Pacira Pharmaceuticals, Inc. Form 10-Q November 01, 2012 Table of Contents

SECURITIE	S AND EXCHANGE COMMISSION
	Washington, D.C. 20549
	FORM 10-Q
	EPORT PURSUANT TO SECTION 13 OR 15(d) OF SECURITIES EXCHANGE ACT OF 1934
THE	
THE	SECURITIES EXCHANGE ACT OF 1934
THE	SECURITIES EXCHANGE ACT OF 1934 the Quarterly Period Ended September 30, 2012
THE	SECURITIES EXCHANGE ACT OF 1934 the Quarterly Period Ended September 30, 2012

Delaware (State or Other Jurisdiction of Incorporation or Organization)

51-0619477 (I.R.S. Employer Identification No.)

5 Sylvan Way, Suite 100

Parsippany, New Jersey 07054

(Address of Principal Executive Offices) (Zip Code)

(973) 254-3560

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes o No

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.) x Yes o No

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

Large accelerated filer o

Accelerated filer o

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

Smaller reporting company x

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

As of October 25, 2012, 32,553,672 shares of the registrant s common stock, \$0.001 par value per share, were outstanding.

PACIRA PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

PACIRA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2012	December 31, 2011 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,709	\$ 46,168
Restricted cash	1,791	1,299
Short-term investments	58,240	29,985
Accounts receivable, net of allowances	2,459	2,113
Inventories	11,906	1,245
Prepaid expenses and other current assets	2,024	1,839
Total current assets	85,129	82,649
Fixed assets, net	35,319	25,103
Goodwill	8,109	
Intangibles, net	3,721	5,259
Other assets	548	479
Total assets	\$ 132,826	\$ 113,490
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 4,789	\$ 3,440
Accrued expenses	13,036	7,159
Current portion of royalty interest obligation	837	1,219
Current portion of deferred revenue	1,166	13,054
Current portion of long-term debt		7,039
Total current liabilities	19,828	31,911
Long-term debt	24,930	18,537
Royalty interest obligation	881	1,537
Deferred revenue	4,343	8,416
Contingent purchase liability		2,042
Other liabilities	2,399	2,778
Total liabilities	52,381	65,221
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, par value \$0.001; 5,000,000 shares authorized, none issued and outstanding		
Common stock, par value \$0.001 par value; 250,000,000 shares authorized, 32,483,878 shares		
issued and 32,482,813 shares outstanding at September 30, 2012; 25,340,103 shares issued		
and 25,339,038 shares outstanding at December 31, 2011	32	25

Additional paid-in capital	296,525	228,470
Accumulated deficit	(216,174)	(180,239)
Accumulated other comprehensive income	64	15
Treasury stock at cost, 1,065 shares	(2)	(2)
Total stockholders equity	80,445	48,269
Total liabilities and stockholders equity	\$ 132,826 \$	113,490

PACIRA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2012	Í	2011	2012		2011	
Revenues:								
Net product sales	\$	4,550	\$	1,682 \$	9,978	\$	4,868	
Collaborative licensing and development								
revenue		3,484		1,352	16,574		3,845	
Royalty revenue		452		922	2,082		2,743	
Total revenues		8,486		3,956	28,634		11,456	
Operating expenses:								
Cost of revenues		9,287		3,357	22,467		10,138	
Research and development		3,527		4,360	6,693		12,742	
Selling, general and administrative		11,378		4,972	32,943		12,960	
Total operating expenses		24,192		12,689	62,103		35,840	
Loss from operations		(15,706)		(8,733)	(33,469)		(24,384)	
Other (expense) income:								
Interest income		87		46	218		111	
Interest expense		(456)		(910)	(1,464)		(4,068)	
Loss on early extinguishment of debt					(1,062)			
Royalty interest obligation		378		116	(47)		235	
Other, net		(48)		(27)	(111)		61	
Total other expense, net		(39)		(775)	(2,466)		(3,661)	
Net loss	\$	(15,745)	\$	(9,508) \$	(35,935)	\$	(28,045)	
Net loss per share:								
Basic and diluted net loss per common share	\$	(0.49)	\$	(0.55) \$	(1.21)	\$	(1.89)	
Weighted average common shares outstanding:								
Basic and diluted		32,436,207		17,230,826	29,585,716		14,826,054	

PACIRA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Mon Septem		Nine Months Ended September 30,			
	2012		2011	2012		2011
Net loss	\$ (15,745)	\$	(9,508) \$	(35,935)	\$	(28,045)
Other comprehensive (loss) income:						
Net unrealized (loss) gain on investments	(34)		(5)	49		(5)
Total other comprehensive (loss) income	(34)		(5)	49		(5)
Comprehensive loss	\$ (15,779)	\$	(9,513) \$	(35,886)	\$	(28,050)

PACIRA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

For the Nine Months Ended September 30, 2012

(Unaudited)

(In thousands)

	Comm Shares	on Stock Am	ount	Additional Paid-In Capital	1	Accumulated Deficit	7	Гreasury Stock	 ccumulated Other nprehensive Income	Total
Balances at December 31,				•						
2011	25,339	\$	25	\$ 228,470	\$	(180,239)	\$	(2)	\$ 15 \$	48,269
Exercise of stock options	207			533						533
Exercise of warrants	37			100						100
Stock-based compensation				3,220						3,220
Unrealized gain on										
short-term investments									49	49
Follow-on offering, net of										
issuance costs	6,900		7	62,848						62,855
Debt discount on issuance										
of warrants				1,354						1,354
Net loss						(35,935)				(35,935)
Balances at										
September 30, 2012	32,483	\$	32	\$ 296,525	\$	(216,174)	\$	(2)	\$ 64 \$	80,445

PACIRA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

		Nine Mont Septem		
Operating activities:		2012		2011
Net loss	\$	(35,935)	\$	(28,045)
Adjustments to reconcile net loss to net cash used in operating activities:	Ψ	(33,933)	Ψ	(20,043)
Depreciation and amortization		4,202		3,030
Amortization of unfavorable lease obligation and deferred financing costs		(178)		(29)
Amortization of end of term fee and warrants		571		1,540
Loss on disposal of fixed assets		3/1		3
Loss on extinguishment of debt		1,062		3
Stock-based compensation		3,220		1,965
Changes in operating assets and liabilities:		3,220		1,703
Restricted cash		(492)		(373)
Accounts receivable, net of allowances		(346)		(305)
Inventories		(10,661)		(62)
Prepaid expenses and other assets		(161)		(908)
Accounts payable and accrued expenses		6,849		697
Royalty interest obligation		(1,038)		(1,435)
Other liabilities		(83)		722
Deferred revenue		(15,961)		(204)
Net cash used in operating activities		(48,951)		(23,404)
Investing activities:		(=)- = /		(-, - ,
Purchase of fixed assets		(13,525)		(3,684)
Proceeds from sales of fixed assets		1		
Net purchases of short-term investments		(28,206)		(20,671)
Payment of contingent consideration		(10,151)		
Net cash used in investing activities		(51,881)		(24,355)
Financing activities:				
Proceeds from exercise of stock options and warrants		633		12
Proceeds from borrowings on long-term debt		27,500		
Proceeds from offering, net		62,855		38,016
Repayment of debt		(26,250)		
Payment of debt issuance and financing costs		(1,365)		
Net cash provided by financing activities		63,373		38,028
Net decrease in cash and cash equivalents		(37,459)		(9,731)
Cash and cash equivalents, beginning of period		46,168		26,133
Cash and cash equivalents, end of period	\$	8,709	\$	16,402
Supplemental cash flow information				
Cash paid for interest, including royalty interest obligation	\$	3,290	\$	3,573
Initial public offering costs paid in 2010				907
Non cash investing and financing activities:				

Conversion of notes to common stock	51,222
Conversion of preferred stock to common stock	6
Value of warrants issued with debt	1,354

PACIRA PHARMACEUTICALS, INC.

CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1 DESCRIPTION OF BUSINESS

Pacira Pharmaceuticals, Inc. and its subsidiaries (collectively, the Company or Pacira) is an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on its proprietary DepoFoam extended release drug delivery technology, for use in hospitals and ambulatory surgery centers. The Company s lead product EXPAREL®, which consists of bupivacaine encapsulated in DepoFoam, was approved by the United States Food and Drug Administration, or FDA, on October 28, 2011. The Company commercially launched EXPAREL in April 2012. DepoFoam is also the basis for the Company s other FDA-approved commercial product, DepoCyt(e), which the Company manufactures for its commercial partners.

Pacira Pharmaceuticals, Inc. is the holding company for the California operating subsidiary of the same name, also referred to as PPI-California, which was acquired from Skyepharma Holding, Inc., or Skyepharma, in March 2007, referred to herein as the Acquisition.

Note 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, for interim reporting. Pursuant to these rules and regulations, certain information and footnote disclosures normally included in complete annual financial statements have been condensed or omitted. Therefore, these interim financial statements should be read in conjunction with the audited annual consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 27, 2012.

The consolidated financial statements at September 30, 2012, and for the three and nine months ended September 30, 2012 and 2011, are unaudited, but include all adjustments (consisting of only normal recurring adjustments) which, in the opinion of management, are necessary to present fairly the financial information set forth herein in accordance with GAAP. The balance sheet as of December 31, 2011, has been derived from the audited financial statements included in the Form 10-K for that year. Certain reclassifications were made to conform to the current presentation. Specifically, for the three and nine months ended September 30, 2011, the Company reclassified less than \$0.1 million and \$0.5 million, respectively, of stock-based compensation expense from selling, general and administrative expense to research and development expense. This reclassification had no impact on net loss or stockholders equity as previously reported. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in

consolidation.

The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. The Company has incurred losses and negative operating cash flow since inception and future losses are anticipated.

Liquidity

In April 2012, the Company sold 6,900,000 shares of common stock at a price of \$9.75 per share in a registered public offering, which includes the underwriter s exercise of the overallotment option. The Company raised approximately \$62.9 million in net proceeds after deducting underwriting discounts and offering expenses.

Management believes that the Company s existing cash and cash equivalents, short-term investments and revenue from product sales will be sufficient to enable the Company to meet its planned operating expenses, capital expenditure requirements and service its indebtedness through September 30, 2013. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. The Company expects to continue to incur substantial additional operating losses as it commercializes EXPAREL and develops and seeks regulatory approval for its product candidates.

Revenue Recognition

The Company sells EXPAREL mostly to wholesalers based on orders of the product from hospitals and other end user customers such as ambulatory surgery centers and doctors. The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. Sales to wholesalers

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provide for selling prices that are fixed on the date of sale. EXPAREL is delivered directly to the end user with the wholesaler never taking physical possession of the product. The Company records revenue at the time the product is delivered to the end user.
At the time the Company recognizes revenue, it also records certain sales reserves and allowances as a reduction of revenue. These reserves and allowances include a prompt payment reserve, return reserves, volume rebates, chargeback reserve and wholesaler service fee. Due to estimates and assumptions inherent in determining some of the sales reserves, the actual amount of volume rebates, chargebacks and returns may be different from estimates, at which time the Company would adjust the reserves accordingly.
Prompt pay reserve
The prompt payment reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. The Company accounts for these discounts at the time the sale is made and reduces accounts receivable accordingly.
Returns reserve
The Company allows customers to return product that is damaged or received in error. In addition, the Company allows for product to be returned beginning six months prior to, and twelve months following product expiration. As EXPAREL is a new commercially available product, the Company is estimating its sales return reserve based on return history from other hospital-based products with similar distribution models, which management believes is the best estimate of the anticipated product to be returned. The returns reserve is recorded at the time of sale as a reduction to sales and an increase in returns liability.
Volume rebates and chargeback reserve
Volume rebates and chargeback reserve are based upon contracted discounts and promotional offers the Company provides to certain end users, including hospitals and ambulatory surgery centers such as members of group purchasing organizations. The volume rebates and chargeback reserve are recorded as a reduction to sales and a customer payable and reduction to receivables, respectively.
Wholesaler service fee

The Company s customers include major and regional wholesalers with whom the Company has contracted a fee for service based on a percentage of sales. This fee for service is recorded as a reduction to gross sales and a liability is established at the time the sale is recorded

based on the contracted percentage.

Allowance for doubtful accounts

The Company evaluates accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. The Company s sales to date are primarily to established customers. As of September 30, 2012, the accounts receivable was considered collectible and no allowance for doubtful accounts was recorded.

Concentration of Major Customers

The Company s customers are its major and regional wholesalers and commercial, distribution and licensing partners. The Company is dependent on its commercial partners to market and sell DepoCyt(e). The table below includes the percentage of revenue comprised by the three largest customers in each year presented.

	Three Mont	hs Ended	Nine Months Ended				
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011			
Largest customer	38%	48%	41%	45%			
Second largest customer	22%	21%	14%	20%			
Third largest customer	14%	17%	10%	19%			
	74%	86%	65%	84%			

No other individual customer accounted for more than 10% of the Company s revenues for these periods.

On January 3, 2012, EKR Therapeutics, Inc., or EKR, delivered a notice to the Company to terminate the licensing, distribution and marketing agreement relating to DepoDur. Pursuant to the terms of the agreement, the termination of the agreement was effective 180 days from the date of the notice, or July 1, 2012. The associated supply agreement also terminated concurrently with the termination of the licensing, distribution and marketing agreement. Both parties agreed to terminate the agreements effective June 8, 2012. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in June 2012. During the nine months ended September 30, 2012, the Company recognized \$11.6 million of milestone revenue relating to the EKR agreements in collaborative licensing and development revenue on the consolidated statements of operations.

On June 29, 2012, the Company received a notice of termination from Novo Nordisk AS, or Novo, of the Development and License Agreement, dated January 14, 2011. Pursuant to the terms of the agreement, the termination of the agreement was effective

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60 days from the date of the notice, or August 28, 2012. Under the agreement, the Company granted exclusive rights to Novo under certain of the Company s patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using the Company s DepoFoam drug delivery technology. The agreement was terminated due to Novo s decision to discontinue development of the proprietary drug subject to the agreement. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in August 2012. During the three and nine months ended September 30, 2012, the Company recognized \$3.2 million and \$4.1 million, respectively, of revenue relating to the Novo Nordisk agreement in collaborative licensing and development revenue on the consolidated statements of operations.

Note 3 FINANCIAL INSTRUMENTS

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction. To increase consistency and comparability in fair value measurements, the Financial Accounting Standards Board, or FASB, established a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels are:

- Level 1 Values are unadjusted quoted prices for identical assets and liabilities in active markets.
- Level 2 Inputs include quoted prices for similar assets or liabilities in active markets, quoted prices from those willing to trade in markets that are not active, or other inputs that are observable or can be corroborated by market data for the term of the instrument.
- Level 3 Certain inputs are unobservable (supported by little or no market activity) and significant to the fair value measurement.

The carrying value of financial instruments including cash and cash equivalents, restricted cash, accounts receivable and accounts payable approximate their respective fair values due to the short-term maturities of these instruments and debts. The fair value of the Company s long-term debt is calculated using a discounted cash flow analysis factoring in current market borrowing rates for similar types of borrowing arrangements under a similar credit profile. The carrying amount and fair value of the Company s long-term debt is as follows (in thousands):

	(Carrying		Fair Value Me	easurements Usi	ing
Financial Liabilities		Value	Level 1	L	evel 2	Level 3
September 30, 2012						
Long-term debt- current and						
long-term *	\$	27,500	\$	\$	27,500	\$
December 31, 2011						
	\$	26,250	\$	\$	27,929	\$

Long-term	debt-	current	and
long-term			

Short-term investments consist of investment grade commercial paper, asset-backed securities collateralized by credit card receivables, and corporate bonds with initial maturities of greater than three months at the date of purchase but less than one year. The net unrealized gains (losses) from the Company s short-term investments are captured in other comprehensive gain (loss). All of the Company s short-term investments are classified as available for sale investments and determined to be Level 2 instruments. The fair value of the commercial paper is measured based on a standard industry model that uses the 3-month Treasury bill rate as an observable input. The fair value of the corporate bonds and asset-backed securities is principally measured or corroborated by trade data for identical issues or that of comparable securities in which related trading activity is not sufficiently frequent to be considered a Level 1 input. At September 30, 2012, the Company had \$58.2 million invested in short-term investments which were rated A or better by Standard & Poor s and had maturities ranging from 162 to 356 days from date of purchase.

The following summarizes the Company s short-term investments at September 30, 2012, and December 31, 2011 (in thousands):

^{*}The carrying value of the long-term debt at September 30, 2012 approximates its fair value since the interest rate approximates the current market rate for similar instruments.

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Gross Gross
Amortized Unrealized