
DEPOMED INC
Entity Central Index Key
Document Type
10-Q

<u>Document Period End Date</u> Sep. 30, 2011

Amendment Flag false

Document Fiscal Year Focus 2011

Document Fiscal Period Focus Q3

Current Fiscal Year End Date --12-31

Entity Filer Category Accelerated Filer

Entity Common Stock, Shares Outstanding 55,400,451

# COMPREHENSIVE INCOME (LOSS)

9 Months Ended Sep. 30, 2011

COMPREHENSIVE
INCOME (LOSS)
COMPREHENSIVE INCOME (LOSS)

## NOTE 7. COMPREHENSIVE INCOME (LOSS)

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

	Three Months Ended September 30,					Nine Mon Septen					
		2011 2010			2011 2010 2011			2011	2010		
Net income (loss) Unrealized gain (loss) on	\$	(8,576)	\$	1,891	\$	84,563	\$	2,188			
available-for-sale securities Total comprehensive income		(187)		19	_	(101)	_	66			
(loss)	\$	(8,763)	\$	1,910	\$	84,462	\$	2,254			

## **INCOME TAXES**

# 9 Months Ended Sep. 30, 2011

INCOME TAXES
INCOME TAXES

#### NOTE 12. INCOME TAXES

As of December 31, 2010 and September 30, 2011, the Company had \$3.4 million and \$3.5 million of unrecognized tax benefits, respectively. All tax years since inception remain open to examination by the Internal Revenue Service and the California Franchise Tax Board until such time the Company's net operating losses and credits are either utilized or expire. Interest and penalties, if any, related to unrecognized tax benefits, would be recognized as income tax expense by the Company. The Company does not have any accrued interest or penalties associated with unrecognized tax benefits.

# NET LOSS PER COMMON SHARE

9 Months Ended Sep. 30, 2011

NET LOSS PER COMMON
SHARE
NET LOSS PER COMMON
SHARE

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

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period, plus dilutive common shares for the period determined using the treasury-stock method. For purposes of this calculation, options to purchase stock are considered to be potential common shares and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive. Basic and diluted earnings per share are calculated as follows:

(in thousands, except for per share amounts)	Three Months Ended September 30,				Nine Months Ended September 30,			
		2011	2010		2011			2010
Numerator:								
Net income (loss)	\$	(8,576)	\$	1,891	\$	84,563	\$	2,188
Denominator for basic net income (loss) per								
share		55,372		52,595		54,268		52,445
Net effect of dilutive common stock equivalents				711		1,804		616
Denominator for diluted net income (loss) per share:	_	55,372	_	53,306	_	56,072	_	53,061
		(0.4.5)			Φ.			
Basic net income (loss) per share	\$	(0.15)	\$	0.04	\$	1.56	\$	0.04
Diluted net income (loss) per share	\$	(0.15)	\$	0.04	\$	1.51	\$	0.04

For the three and nine months ended September 30, 2011, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 4.9 million and 1.2 million, respectively. For the three and nine months ended September 30, 2010, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 3.0 million and 3.4 million, respectively.

# ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

# 9 Months Ended Sep. 30, 2011

## NOTE 9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	eptember 30, 2011	December 31, 2010	10
Accounts payable	\$ 3,380	\$ 1,655	55
Accrued			
compensation	2,827	2,638	8
Accrued clinical			
trial expense	1,094	30′	)7
Accrued rebates and			
sales discounts	2,232	2,623	25
Allowance for			
product returns	9,333	5,355	55
Accrued promotion			
fee		2,490	0
Other accrued			
liabilities	6,922	3,403	)3
Total accounts			
payable and			
accrued liabilities	\$ 25,788	\$ 18,473	<i>'</i> 3

# SUBSEQUENT EVENTS

# 9 Months Ended Sep. 30, 2011

SUBSEQUENT EVENTS
SUBSEQUENT EVENTS

# NOTE 14. SUBSEQUENT EVENTS

In October 2011, the Company announced the commercial availability of Gralise and began distributing Gralise to wholesalers and retail pharmacies.

# SHAREHOLDERS' EQUITY

9 Months Ended Sep. 30, 2011

SHAREHOLDERS'
EQUITY

## SHAREHOLDERS' EQUITY NOTE 10. SHAREHOLDERS' EQUITY

## **Option Exercises**

For the three and nine months ended September 30, 2011, employees and consultants exercised options to purchase 58,105 and 2,370,358 shares of the Company's common stock with net proceeds to the Company of approximately \$0.3 million and \$7.6 million, respectively.

## Employee Stock Purchase Plan

In May 2011, the Company sold 69,922 shares under the ESPP. The shares were purchased at a weighted average purchase price of \$4.37 per share with proceeds of approximately \$0.3 million.

## **INVENTORIES**

# 9 Months Ended Sep. 30, 2011

# INVENTORIES INVENTORIES

#### **NOTE 8. INVENTORIES**

Inventories relate to the manufacture of the Company's Gralise and Proquin XR products at September 30, 2011 and Gralise, Glumetza and Proquin XR products at December 31, 2010. In August 2011, the Company sold its Glumetza inventory, at cost, to Santarus as part of the commercialization agreement. See Note 4 for further information with regards to the Santarus commercialization agreement. Inventories are stated at the lower of cost or market and consist of the following (in thousands):

	Sept	ember 30,	December 31, 2010			
		2011				
Raw materials	\$	1,273	\$	74		
Work-in-process		258		202		
Finished goods		1,746		1,254		
Deferred costs		15		41		
Total	\$	3,292	\$	1,571		

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

# SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

9 Months EndedSep. 30, 2011

SUMMARY OF
SIGNIFICANT
ACCOUNTING POLICIES
SUMMARY OF
SIGNIFICANT
ACCOUNTING POLICIES

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

#### Basis of Presentation

These unaudited condensed financial statements and the related footnote information of Depomed, Inc. (the Company or Depomed) have been prepared pursuant to the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of the Company's management, the accompanying interim unaudited condensed financial statements include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the periods presented. The results for the interim period ended September 30, 2011 are not necessarily indicative of results to be expected for the entire year ending December 31, 2011 or future operating periods.

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2010, included in the Company's Annual Report on Form 10-K filed with the SEC. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date.

#### Reclassifications

Certain reclassifications have been made to the December 31, 2010 balance sheet in order to conform to the Company's current presentation. The Company has now classified receivables from collaborative partners as a separate line-item on its balance sheet, which was previously included under accounts receivable.

#### Use of Estimates

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

#### Revenue Recognition

The Company recognizes revenue from the sale of its products, royalties earned, and on payments received and services performed under contractual arrangements. Revenue arrangements with multiple elements are evaluated to determine whether the multiple elements met certain criteria for dividing the arrangement into separate units of accounting, including whether the delivered element(s) have stand-alone value to the Company's customer or licensee. Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period that we remain obligated to perform services.

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

#### Product Sales:

Glumetza®: Up until August 2011, the Company distributed and recorded product sales on shipments of Glumetza® (metformin hydrochloride extended release tablets) to wholesalers and retail pharmacies. The Company and Santarus, Inc. (Santarus) entered into a commercialization agreement in August 2011, under which Depomed transferred the rights to distribute Glumetza in the United States to Santarus. Santarus commenced distribution of Glumetza in September 2011 and began recording product sales. See Note 4 for further information on the Santarus commercialization agreement.

Product distributed by Depomed up until August 2011 is subject to rights of return six months before product expiration and up to twelve months after product expiration. The Company recognized revenue for Glumetza sales at the time title transferred to its customers, which occurred at the time product was delivered to its customers.

- Proquin®XR: Up until October 2010, the Company sold Proquin® XR (ciprofloxacin hydrochloride) to wholesalers and retail pharmacies subject to rights of return six months before product expiration and up to twelve months after product expiration. Given the Company's limited history of selling Proquin XR and declining prescription demand for Proquin XR, the Company was not able to reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Proquin XR until the right of return no longer exists, which occurs at the earlier of the time Proquin XR units are dispensed through patient prescriptions or expiration of the right of return. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including third-party market research data and information obtained from wholesalers with respect to inventory levels and inventory movement. As a result of this policy, the Company has a deferred revenue balance of \$0.4 million at September 30, 2011 related to Proquin XR product shipments that have not been recognized as revenue, which is net of wholesaler fees, retail pharmacy discounts and prompt payment discounts. In addition, the costs of manufacturing Proquin XR associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.
- Product Sales Allowances The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company's agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from the Company's estimates, the Company may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company's product sales allowances include:
  - Product Returns The Company estimates product returns on sales of Glumetza that were originally distributed by the Company. The Company allows customers to return product that is within six months before and up to twelve months after its product expiration date. The shelf life of the 500mg Glumetza is currently 48 months from the date of tablet manufacture. On product launch in August 2006 and through the second

quarter of 2008, the shelf life of 500mg Glumetza product shipped was 36 months from the date of tablet manufacture. The shelf life of the 1000mg Glumetza is 24 to 36 months from the date of tablet manufacture. The Company monitors actual return history on individual product lot basis since product launch, which provides it with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

- Managed Care Rebates The Company offers rebates under contracts with certain managed care organizations. The Company establishes an accrual equal to its estimates of future managed care rebates attributable to sales and recognizes the estimated rebates as a reduction of revenue in the same period the related revenue is recognized. The Company estimates its managed care rebates based on the terms of each agreement, estimated levels of inventory in the distribution channel, and historical and expected future utilization of product by the managed care organization.
- Wholesaler and Retail Pharmacy Discounts The Company offers discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.
- Prompt Pay Discounts The Company offers cash discounts to its
  customers, generally 2% of the sales price, as an incentive for prompt
  payment. Based on the Company's experience, the Company expects its
  customers to comply with the payment terms to earn the cash discount.
  The Company accounts for cash discounts by reducing accounts receivable
  by the full amount and recognizes the discount as a reduction of revenue in
  the same period the related revenue is recognized.
- Medicaid Rebates The Company participates in Medicaid rebate programs, which provide assistance to certain eligible low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three months after the quarter in which the prescription is filled. The Company estimates and accrues Medicaid rebates based on product pricing, current rebates and changes in the level of discounts the Company offers that may affect the level of Medicaid discount, historical and estimated future percentages of product sold to Medicaid recipients and estimated levels of inventory in the distribution channel
- Chargebacks The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity.
- Patient Discount Programs The Company offers loyalty card programs to patients for Glumetza in which patients receive certain discounts at participating retail pharmacies that are reimbursed by the Company. The

Company estimates and accrues future redemptions based on historical redemption activity.

Royalties - Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectability is reasonably assured. Under the commercialization agreement between the Company and Santarus, the Company receives royalties on net sales of Glumetza distributed by Santarus in the United States. Santarus commenced distributing and recording product sales on shipments of Glumetza in September 2011. Royalties from Santarus are recognized in the period earned as the royalty amounts can reliably be estimated and collectability is reasonably assured. See Note 4 for further information on the Santarus commercialization agreement.

Royalties received under the Company's agreements with Valeant Pharmaceuticals International, Inc. (Valeant) and LG Life Sciences (LG) are recognized when the royalty payments are received as they cannot reliably be estimated.

License and Collaborative Arrangements - Revenue from license and collaborative arrangements is recognized when the Company has substantially completed its obligations under the terms of the arrangement and the Company's remaining involvement is inconsequential and perfunctory. If the Company has significant continuing involvement under such an arrangement, license and collaborative fees are recognized over the estimated performance period. The Company recognizes milestone payments for its research and development collaborations upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement; (2) consideration earned relates to past performance, and (3) the milestone payment is nonrefundable. A milestone is considered substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone or consistent with the increase in value to the collaboration resulting from the Company's performance. the consideration earned relates solely to past performance, and the consideration earned is reasonable relative to all of the other deliverables and payments within the arrangement. License, milestones and collaborative fee payments received in excess of amounts earned are classified as deferred revenue until earned.

## Recently Issued Accounting Standards

In September 2009, the Financial Accounting Standards Board (FASB) revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company elected to adopt this guidance prospectively, effective for the Company's fiscal year beginning January 1, 2011. Upon adoption, the guidance did not have a material impact on the Company's financial statements and is not expected to have a material impact on the Company's future operating results.

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, the Company will have the option to report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. The Company does not anticipate the adoption of this guidance will have a material impact on its financial statements.

# LICENSE AND COLLABORATIVE ARRANGEMENTS

LICENSE AND
COLLABORATIVE
ARRANGEMENTS
LICENSE AND
COLLABORATIVE
ARRANGEMENTS

# 9 Months Ended Sep. 30, 2011

#### NOTE 4. LICENSE AND COLLABORATIVE ARRANGEMENTS

#### Santarus, Inc.

In August 2011, the Company entered into a commercialization agreement with Santarus granting Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. The commercialization agreement supersedes the previous promotion agreement between the parties originally entered into in July 2008.

Under the commercialization agreement, the Company will transition to Santarus responsibility for manufacturing, distribution, pharmacovigilance and regulatory affairs. The Company ceased shipments of Glumetza in August 2011 and Santarus began distributing and recording product sales on shipments of Glumetza in September 2011. Santarus will continue to be responsible for advertising and promotional marketing activities for Glumetza.

Santarus will be required to pay the Company royalties on net product sales of Glumetza in the United States of 26.5% in 2011; 29.5% in 2012; 32.0% in 2013 and 2014; and 34.5% in 2015 and beyond prior to generic entry of a Glumetza product. In the event of generic entry of a Glumetza product in the United States, the parties will equally share proceeds based on a gross margin split. Santarus has the exclusive right to commercialize authorized generic versions of the Glumetza products. Santarus will not pay additional sales milestones to the Company as was required under the prior promotion agreement.

In connection with its assumption of distribution and sales responsibility of Glumetza, Santarus purchased Depomed's existing inventory of Glumetza and bulk metformin hydrochloride at cost. Depomed will be financially responsible for returns of Glumetza distributed by Depomed, up to the amount of the product returns reserve account for Glumetza product returns on the date immediately before Santarus begins distributing Glumetza. Depomed will be financially responsible for Glumetza rebates and chargebacks up to the amount of its reserve accounts for those items. Santarus will be responsible for all other Glumetza returns, rebates and chargebacks.

Pursuant to the terms of the commercialization agreement, Depomed has the option to copromote Glumetza products to physicians other than those called on by Santarus, subject to certain limitations. Depomed will be entitled to receive a royalty equal to 70% of net sales attributable to prescriptions generated by its called on physicians over a pre-established baseline.

Under the commercialization agreement, Depomed will continue to manage the ongoing patent infringement lawsuits against Sun Pharmaceutical Industries, Inc. (Sun) and Lupin Limited (Lupin), subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. Santarus will reimburse Depomed for 70% of its out-of-pocket costs, and Depomed will reimburse Santarus for 30% of its out-of-pocket costs related to these two existing infringement cases.

The commercialization agreement will continue in effect for so long as Santarus commercializes branded Glumetza or authorized generic products, unless terminated sooner. Subject to 60 days prior written notice to Santarus, Depomed may terminate the agreement if Santarus fails to meet its obligations with respect to minimum promotion and expenditure obligations and fails to cure such breach within a specified time period. Either party may terminate the agreement if the other party fails to perform any material term of the agreement and

fails to cure such breach, subject to prior written notice within a specified time period. In addition, either party may terminate the agreement if a force majeure event prevents the other party from carrying out its material obligations under the agreement for a period of at least six months. Finally, either party may terminate the agreement if the other party becomes insolvent, files or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it, and within a specified time period, such filing has not been dismissed. Santarus has a voluntary right to terminate the agreement upon 120 days' written notice.

During the quarter ended September 30, 2011, Depomed distributed Glumetza for the first two months of the quarter, recognized Glumetza product sales on those respective sales and paid Santarus a promotion fee equal to 75% of Glumetza gross margin. In the final month of the quarter, the distribution and sales responsibility transitioned to Santarus. Santarus sold Glumetza for the final month of the quarter, recognized Glumetza product sales on those respective sales and paid Depomed a royalty equal to 26.5% of net sales.

For the three and nine months ended September 30, 2011, the Company recognized \$6.0 million and \$27.3 million, respectively, in promotion fee expense to Santarus related to sales of Glumetza by Depomed. For the three and nine months ended September 30, 2010, the Company recognized \$6.8 million and \$23.8 million, respectively, in promotion fee expense to Santarus. Promotion fee expense is classified within selling, general and administrative expense.

Royalty revenue from Santarus during three and nine months ended September 30, 2011 was \$2.1 million and represented one month of Santarus distributing Glumetza under the commercialization agreement. There were no royalty revenue amounts from Santarus in the prior year.

The Company accounted for the transaction as a sale of a business as defined by FASB Accounting Standards Codification Topic 805, "Business Combinations". In connection with entering into the commercialization agreement with Santarus, no additional consideration was exchanged between the two parties. Accordingly, the Company did not record a gain or loss with respect to this transaction and related transfer of Glumetza manufacturing and distribution activities. As the Company will have significant continuing cash inflows with respect to receiving royalties on net sales of Glumetza by Santarus, the previously reported and future activities related to Glumetza will continue to be presented in income from continuing operations in the Company's income statement.

Pursuant to the promotion agreement originally entered into in July 2008, Santarus paid the Company a \$12.0 million upfront fee. The upfront payment received was originally being amortized as revenue ratably until October 2021, which represented the estimated length of time the Company's obligations existed under the promotion agreement related to manufacturing Glumetza and paying Santarus promotion fees on gross margin of Glumetza. The commercialization agreement in August 2011 superseded the promotion agreement and removed the manufacturing and promotion fee obligations of the Company. The commercialization agreement includes obligations with respect to manufacturing and regulatory transition to Santarus and managing the ongoing patent infringement lawsuits against Sun and Lupin. These obligations are estimated to be completed in December 2013. Accordingly, on the effective date of the commercialization agreement, the amortization period related to remaining deferred revenue on the \$12.0 million upfront fee has been adjusted, and the remaining deferred revenue will be recognized ratably until December 2013. The Company recognized approximately \$0.6 million and \$1.0 million of license revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. For the three and nine months ended September 30, 2010, the Company recognized \$0.2 million and \$0.7 million of license revenue associated with this upfront license fee. The remaining deferred revenue balance related to this upfront payment is \$8.8 million at September 30, 2011.

Ventiv Commercial Services, LLC

In June 2011, the Company entered into a service agreement with Ventiv Commercial Services, LLC (Ventiv), pursuant to which inVentiv Selling Solutions, Ventiv's outsourced sales business, will provide sales force recruiting, training, deployment and ongoing operational support to the Company to promote Gralise. The agreement provides for a sales force of 164 full-time sales representatives dedicated to the Company, all of whom are employees of Ventiv.

Under the terms of the agreement, the Company paid Ventiv an upfront implementation fee and will pay an agreed upon fixed monthly management fee of \$1.8 million, which is subject to adjustment based on actual staffing levels. During the term of the agreement, a portion of Ventiv's monthly management fee will be subject to payment by the Company only to the extent that specified performance objectives are met. The Company will also pay certain pass-through costs of Ventiv incurred in connection with the agreement, which primarily include bonuses, travel costs and certain administrative expenses. The Company incurred \$1.6 million and \$2.5 million of expense related to Ventiv for the three and nine months ended September 30, 2011.

The agreement will expire on the second anniversary of the date on which sales representatives hired by Ventiv are deployed. The agreement is subject to early termination under certain circumstances and may be terminated by either party upon advance notice beginning in October 2012.

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

In November 2008, the Company entered into an exclusive license agreement with Solvay Pharmaceuticals, Inc. (Solvay) granting Solvay exclusive rights to develop and commercialize Gralise TM (gabapentin) for pain indications in the United States, Canada and Mexico. In February 2010, Abbott Laboratories acquired the pharmaceutical business of Solvay and Abbott Products, a subsidiary of Abbott Laboratories, became responsible for the Gralise license agreement with the Company.

In March 2010, Abbott Products submitted an NDA for Gralise to the U.S. Food and Drug Administration (FDA) for the management of postherpetic neuralgia (PHN). In May 2010, the FDA accepted the NDA filing for Gralise, which triggered a \$10.0 million milestone payment from Abbott Products which Depomed received in June 2010. As the nonrefundable milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement and the milestone was related to past performance, the Company recognized the entire \$10.0 million as revenue in the second quarter of 2010.

In January 2011, Abbott Products received FDA approval of Gralise for the management of PHN, which triggered a \$48.0 million development milestone from Abbott Products to the Company, which the Company received in February 2011. As the nonrefundable milestone was substantive in nature, achievement of the milestone was not reasonably assured at the inception of the agreement and the milestone was related to past performance, the entire \$48.0 million was recognized as license revenue in the first quarter of 2011.

In March 2011, the Company entered into a settlement agreement with Abbott Laboratories which provided for (i) the immediate termination of the Gralise license agreement; (ii) the transition of Gralise back to Depomed; and (iii) a \$40.0 million payment to Depomed which the Company received in March 2011. The \$40.0 million payment was recognized as a gain within operating income in the first quarter of 2011.

Pursuant to the exclusive license agreement originally entered into in November 2008, Solvay paid the Company a \$25.0 million upfront fee in February 2009. The upfront payment received was originally being amortized as revenue ratably until January 2013, which represented the estimated length of time the Company's development and supply obligations existed under the agreement. In connection with the termination of the license agreement with Abbott Products, the Company no longer has continuing obligations to Abbott Products. Accordingly, all remaining deferred revenue related to the \$25.0 million upfront license fee previously received from Abbott

Products was fully recognized as revenue in March 2011, resulting in immediate recognition of approximately \$11.3 million of license revenue.

#### Boehringer Ingelheim International GMBH

In March 2011, the Company entered into a license and service agreement with Boehringer Ingelheim International GMBH (Boehringer Ingelheim) granting Boehringer Ingelheim a license to certain patents related to the Company's Acuform drug delivery technology to be used in developing fixed dose combinations of extended release metformin and proprietary Boehringer Ingelheim compounds in development for type 2 diabetes. Under the terms of the agreement, Boehringer Ingelheim was also granted a right of reference to the New Drug Application covering the Company's Glumetza product and associated data for use in potential regulatory submission processes.

In connection with the license and service agreement, the Company received an upfront payment of \$10.0 million less applicable withholding taxes of approximately \$1.5 million, for a net receipt of approximately \$8.5 million in April 2011. The Company received the remaining \$1.5 million of taxes previously withheld directly from German tax authorities in June 2011.

The \$10.0 million upfront fee is being amortized ratably through November 2011, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. The Company recognized approximately \$3.8 million and \$8.6 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011, respectively. The remaining deferred revenue balance is \$1.4 million at September 30, 2011.

Under the terms of the agreement, the Company may receive an additional \$2.5 million upon delivery of experimental batches of prototype formulations that meet certain specification. The Company is also eligible to receive additional milestone payments based on regulatory filing and approval events, as well as royalties on worldwide net sales of products.

Depomed is responsible for providing certain initial formulation work associated with the fixed dose combination products. Work performed by the Company under the service agreement will be reimbursed by Boehringer Ingelheim on an agreed-upon FTE rate per hour plus out-of-pocket expenses. The Company recognized approximately \$0.2 million and \$0.8 million of revenue associated with the reimbursement of formulation work under the service agreement during the three and nine months ended September 30, 2011, respectively.

#### Ironwood Pharmaceuticals, Inc.

In July 2011, the Company entered into a collaboration and license agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) granting Ironwood a license for worldwide rights to the Company's Acuform drug delivery technology for an undisclosed Ironwood early stage development program.

In connection with the agreement, the Company received an upfront payment of \$0.9 million which is being amortized ratably through June 2012, which is the estimated length of time Depomed is obligated to perform formulation work under the agreement. The Company recognized approximately \$0.2 million of revenue associated with this upfront license fee during the three and nine months ended September 30, 2011. The remaining deferred revenue balance related to this upfront payment is \$0.7 million at September 30, 2011.

Under the terms of the agreement, the Company will assist with initial product formulation and Ironwood will be responsible for all development and commercialization of the product. The initial formulation work performed by the Company under the agreement will be reimbursed by Ironwood on an agreed-upon FTE rate per hour plus out-of-pocket expenses. The Company recognized approximately \$0.1 million of revenue associated with the reimbursement of formulation work under the agreement during the three and nine months ended September 30, 2011.

sales.

Under the terms of the agreement, the Company may receive additional payments pending achievement of certain development and regulatory milestones, as well as royalties on product

#### LONG-TERM DEBT

# 9 Months Ended Sep. 30, 2011

# LONG-TERM DEBT LONG-TERM DEBT

#### NOTE 5. LONG-TERM DEBT

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

The Company paid interest only on the first tranche for the first six months at an interest rate of 11.59%. Beginning in January 2009, the Company began principal payments on the first tranche, plus interest at such rate, which will be paid in 30 equal monthly installments. The second tranche was interest-only through December 31, 2008, with principal and interest payable thereafter in 30 equal monthly installments at an interest rate of 11.59%. Interest expense, which includes amortization of debt issuance costs, was approximately \$24,000 and \$133,000 for the three and nine months ended September 30, 2011, respectively.

The credit facility was fully repaid in July 2011.

#### LEASE AMENDMENTS

# 9 Months Ended Sep. 30, 2011

# LEASE AMENDMENTS LEASE AMENDMENTS

#### NOTE 13. LEASE AMENDMENTS

In June 2011, the Company entered into amendments to its existing leases for the Company's premises located at 1330 and 1360 O'Brien Drive, Menlo Park, California, consisting of approximately 46,000 rentable square feet. The lease amendments extend the term of the existing leases for twelve months, from February 1, 2012 through January 31, 2013. All material provisions of the leases remain the same, except that the Company may not extend either of the lease terms. The lease for the Company's premises located at 1430 O'Brien Drive, consisting of approximately 9,000 rentable square feet, was not amended by the lease amendments, and has a term through January 31, 2012.

# STOCK-BASED COMPENSATION

STOCK-BASED COMPENSATION STOCK-BASED COMPENSATION

# 9 Months Ended Sep. 30, 2011

#### NOTE 6. STOCK-BASED COMPENSATION

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

	T	Three Months Ended September 30,				Nine Months Ende September 30,			
		2011		2011 2010			2011		2010
Cost of sales	\$	17	\$	8	\$	50	\$	14	
Research and development expense		155		119		466		428	
Selling, general and administrative expense		769		348		2,292		1,094	
Total	\$	941	\$	475	\$	2,808	\$	1,536	

For the three and nine months ended September 30, 2011, the Company recognized zero and approximately \$0.4 million in stock-compensation expense, respectively, associated with the accelerated vesting of stock options in connection with a separation agreement and release with Carl A. Pelzel, the Company's former President and Chief Executive Officer. See Note 11 for further information with regards to the separation agreement and release.

At September 30, 2011, the Company had \$7.6 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants that will be recognized over an average vesting period of 2.6 years.

CONDENSED	9 Mont	ths Ended
STATEMENTS OF CASH FLOWS (USD \$) In Thousands	Sep. 30, 2011	Sep. 30, 2010
Operating Activities		
Net income (loss)	\$ 84,563	\$ 2,188
Adjustments to reconcile net income (loss) to net cash (used in) provided by		
operating activities:		
Depreciation and amortization	232	331
Loss on disposal of property and equipment	0	46
Stock-based compensation	2,807	1,537
Changes in assets and liabilities:		
Accounts receivable	(1,125)	(4,337)
<u>Inventories</u>	(1,722)	1,603
<u>Prepaid and other assets</u>	(4,157)	(772)
Accounts payable and other accrued liabilities	6,862	1,331
Accrued compensation	189	(408)
<u>Deferred revenue</u>	(15,268)	(4,956)
Net cash provided by (used in) operating activities	72,381	(3,437)
<u>Investing Activities</u>		
Purchases of property and equipment	(665)	(86)
<u>Purchases of marketable securities</u>	(153,875)	(56,110)
Maturities of marketable securities	41,117	47,482
Sales of marketable securities	32,832	7,485
Net cash provided by (used in) investing activities	(80,591)	(1,229)
Financing Activities		
Principal payments on long-term debt	(2,243)	(2,840)
Proceeds from issuance of common stock	7,872	910
Net cash provided by (used in) financing activities	5,629	(1,930)
Net increase (decrease) in cash and cash equivalents	(2,581)	(6,596)
Cash and cash equivalents at beginning of period	22,526	26,821
Cash and cash equivalents at end of period	\$ 19,945	\$ 20,225

# CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

Sep. 30, 2011

9 Months Ended

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

Securities classified as cash and cash equivalents and available-for-sale marketable securities as of September 30, 2011 and December 31, 2010 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

Amortized

Gross

Unrealized

Gross

Unrealized

September 30, 2011	E	Cost	Gains		Losses		F	Fair Value	
Cash and cash equivalents:	_		_						
Cash	\$	5,086	\$		\$		\$	5,086	
Money market funds	•	6,410	•		•		,	6,410	
U. S. corporate debt securities		8,449				_		8,449	
Total cash and cash equivalents	\$	19,945	\$		\$		\$	19,945	
Available-for-sale securities:  Total maturing within 1 year and included in marketable securities:									
U.S. corporate debt securities U.S. government agency debt		44,865		3		(24)		44,844	
securities		2,997		2		_		2,999	
U.S. Treasury securities  Total maturing between 1 and 2 years and included in marketable securities:		41,129		45		_		41,174	
U.S. corporate debt securities U.S. government agency debt		19,225		6		(89)		19,142	
securities		21,061		18		(5)		21,074	
U.S. Treasury securities		5,006		12				5,018	
Total available-for-sale securities	\$	134,283	\$	86	\$	(118)	\$	134,251	
Total cash, cash equivalents and marketable securities	\$	154,228	\$	86	\$	(118)	\$	154,196	
	A	Amortized	U	Gross Inrealized	Un	Gross realized			
December 31, 2010		Cost	_	Gains		Losses	<u> </u>	air Value	
Cash and cash equivalents: Cash	\$	3,913	\$		\$		\$	3,913	
Money market funds	Þ	17,613	Ф	_	Ф	_	Ф	17,613	
U.S. Treasury securities		1,000						1,000	
Total cash and cash equivalents	\$	22,526	\$		\$		\$	22,526	
Total Cash and Cash equivalents	Ψ	22,320	Ψ		Ψ		Ψ	22,320	
Available-for-sale securities:  Total maturing within 1 year and included in marketable securities:									
U.S. corporate debt securities		12,099		4		(2)		12,101	
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U.S. government agency debt				
securities	25,667	21		25,688
U.S. Treasury securities	10,015	21		10,036
Total maturing between 1 and 2 years				
and included in marketable				
securities:				
U.S. corporate debt securities	_	_		_
U.S. government agency debt				
securities				
U.S. Treasury securities	 6,512	 25	 	6,537
Total available-for-sale securities	\$ 54,293	\$ 71	\$ (2)	\$ 54,362
Total cash, cash equivalents and	 	 	 	 
marketable securities	\$ 76,819	\$ 71	\$ (2)	\$ 76,888

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks, money market instruments and commercial paper. The Company places its cash, cash equivalents and marketable securities with high quality, U.S. financial institutions and, to date has not experienced material losses on any of its balances. All marketable securities are classified as available-for-sale since these instruments are readily marketable. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive gain within shareholders' equity. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in "interest and other income" in the condensed statement of operations.

At September 30, 2011, the Company had thirty-two securities in an unrealized loss position. The following table shows the gross unrealized losses and fair value of the Company's investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at September 30, 2011 (in thousands):

	Less than	12 months	12 months	or greater	Total			
		Gross Unrealized		Gross Unrealized		Gross Unrealized		
	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses		
U.S. corporate debt	\$	\$			\$	\$		
securities	45,741	(113)		_	45,741	(113)		
U.S. government agency								
debt securities	15,010	(5)			15,010	(5)		
U.S. Treasury securities								
Total available-for-sale	\$ 60,751	\$ (118)	<u>\$</u>	<u>\$</u>	\$ 60,751	\$ (118)		

The gross unrealized losses above were caused by interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of the Company's securities. Based on the Company's review of these securities, including the assessment of the duration and severity of the unrealized losses and the Company's ability and intent to hold the investments until maturity, there were no material other-than-temporary impairments for these securities at September 30, 2011.

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

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

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

The following table represents the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

	I	Level 1	Level 2		Level 3		Total	
Money market funds	\$	6,410	\$	_	\$			6,410
U.S. corporate debt securities				72,435				72,435
U.S. government agency debt								
securities				24,073				24,073
U.S. Treasury securities				46,192				46,192
Total	\$	6,410	\$	142,700	\$		\$	149,110

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

	 Level 1	Level 2	I	Level 3	Total
Money market funds	\$ 17,613	\$ 	\$		\$ 17,613
U.S. corporate debt securities		12,101			12,101
U.S. government agency debt					
securities		25,688			25,688
U.S. Treasury securities	 	 17,573			 17,573
Total	\$ 17,613	\$ 55,362	\$		\$ 72,975

There are no financial liabilities measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010.

# RELATED PARTY TRANSACTIONS

RELATED PARTY
TRANSACTIONS
RELATED PARTY
TRANSACTIONS

# 9 Months Ended Sep. 30, 2011

#### NOTE 11. RELATED PARTY TRANSACTIONS

#### Carl A. Pelzel

In April 2011, the Company entered into a separation agreement and release with Carl A. Pelzel, the Company's former President and Chief Executive Officer. Pursuant to the separation agreement, Mr. Pelzel will be paid \$520,000, which is equivalent to one year of his base salary. Payments are being made over one year, and will be reduced dollar-for-dollar by any compensation Mr. Pelzel receives in connection with employment (or full-time consulting) by another employer (or third party). The Company will also pay Mr. Pelzel's health and dental insurance COBRA premiums for up to 18 months following his separation from the Company. The separation agreement further provides for three months' accelerated vesting of Mr. Pelzel's options to purchase the Company's common stock, and a release of claims in favor of the Company. The Company incurred a one-time severance charge of approximately \$1.0 million in the second quarter of 2011 with respect to this separation agreement, consisting of approximately \$0.4 million in stock-based compensation related to the accelerated vesting of Mr. Pelzel's awards and approximately \$0.6 million of severance expense related to future payments and health care benefits

CONDENSED BALANCE	9 Months Ended 12 Months Ended					
SHEETS (USD \$) In Thousands	Sep. 30, 2011	Dec. 31, 2010				
<u>ASSETS</u>						
Cash and cash equivalents	\$ 19,945	\$ 22,526				
Marketable securities	89,018	47,825				
Accounts receivable	827	6,094				
Receivables from collaborative partners	6,645	253				
<u>Inventories</u>	3,292	1,571				
Prepaid and other current assets	5,516	1,330				
Total current assets	125,243	79,599				
Marketable securities, long-term	45,233	6,537				
Property and equipment, net	1,140	698				
Other assets	169	197				
TOTAL ASSETS	171,785	87,031				
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>						
Accounts payable and accrued liabilities	25,788	18,473				
<u>Deferred product sales</u>	379	1,041				
<u>Deferred license revenue</u>	7,664	10,665				
Other current liabilities	387	635				
<u>Current portion of long-term debt</u>	0	2,170				
Total current liabilities	34,218	32,984				
Deferred license revenue, non-current portion	19,320	30,926				
Other long-term liabilities	0	15				
Commitments						
<b>Shareholders' equity:</b>						
Preferred stock, no par value						
Common stock, no par value	202,022	191,343				
Accumulated deficit	(83,743)	(168,306)				
Accumulated other comprehensive gain	(32)	69				
Total shareholders' equity	118,247	23,106				
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>~</u> \$ 171,785	\$ 87,031				