

Pacira Pharmaceuticals, Inc.
Form 10-Q
November 01, 2012
[Table of Contents](#)

**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, 2012

Commission File Number: 001-35060

PACIRA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

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. Yes 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.) Yes No

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

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

Table of Contents

PACIRA PHARMACEUTICALS, INC.

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1.</u> <u>Financial Statements</u>	
<u>Consolidated Balance Sheets</u>	1
<u>Consolidated Statements of Operations</u>	2
<u>Consolidated Statements of Comprehensive Loss</u>	3
<u>Consolidated Statement of Stockholders' Equity</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Condensed Notes to Consolidated Financial Statements</u>	6
<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
<u>Item 4.</u> <u>Controls and Procedures</u>	23
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1.</u> <u>Legal Proceedings</u>	24
<u>Item 1A.</u> <u>Risk Factors</u>	24
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
<u>Item 3.</u> <u>Defaults upon Senior Securities</u>	29
<u>Item 4.</u> <u>Mine Safety Disclosures</u>	29
<u>Item 5.</u> <u>Other Information</u>	29
<u>Item 6.</u> <u>Exhibits</u>	30
<u>Signatures</u>	31

Table of Contents**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

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

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

See accompanying condensed notes to consolidated financial statements.

Table of Contents**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	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

See accompanying condensed notes to consolidated financial statements.

Table of Contents

PACIRA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Months Ended September 30,		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)

See accompanying condensed notes to consolidated financial statements.

Table of Contents**PACIRA PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY****For the Nine Months Ended September 30, 2012****(Unaudited)****(In thousands)**

	Common Stock		Additional	Accumulated	Treasury	Accumulated	Total
	Shares	Amount	Paid-In	Deficit	Stock	Other	
			Capital			Comprehensive	
						Income	
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

See accompanying condensed notes to consolidated financial statements.

Table of Contents**PACIRA PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(In thousands)**

	Nine Months Ended September 30,	
	2012	2011
Operating activities:		
Net loss	\$ (35,935)	\$ (28,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
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
Loss on extinguishment of debt	1,062	
Stock-based compensation	3,220	1,965
Changes in operating assets and liabilities:		
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:		

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

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

See accompanying condensed notes to consolidated financial statements.

Table of Contents

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

Table of Contents

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 Months 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

Table of Contents

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):

Financial Liabilities	Carrying Value	Fair Value Measurements Using		
		Level 1	Level 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

*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.

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):

Table of Contents

September 30, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Debt securities:				
Commercial Paper	\$ 33,338	\$ 52	\$	\$ 33,390
Corporate Bonds	18,727	5	(2)	18,730
Asset-backed Securities	6,111	9		6,120
Total	\$ 58,176	\$ 66	\$ (2)	\$ 58,240

December 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Debt securities:				
US Treasury Securities	\$ 1,000	\$	\$	\$ 1,000
Commercial Paper	11,476	23		11,499
Corporate Bonds	17,494	2	(10)	17,486
Total	\$ 29,970	\$ 25	\$ (10)	\$ 29,985

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments and accounts receivable. The Company maintains its cash and cash equivalents with high-credit quality financial institutions. At times, such amounts may exceed Federal insured limits.

As of September 30, 2012, four customers accounted for 35%, 20%, 15%, and 14% of the Company's accounts receivable. As of December 31, 2011, two customers accounted for 56% and 41% of the Company's accounts receivable. No other individual customer accounted for more than 10% of the Company's accounts receivable for these periods.

Note 4 INVENTORIES

The components of inventories were as follows (in thousands):

	September 30, 2012	December 31, 2011
Raw materials	\$ 4,486	\$ 862
Work-in-process	1,032	96
Finished goods	6,388	287
Total	\$ 11,906	\$ 1,245

As of September 30, 2012 and December 31, 2011, the Company had a reserve of inventory of \$0.4 million and \$0.2 million, respectively. Included in the inventory reserve at September 30, 2012 is \$0.3 million of DepoCyte finished inventory related to the amount of excess product

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

that may not be marketable under the remediation plan committed to the Medicines and Healthcare products Regulatory Agency, or MHRA. See Note 11, *Commitments and Contingencies*, for further discussion.

Note 5 FIXED ASSETS

Fixed assets, summarized by major category, consist of the following (in thousands):

9

Table of Contents

	September 30, 2012	December 31, 2011
Machinery and laboratory equipment	\$ 12,535	\$ 12,188
Computer equipment and software	1,513	1,133
Office furniture and equipment	431	352
Leasehold improvements	6,217	6,056
Construction in progress	25,669	13,656
Total	46,365	33,385
Less accumulated depreciation	(11,046)	(8,282)
Fixed assets, net	\$ 35,319	\$ 25,103

Depreciation expense was \$0.9 million and \$0.5 million for the three months ended September 30, 2012 and 2011, respectively. Depreciation expense was \$2.7 million and \$1.3 million for the nine months ended September 30, 2012 and 2011, respectively. For the three and nine months ended September 30, 2012, the Company capitalized interest of \$0.5 million and \$1.4 million, respectively, on the construction of its manufacturing sites. Capitalized interest was \$0.2 million and \$0.5 million for the three and nine months ended September 30, 2011, respectively.

Note 6 GOODWILL AND INTANGIBLE ASSETS

The Company applies Accounting Standards Codification (ASC) Topic 350, *Intangibles - Goodwill and Other Intangible Assets*, to record goodwill and intangible assets. In accordance with ASC 350, certain intangible assets are to be assessed periodically for impairment using fair value measurement techniques. Goodwill is tested for impairment on an annual basis as of the end of the Company's fiscal year, or more frequently when impairment indicators arise. The Company evaluates the recoverability of intangible assets periodically and takes into account events and circumstances which indicate that impairment exists.

The Company's goodwill as of September 30, 2012 and December 31, 2011 was \$8.1 million and \$0.0, respectively. Goodwill arose from the triggering in April 2012 of a contingent milestone payment to Skyepharma in connection with the Acquisition. The Acquisition was accounted for under Statement of Financial Accounting Standards 141, *Accounting for Business Combinations*, which was the effective GAAP at the Acquisition date. In connection with the Acquisition, the Company agreed to certain earn-out payments based on a percentage of net sales of EXPAREL collected and certain other yet-to-be-developed products, as well as milestone payments for EXPAREL as follows:

- (a) \$10.0 million upon first commercial sale in the United States;
- (b) \$4.0 million upon first commercial sale in a major EU country (United Kingdom, France, Germany, Italy and Spain);
- (c) \$8.0 million when annual net sales collected reach \$100.0 million;
- (d) \$8.0 million when annual net sales collected reach \$250.0 million; and
- (e) \$32.0 million when annual net sales collected reach \$500.0 million.

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

The Company's contingent purchase liability as of September 30, 2012 and December 31, 2011 was \$0.0 and \$2.0 million, respectively. The first contingency was resolved in April 2012, resulting in a \$10.0 million payment to Skyepharma. The Company recorded this payment net of the \$2.0 million contingent consideration liability recognized at the time of the Acquisition resulting in \$8.0 million recorded as goodwill. Additionally, as of September 30, 2012, the Company also recorded \$0.2 million as goodwill for the percentage payments on net sales of EXPAREL collected. Any remaining earn-out payments will also be treated as additional cost of the Acquisition and, therefore, recorded as goodwill if and when each contingency is resolved.

Intangible assets are summarized as follows (in thousands):

Table of Contents

	September 30, 2012	December 31, 2011	Estimated Useful Life
Core Technology:			
Gross amount	\$ 2,900	\$ 2,900	9 years
Accumulated amortization	(1,772)	(1,530)	
Net	1,128	1,370	
Developed Technology:			
Gross amount	11,700	11,700	7 years
Accumulated amortization	(9,193)	(7,939)	
Net	2,507	3,761	
Trademarks and trade names:			
Gross amount	400	400	7 years
Accumulated amortization	(314)	(272)	
Net	86	128	
Intangible assets, net	\$ 3,721	\$ 5,259	

Amortization expense for intangibles was \$0.5 million and \$0.6 million for the three months ended September 30, 2012 and 2011, respectively. Amortization expense for intangibles was \$1.5 million and \$1.7 million for the nine months ended September 30, 2012 and 2011, respectively.

The approximate amortization expense for intangibles, all of which are subject to amortization on a straight-line basis, is as follows (in thousands):

	Core Technology	Developed Technology	Trademarks and Tradenames	Total
2012 (remaining three months)	\$ 80	\$ 418	\$ 16	\$ 514
2013	322	1,671	57	2,050
2014	322	418	13	753
2015	322			322
2016	82			82
Total	\$ 1,128	\$ 2,507	\$ 86	\$ 3,721

Note 7 DEBT AND FINANCING OBLIGATIONS

The composition of the Company's debt and financing obligations is as follows (in thousands):

	September 30, 2012	December 31, 2011
Debt:		
Current portion of long-term debt	\$	\$ 7,039
Long-term debt	27,500	19,211
Discount on debt	(2,570)	(674)
Total debt, net of debt discount	24,930	25,576
Financing obligations:		

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

Current portion of royalty interest obligation	837	1,219
Long-term portion of royalty interest obligation	881	1,537
Total royalty interest obligation	1,718	2,756
Total debt and financing obligations	\$ 26,648	\$ 28,332

On May 2, 2012, the Company entered into a definitive loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, or the Lender, and borrowed the principal amount of \$27.5 million, or the Loan Facility, at a fixed rate of 9.75%, with

Table of Contents

the first principal payment due December 1, 2013. Payments under the Loan Agreement are interest-only in arrears through November 30, 2013, followed by 30 equal monthly payments of principal and interest. In addition, a payment equal to 6% of the Loan Facility will be due on the final payment date, or such earlier date as specified in the Loan Agreement. The \$1.65 million end of term fee was recorded as a debt discount and is being amortized to interest expense over the term of the loan. The proceeds from the Loan Agreement were used by the Company to repay the entire \$24.2 million outstanding balance plus accrued interest, \$0.6 million end of term fee and \$0.3 million early prepayment penalty on its credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P., as lenders, or Hercules Credit Facility. The Company recorded a loss on extinguishment of debt of \$1.1 million comprised of the remaining unamortized debt issuance costs, warrants and end of term fee, as well as the early prepayment penalty on the note issued under the Hercules Credit Facility.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets, other than its intellectual property. The Company agreed not to pledge or otherwise encumber its intellectual property assets, except for permitted liens or to the extent the intellectual property constitutes royalty collateral, as such terms are defined in the Loan Agreement and except as otherwise provided in the Loan Agreement.

If the Company repays all or a portion of the Loan Facility prior to maturity, it will pay the Lender a prepayment fee based on a percentage of the then outstanding principal balance equal to: 3.00% if the prepayment occurs prior to or on the first anniversary of the funding date, 2.00% if the prepayment occurs after the first anniversary of the funding date but prior to or on the second anniversary of the funding date, or 1.00% if the prepayment occurs after the second anniversary of the funding date.

The Loan Agreement includes customary affirmative and restrictive covenants for transactions of this type and customary events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, the occurrence of certain events under the Company's royalty agreements, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, a material adverse change in the business, operations or condition of the Company or any of its subsidiaries and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% may be applied to the outstanding loan balance and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

In connection with the Loan Agreement, the Company issued to the Lender warrants that are exercisable for an aggregate of 162,885 shares of its common stock at a per share exercise price of \$10.97. Each warrant may be exercised on a cashless basis in whole or in part. The value of the warrants was recorded as a debt discount and is being amortized over the term of the loan to interest expense. The fair value of the warrants was determined using Black-Scholes option model (using a discount rate of 1.96%, volatility of 69.69%, a dividend yield of 0%, and a contractual term of 10 years). The relative fair value of the warrants totaled \$1.4 million. See Note 12, *Subsequent Events*, for further information.

The Company's principal payments are due under the Loan Agreement as follows: \$0.8 million in 2013, \$10.3 million in 2014, \$11.3 million in 2015 and \$5.1 million in 2016.

Note 8 STOCKHOLDERS' EQUITY

Stock-Based Compensation

The Company recognized stock-based compensation expense in its consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012		2011		2012		2011	
Cost of revenues	\$	200	\$	31	\$	400	\$	145
Research and development		281		71		745		737
Selling, general and administrative		988		340		2,075		1,083
Total	\$	1,469	\$	442	\$	3,220	\$	1,965

Table of Contents**Stock Incentive Plans**

The Company's 2011 stock incentive plan, or 2011 Plan, previously contained an evergreen provision, which allowed for an increase in the number of shares authorized for issuance under the 2011 Plan on the first day of each calendar year from 2012 through 2015. On January 1, 2012, the evergreen provision increased the number of shares of common stock authorized for issuance under the 2011 Plan by 557,880 shares. On June 5, 2012, the 2011 Plan was amended, to, among other things: (i) increase the number of shares of common stock authorized for issuance under the 2011 Plan by 2,100,000, (ii) remove the evergreen provision and (iii) require stockholder approval prior to any repricing of awards granted under the 2011 Plan.

The following table contains information about the Company's plans at September 30, 2012:

Plan	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2011 Plan	3,130,271	2,314,217	816,054
2007 Plan	2,074,266	2,074,266	
	5,204,537	4,388,483	816,054

The following table summarizes the Company's stock option activity and related information for the period from December 31, 2011 to September 30, 2012:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2011	2,337,017	\$ 3.92
Granted	2,000,000	11.28
Exercised	(206,584)	2.58
Forfeited	(125,124)	7.30
Outstanding at September 30, 2012	4,005,309	7.55

Note 9 LOSS PER SHARE

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing net loss available to common stockholders by the weighted average number of common stock and dilutive common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potential common shares in the diluted net loss per share computation are excluded to the extent that they would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented.

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

The following table sets forth the computation of basic and diluted loss per share for the three and nine months ended September 30, 2012 and 2011 (in thousands, except per share amounts):

	Three Months Ended		Nine Months Ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Numerator for basic and diluted loss per share				
Net loss	\$ (15,745)	\$ (9,508)	\$ (35,935)	\$ (28,045)
Denominator				
Weighted average shares of common stock outstanding	32,436	17,231	29,586	14,826
Effect of dilutive securities				
Weighted average shares of common stock -diluted	32,436	17,231	29,586	14,826
Net loss per share				
Basic net loss per share of common stock	\$ (0.49)	\$ (0.55)	\$ (1.21)	\$ (1.89)
Diluted net loss per share of common stock	\$ (0.49)	\$ (0.55)	\$ (1.21)	\$ (1.89)

The stock options and warrants are excluded from the calculation of diluted loss per share because the net loss for the three and nine months ended September 30, 2012 and 2011 causes such securities to be anti-dilutive. The potential dilutive effect of these

Table of Contents

securities is shown in the chart below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Weighted average shares of common stock outstanding basic	32,436	17,231	29,586	14,826
Stock options	1,374	1,164	1,247	791
Warrants	227	115	158	78
Weighted average shares of common stock -diluted	34,037	18,510	30,991	15,695

Note 10 RELATED PARTY TRANSACTIONS

In June 2011, the Company entered into an agreement with Gary Pace, a member of the Company's board of directors, to provide consulting services for manufacturing related activities. The fees payable under the agreement may not exceed \$60,000 per year. In connection with these services, Dr. Pace received an option to purchase 10,000 shares of common stock at an exercise price of \$11.02 per share. In April 2012, the Company entered into an amended and restated consulting agreement with Gary Pace, whereby Dr. Pace will provide consulting services at the rate of \$10,000 per month and received an option to purchase 20,000 shares of common stock at an exercise price of \$11.02 per share pursuant to the consulting arrangement. In August 2012, the Company further amended and restated the consulting agreement with Gary Pace, whereby Dr. Pace provides consulting services at the rate of \$15,000 per month and is eligible for a bonus up to \$0.2 million if certain targets are met for an expanded manufacturing line. Dr. Pace also received an option to purchase 70,000 shares of common stock at an exercise price of \$16.67 pursuant to the amended and restated consulting arrangement. The amount of fees incurred for each of the three and nine months ended September 30, 2012 was \$0.1 million. At September 30, 2012, and December 31, 2011, the amount payable to Dr. Pace was not material.

MPM Asset Management, or MPM, an investor in the Company, provides clinical management and subscription services to the Company. The Company incurred expenses of approximately \$0.1 million for the three months ended September 30, 2012 and 2011. The Company incurred expenses of approximately \$0.3 million for the nine months ended September 30, 2012 and 2011. Approximately \$0.1 million was payable to MPM at September 30, 2012 and December 31, 2011.

Note 11 COMMITMENTS AND CONTINGENCIES

In July 2012, the Company received an inspection letter from the MHRA noting certain critical and major deficiencies in the DepoCyt(e) manufacturing line, which is located in a separate building from the EXPAREL manufacturing site. As a result of the findings, the European Medicines Agency issued an assessment report which recommended that, until corrective actions are taken allowing new supply to enter the market, alternative medicines be used in European Union member countries where there are suitable alternatives. The assessment report also recommended a selective recall of DepoCyt(e) in European Union member countries where DepoCyt(e) is not considered to be an essential medicinal product. In European Union member countries where the product is classified as an essential medicinal product, DepoCyt(e) can be used with specific recommendations to monitor patients' safety. During the three and nine months ended September 30, 2012, the Company recorded a charge of \$0.6 million and \$1.3 million, respectively, in cost of revenues associated with the implementation of a remediation plan and estimated costs to replace the product. While the corrective actions and upgrades to the facilities are taking place, the Company has stopped manufacturing DepoCyt(e) and will not begin manufacturing product for the European markets until the manufacturing facility is re-inspected by the MHRA. The Company does not expect new product to be available to the European market until the second quarter

of 2013. No regulatory action has been taken by the FDA in the United States as a result of these inspection findings. Assuming a successful reinspection and the startup of its manufacturing operations shortly thereafter, the Company does not currently expect an out of stock situation in either the United States or Europe as a result of the interruption in manufacturing of DepoCyt(e). It is possible that additional charges may be required in future periods based on new information and changes in estimates.

In May 2012, the Company entered into a construction management agreement with DPR Construction, a General Partnership, or DPR. Under the terms of the agreement, DPR is responsible for the management of the renovation of the Company's existing manufacturing facility in San Diego, California. The manufacturing facility is being renovated to allow the Company to expand the current manufacturing capacity and meet anticipated future market demand for EXPAREL. Pursuant to the agreement, the contract sum (the cost of the work plus the contractor fee) will not exceed approximately \$7.7 million, provided that such amount is subject to change based on agreed-upon changes to the scope of work.

Note 12 SUBSEQUENT EVENTS

On October 5, 2012, Oxford Finance LLC did a cashless exercise of 162,885 warrants issued in connection with the Loan Facility into 67,279 shares of common stock.

Table of Contents

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to risks, uncertainties and assumptions that are difficult to predict. All statements in this Quarterly Report on Form 10-Q, other than statements of historical fact, are forward-looking statements. These forward-looking statements are made pursuant to safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements include statements, among other things, regarding our plans to develop, manufacture and commercialize EXPAREL; our plans to continue to manufacture and provide support services for our commercial partners who have licensed DepoCyt(e); the anticipated success of our remediation plans in response to the inspection report from the Medicines and Healthcare products Regulatory Agency and the timing of recommencing our DepoCyt(e) manufacturing operations; the success of our commercialization of EXPAREL; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and our ability to serve those markets; our plans to expand the indications of EXPAREL to include nerve block; our manufacturing, commercialization and marketing capabilities, regulatory developments in the United States and foreign countries; our ability to obtain and maintain intellectual property protection; the accuracy of our estimates regarding expenses and capital requirements; and the loss or hiring of key scientific or management personnel. In some cases, you can identify these statements by forward-looking words, such as estimate, expect, anticipate, project, plan, intend, believe, forecast, foresee, likely, may, should, goal, target, might, could, predict, and continue, the negative or plural of these words and other comparable terminology. Forward-looking statements are only predictions based on our current expectations and our projections about future events. All forward-looking statements included in this Quarterly Report on Form 10-Q are based upon information available to us as of the filing date of this Quarterly Report on Form 10-Q. You should not place undue reliance on these forward-looking statements. We undertake no obligation to update any of these forward-looking statements for any reason. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in Part II-Item 1A. Risk Factors.

Unless the context requires otherwise, references to Pacira, we, the company, us and our in this Quarterly Report on Form 10-Q refers to Pacira Pharmaceuticals, Inc. and its subsidiaries. In addition, references in this Quarterly Report on Form 10-Q to DepoCyt(e) mean DepoCyt when discussed in the context of the United States and Canada and DepoCyt(e) when discussed in the context of Europe.

Overview

We are an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers.

On October 28, 2011, the United States Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for our lead product candidate, EXPAREL, a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia. We have developed a sales force entirely dedicated to commercializing EXPAREL comprised of approximately 60 hospital specialists, seven regional directors and a national sales director. We have developed this sales force pursuant to a contract with Quintiles Commercial US, Inc., a division of Quintiles, Inc., or Quintiles, and under the terms of this contract we have the flexibility to hire all or a portion of the sales force dedicated to commercializing EXPAREL as full-time employees of Pacira, upon 60 days notice to Quintiles. We commercially launched EXPAREL in April 2012. As a result of our first commercial sale of EXPAREL, we triggered a

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

\$10.0 million payment obligation to Skyepharma Holding Inc., or Skyepharma, in connection with the acquisition of our California operating subsidiary, which we refer to as the Acquisition.

We also sell our other approved product, DepoCyt(e), to commercial partners. DepoCyt(e) is a sustained release liposomal formulation of the chemotherapeutic agent cytarabine and is indicated for the intrathecal treatment of lymphomatous meningitis. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. In July 2012, we received an inspection letter from the MHRA noting certain critical and major deficiencies in the DepoCyt(e) manufacturing line, which is located in a separate building from the EXPAREL manufacturing site. As a result of the findings, the European Medicines Agency issued an assessment report which recommended that, until corrective actions are taken allowing new supply to enter the market, alternative medicines be used in European Union member countries where there are suitable alternatives. The assessment report also recommended a selective recall of DepoCyt(e) in European Union member countries where DepoCyt(e) is not considered to be an essential medicinal product. In European Union member countries where DepoCyt(e) is classified as an essential medicinal product, DepoCyt(e) can be used with specific recommendations to monitor patients' safety. While the corrective actions and upgrades to the facilities are taking place, we have stopped manufacturing DepoCyt(e) and will not begin manufacturing product for the

Table of Contents

European markets until the manufacturing facility is re-inspected by the MHRA. The Company does not expect new product to be available to the European market until the second quarter of 2013. No regulatory action has been taken by the Food and Drug Administration in the United States as a result of these inspection findings. Assuming a successful reinspection and the startup of its manufacturing operations shortly thereafter, the Company does not currently expect an out of stock situation in either the United States or Europe as a result of the interruption in manufacturing of DepoCyt(e). The selective recall contributed to a reduction in product sales and royalty revenue of Depocyt(e) for the three and nine months ended September 30, 2012, respectively.

We also partner with other companies who desire access to our proprietary DepoFoam extended release drug delivery technology to conduct research, feasibility and formulation work with their products. On June 29, 2012, we received a notice of termination from Novo Nordisk AS, or Novo, of a Development and License Agreement, dated January 14, 2011. Pursuant to the terms of the agreement, the termination of the agreement is effective 60 days from the date of the notice, or August 28, 2012. Under the agreement, we 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 our DepoFoam drug delivery technology. The agreement was terminated due to Novo's decision to discontinue development of the proprietary drug subject to in the agreement. As a result, our future collaborative licensing and development revenue may be negatively impacted.

We expect to continue to incur significant expenses as we commercialize EXPAREL and advance the development of product candidates, seek FDA approval for our product candidates that successfully complete clinical trials and develop our sales force and marketing capabilities to prepare for their commercial launch. We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts and our obligations as a public reporting company. For us to become and remain profitable, we believe that we must succeed in commercializing EXPAREL or other product candidates with significant market potential.

Results of Operations*Comparison of Three and Nine Months Ended September 30, 2012 and 2011**Revenues*

The following table sets forth a summary of revenues during the periods indicated (in thousands):

	Three Months Ended		% Increase/ Decrease	Nine Months Ended		% Increase/ Decrease
	September 30, 2012	2011		September 30, 2012	2011	
Net product sales:						
EXPAREL	\$ 4,550	\$	N/A	\$ 6,835	\$	N/A
DepoCyt(e)		1,682	(100)%	3,080	4,868	(37)%
DepoDur			N/A	63		N/A
Total net product sales	4,550	1,682	171%	9,978	4,868	105%
	3,484	1,352	158%	16,574	3,845	331%

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

Collaborative licensing and development revenue

Royalty revenue	452	922	(51)%	2,082	2,743	(24)%
Total revenues	\$ 8,486	\$ 3,956	115%	\$ 28,634	\$ 11,456	150%

Total revenues increased by \$4.5 million, or 115%, to \$8.5 million in the three months ended September 30, 2012, as compared to \$4.0 million in the three months ended September 30, 2011. In April 2012, we commercially launched EXPAREL resulting in \$4.6 million of net product sales for the three months ended September 30, 2012. We report product sales net of allowances for sales returns, prompt pay discounts, volume rebates and distribution service fees payable to wholesalers. We ship products directly to the end user based on orders placed to wholesalers or directly to us and have no product held by wholesalers.

We had no product sales of DepoCyt(e) during the three months ended September 30, 2012 resulting in a \$1.7 million decrease in DepoCyt(e) product sales. There was also a corresponding decrease in royalty revenue of \$0.5 million due to lower end user sales by our commercial partner, Mundi Pharmaceuticals. These decreases are driven by the reduction in sales of DepoCyt(e) due to a selective recall of Depocyt(e) recommended by the European Medicines Agency for European Union member countries where DepoCyt(e) is not considered to be an essential medicinal product. The increase in collaborative licensing and development revenue of \$2.1 million was primarily driven by the recognition of deferred milestone revenue in connection with the termination of the licensing agreement with Novo, which was offset by lower collaborative revenues with Novo. We recognized any unamortized deferred revenue related to milestones received from Novo through August 2012.

Total revenues increased by \$17.2 million, or 150%, to \$28.6 million in the nine months ended September 30, 2012, as

Table of Contents

compared to \$11.5 million in the nine months ended September 30, 2011. Collaborative licensing and development revenue increased \$12.7 million in the nine months ended September 30, 2012 primarily due to the recognition of deferred revenue in connection with the termination of the license agreement with EKR for the DepoDur product and deferred revenue associated with the termination of the license agreement with Novo, as discussed above. The increase in net product sales of \$5.1 million was driven by \$6.8 million of EXPAREL sales since the launch in April 2012, offset by a decrease of Depocyt(e) sales of \$1.8 million. Royalty revenue decreased by \$0.7 million in the nine months ended September 30, 2012 due to lower end user sales by our commercial partners resulting from the restriction on sales in Europe as discussed above.

Cost of Revenues

The following table provides information regarding our cost of revenues during the periods indicated (in thousands):

	Three Months Ended September 30,		% Increase/ Decrease	Nine Months Ended September 30,		% Increase/ Decrease
	2012	2011		2012	2011	
Cost of goods sold	\$ 9,287	\$ 3,059	204%	\$ 22,072	\$ 9,100	143%
Cost of collaborative licensing and development revenue		298	(100)%	395	1,038	(62)%
Total cost of revenues	\$ 9,287	\$ 3,357	177%	\$ 22,467	\$ 10,138	122%

Cost of revenues increased by \$5.9 million, or 177%, to \$9.3 million in the three months ended September 30, 2012, as compared to \$3.4 million in the three months ended September 30, 2011. Cost of goods sold increased by \$6.2 million primarily due to (i) the cost of goods for EXPAREL sales which we commercially launched in April 2012, (ii) approximately \$1.8 million of expense for the voluntary but non-routine shutdown period of the EXPAREL manufacturing site for repairs and maintenance and deployment of new manufacturing skids for our Suite C manufacturing expansion project, (iii) a \$0.6 million charge for the temporary shutdown of DepoCyt(e) manufacturing site, including inventory reserve, additional testing of current product and the cost of replacement product due to the action taken by the European Medicines Agency. We have a substantial level of infrastructure cost relating to running two cGMP facilities and any extended or non-routine shutdown results in these costs being charged directly to cost of goods sold.

Cost of revenues increased by \$12.4 million, or 122%, to \$22.5 million in the nine months ended September 30, 2012, as compared to \$10.1 million in the nine months ended September 30, 2011. The increase was primarily driven by (i) the cost of goods for EXPAREL sales which we launched in April 2012, (ii) \$1.3 million charge for corrective actions taken on the DepoCyt(e) manufacturing line based on the remediation plan, inventory replacement and reserve costs, (iii) EXPAREL production costs, which were expensed as incurred until March 2012 when the first commercial batch was produced and (iv) approximately \$1.8 million of expense for the extended shutdown of the EXPAREL manufacturing site. Cost of collaborative licensing and development revenue decreased by \$0.6 million due to decreased services performed under the Novo agreement for which we received a notice of termination in June 2012.

Research and Development Expense

The following table provides information regarding our research and development expenses during the periods indicated (in thousands):

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

	Three Months Ended September 30,		% Increase/ Decrease	Nine Months Ended September 30,		% Increase/ Decrease
	2012	2011		2012	2011	
Research and development expense	\$ 3,527	\$ 4,360	(19)%	\$ 6,693	\$ 12,742	(47)%

Research and development expenses decreased by \$0.9 million, or 19%, to \$3.5 million in the three months ended September 30, 2012, as compared to \$4.4 million in the three months ended September 30, 2011, due to the shift of EXPAREL production line expenses from research and development expenses to cost of revenues following the approval of EXPAREL by the FDA in October 2011. In the three months ended September 30, 2012, we spent \$2.4 million on clinical development primarily for the initiation of our Phase 2/3 pivotal trial of EXPAREL administered as a single-dose injection femoral nerve block for total knee arthroplasty surgery, in which the first patient was dosed in September 2012, and start-up costs for our Phase 3 pivotal trial of EXPAREL for intercostal nerve block for thoracotomy. We also incurred \$0.9 million on a potential new manufacturing process for EXPAREL which is in pre-clinical stage.

Research and development expenses decreased by \$6.0 million, or 47%, to \$6.7 million in the nine months ended September 30, 2012, as compared to \$12.7 million in the nine months ended September 30, 2011, due to the shift of EXPAREL production line expenses from research and development expenses to cost of revenues as discussed above. In the nine months ended September 30, 2012, we spent \$3.8 million on clinical development primarily for the dose ranging EXPAREL nerve block trial and two Phase 2/3

Table of Contents

pivotal trials of EXPAREL and \$2.2 million on pre-clinical studies for a new manufacturing process for EXPAREL.

Selling, General and Administrative Expense

The following table provides information regarding our selling, general and administrative expenses during the periods indicated (in thousands):

	Three Months Ended September 30,		% Increase/ Decrease	Nine Months Ended September 30,		% Increase/ Decrease
	2012	2011		2012	2011	
General and administrative	\$ 4,682	\$ 2,828	66%	\$ 11,542	\$ 7,361	57%
Sales and marketing	6,696	2,144	212%	21,401	5,599	282%
Total selling, general and administrative expense	\$ 11,378	\$ 4,972	129%	\$ 32,943	\$ 12,960	154%

Selling, general and administrative expenses increased by \$6.4 million, or 129%, to \$11.4 million in the three months ended September 30, 2012, as compared to \$5.0 million in the three months ended September 30, 2011 due to the following:

- sales and marketing expenses increased by \$4.6 million primarily due to a \$3.1 million increase in the cost of our sales force entirely dedicated to commercializing EXPAREL, which was comprised of approximately 60 hospital specialists, seven regional directors and a national sales director, a \$0.7 million increase in compensation and related expenses due to the expansion of our internal selling and marketing capabilities, and a \$0.6 million increase in promotional costs to support the launch of EXPAREL including simulcasts, speaker trainings, educational programs, publications, promotional materials and health outcomes collaboratives; and
- general and administrative expenses increased by \$1.9 million mainly due to increases of \$0.5 million in salaries and benefits associated with our increased headcount, \$0.5 million in consulting costs primarily to support our information technology infrastructure and recruiting efforts, along with a \$0.3 million increase in both facilities and legal costs.

Selling, general and administrative expenses increased by \$19.9 million, or 154%, to \$32.9 million in the nine months ended September 30, 2012, as compared to \$13.0 million in the nine months ended September 30, 2011, due to the following:

- sales and marketing expenses increased by \$15.8 million primarily due to a \$9.7 million increase in the cost of our sales force entirely dedicated to commercializing EXPAREL, a \$3.2 million increase in promotional costs to support the launch of EXPAREL, a \$ 1.9 million increase in compensation and related expenses due to the expansion of our internal selling and marketing capabilities, and a \$1.0 million increase related to our Phase IV IMPROVE health outcome studies in targeted surgeries, in which we have been enrolling patients since the second quarter of 2012; and

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

- general and administrative expenses increased by \$4.2 million mainly due to increases of \$1.2 million in salaries and benefits associated with higher headcount, \$1.5 million in consulting costs to support our information technology infrastructure and recruiting efforts, \$0.6 million increase in facilities related costs and \$0.3 million increase in legal costs.

Other Income (Expense)

The following table provides information regarding our other income (expense) during the periods indicated (in thousands):

	Three Months Ended September 30,		% Increase/ Decrease	Nine Months Ended September 30,		% Increase/ Decrease
	2012	2011		2012	2011	
Interest income	\$ 87	\$ 46	89%	\$ 218	\$ 111	96%
Interest expense	(456)	(910)	(50)%	(1,464)	(4,068)	(64)%
Loss on early extinguishment of debt			N/A	(1,062)		N/A
Royalty interest obligation	378	116	226%	(47)	235	(120)%
Other, net	(48)	(27)	78%	(111)	61	(282)%
Total other (expense), net	\$ (39)	\$ (775)	(95)%	\$ (2,466)	\$ (3,661)	(33)%

Total other (expense) income, net decreased by \$0.7 million, or 95%, to \$0.1 million in the three months ended September 30, 2012, as compared to \$0.8 million in the three months ended September 30, 2011, primarily due to a \$0.3 million decrease in royalty interest obligation expense due to a forecast reduction in end user Depocyt(e) sales relating to the restriction on sales in the European Union, and by a reduction in interest expense of \$0.4 million which was driven by an increase in capitalized interest related to our Suite C manufacturing expansion project for EXPAREL.

Table of Contents

Total other (expense) income, net decreased by \$1.2 million, or 33%, to \$2.5 million in the nine months ended September 30, 2012, as compared to \$3.7 million in the nine months ended September 30, 2011, primarily due to a \$2.6 million decrease in interest expense. The decrease in interest expense is due to the following:

- \$1.1 million decrease of warrant expense recognized during the first quarter of 2011 in connection with the conversion of these warrants upon our initial public offering;
- \$0.9 million increase in capitalized interest related to our Suite C manufacturing expansion project;
- \$0.4 million decrease in interest expense associated with our 2009 and 2010 convertible and secured debt facilities which were converted to common shares in connection with our initial public offering in the first quarter of 2011.

The preceding decreases in interest expense were offset by a \$1.1 million loss on the extinguishment of our Hercules Credit Facility. There was a \$0.3 million increase in royalty interest obligation expense due to a forecast reduction in end user Depocyt(e) sales that took place in the second quarter of 2011.

Liquidity and Capital Resources

Since our inception in 2007, we have devoted most of our cash resources to manufacturing, research and development and selling, general and administrative activities primarily related to the development of EXPAREL. We have financed our operations primarily with the proceeds from the sale of convertible preferred stock and common stock, secured and unsecured notes and borrowings under debt facilities, product sales, collaborative licensing and development revenue and royalty revenue. We raised approximately \$37.1 million in net proceeds through an initial public offering completed on February 8, 2011 and approximately \$49.0 million in net proceeds through a follow-on offering completed on November 21, 2011. In April 2012, we 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. We raised approximately \$62.9 million in net proceeds after deducting underwriting discounts and offering expenses.

We have generated limited revenue, and we are highly dependent on the commercial success of EXPAREL, which we launched in April 2012. We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2012, we had an accumulated deficit of \$216.2 million, cash and cash equivalents, restricted cash and short-term investments of \$68.7 million and working capital of \$65.3 million.

Summary of Cash Flows

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

The following table summarizes our cash flows from operating, investing and financing activities for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2012	2011
Net cash provided by (used in):		
Operating activities	\$ (48,951)	\$ (23,404)
Investing activities	(51,881)	(24,355)
Financing activities	63,373	38,028
Net decrease in cash and cash equivalents	\$ (37,459)	\$ (9,731)

Operating Activities

During the nine months ended September 30, 2012 and 2011, our net cash used in operating activities was \$49.0 million and \$23.4 million, respectively. The \$25.6 million increase in net cash used in operating activities was driven by higher operating expenses of (i) selling, marketing and administrative expenses driven by the launch of EXPAREL in April 2012 including the hiring of our sales force dedicated to EXPAREL, (ii) increased manufacturing costs and an increase in inventory in connection with our commercial launch of EXPAREL, (iii) initiation of our Phase 2/3 EXPAREL nerve block trial in total knee arthroplasty and start-up costs for our Phase 3 nerve block trial in thoracotomy and (iv) a \$1.5 million up-front payment received in January 2011 from Novo.

Table of Contents

Investing Activities

During the nine months ended September 30, 2012 and 2011, our net cash used in investing activities was \$51.9 million and \$24.4 million, respectively. The \$27.5 million increase in cash used in investing activities was primarily due to a \$10.0 million contingent milestone payment made in April 2012 to Skyepharma in connection with the first commercial sale of EXPAREL, a \$9.8 million increase in the purchase of fixed assets relating to the construction of our Suite C manufacturing line for EXPAREL, which we re-commenced following approval from the United States Food and Drug Administration in October 2011, and a \$7.5 million increase in the purchase of short-term investments from the proceeds of our secondary offering in 2012

Financing Activities

During the nine months ended September 30, 2012 and 2011, net cash provided by financing activities was \$63.4 million and \$38.0 million, respectively. In April 2012, we raised \$62.9 million in net proceeds through a secondary offering of 6,900,000 shares of common stock. Additionally, in May 2012, we borrowed a principal amount of \$27.5 million from Oxford Finance LLC and used the funds to repay the remaining principal on the Hercules Credit Facility of \$24.2 million, early prepayment penalty of \$0.3 million and the end of term fee of \$0.6 million. In 2011, we raised approximately \$37.1 million in net proceeds from our initial public offering, after deducting \$4.9 million in offering expenses of which \$0.9 million was paid prior to December 31, 2010.

Debt Facilities

On May 2, 2012, we entered into a definitive loan and security agreement, or Loan Agreement, with Oxford Finance LLC, who we refer to as the Lender, and borrowed the principal amount of \$27.5 million, at a fixed rate of 9.75%, with the first principal payment due December 1, 2013. Payments under the Loan Agreement are interest-only in arrears through November 30, 2013, followed by 30 equal monthly payments of principal and interest. In addition, a final payment equal to 6% of the Loan Facility will be due on the final payment date, or such earlier date as specified in the Loan Agreement. The proceeds from the Loan Agreement were used by us to repay all of our outstanding obligations with respect to the Hercules Credit Facility.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We have also agreed not to pledge or otherwise encumber our intellectual property assets, except for permitted liens or to the extent the intellectual property constitutes royalty collateral, as such terms are defined in the Loan Agreement and except as otherwise provided in the Loan Agreement.

If we repay all or a portion of the Loan Facility prior to maturity, we will pay the Lender a prepayment fee based on a percentage of the then outstanding principal balance equal to: 3.00% if the prepayment occurs prior to or on the first anniversary of the funding date, 2.00% if the prepayment occurs after the first anniversary of the funding date but prior to or on the second anniversary of the funding date, or 1.00% if the prepayment occurs after the second anniversary of the funding date.

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

The Loan Agreement includes customary affirmative and restrictive covenants for transactions of this type and customary events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, the occurrence of certain events under our royalty agreements, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, a material adverse change in the business, operations or condition of us or any of our subsidiaries and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% may be applied to the outstanding loan balance and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

As of September 30, 2012, we had \$27.5 million in outstanding principal debt under the Oxford Loan Facility. As of September 30, 2012, we were in compliance with all covenants under the facility.

Future Capital Requirements

As of September 30, 2012, we had cash and cash equivalents, restricted cash and short-term investments of \$68.7 million. We believe that our existing cash and cash equivalents, restricted cash, short-term investments and revenue from product sales will be sufficient to enable us to meet our planned operating expenses, capital expenditure requirements and service our indebtedness through September 30, 2013. However, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we make in the future. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. We may need to raise substantial additional capital in order to engage in any of these types of transactions.

Table of Contents

We expect to continue to incur substantial additional operating losses as we commercialize EXPAREL and develop and seek regulatory approval for our product candidates. We will continue to incur significant sales and marketing and manufacturing expenses due to the commercialization of EXPAREL. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements to us as a public company.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the level and timing of our sales of EXPAREL;
- the costs of our commercialization activities for EXPAREL;
- the cost and timing of expanding our manufacturing facilities and purchasing manufacturing and other capital equipment for EXPAREL and our other product candidates;
- the costs of performing additional clinical trials for EXPAREL, including the pediatric trials required by the FDA as a condition of approval and the two Phase 2/3 nerve block trials;
- the scope, progress, results and costs of development for additional indications for EXPAREL and for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our product candidates; and
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. The covenants under the Oxford Loan Facility and the Amended and Restated Royalty Interests Assignment Agreement between us with Royalty Securitization Trust I, an affiliate of Paul Capital Advisors, LLC, and the pledge of our assets as collateral limit our ability to obtain additional debt financing. We have no committed external sources of funds. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any additional debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, except for operating leases, or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities. None of our off-balance sheet arrangements have, or are reasonably likely to have, a current or future material effect on our financial condition or changes in financial condition.

Critical Accounting Policies and Estimates

We sell EXPAREL to wholesalers based on orders of the product from hospitals and other end user customers such as ambulatory surgery centers and doctors. We recognize 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 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. We record revenue at the time the product is delivered to the end user.

At the time we recognize revenue, we also record 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 our sales reserves, the actual amount of volume rebates, chargebacks and returns may be different from our estimates, at which time we would adjust our reserves accordingly.

Table of Contents

Prompt pay reserve

The prompt payment reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. We account for these discounts at the time the sale is made and reduce accounts receivable accordingly.

Returns reserve

We allow customers to return product that is damaged or received in error. In addition, we allow for product to be returned beginning six months prior to, and twelve months following product expiration. As EXPAREL is a new commercially available product, we are estimating our sales return reserve based on return history from other hospital based products with similar distribution models, which we believe is the best estimate of the anticipated product to be returned. The returns reserve is recorded at the time of sale and 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 we provide to certain end users 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

Our customers include major and regional wholesalers with whom we have 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

We evaluate accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. Our sales are mostly to established customers. As of September 30, 2012, the accounts receivable was considered collectible and no allowance for doubtful accounts was recorded.

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

For a description of any other critical accounting policies that affect our other significant judgments and estimates used in the preparation of our consolidated financial statements, refer to our most recent Annual Report on Form 10-K for the year ended December 31, 2011. There have been no other significant changes to our critical accounting policies since December 31, 2011.

Table of Contents

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission (SEC) rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on their evaluation with the participation of the Company's management, as of the end of the period covered by this Quarterly Report on Form 10-Q, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

No change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2012, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(c) Inherent Limitations on Effectiveness of Controls

Our management, including our President and Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Pacira have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Table of Contents

PART II OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results, financial condition or cash flows.

Item 1A. RISK FACTORS

In addition to the risks identified below and the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A: Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2011, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2011, are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results. Other than the risk factors set forth below, there have been no material changes in the risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2011.

The Medicines and Healthcare products Administration recently issued an inspection report noting certain critical deficiencies in our manufacturing of DepoCyt(e) and remediation of these deficiencies could result in significant costs or delays in the production and sale of DepoCyt(e).

In July 2012, the Medicines and Healthcare products Administration, or MHRA, conducted its standard inspection of our DepoCyt(e) manufacturing facility, which is located in a separate building from our EXPAREL manufacturing facility. Following its inspection, the MHRA issued its inspection report in which the MHRA noted certain critical and major failures to comply with the Principles and Guidelines of Good Manufacturing Practices. We temporarily ceased manufacturing DepoCyt(e) in order to implement a remediation plan and address the failures noted in the MHRA inspection report. In connection with the inspection report, the European Medicines Agency issued an assessment report which recommended the use of alternative treatments in countries where DepoCyt(e) is not deemed to be an essential medical product. The assessment report recommended a selective recall of DepoCyt(e) in European Union member countries where DepoCyt(e) is not considered to be an essential medicinal product. The assessment report did not recommend a recall for member countries where DepoCyt(e) is considered to have essential medicinal product status. European Union member countries give essential medicinal product status to a product if there are no alternative products/therapies in such countries and each country made a determination of whether DepoCyt(e) was an essential medicinal product on a country by country basis. The extent of the recall's impact on our sales of Depocyt(e) is difficult to predict because a number of countries that determined Depocyt(e) was not an essential medicinal product also determined that it could still be used in exceptional circumstances or upon special request. The recall contributed to a reduction in product sales of Depocyt(e) for the three and nine month ended September 30, 2012, respectively. We expect our sales of Depocyt(e) in the European Union to continue to decrease until we restart our manufacturing operations.

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

We expect our remediation plan to be completed and to be inspected by the MHRA again during the fourth quarter of our fiscal year. Our ability to recommence manufacturing of DepoCyt(e) depends on the outcome of this inspection. While we will conduct additional training to address the MHRA inspection findings, we may be required to take steps to address the MHRA inspection findings that are in addition to the remediation plan we have completed. This could result in additional costs or delays in the production and sale of DepoCyt(e), which could have a material adverse effect on our business, financial position and results of operations.

EXPAREL and any other products we may market, including DepoCyt(e), will remain subject to substantial regulatory scrutiny.

EXPAREL, DepoCyt(e) and any product candidates that we may develop, license or acquire will also be subject to ongoing FDA requirements with respect to the manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping, post-market testing, and submission of safety and other post-market information on the drug. In addition, the subsequent discovery of previously unknown problems with a product, including undesirable side effects, may result in restrictions on the product, including withdrawal of the product from the market.

If EXPAREL, DepoCyt(e) or any other product that we may develop, license or acquire fails to comply with applicable regulatory requirements, such as cGMP regulations, a regulatory agency may:

- issue warning letters or untitled letters;

Table of Contents

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose fines and other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

For example, in July 2012, the MHRA issued its inspection report in which the MHRA noted certain critical and major failures to comply with the Principles and Guidelines of Good Manufacturing Practices related to our Depocyt(e) manufacturing facility. We have responded to the MHRA regarding the inspectional observations, however the MHRA may require us to take additional steps to address the MHRA inspection findings, which could result in additional costs or delays in the production and sale of DepoCyt(e), which could have a material adverse effect on our business, financial position and results of operations.

The design, development, manufacture, supply, and distribution of EXPAREL and DepoCyt(e) is highly regulated and technically complex.

The design, development, manufacture, supply, and distribution of our products EXPAREL and DepoCyt(e) is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. In addition, the facilities used to manufacture, store, and distribute our products are subject to inspection by regulatory authorities at any time to determine compliance with applicable regulations.

The manufacturing techniques and facilities used for the manufacture and supply of our products must be operated in conformity with cGMP and other FDA, DEA and MHRA regulations. In addition, any expansion of our existing manufacturing facilities or the introduction of any new manufacturing facilities would also require conformity with cGMP and other FDA, DEA and MHRA regulations. In complying with these requirements, we, along with our suppliers, must continually expend time, money and effort in production, record keeping, and quality assurance and control to ensure that our products meet applicable specifications and other requirements for safety, efficacy and quality. In addition, we, along with our suppliers, are subject to unannounced inspections by the FDA, MHRA and other regulatory authorities.

Any failure to comply with regulatory and other legal requirements applicable to the manufacture, supply and distribution of our products could lead to remedial action (such as recalls), civil and criminal penalties and delays in manufacture, supply and distribution of our products. For instance, in July 2012, the MHRA issued its inspection report in which the MHRA noted certain critical and major failures to comply with the Principles and Guidelines of Good Manufacturing Practices related to our Depocyt(e) manufacturing facility. We have responded to the MHRA regarding the inspectional observations and expect to complete our proposed remediation plan in the fourth quarter of 2012, however the MHRA

may require us to take additional steps to address the MHRA inspection findings, which could result in additional costs or delays in the production and sale of DepoCyt(e), which could have a material adverse effect on our business, financial position and results of operations.

If we fail to manufacture EXPAREL in sufficient quantities and at acceptable quality and pricing levels, or to fully comply with cGMP regulations, we may face delays in the commercialization of this product or be unable to meet market demand, and may lose potential revenues.

The manufacture of EXPAREL requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We must comply with federal, state and foreign regulations, including FDA's regulations governing current Good Manufacturing Practices, or cGMP, enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory authorities at any time may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

In addition, we purchase raw materials and components from various suppliers in order to manufacture EXPAREL. If we are unable to source the required raw materials from our suppliers, we may experience delays in manufacturing EXPAREL and may not be able to meet our customers' demands for EXPAREL.

Table of Contents

If we are unable to produce the required commercial quantities of EXPAREL to meet market demand for EXPAREL on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of EXPAREL, we will suffer damage to our reputation and commercial prospects and we will lose potential revenues.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payers for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under federally funded healthcare programs, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims and false statement laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent or making any materially false statement in connection with the delivery or payment for healthcare benefits, items, or services;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, which created federal criminal and civil statutes that prohibit executing a scheme to defraud any healthcare benefit program;
- federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations.

Further, there has been a recent trend in the increase of federal and state laws and regulations regarding consulting arrangements with physicians. Some states, such as California, Massachusetts and Vermont, mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to physicians, and/or report compliance information to the state authorities. Some states, such as Massachusetts, have created an internet database to provide disclosed information on certain transactions with physicians to the public. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increases the possibility that a pharmaceutical company may run afoul of one or more of the requirements.

If our past or present operations, or those of our distributors are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Similarly, if the healthcare providers, distributors or other entities with whom we do business are found to be out of compliance with applicable laws and regulations, they may be subject to sanctions, which could also have a negative impact on us. The risk of being

Table of Contents

found to have violated such laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

We are subject to new legislation, regulatory proposals and healthcare payer initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Health Care Reform Law. The Health Care Reform Law makes extensive changes to the delivery of health care in the United States. Among the provisions of the Health Care Reform Law of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;
- new requirements to report certain financial arrangements with physicians and others, including reporting any transfer of value made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013, subject to federal implementation and enforcement policies;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012, subject to federal implementation and enforcement policies;

Edgar Filing: Pacira Pharmaceuticals, Inc. - Form 10-Q

- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending, beginning by January 1, 2011.

These measures could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. Congress has also proposed a number of legislative initiatives, including possible repeal of the Health Care Reform Law. At this time, it remains unclear whether there will be any changes made to the Health Care Reform Law, whether to certain provisions or its entirety. In addition, some details regarding the implementation of the Health Care Reform Law are yet to be determined, and at this time, the full effect that the Health Care Reform Law would have on our business remains unclear.

Table of Contents

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee may consider all elements of discretionary and non-discretionary spending, and its recommendations could result in reduced spending under Medicare and Medicaid for prescription drugs. In the event that the Joint Select Committee is unable to achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, or Congress does not act on the committee's recommendation, without amendment, by December 23, 2011, an automatic reduction is triggered. These automatic cuts would be made to several government programs and, with respect to Medicare, would include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. The full impact on our business of the new law is uncertain. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would affect the demand for our products.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Most recently, the President signed into law the Food and Drug Administration Safety and Innovation Act, or FDASIA. The new law and related agreements make several significant changes to the Federal Food, Drug, and Cosmetic Act and FDA's processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

- Reauthorizes the Prescription Drug User Fee Act, or PDUFA, increases the amount of associated user fees, and, for certain types of applications, increases the agreed-upon time frame for FDA review of the application;
- Permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provides for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;
- Revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;
- Creates incentives for the development of certain antibiotic drug products;
- Modifies the standards for accelerated approval of certain new medical treatments;
- Expands the reporting requirements for potential and actual drug shortages;
- Requires FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;
- Requires FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone; and
- Requires electronic submission of certain marketing applications following the issuance of final FDA regulations

The full impact on our business of the new law is uncertain.

We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are an emerging specialty pharmaceutical company with a limited operating history. We have focused primarily on developing and commercializing EXPAREL. We have incurred losses in each year since our inception in December 2006, including net losses of \$43.3 million, \$27.1 million and \$31.7 million, for the years ended December 31, 2011, 2010, and 2009, respectively. As of September 30, 2012, we had an accumulated deficit of \$216.2 million. These losses, among other things, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We incurred increased pre-commercialization expenses during 2010 and 2011 as we prepared for the potential commercial launch of EXPAREL, and we expect to incur significant sales, marketing and manufacturing expenses, as well as continued development expenses related to the commercialization of EXPAREL. As a result, we expect to continue to incur significant losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

The market price of our common stock is highly volatile.

Our stock price is volatile, and from February 3, 2011, the first day of trading of our common stock, to September 30, 2012,

Table of Contents

the trading prices of our stock have ranged from \$6.16 to \$19.31 per share. Our stock could be subject to wide fluctuations in price in response to various factors, including the following:

- the commercial success of EXPAREL;
- results of clinical trials of our product candidates or those of our competitors;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general economic and market conditions and overall fluctuations in U.S. equity markets;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- additions or departures of key scientific or management personnel;
- issuances of debt, equity or convertible securities;
- changes in the market valuations of similar companies; and
- the other factors described in this Risk Factors section.

In addition, the stock market in general, and the market for small pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and 5% stockholders and their affiliates beneficially own approximately 46% of our outstanding voting stock. As a result, these stockholders have significant influence and may be able to determine matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms

that other stockholders may desire.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

There were no issuances of unregistered shares of capital stock during the three month period ended September 30, 2012 covered by this report.

Use of Proceeds

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Table of Contents

Item 6. EXHIBITS

The exhibits listed in the Exhibit Index are incorporated herein by reference.

EXHIBIT INDEX

- 10.1 Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace*
- 31.1 Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as amended.*
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as amended.*
- 32.1 Certification of Executive Chairman of the Board pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
- 101 The following materials from the Quarterly Report on Form 10-Q of Pacira Pharmaceuticals, Inc. for the quarter ended September 30, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statement of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) the Condensed Notes to Consolidated Financial Statements, tagged as blocks of text
- 101.INS XBRL Instance Document.**
- 101.SCH XBRL Taxonomy Extension Schema Document. *
- 101.CAL XBRL Taxonomy Calculation Linkbase Document. *
- 101.LAB XBRL Taxonomy Label Linkbase Document. *
- 101.PRE XBRL Taxonomy Presentation Linkbase Document.*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document.*

* Filed herewith

** Furnished herewith

*** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

Table of Contents

SIGNATURES

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.

PACIRA PHARMACEUTICALS, INC.
(REGISTRANT)

Dated: November 1, 2012

/s/ DAVID STACK
David Stack
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 1, 2012

/s/ JAMES SCIBETTA
James Scibetta
Chief Financial Officer
(Principal Financial Officer)

Dated: November 1, 2012

/s/ LAUREN RIKER
Lauren Riker
Executive Director, Accounting & Reporting
(Principal Accounting Officer)