

Pacira Pharmaceuticals, Inc.  
Form 10-Q  
October 31, 2011  
[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, 2011**

**Commission File Number: 001-35060**

---

**PACIRA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in its Charter)

---

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

(State or Other Jurisdiction of  
Incorporation or Organization)

(I.R.S. Employer  
Identification No.)

**5 Sylvan Way, Suite 125**

**Parsippany, New Jersey 07054**

**(973) 254-3560**

(Address of Principal Executive Offices, Including Zip Code)

(Registrant's Telephone Number, Including Area Code)

---

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

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

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

Large accelerated filer o

Accelerated filer o

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

Smaller reporting company o

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

As of October 24, 2011, 17,228,827 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

Table of Contents

**PACIRA PHARMACEUTICALS, INC.**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	3
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations</u>	4
<u>Consolidated Statement of Stockholders' Equity (Deficit)</u>	5
<u>Consolidated Statements of Cash Flows</u>	6
<u>Condensed Notes to Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4. Controls and Procedures</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	26
<u>Item 1A. Risk Factors</u>	26
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	50
<u>Item 3. Defaults upon Senior Securities</u>	50
<u>Item 4. [Removed and Reserved]</u>	50
<u>Item 5. Other Information</u>	51
<u>Item 6. Exhibits</u>	52
<u>Signatures</u>	53

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)**

	<b>September 30, 2011</b>	<b>December 31, 2010 (Note 2)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,402	\$ 26,133
Restricted cash	1,687	1,314
Short-term investments	20,666	
Trade accounts receivable	1,496	1,191
Inventories	1,667	1,605
Prepaid expenses and other current assets	1,482	812
Total current assets	43,400	31,055
Fixed assets, net	25,825	23,950
Intangibles, net	7,204	8,912
Other assets, net	1,180	2,645
Total assets	\$ 77,609	\$ 66,562
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 4,313	\$ 5,775
Accrued expenses	4,998	3,523
Current portion of royalty interest obligation	1,293	1,575
Current portion of deferred revenue	2,354	2,267
Current portion of long-term debt	4,871	3,182
Total current liabilities	17,829	16,322
Related party debt, including accrued interest		49,795
Long-term debt	20,603	21,869
Royalty interest obligation	1,842	2,996
Deferred revenue	17,847	18,138
Contingent purchase liability	2,042	2,042
Other liabilities	3,571	3,783
Total liabilities	63,734	114,945
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001; 5,000,000 shares authorized, none issued and outstanding at September 30, 2011; 88,000,000 shares authorized, 6,322,640 shares issued and outstanding at December 31, 2010 (liquidation preference \$85,000,000)		6
	17	1

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

Common stock, par value \$0.001; 250,000,000 shares authorized, 17,229,892 shares issued and 17,228,827 shares outstanding at September 30, 2011; 120,000,000 authorized, 575,095 shares issued and 574,030 shares outstanding at December 31, 2010

Additional paid-in capital	178,821	88,523
Accumulated deficit	(164,956)	(136,911)
Accumulated other comprehensive loss	(5)	
Treasury stock at cost, 1,065 shares at September 30, 2011 and December 31, 2010	(2)	(2)
Total stockholders' equity (deficit)	13,875	(48,383)
Total liabilities and stockholders' equity (deficit)	\$ 77,609	\$ 66,562

*See accompanying 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,	
	2011	2010	2011	2010
Revenues:				
Supply revenue	\$ 1,682	\$ 2,744	\$ 4,868	\$ 7,127
Royalties	922	1,023	2,743	2,693
Collaborative licensing and development revenue	1,352	765	3,845	2,551
Total revenues	3,956	4,532	11,456	12,371
Operating expenses:				
Cost of revenues	3,357	3,573	10,138	10,168
Research and development	4,344	5,716	12,237	14,954
Selling, general and administrative	4,988	1,694	13,465	3,948
Total operating expenses	12,689	10,983	35,840	29,070
Loss from operations	(8,733)	(6,451)	(24,384)	(16,699)
Other (expense) income:				
Interest income	46	39	111	112
Interest expense	(910)	(1,077)	(4,068)	(2,577)
Royalty interest obligation	116	(444)	235	(1,048)
Other, net	(27)	33	61	107
Total other (expense), net	(775)	(1,449)	(3,661)	(3,406)
Net loss	\$ (9,508)	\$ (7,900)	\$ (28,045)	\$ (20,105)
Net loss per share:				
Basic and diluted net loss per common share	\$ (0.55)	\$ (13.77)	\$ (1.89)	\$ (35.02)
Weighted average common shares outstanding:				
Basic and diluted	17,230,826	573,521	14,826,054	574,112

*See accompanying notes to consolidated financial statements.*

[Table of Contents](#)
**PACIRA PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)**
**For the nine months ended September 30, 2011**
**(Unaudited)**
**(In thousands)**

	Preferred Stock		Common Stock		Additional	Accumulated	Treasury	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	Stock	Other Comprehensive Loss	
<b>Balances at December 31, 2010</b>	6,322	\$ 6	575	\$ 1	\$ 88,523	\$ (136,911)	\$ (2)		\$ (48,383)
Exercise of stock options			7		12				12
Share-based compensation					1,965				1,965
Initial public offering, net of issuance costs			6,000	6	37,103				37,109
Conversion of preferred stock	(6,322)	(6)	6,322	6					
Conversion of 2009 Convertible Notes			872	1	11,717				11,718
Conversion of 2009 Secured Notes			928	1	12,473				12,474
Conversion of 2010 Secured Notes			1,157	1	15,548				15,549
Conversion of 2010 Convertible Notes			1,071	1	7,499				7,500
Conversion of HBM Secured Notes			297		3,981				3,981
Unrealized loss on short-term investments								(5)	(5)
Net loss						(28,045)			(28,045)
<b>Balances at September 30, 2011</b>		\$ 17,229	\$ 17	\$ 178,821	\$ (164,956)	\$ (2)	\$ (5)		13,875

*See accompanying notes to consolidated financial statements.*

Table of Contents

**PACIRA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2011	2010
<b>Operating activities:</b>		
Net loss	\$ (28,045)	\$ (20,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,030	3,066
Amortization of deferred financing costs and unfavorable lease obligation	(29)	(58)
Amortization of note discounts and warrants	1,540	94
Loss on disposal of fixed assets	3	
Share-based compensation	1,965	17
Change in royalty interest obligation	(1,435)	(191)
Changes in operating assets and liabilities:		
Restricted cash	(373)	(863)
Trade accounts receivable	(305)	(1,076)
Inventories	(62)	679
Prepaid expenses and other assets	(908)	13
Accounts payable	(778)	262
Other liabilities	2,197	909
Deferred revenue	(204)	(1,788)
Net cash used in operating activities	(23,404)	(19,041)
<b>Investing activities:</b>		
Purchase of fixed assets	(3,684)	(3,821)
Purchase of short-term investments	(20,671)	
Net cash used in investing activities	(24,355)	(3,821)
<b>Financing activities:</b>		
Proceeds from exercise of stock options	12	1
Purchase of treasury stock		(2)
Proceeds from initial public offering, net	38,016	
Proceeds from secured promissory notes		18,750
Proceeds from credit facility		11,250
Financing costs		(363)
Net cash provided by financing activities	38,028	29,636
Net (decrease) increase in cash and cash equivalents	(9,731)	6,774
Cash and cash equivalents, beginning of period	26,133	7,077
Cash and cash equivalents, end of period	\$ 16,402	\$ 13,851
<b>Supplemental cash flow information</b>		
Cash paid for interest, including royalty interest obligation	\$ 3,573	\$ 1,787
Initial public offering costs paid in 2010	907	
<b>Non cash investing and financing activities:</b>		
Conversion of notes to common stock	\$ 51,222	\$
Conversion of preferred stock to common stock	6	



*See accompanying 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 FDA on October 28, 2011. DepoFoam is also the basis for the Company's other two FDA-approved commercial products, DepoCyt(e) and DepoDur, which the Company manufactures for its commercial partners.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has reported for the nine months ended September 30, 2011 net losses of \$28.0 million and cash flows used in operating activities of \$23.4 million. As of September 30, 2011, the Company had stockholders' equity of \$13.9 million. The Company has incurred losses and negative operating cash flow since inception and future losses are anticipated. The Company's continued operations will depend on its ability to raise additional funds through sources such as equity and debt financing and revenues from the commercial sale of EXPAREL. Insufficient funds could require the Company to delay, scale back or eliminate one or more of its research and development programs. The ability of the Company to continue as a going concern is dependent on improving the Company's profitability and cash flow and securing additional financing. While the Company believes in the viability of its strategy to raise additional funds, and believes that the actions presently being taken by the Company provide the opportunity for it to continue as a going concern, there can be no assurance that any financing will be available on acceptable terms, or at all. These consolidated financial statements do not include any adjustments related to the recoverability and classification of asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

**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 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, 2010, filed with the SEC on March 31, 2011.

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

The consolidated financial statements at September 30, 2011 and for the three and nine months ended September 30, 2011 and 2010, are unaudited, but includes 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, 2010 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. 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. As further described in Note 8, the Company raised \$42.0 million of gross proceeds, and approximately \$37.1 million in net proceeds after deducting underwriting discounts and commissions and offering expense

Table of Contents

through an initial public offering completed on February 8, 2011.

***Recently Issued Accounting Guidance***

In September 2011, the Financial Accounting Standards Board, or FASB, released Accounting Standards Update, or ASU, No. 2011-08, Intangibles-Goodwill and Other. The amended guidance will allow companies to assess qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment test required under current accounting standards. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 (January 1, 2012 for the Company). The Company has determined that this guidance will not have a material impact on its consolidated financial statements.

In June 2011, the FASB issued ASU, No. 2011-05, Presentation of Comprehensive Income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements; the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity was eliminated. ASU No. 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 (January 1, 2012 for the Company) and interim and annual periods thereafter. Early adoption is permitted, and full retrospective application is required. Since this ASU pertains to presentation requirements only, the adoption of this ASU will not have a material impact on the Company's consolidated financial statements.

***Changes in Capital Structure***

On January 12, 2011, the Company effected a one-for-10.755 reverse stock split of the Company's outstanding common stock. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment for such fractional shares in lieu of receiving fractional shares. The reverse stock split affected all holders of the Company's preferred stock and common stock uniformly. All references to common stock and per share information, except par value, in the accompanying consolidated financial statements and notes thereto have been adjusted retrospectively to reflect the effect of the reverse stock split.

On February 8, 2011, the Company completed an initial public offering of common stock, as further described in Note 8. Upon the closing of the initial public offering, all outstanding shares of Series A convertible preferred stock and the principal and accrued interest balance on the 2009 Convertible Notes, 2009 Secured Notes, 2010 Secured Notes, 2010 Convertible Notes, and HBM Secured Notes were converted into 10,647,549 shares of common stock. On February 8, 2011, the Company filed an Amended and Restated Certificate of Incorporation (Amended Certificate of Incorporation), whereby the Company (i) increased its authorized common stock from 120,000,000 shares (\$0.001 par value) to 250,000,000 shares (\$0.001 par value), (ii) authorized 5,000,000 shares (\$0.001 par value) of preferred stock, and (iii) eliminated the previously existing series of preferred stock.

***Concentration of Major Customers***

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

The Company's customers are its commercial, distribution and licensing partners. For the three months ended September 30, 2011, the Company's three largest customers accounted for 47%, 21% and 17%, respectively, of the Company's revenues. For the three months ended September 30, 2010, the Company's three largest customers accounted for 59%, 16% and 10%, respectively, of the Company's revenues.

For the nine months ended September 30, 2011, the Company's three largest customers accounted for 45%, 20% and 19%, respectively, of the Company's revenues. For the nine months ended September 30, 2010, the Company's four largest customers accounted for 52%, 21%, 11% and 10% individually, of the Company's revenues. No other individual customer accounted for more than 10% of the Company's revenues for these periods. The Company is dependent on its commercial partners to market and sell DepoCyt(e) and DepoDur, from which a substantial portion of its revenues is derived. Therefore, the Company's future revenues from these products are highly dependent on commercial and distribution arrangements.

Table of Contents

*Per Share Data*

Net loss per share was determined in accordance with the two-class method. This method is used for computing basic net loss per share when companies have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the Company. Under the two-class method, net loss is allocated between common shares and other participating securities based on their participation rights in both distributed and undistributed earnings. The Company's Series A convertible preferred stock was a participating security, because the stockholders of the Series A Convertible preferred stock were entitled to share in dividends declared by the board of directors with the common stock based on their equivalent common shares.

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. Because the holders of the Series A Convertible Preferred Stock were not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per common share no allocation to preferred stock was made.

Diluted net loss per share is calculated by dividing net loss available to common stockholders as adjusted for the effect of dilutive securities, if any, 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) and the conversion of the shares of Series A convertible preferred stock (using the more dilutive of the (a) as converted method or (b) the two-class 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. Potentially dilutive securities that would be issued upon the conversion of convertible notes, conversion of Series A convertible preferred stock and the exercise of outstanding warrants and stock options, were 1.3 million and 7.2 million for the three months ended September 30, 2011 and 2010, respectively. Potentially dilutive securities that would be issued upon the conversion of convertible notes, conversion of Series A convertible preferred stock and the exercise of outstanding warrants and stock options, were 1.4 million and 7.2 million for the nine months ended September 30, 2011 and 2010, respectively.

**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 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.

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

- 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, notes receivable, and accounts payable approximate their respective fair values due to the short-term maturities of these instruments and debts. The carrying value of the long-term debt approximates its fair value since the interest rate approximates current market rates for similar instruments.

Short-term investments consist of investment grade commercial paper 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 loss. At September 30, 2011, all of the Company's short-term investments are classified as available for sale investments and determined to be Level 2 instruments, which are measured at fair value using standard industry models with observable inputs. At September 30, 2011, we had \$20.7 million invested in short-term investments which were rated A or better by Standard & Poor's and had maturities ranging from 134 to

# Table of Contents

173 days from date of purchase. The following summarizes the Company's short-term investments at September 30, 2011 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Debt securities:				
Commercial Paper	\$ 13,497	\$ 3	\$	\$ 13,500
Corporate Bonds	7,174		(8)	7,166
Total	\$ 20,671	\$ 3	\$ (8)	\$ 20,666

## 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, 2011, three customers accounted for 70%, 19% and 10%, respectively, of the Company's trade accounts receivable. As of December 31, 2010, three customers accounted for 66%, 17% and 11%, respectively, of the Company's trade accounts receivable.

## Note 4 INVENTORIES

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

	September 30, 2011	December 31, 2010
Raw materials	\$ 822	\$ 1,108
Work-in-process	439	10
Finished goods	406	487
Total	\$ 1,667	\$ 1,605

## Note 5 FIXED ASSETS

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

September 30, December 31,



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

	2011	2010
Machinery and laboratory equipment	\$ 7,349	\$ 7,002
Computer equipment and software	848	765
Office furniture and equipment	157	167
Leasehold improvements	4,332	3,938
Construction in progress	20,489	18,144
Total	33,175	30,016
Less accumulated depreciation	(7,350)	(6,066)
Fixed assets, net	\$ 25,825	\$ 23,950

Depreciation expense was \$0.5 million for each of the three months ended September 30, 2011 and 2010. Depreciation expense was \$1.3 million and \$1.4 million for the nine months ended September 30, 2011 and 2010 respectively.

Table of Contents**Note 6 INTANGIBLE ASSETS**

Intangible assets are summarized as follows (in thousands):

	September 30, 2011	December 31, 2010	Estimated Useful Life
<b>Core Technology</b>			
Gross amount	\$ 2,900	\$ 2,900	9 years
Accumulated amortization	(1,450)	(1,208)	
Net	1,450	1,692	
<b>Developed Technology</b>			
Gross amount	11,700	11,700	7 years
Accumulated amortization	(7,521)	(6,268)	
Net	4,179	5,432	
<b>Trademarks and trade names</b>			
Gross amount	500	500	7 years
Accumulated amortization	(310)	(253)	
Net	190	247	
<b>DepoDur Rights</b>			
Gross amount	2,058	2,058	Remaining patent life ending November 2018
Accumulated amortization	(673)	(517)	
Net	1,385	1,541	
<b>Intangible assets, net</b>	<b>\$ 7,204</b>	<b>\$ 8,912</b>	

Amortization expense for intangibles was \$0.6 million for each of the three months ended September 30, 2011 and 2010. Amortization expense for intangibles was \$1.7 million for each of the nine months ended September 30, 2011 and 2010. Amortization expenses associated with the Company's commercial products and developed technology are included in cost of revenues. Amortization expenses associated with the Company's products in development are included in research and development expenses.

The approximate amortization expense for intangibles, all of which are subject to amortization, is as follows (in thousands):

	Core Technology	Developed Technology	Trademarks and Tradenames	DepoDur Rights	Total
2011 (remaining three months)	\$ 81	\$ 418	\$ 18	\$ 49	\$ 566
2012	322	1,671	76	196	2,265
2013	322	1,671	76	196	2,265
2014	322	419	20	196	957
2015	322			196	518
Thereafter	81			552	633
<b>Total</b>	<b>\$ 1,450</b>	<b>\$ 4,179</b>	<b>\$ 190</b>	<b>\$ 1,385</b>	<b>\$ 7,204</b>



Table of Contents**Note 7 DEBT AND FINANCING OBLIGATIONS**

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

	September 30, 2011	December 31, 2010
Related party debt, including accrued interest:		
2009 Convertible Notes	\$	\$ 11,655
2009 Secured Notes		12,324
2010 Secured Notes		15,462
2010 HBM Secured Notes		3,945
2010 Convertible Notes, net of debt discount		6,409
		49,795
Financing obligations:		
Hercules Note, current portion	4,871	3,182
Hercules Note, long-term portion, net of debt discount	20,603	21,869
Royalty interest obligation, current portion	1,293	1,575
Royalty interest obligation, long-term portion	1,842	2,996
	28,609	29,622
Total debt and financing obligations	\$ 28,609	\$ 79,417

***2009 Convertible Notes***

Upon completion of the initial public offering in February 2011, all outstanding principal and accrued interest, which totaled \$11.7 million under the 2009 Convertible Notes was converted into 871,635 shares of common stock.

***2009 Secured Notes***

Upon the completion of the initial public offering in February 2011, all outstanding principal and accrued interest, which totaled \$12.5 million under the 2009 Secured Notes was converted into an aggregate of 927,881 shares of common stock.

***2010 Secured Notes***

Upon the completion of the initial public offering in February 2011, all outstanding principal and accrued interest, which totaled \$15.5 million under the 2010 Secured Notes was converted into an aggregate of 1,156,606 shares of common stock.

***2010 Convertible Notes***

Upon the completion of the initial public offering in February 2011, all outstanding principal on the 2010 Convertible Notes of \$7.5 million was converted into an aggregate of 1,071,428 shares of common stock. Due to this conversion, the combined value of \$1.1 million representing the warrants, which were issued in connection with the issuance and sale of the 2010 Convertible Notes, and the beneficial conversion feature was amortized in full.

***HBM Secured Notes***

Upon the completion of the initial public offering in February 2011, all outstanding principal and accrued interest, which totaled \$4.0 million, and an early prepayment penalty, under the HBM Secured Notes was converted into 297,359 shares of common stock.

Table of Contents

***Hercules Note***

The outstanding principal on the term loan (Hercules Note) under the Hercules Credit Facility entered into on November 24, 2010 was \$26.3 million as of September 30, 2011 and December 31, 2010. The term loan under the Hercules Credit Facility is comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan is comprised of \$11.3 million in principal and carries a floating per annum interest rate equal to 10.25% plus the amount, if any, by which the prime rate exceeds 4.00%. The Tranche B portion of the term loan is comprised of \$15.0 million in principal and carries a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeds 4.00%. As of September 30, 2011, the blended interest rate on the Hercules Note was 11.62%.

The Hercules Note provides for an interest only period when no principal amounts are due and payable. The interest only period was initially from November 24, 2010 through August 31, 2011, but was extended through November 30, 2011, upon the Company's request after certain conditions were met. See Note 12 Subsequent Events for further discussion. Following the end of the interest only period, the term loan is to be repaid in 33 monthly installments of principal and interest beginning on the first business day after the month in which the interest only period ends. The Company's principal payments as of September 30, 2011 are currently due as follows: \$7.1 million in 2012, \$9.4 million in 2013 and \$9.8 million in 2014.

**Note 8 STOCKHOLDERS' EQUITY (DEFICIT)**

***Initial Public Offering***

On February 8, 2011, the Company completed an initial public offering of its common stock pursuant to a registration statement on Form S-1, as amended (File No. 333-170245) that was declared effective by the SEC on February 2, 2011. An aggregate of 6,000,000 shares of common stock registered under the registration statement were sold at a price to the public of \$7.00 per share. The over-allotment option was not exercised by the underwriters. As a result of the initial public offering, the Company raised a total of \$42.0 million in gross proceeds, and approximately \$37.1 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.

Upon the closing of the initial public offering, all shares of outstanding Series A convertible preferred stock and the principal and accrued interest balance on the 2009 Convertible Notes, 2009 Secured Notes, 2010 Secured Notes, 2010 Convertible Notes, and HBM Secured Notes were converted into an aggregate of 10,647,549 shares of common stock, as shown in the table below:

	Conversion Shares
Series A Convertible Preferred Stock	6,322,640
2009 Convertible Notes	871,635
2009 Secured Notes	927,881
2010 Secured Notes	1,156,606
HBM Secured Notes	297,359
2010 Convertible Notes	1,071,428
	10,647,549

*Share-Based Compensation*

The Company recognized share-based compensation in its consolidated statements of operations for the periods ended September 30, 2011 and 2010 as follows (in thousands):

# Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Cost of revenues	\$ 31	\$ 3	\$ 145	\$ 9
Research and development	55	3	234	7
Selling, general and administrative	356		1,586	1
Total	\$ 442	\$ 6	\$ 1,965	\$ 17

The terms of the stock options granted in September and December 2010 stipulated that they may be exercised only upon the completion of the initial public offering. Consequently, the expense associated with these options was deferred until the successful completion of the initial public offering in February 2011.

## Stock Incentive Plans

The Company's 2011 stock incentive plan, or 2011 Plan, which became effective immediately prior to the completion of the Company's initial public offering in February 2011, was adopted by its board of directors and approved by its stockholders in December 2010. The 2011 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. The remaining shares available for issuance under the 2007 Plan at the time of the completion of the Company's initial public offering were reallocated to the 2011 Plan. The 2011 Plan contains an "evergreen" provision, which allows for an increase in the number of shares available for issuance under the 2011 Plan on the first day of each calendar year from 2012 through 2015. The following table contains information about the Company's plans at September 30, 2011:

Plan	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2011 Plan	407,476	346,234	61,242
2007 Plan	2,139,181	2,139,181	
	2,546,657	2,485,415	61,242

Included in the awards issued as shown above are options to purchase 36,750 shares of the Company's stock that were approved as of September 30, 2011, but priced in October 2011. The following table summarizes the Company's stock option activity and related information for the period from December 31, 2010 to September 30, 2011:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2010	2,073,700	\$ 2.69
Granted	309,484	10.58
Exercised	(7,245)	1.65
Forfeited	(41,967)	3.49
Expired	(1,685)	2.69
Outstanding at September 30, 2011	2,332,287	\$ 3.72





Table of Contents

**Note 9 COMMERCIAL PARTNERS AND AGREEMENTS**

***Novo Nordisk Development and License Agreement***

In January 2011, the Company entered into an agreement, or the Novo Agreement, with Novo Nordisk A/S, or Novo, pursuant to which it granted non-exclusive rights to Novo under certain of its patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using the Company's DepoFoam drug delivery technology. Under the Novo Agreement, the Company agreed to undertake specified development and technology transfer activities and to manufacture pre-clinical and certain clinical supplies of such DepoFoam formulated Novo product until the completion of such technology transfer activities. Novo is obligated to pay for all costs incurred by the Company in conducting such development, manufacturing and technology transfer activities. The Company received an upfront license fee of \$1.5 million from Novo, which is being recognized on a straight-line basis over the estimated contract term as collaborative licensing and development revenue. The Company is also entitled to receive single-digit royalties on sales of such Novo product if approved for commercialization. In addition, the Company is entitled to receive up to \$24.0 million in milestone payments based on achievement of specified development events, and up to an additional \$20.0 million in milestone payments based on sales of such Novo product exceeding specified amounts. The term of the Novo Agreement shall expire, on a country-by-country basis, upon the later of the date of expiration of all payment obligations under the agreement or twelve years following the first commercial sale of such Novo product. The Novo Agreement is subject to earlier termination under certain circumstances.

**Note 10 RELATED PARTY TRANSACTIONS**

In June 2011, the Company entered into an agreement with one of the members of its board of directors to provide consulting services for manufacturing related activities. The fees payable under the agreement may not exceed \$60,000 per year. The amount of fees incurred for the three and nine months ended September 30, 2011 was not material.

During 2009 and 2010, the Company entered into 2009 Convertible Note, 2009 Secured Note, 2010 Secured Note, 2010 Convertible Note and HBM Secured Notes, with certain investors in the Company (see Note 7). Upon the completion of the initial public offering in February 2011, the outstanding balances due to these investors of \$51.2 million, including accrued interest of \$4.8 million, were converted into an aggregate of 4,324,909 shares of common stock.

The Company incurred expenses under the services agreement with Stack Pharmaceuticals Inc., or SPI, an entity controlled by David Stack, the Company's chief executive officer, of approximately \$0.1 million for each of the three months ended September 30, 2011 and 2010, respectively. The Company incurred expenses of approximately \$0.2 million for each of the nine months ended September 30, 2011 and 2010. As of September 30, 2011 and December 31, 2010, the Company had no outstanding balance payable to SPI.

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 and \$0.4 million for the three months ended September 30, 2011 and 2010, respectively, and approximately \$0.3 million and \$0.6 million for the nine months ended September 30, 2011 and 2010, respectively. Approximately \$0.1 million was payable to MPM as of September 30, 2011 and December 31, 2010.

**Note 11 LEASES**

In August 2011, the Company entered into a new lease contract for its corporate headquarters in Parsippany, New Jersey. The lease for this facility begins in November 2011 and expires in June 2017. Under the lease, the Company is required to pay certain maintenance expenses in addition to rent. The annual minimum rental payments due under the new lease are as follows (in thousands):

Table of Contents

Year	Rent Payment
2011 (remaining three months)	\$
2012	282
2013	313
2014	323
2015	357
2016	400
2017 (six months)	268
Total	\$ 1,943

**Note 12 SUBSEQUENT EVENTS**

On October 28, 2011, the FDA approved the Company's New Drug Application, or NDA, for its 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.

Tranche A of the Hercules Credit Facility is guaranteed by certain of the Company's investors which guarantee is limited to each investor's pro rata portion of the outstanding principal and accrued and unpaid interest of Tranche A under the Hercules Credit Facility, but in no event exceeding \$11.3 million in the aggregate. The Hercules loan agreement provides that, upon the occurrence of certain circumstances and upon the Company's request, the investors' guarantee may be terminated and released. On October 28, 2011, the Company met the required conditions and requested the release of the guaranty. Upon the release of the investors' guaranty, the interest rate on the Tranche A portion of the term loan will increase to a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. In addition, the Company also elected to extend the interest only period from November 30, 2011 to February 28, 2012.

On October 18, 2011, a development milestone was triggered pursuant to the Novo Agreement (see Note 9), which entitles the Company to a \$2.0 million cash payment.

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 and commercialize EXPAREL; our plans to continue to manufacture and provide support services for its commercial partners who have licensed DepoCyt(e) and DepoDur; the success and timing of our commercial launch 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 and epidural administration; and our commercialization and marketing capabilities. 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, will, 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.*

*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. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. 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.*

*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 are developing a sales force entirely dedicated to commercializing EXPAREL comprised of approximately 60 representatives, seven regional managers and a national sales manager. We intend to develop 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 believe that our pre-launch activities including significant personal interactions with our hospital customers, position us for a successful launch of EXPAREL in the first quarter of 2012.

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

Our two marketed products, DepoCyt(e) and DepoDur, and our proprietary DepoFoam extended release drug delivery technology were acquired as part of the acquisition of our California operating subsidiary, Pacira Pharmaceuticals, Inc., or PPI-California, on March 24, 2007, or the Acquisition. 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. DepoDur is an extended release injectable formulation of morphine indicated for epidural administration for the treatment of pain following major surgery. DepoDur was approved by the FDA in 2004.

We do not expect our currently marketed products, other than EXPAREL, to generate revenue that is sufficient for us to achieve profitability because we expect to continue to incur significant expenses as we commercially launch EXPAREL.

Table of Contents

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.

**Recent Developments**

***FDA Approval of EXPAREL***

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.

***Hercules Note***

Tranche A of the Hercules Credit Facility is guaranteed by certain of our investors which guarantee is limited to each investor's pro rata portion of the outstanding principal and accrued and unpaid interest of Tranche A under the Hercules Credit Facility, but in no event exceeding \$11.3 million in the aggregate. The Hercules loan agreement provides that, upon the occurrence of certain circumstances and upon our request, the investors' guarantee may be terminated and released. On October 28, 2011, we met the required conditions and requested the release of the guaranty. Upon the release of the investors' guaranty, the interest rate on the Tranche A portion of the term loan will increase to a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. In addition, we also elected to extend the interest only period from November 30, 2011 to February 28, 2012.

Table of Contents*Novo Milestone*

On October 18, 2011, a development milestone was met pursuant to our agreement, or the Novo agreement, with Novo Nordisk A/S, or Novo, further discussed below, which entitles us to a \$2.0 million cash payment.

**Novo Agreement**

In January 2011, we entered into the Novo Agreement, pursuant to which we granted non-exclusive rights to Novo under certain of our patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using our DepoFoam drug delivery technology. Under this agreement, we agreed to undertake specified development and technology transfer activities and to manufacture pre-clinical and certain clinical supplies of such DepoFoam formulated Novo product until the completion of such technology transfer activities. Novo is obligated to pay for all costs we incur in conducting such development, manufacturing and technology transfer activities. We received an upfront license fee of \$1.5 million from Novo. We are also entitled to receive single-digit royalties on sales of such Novo product for up to twelve years following the first commercial sale of such Novo product. In addition, we are entitled to receive up to \$24 million in milestone payments based on achievement of specified development events, and up to an additional \$20 million in milestone payments based on sales of such Novo product exceeding specified amounts.

**Results of Operations***Comparison of Three and Nine Months Ended September 30, 2011 and 2010*

The following table sets forth a summary of our supply revenue, royalties and collaborative licensing and development revenue during the periods indicated:

(000 \$)	Three Months Ended		% Increase/ Decrease	Nine Months Ended		% Increase/ Decrease
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
DepoCyt(e) (1)						
Supply revenue	\$ 1,682	\$ 2,431	(31)%	\$ 4,868	\$ 6,497	(25)%
Royalties	881	966	(9)%	2,600	2,470	5%
	2,563	3,397	(25)%	7,468	8,967	(17)%
DepoDur (1)						
Supply revenue		313	(100)%		630	(100)%
Royalties	41	57	(28)%	143	223	(36)%
	41	370	(89)%	143	853	(83)%
Total DepoCyt(e) and DepoDur revenue (1)	2,604	3,767	(31)%	7,611	9,820	(22)%
Collaborative licensing and development revenue	1,352	765	77%	3,845	2,551	51%



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

Total revenues	\$	3,956	\$	4,532	(13)%	\$	11,456	\$	12,371	(7)%
----------------	----	-------	----	-------	-------	----	--------	----	--------	------

---

(1) Total DepoCyt(e) and DepoDur revenue does not include collaborative licensing and development revenue related to DepoCyt(e) and DepoDur.

Total revenues decreased by \$0.5 million, or 13%, to \$4.0 million in the three months ended September 30, 2011 as compared to \$4.5 million the three months ended September 30, 2010 primarily due to a decrease in supply revenue of \$1.1 million, partially offset by a \$0.6 million increase in collaborative licensing and development revenue. The decrease in supply revenue reflects a lower number of lot sales to our commercial partners. The increase in collaborative licensing and development revenue is primarily attributable to activities performed under the Novo Agreement signed in January 2011.

Total revenues decreased by \$0.9 million, or 7%, to \$11.5 million in the nine months ended September 30, 2011 as compared to \$12.4 million in the nine months ended September 30, 2010 primarily due to a decrease in supply revenue of \$2.3 million that was partially offset by \$1.3 million increase in collaborative licensing and development revenue. The

Table of Contents

decrease in supply revenue and increase in collaborative licensing and development revenue is attributable to the same factors discussed in the preceding paragraph.

(000 \$)	Three Months Ended September 30,			% Increase/ Decrease	Nine Months Ended September 30,			% Increase/ Decrease		
	2011		2010		2011		2010			
Cost of revenues	\$	3,357	\$	3,573	(6)%	\$	10,138	\$	10,168	(0)%

Cost of revenues decreased by \$0.2 million, or 6%, in the three months ended September 30, 2011 as compared to the three months ended September 30, 2010. The decrease is driven by a lower number of lot sales of Depocyt(e) and DepoDur to our commercial partners which was partially offset by an increase in costs associated with excess capacity. We have excess capacity and we incur a substantially fixed level of infrastructure cost to keep our manufacturing facilities cGMP compliant. The cost of excess manufacturing capacity was \$2.1 million and \$1.5 million for the three months ended September 30, 2011 and 2010, respectively.

Cost of revenues remained consistent for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010. The cost of revenues in 2011 reflects a reduction from 2010 of \$1.8 million due to lower lot sales of Depocyt(e) and DepoDur to our commercial partners which was offset by an increase in our excess capacity costs. The cost of excess manufacturing capacity was \$6.2 million and \$4.4 million for the nine months ended September 30, 2011 and 2010, respectively. The impact of excess manufacturing capacity reflects that our production cost associated with DepoCyt(e) and DepoDur is mostly fixed.

(000 s)	Three Months Ended September 30,			% Increase/ Decrease	Nine Months Ended September 30,			% Increase/ Decrease		
	2011		2010		2011		2010			
Research and development	\$	4.344	\$	5.716	(24)%	\$	12.237	\$	14.954	(18)%

Research and development expenses decreased by \$1.4 million, or 24%, to \$4.3 million in the three months ended September 30, 2011 as compared to \$5.7 million in the three months ended September 30, 2010 primarily due to \$2.7 million in lower clinical trial costs related to the close out of our pivotal Phase 3 placebo controlled studies in EXPAREL and NDA preparation costs. This reduction was partially offset by a \$1.3 million increase in compensation related expenses, including stock-based compensation and bonus accrual, which were not present in 2010, and an increase in EXPAREL pre-commercial manufacturing-related costs. In the three months ended September 30, 2011 and 2010, research and development expenses attributable to EXPAREL were \$4.3 million, or 100%, and \$5.4 million, or 95%, of total research and development expenses, respectively.

Research and development expenses decreased by \$2.8 million, or 18%, to \$12.2 million in the nine months ended September 30, 2011 as compared to \$15.0 million in the nine months ended September 30, 2010 primarily due to a \$4.5 million decrease in third party clinical trials costs. This decrease, as mentioned above, is related to the close out of our pivotal Phase 3 placebo controlled studies in EXPAREL and NDA preparation costs in 2010. This reduction was partially offset by a \$1.8 million increase in compensation costs, including stock-based compensation and bonus accrual, which were not present in 2010, and an increase in EXPAREL pre-commercial manufacturing-related costs. In the nine months ended September 30, 2011 and 2010, research and development expenses attributable to EXPAREL were \$12.1 million, or 99% and \$14.2 million, or 95% of total research and development expenses, respectively. The EXPAREL related research and development expenses incurred during the three and nine months ended September 30, 2011 includes manufacturing-related costs that we expensed prior to regulatory approval of the product. The remaining research and development expenses relate to our product candidate initiatives including DepoNSAID and DepoMethotrexate.

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

(000 s)	Three Months Ended September 30,		% Increase/ Decrease	Nine Months Ended September 30,		% Increase/ Decrease
	2011	2010		2011	2010	
Selling, general and administrative	\$ 4,988	\$ 1,694	194%	\$ 13,465	\$ 3,948	241%

Selling, general and administrative expenses increased by \$3.3 million, or 194%, to 5.0 million in the three months ended September 30, 2011 as compared to \$1.7 million in the three months ended September 30, 2010 due to the following:

# Table of Contents

- selling and marketing expenses increased by \$2.1 million to \$2.1 million in the three months ended September 30, 2011 as compared to \$0.0 million for the three months ended September 30, 2010 primarily due to the hiring of commercial personnel and activities supporting the commercialization of EXPAREL, including costs incurred for our retrospective and prospective health outcome studies and promotional/educational material; and

- general and administrative expenses increased by \$1.2 million to \$2.9 million in the three months ended September 30, 2011 as compared to \$1.7 million for the three months ended September 30, 2010 due to the impact of compensation related expenses of \$1.2 million, including bonus, stock-based compensation and severance costs, and other expenses associated with being a public company.

Selling, general and administrative expenses increased by \$9.6 million, or 241%, to \$13.5 million in the nine months ended September 30, 2011 as compared to \$3.9 million in the nine months ended September 30, 2010 due to the following:

- selling and marketing expenses increased by \$5.6 million to \$5.6 million in the nine months ended September 30, 2011 as compared to \$0.0 million for the nine months ended September 30, 2010 due to the hiring of commercial personnel and activities supporting the commercialization of EXPAREL, including costs incurred for our retrospective and prospective health outcome studies and promotional/educational material; and

- general and administrative expenses increased by \$4.0 million to \$7.9 million in the nine months ended September 30, 2011 as compared to \$3.9 million for the nine months ended September 30, 2010 primarily due to additional compensation related expenses of \$2.7 million, including bonus, stock-based compensation and severance costs, and other expenses associated with being a public company.

(000 \$)	Three Months Ended September 30,			% Increase/ Decrease	Nine Months Ended September 30,			% Increase/ Decrease		
	2011		2010		2011		2010			
Interest income	\$	46	\$	39	18%	\$	111	\$	112	(1)%
Interest expense		(910)		(1,077)	(16)%		(4,068)		(2,577)	58%
Royalty interest obligation		116		(444)	(126)%		235		(1,048)	(122)%
Other, net		(27)		33	(182)%		61		107	(43)%
Total other (expense) income, net	\$	(775)	\$	(1,449)	(47)%	\$	(3,661)	\$	(3,406)	7%

Total other (expense) income, net decreased by \$0.7 million, or 47%, to \$0.8 million in the three months ended September 30, 2011 as compared to \$1.5 million in the three months ended September 30, 2010 primarily due to a \$0.6 million decrease in royalty interest obligation due to changes in forecasted sales projections based on plateauing sales trends and the weakening Euro exchange rate. This obligation is due under an agreement, further discussed below in [Liquidity and Capital Resources](#), which provides Paul Capital a right to receive an interest in sales relating to Depocyt(e) and DepoDur.

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

Total other (expense) income, net increased by \$0.3 million, or 7%, to \$3.7 million in the nine months ended September 30, 2011 as compared to \$3.4 million in the nine months ended September 30, 2010 primarily due to:

- a \$1.5 million increase in interest expense primarily due to \$1.1 million of amortization of the remaining value of the warrants and beneficial conversion feature associated with the convertible notes we issued in 2010 due to the conversion of these notes into common stock upon closing of our initial public offering in February 2011. The remaining increase is due to interest expense associated with the Hercules Credit Facility entered into on November 24, 2010, partially offset by a net reduction in interest expense on our secured convertible notes we issued in 2009 and 2010, which were converted to common stock upon the completion of our initial public offering; and
- a \$1.3 million decrease in the royalty interest obligation due to changes in forecasted sales projections based on plateauing sales trends and the weakening Euro exchange rate.

### **Liquidity and Capital Resources**

Since our inception in 2007, we have devoted most of our cash resources to research and development and 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, secured and unsecured notes and borrowings under debt facilities, supply revenue, royalties and collaborative licensing and development revenue. We raised approximately \$37.1

## Table of Contents

million in net proceeds through an initial public offering completed on February 8, 2011. We have generated limited supply revenue and royalties, and we do not anticipate generating any revenues from the sale of EXPAREL, until the first quarter of 2012. We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2011, we had an accumulated deficit of \$165.0 million, cash and cash equivalents and short-term investments of \$37.1 million and working capital of \$25.6 million.

On February 8, 2011, we completed our initial public offering of our common stock pursuant to a registration statement on Form S-1, as amended (File No. 333-170245) that was declared effective on February 2, 2011. An aggregate of 6,000,000 shares of common stock registered under the registration statement were sold at a price to the public of \$7.00 per share. The over-allotment option was not exercised by the underwriters. As a result of our initial public offering, we raised a total of \$42.0 million in gross proceeds, and approximately \$37.1 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses. Upon the closing of the initial public offering, all shares of our then outstanding Series A convertible preferred stock and the principal and accrued interest balance on the 2009 Convertible Notes, 2009 Secured Notes, 2010 Secured Notes, 2010 Convertible Notes, and HBM Secured Notes were converted into an aggregate of 10,647,549 shares of our common stock.

## Summary of Cash Flows

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

(000 \$)	Nine Months Ended September 30,	
	2011	2010
<b>Consolidated Statement of Cash Flows Data:</b>		
Net cash provided by (used in):		
Operating activities	\$ (23,404)	\$ (19,041)
Investing activities	(24,355)	(3,821)
Financing activities	38,028	29,636
Net increase (decrease) in cash and cash equivalents	\$ (9,731)	\$ 6,774

## Operating Activities

During the nine months ended September 30, 2011 and 2010, our net cash used in operating activities was \$23.4 million and \$19.0 million, respectively. The \$4.4 million increase in net cash used in operating activities was driven by (i) a \$2.3 million decrease in supply revenue due to lower lot sales to our commercial partners, (ii) a \$1.8 million increase in interest paid primarily due to cash paid for interest monthly on the Hercules Note versus accrual of interest on the convertible and secured notes, which was converted into equity upon the initial public offering, and (iii) higher selling, general and administrative expenses as we prepare for the commercialization of EXPAREL. This increase was partially offset by a \$1.5 million up-front payment received from our development partner Novo pursuant to the Novo Agreement and lower research and development expenses due to the closeout of our two pivotal Phase 3 clinical trials in EXPAREL.

## Investing Activities

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

During the nine months ended September 30, 2011 and 2010, our net cash used in investing activities was \$24.4 million and \$3.8 million, respectively. In 2011, we invested \$20.7 million from the net proceeds of our initial public offering in investment grade commercial paper and corporate bonds with maturities of less than one year. We purchased fixed assets of \$3.7 million and \$3.8 million during the nine months ended September 30, 2011 and 2010, respectively, primarily for the construction of our manufacturing facilities.

### *Financing Activities*

During the nine months ended September 30, 2011 and 2010, our net cash provided by financing activities was \$38.0 million and \$29.6 million, respectively. The net cash provided by financing activities in 2011 was primarily from the issuance of common stock in connection with our initial public offering completed in February 2011. We raised approximately \$37.1 million in net proceeds in the initial public offering, after deducting \$4.9 million in offering expenses of which \$0.9 million was paid prior to December 31, 2010. The net cash provided by financing activities in the nine months ended September 30, 2010 was primarily due to

Table of Contents

the issuance of \$18.8 million in principal amount of secured notes to certain of our existing investors and the borrowings on a credit facility we had with General Electric Capital Corporation of \$11.3 million partially offset by \$0.4 million in financing costs.

***Debt Facilities***

As of September 30, 2011, we had \$26.3 million in outstanding principal debt under a credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders, or the Hercules Credit Facility. The Hercules Credit Facility provides for an interest only period when no principal amounts are due and payable. The interest only period runs through February 28, 2012. Following the end of the interest only period, the term loan is to be repaid in 33 monthly installments of principal and interest beginning on the first business day after the month in which the interest only period ends. As of September 30, 2011, we were in compliance with all covenants under the facility.

Upon completion of our initial public offering in February 2011, all principal and accrued interest on the convertible and secured notes (other than the 2010 Convertible Notes) converted into 3,253,481 shares of our common stock at a conversion price of \$13.44, pursuant to an agreement entered into in October 2010 between us and the holders of the convertible and secured notes. The 2010 Convertible Notes were converted into 1,071,428 shares of our common stock at a conversion price equal to our initial public offering price of \$7.00 per share. The table below shows the number of shares of common stock that our indebtedness was converted into:

Notes	Conversion Shares
2009 Convertible Notes	871,635
2009 Secured Notes	927,881
2010 Secured Notes	1,156,606
HBM Secured Notes	297,359
2010 Convertible Notes	1,071,428

***Royalty Interests Assignment Agreement***

On March 23, 2007, we entered into the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital, pursuant to which we assigned to Paul Capital the right to receive up to approximately 20% of our royalty payments from DepoCyt(e) and DepoDur. The original agreement was entered into prior to the Acquisition by SkyePharma Holdings, Inc. in order to monetize certain royalty payments from DepoCyt(e) and DepoDur. In connection with the Acquisition, the original agreement with Paul Capital was amended and restated and the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur was transferred to us and we were required to make payments to Paul Capital upon the occurrence of certain events. To secure our obligations to Paul Capital, we granted Paul Capital a security interest in collateral which includes the royalty payments we are entitled to receive with respect to sales of DepoCyt(e) and DepoDur, as well as to bank accounts to which such payments are deposited. Under our arrangement with Paul Capital, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in DepoCyt(e) and/or DepoDur, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Amended and Restated Royalty Interests Assignment Agreement, or sales of DepoCyt(e) and/or DepoDur are suspended due to an injunction or if we elect to suspend sales of DepoCyt(e) and/or DepoDur as a result of a lawsuit filed by certain third parties, Paul Capital may require us to repurchase the rights we assigned to it at a cash price equal to (a) 50% of all cumulative payments made by us to Paul Capital under the Amended and Restated Royalty Interests Assignment Agreement during the preceding 24 months, multiplied by (b) the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365. Under the terms of the Amended and Restated Royalty Interests Assignment Agreement, our initial public offering did not constitute a change of control.



*Future Capital Requirements*

As of September 30, 2011, we had cash and cash equivalents and short-term investments of \$37.1 million. We believe that our existing cash and cash equivalents, short-term investments and revenue from product sales will not be sufficient to enable us to meet our planned operating expenses, such as the commercial launch of EXPAREL, capital expenditure requirements and service our indebtedness through the next twelve months unless we secure additional funds through debt and/or equity financing. While we believe in the viability of our strategy to secure financing, and believe that the actions presently being taken by us provide the opportunity for us to continue as a going concern, there can be no

Table of Contents

assurance that any financing will be available on acceptable terms, or at all. Moreover, 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.

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 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.

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

- 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 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 Hercules Credit Facility and the Amended and Restated Royalty Interests Assignment Agreement 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.

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

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. 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 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.

### **Critical Accounting Policies and Estimates**

For a description of the critical accounting policies that affect our more 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, 2010. There have been no significant changes to our critical accounting policies since December 31, 2010.

Table of Contents

**Recent Accounting Pronouncements**

In September 2011, the Financial Accounting Standards Board, or FASB, released Accounting Standards, or ASU, Update No. 2011-08, Intangibles-Goodwill and Other. The amended guidance will allow companies to assess qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment test required under current accounting standards. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 (January 1, 2012 for us). We have determined that this guidance will not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU, No. 2011-05, Presentation of Comprehensive Income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements; the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity was eliminated. ASU No. 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 (January 1, 2012 for us) and interim and annual periods thereafter. Early adoption is permitted, and full retrospective application is required. Since this ASU pertains to presentation requirements only, the adoption of this ASU will not have a material impact on our consolidated financial statements.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents and short-term investments. As of September 30, 2011, we had cash and cash equivalents and short-term investments of \$37.1 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents and short-term investments, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

We have commercial partners for DepoCyt(e) and DepoDur who sell our products in the EU. Under these agreements, we provide finished goods to our commercial partners in exchange for euro-denominated supply revenue, and we also receive euro-denominated royalties on market sales when the products are sold to end users. Because of these agreements, we are subject to fluctuations in exchange rates, specifically in the relative values of the U.S. dollar and the euro.

**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

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

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 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 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, 2011 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 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

Table of Contents

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.

**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**

**RISK FACTORS**

In addition to the other information in this Quarterly Report on Form 10-Q, any of the factors set forth below could significantly and negatively affect our business, financial condition, results of operations or prospects. The trading price of our common stock may decline due to these risks. This section contains forward looking statements. You should refer to the explanation of the qualification and limitations on forward-looking statements beginning on page 17.

**Risks Related to the Development and Commercialization of our Product Candidates**

*Our success depends on our ability to successfully commercialize EXPAREL.*

We have invested a significant portion of our efforts and financial resources in the development of EXPAREL. Our success depends on our ability to effectively commercialize EXPAREL, which was approved by the FDA on October 28, 2011, for administration into the surgical site

to produce postsurgical analgesia.

We plan to commercially launch EXPAREL in the first quarter of 2012, but our ability to effectively commercialize and generate revenues from EXPAREL will depend on our ability to:

- create market demand for EXPAREL through our marketing and sales activities, and any other arrangements to promote this product we may later establish;
- train, deploy and support a qualified sales force which will be developed on a contract basis with Quintiles;
- secure formulary approvals for EXPAREL at a substantial number of targeted hospitals;
- manufacture EXPAREL in sufficient quantities in compliance with requirements of the FDA and similar foreign regulatory agencies and at acceptable quality and pricing levels in order to meet commercial demand;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- receive adequate levels of coverage and reimbursement for EXPAREL from commercial health plans and governmental health programs;

Table of Contents

- maintain compliance with regulatory requirements;
- ensure that our entire supply chain for EXPAREL efficiently and consistently delivers EXPAREL to our customers; and
- maintain and defend our patent protection and regulatory exclusivity for EXPAREL

Any disruption in our ability to generate revenues from the sale of EXPAREL or lack of success in its commercialization will have a material and adverse impact on our results of operations.

***Our efforts to successfully commercialize EXPAREL are subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.***

As EXPAREL will be a newly marketed drug, none of the members of the EXPAREL sales force have ever promoted EXPAREL. As a result, we are required to expend significant time and resources to train the sales force to be credible and persuasive in convincing physicians and hospitals to use EXPAREL. In addition, we also must train the sales force to ensure that a consistent and appropriate message about EXPAREL is delivered to our potential customers. If we are unable to effectively train the sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of EXPAREL and its proper administration, our efforts to successfully commercialize EXPAREL could be put in jeopardy, which could have a material adverse effect on our future revenues and profits.

In addition to our extensive internal efforts, the successful commercialization of EXPAREL will require many third parties, over whom we have no control, to choose to utilize EXPAREL. These third parties include physicians and hospital pharmacy and therapeutics committees, which we refer to as P&T committees. Generally, before we can attempt to sell EXPAREL in a hospital, EXPAREL must be approved for addition to that hospital's list of approved drugs, or formulary list, by the hospital's P&T committee. A hospital's P&T committee typically governs all matters pertaining to the use of medications within the institution, including the review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. The frequency of P&T committee meetings at hospitals varies considerably, and P&T committees often require additional information to aid in their decision-making process. Therefore, we may experience substantial delays in obtaining formulary approvals. Additionally, hospital pharmacists may be concerned that the cost of acquiring EXPAREL for use in their institutions will adversely impact their overall pharmacy budgets, which could cause pharmacists to resist efforts to add EXPAREL to the formulary, or to implement restrictions on the usage of EXPAREL in order to control costs. We cannot guarantee that we will be successful in obtaining the approvals we need from enough P&T committees quickly enough to optimize hospital sales of EXPAREL.

Even if we obtain hospital formulary approval for EXPAREL, physicians must still prescribe EXPAREL for its commercialization to be successful. Because EXPAREL is a new drug with no track record of sales in the United States, any inability to timely supply EXPAREL to our customers, or any unexpected side effects that develop from use of the drug, particularly early in product launch, may lead physicians to not accept EXPAREL as a viable treatment alternative.



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

If EXPAREL does not achieve broad market acceptance, the revenues that we generate from its sales will be limited. The degree of market acceptance of EXPAREL will also depend on a number of other factors, including:

- changes in the standard of care for the targeted indications for EXPAREL, which could reduce the marketing impact of any claims that we could make following FDA approval;
- the relative convenience and ease of administration of EXPAREL;
- the prevalence and severity of adverse events associated with EXPAREL;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payers, and by government healthcare programs, including Medicare and Medicaid;

Table of Contents

- the extent and strength of our marketing and distribution of EXPAREL;
- the safety, efficacy and other potential advantages over, and availability of, alternative treatments, including, in the case of EXPAREL, a number of products already used to treat pain in the hospital setting; and
- distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan.

Our ability to effectively promote and sell EXPAREL and any product candidates that we may develop, license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and therefore achieve acceptance of the product onto hospital formularies, and our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates.

In addition, the labeling approved by the FDA does not contain claims that EXPAREL is safer or more effective than competitive products and does not permit us to promote EXPAREL as being superior to competing products. Further, the availability of inexpensive generic forms of postsurgical pain management products may also limit acceptance of EXPAREL among physicians, patients and third-party payers. If EXPAREL does not achieve an adequate level of acceptance among physicians, patients and third-party payers, we may not generate meaningful revenues from EXPAREL and we may not become profitable.

***We face significant competition from other pharmaceutical and biotechnology companies. Our operating results will suffer if we fail to compete effectively.***

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as larger research and development staff, more extensive marketing, distribution, sales and manufacturing organizations and experience, more extensive clinical trial and regulatory experience, expertise in prosecution of intellectual property rights and access to development resources like personnel generally and technology. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than EXPAREL or any product candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive or significantly harm the commercial opportunity for EXPAREL or our product candidates.

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

As a result of these factors, our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop other indications for, or commercialize, EXPAREL. Our competitors may also develop drugs that are more effective, useful or less costly than ours and may be more successful than us in manufacturing and marketing their products.

EXPAREL will compete with well-established products with similar indications. Competing products available for postsurgical pain management include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the United States from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, has been approved by the FDA for pain management and fever in adults. In addition, EXPAREL will compete with non-opioid products such as bupivacaine, Marcaine, ropivacaine and other anesthetics/analgesics, all of which are also used in the treatment of postsurgical pain and are available as either oral tablets, injectable dosage forms or administered using novel delivery systems. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel

Table of Contents

opioids, new formulations of currently available opioids and NSAIDS, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDS.

We will also compete with an extended release bupivacaine product in development by Durect Corporation which has been licensed to Hospira in North America (Posidur) and to Nycomed for Europe (Optesia). EXPAREL also competes with elastomeric bag/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009) has marketed these medical devices in the United States since 2004.

***If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell EXPAREL, we may be unable to generate product revenues.***

We are currently building our commercial infrastructure for the marketing, sale and distribution of pharmaceutical products. In order to commercialize EXPAREL, we must build our marketing, sales and distribution capabilities. We have entered into an agreement with Quintiles for the outsourcing of our specialty sales force of approximately 60 representatives. We may also seek to commercialize EXPAREL outside the United States, although we currently plan to do so with a marketing and sales collaborator and not with our own sales force.

The establishment, development and training of our sales force and related compliance plans to market EXPAREL is expensive and time consuming and can potentially delay the commercial launch of EXPAREL. In the event we are not successful in developing our marketing and sales infrastructure, we may not be able to successfully commercialize EXPAREL, which would limit our ability to generate product revenues.

***We rely on third parties to perform many essential services for EXPAREL and any other products that we commercialize, including services related to customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, and financial management and information technology services. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize EXPAREL will be significantly impacted and we may be subject to regulatory sanctions.***

We have entered into agreements with third-party service providers to perform a variety of functions related to the sale and distribution of EXPAREL, key aspects of which are out of our direct control. These service providers provide key services related to customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, and financial management and information technology services. In addition, most of our inventory is stored at a single warehouse maintained by one such service provider. We substantially rely on these providers as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

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

Distribution of our DepoFoam-based products, including EXPAREL, requires cold-chain distribution provided by third parties, whereby the product must be maintained between specified temperatures. We and our partners have utilized similar cold-chain processes for DepoCyt(e) and DepoDur. If a problem occurs in our cold-chain distribution processes, whether through our failure to maintain our products or product candidates between specified temperatures or because of a failure of one of our distributors or partners to maintain the temperature of the products or product candidates, the product or product candidate could be adulterated and rendered unusable. This could have a material adverse effect on our business, financial condition, results of operations and reputation.

***We will need to increase the size of our organization and effectively manage our sales force, and we may experience difficulties in managing growth.***

As of September 30, 2011, we had 122 employees. We will need to substantially expand our managerial, commercial, financial, manufacturing and other personnel resources in order to manage our operations and prepare for the commercialization of EXPAREL. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. In addition, we may not be able to recruit and retain qualified personnel in the future, particularly marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so

Table of Contents

could have a significant negative impact on our future product revenues and business results. We will also need to effectively manage our sales force that we outsource from Quintiles. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring, outsourcing in the case of our sales force, and training of an effective commercial organization for the commercialization of EXPAREL, and establish appropriate systems, policies and infrastructure to support that organization;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

***We are reliant on our contract with Quintiles for the marketing and sale of EXPAREL.***

We have entered into an agreement with Quintiles for the outsourcing of a sales force to commercialize EXPAREL. The risks in outsourcing the sales function to any third party include the following:

- the third party may not apply the expected financial resources or required expertise to successfully market and sell EXPAREL;
- the third party may not comply with applicable legal requirements, including the requirement to promote drug products only for uses for which they have been approved;
- the third party may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of EXPAREL reach their full potential;

- disputes may arise between us and the third party that may delay the commercialization of EXPAREL or adversely affect its sales or profitability; or
- the third party may enter into agreements with other parties that have products that could compete with EXPAREL.

We are substantially dependent on the success of Quintiles in performing its responsibilities and the continued cooperation of Quintiles. Quintiles may not cooperate with us to perform its obligations under our agreement and we cannot control the amount and timing of Quintiles resources that will be devoted to the marketing and sale of EXPAREL. The occurrence of any of these events could adversely affect the commercialization of EXPAREL and materially harm our business and stock price by slowing the pace of growth of such sales, by reducing the profitability of EXPAREL or by adversely affecting the reputation of EXPAREL in the market.

***We may not be able to manage our business effectively if we are unable to attract and retain key personnel.***

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California and Northern New Jersey areas. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development and manufacturing expertise for our DepoFoam delivery technology and the commercialization expertise of certain members of our senior management. In particular, we are highly dependent on the skills and leadership of our management team, including David Stack, our president and chief executive officer. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of

Table of Contents

individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel.

Mr. Stack, our chief executive officer, is also a managing director at MPM Capital and a managing partner of Stack Pharmaceuticals, Inc. Although Mr. Stack has devoted substantially all of his time to our company over the past 12 months, Mr. Stack's responsibilities at MPM Capital and Stack Pharmaceuticals, Inc. might require that he spend less than all his time managing our company in the future.

Under our consulting agreement with Gary Patou, M.D., our chief medical officer, he is not required to devote all of his time to our company. We cannot assure you that Dr. Patou's time commitment to us will be sufficient to perform the duties of our chief medical officer.

***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for DepoCyt(e), DepoDur, EXPAREL or product candidates that we may develop and may have to limit their commercialization.***

The use of DepoCyt(e), DepoDur, EXPAREL and any product candidates that we may develop, license or acquire in clinical trials and the sale of any products for which we obtain regulatory approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- loss of revenues;



- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a \$10.0 million annual aggregate coverage limit. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of additional commercial products upon FDA approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***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

Table of Contents

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.

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.

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.

***We are the sole manufacturer of DepoCyt(e) and DepoDur and we only have two FDA approved manufacturing facilities. Our inability to continue manufacturing adequate supplies of DepoCyt(e) and DepoDur could result in a disruption in the supply of DepoCyt(e) and DepoDur to our partners.***

We are the sole manufacturer of DepoCyt(e) and DepoDur. We develop and manufacture DepoCyt(e) and DepoDur at our facilities in San Diego, California, which are the only FDA approved sites for manufacturing DepoCyt(e) and DepoDur in the world. Our San Diego facilities are subject to the risks of a natural or man-made disaster, including earthquakes and fires, or other business disruption. There can be no assurance that we would be able to meet our requirements for DepoCyt(e) and DepoDur if there were a catastrophic event or failure of our current manufacturing system. If we are required to change or add a new manufacturer or supplier, the process would likely require prior FDA and/or equivalent foreign regulatory authority approval, and would be very time consuming. An inability to continue manufacturing adequate supplies of DepoCyt(e) and DepoDur at our facility in San Diego, California could result in a disruption in the supply of DepoCyt(e) and DepoDur to our partners and breach of our contractual obligations.

***If we fail to manufacture DepoCyt(e) and DepoDur we will lose revenues and be in breach of our licensing obligations.***

We have licensed the commercial rights in specified territories of the world to market and sell our products, DepoCyt(e) and DepoDur. Under those licenses we have obligations to manufacture commercial product for our commercial partners. If we are unable to timely fill the orders placed with us by our commercial partners, we will potentially lose revenue and be in breach of our licensing obligations under the agreements. In addition, we would be in breach of our obligations to comply with our supply and distribution agreements for DepoCyt(e) and DepoDur, which would in turn be a breach of our obligations under our amended and restated royalty interests assignment agreement, or the Amended and Restated Royalty Interests Assignment Agreement, with Royalty Securitization Trust I, an affiliate of Paul Capital Advisors, LLC, or Paul Capital. See Risk Factors Risks Related to Our Financial Condition and Capital Requirements. Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.

We rely on third parties for the timely supply of specified raw materials and equipment for the manufacture of DepoCyt(e) and DepoDur. Although we actively manage these third-party relationships to provide continuity and quality, some events which are beyond our control could result in the complete or partial failure of these goods and services. Any such failure could have a material adverse effect on our financial condition and operations.

The manufacture of pharmaceutical products 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 current Good Manufacturing Practices, or cGMP, regulations and in the case of the manufacturing of DepoDur required government licenses regarding the storage and use of controlled substances. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval for sale, product seizure or recall, or withdrawal of product approval, and

Table of Contents

would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation, product liability claims and litigation.

***Our future growth depends on our ability to identify, develop, acquire or in-license products and if we do not successfully identify develop, acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.***

An important part of our business strategy is to continue to develop a pipeline of product candidates by developing, acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. However, these business activities may entail numerous operational and financial risks, including:

- difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;
- disruption of our business and diversion of our management's time and attention;
- higher than expected development, acquisition or in-license and integration costs;
- exposure to unknown liabilities;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- inability to retain key employees of any acquired businesses;
- difficulty in managing multiple product development programs; and

- inability to successfully develop new products or clinical failure.

We have limited resources to identify and execute the development, acquisition or in-licensing of products, businesses and technologies and integrate them into our current infrastructure. We may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential development, acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

***Our business involves the use of hazardous materials and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Our manufacturing activities involve the controlled storage, use and disposal of hazardous materials, including the components of our products, product candidates and other hazardous compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling, release and disposal of, and exposure to, these hazardous materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future releases.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of

Table of Contents

our product development programs. For example, the loss of clinical trial data from completed clinical trials for EXPAREL could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

*Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.*

Our business model is to commercialize our product candidates in the United States and generally to seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our product candidates in the rest of the world. Accordingly, we may enter into collaboration arrangements in the future on a selective basis. Any future collaboration arrangements that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaboration arrangements.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

**Regulatory Risks**

**We may not receive regulatory approval for any of our product candidates, or the approval may be delayed for various reasons, including successful challenges to the FDA's interpretation of Section 505(b)(2), which would have a material adverse effect on our business and financial condition.**

We may experience delays in our efforts to obtain regulatory approval from the FDA for any of our product candidates, and there can be no assurance that such approval will not be delayed, or that the FDA will ultimately approve these product candidates.

The FDA, as a condition of the EXPAREL approval on October 28, 2011, has required us to study EXPAREL in pediatric patients. We have agreed to a trial timeline where, over several years, we will study pediatric patient populations in descending order starting with 12-18 year olds and ending with children under two years of age. These trials will be expensive and time consuming and we will be required to meet the timelines for completion as agreed with the FDA.

*The FDA may determine that EXPAREL or any of our product candidates have undesirable side effects.*

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. The number of such requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by EXPAREL or any product candidate could also result in the inclusion of unfavorable information in our product labeling, imposition of distribution or use restrictions, a requirement to conduct post-market studies, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of EXPAREL or any product candidate.

For example, the side effects observed in the EXPAREL clinical trials completed to date include nausea and vomiting. In addition, the class of drugs that EXPAREL belongs to has been associated with nervous system and cardiovascular toxicities at high doses. We cannot be certain that these side effects and others will not be observed in the future, or that the FDA will not require additional trials or impose more severe labeling restrictions due to these side effects or other concerns. The active component of EXPAREL is bupivacaine and bupivacaine infusions have been associated with the destruction of articular cartilage, or chondrolysis. Chondrolysis has not been observed in clinical trials of EXPAREL, but we cannot be certain that this side effect will not be observed in the future.

Table of Contents

Following approval of EXPAREL or any of our product candidates, if we or others later identify undesirable side effects caused by such products:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- regulatory authorities may impose restrictions on the distribution or use of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to product liability claims and litigation; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of EXPAREL or any of our product candidates and could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

***Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.***

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for



some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

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

EXPAREL, DepoCyt(e) and DepoDur 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 and submission of safety and other post-market information on the drug. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market.

If EXPAREL, DepoCyt(e) and DepoDur 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, the FDA informed us that certain adverse event reports related to DepoCyt(e) and DepoDur submitted to us during the previous two years were not submitted by us to the FDA within the required 15-day timeframe for reporting such events. In response to the FDA's observations, we enhanced our reporting procedures and hired additional personnel to support our pharmacovigilance efforts.

***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 a federal healthcare program,

such as the Medicare and Medicaid programs;

- federal civil and criminal false claims 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- 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.

Table of Contents

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, disclose marketing payments made to physicians, and 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 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.

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

The design, development, manufacture, supply, and distribution of our products EXPAREL, DepoCyt(e) and DepoDur is technically complex and highly regulated. 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. In complying with cGMP 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 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

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

instance, in connection with routine inspections of one of our manufacturing facilities in April and May 2008, the FDA issued a Form 483 Notice of Inspectional Observations identifying certain deficiencies with respect to our laboratory control system for Depocyt(e). As a result, we did not release new lots of Depocyt(e) for a limited time period as we validated a new assay. We also submitted the new assay to the FDA in July 2008 and in August 2008 we began releasing new lots of DepoCyt(e).

Table of Contents

*If we fail to comply with the extensive regulatory requirements to which we and our products, EXPAREL, DepoCyt(e) and DepoDur, are subject, such products could be subject to restrictions or withdrawal from the market and we could be subject to penalties.*

The testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, export and marketing, among other things, of our products EXPAREL, DepoCyt(e) and DepoDur are subject to extensive regulation by governmental authorities in the United States and elsewhere throughout the world. Quality control and manufacturing procedures regarding EXPAREL, DepoCyt(e) and DepoDur must conform to cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract manufacturers to comply with the laws administered by the FDA or other governmental authorities could result in, among other things, any of the following:

- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- interruption of production;
- operating restrictions;
- warning letters;
- injunctions;
- fines and other monetary penalties;
- criminal prosecutions; and
- unanticipated expenditures.

***If the government or third-party payers fail to provide coverage and adequate coverage and payment rates for EXPAREL, DepoCyt(e), DepoDur or any future products we may develop, license or acquire, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.***

In both domestic and foreign markets, sales of our existing products and any future products will depend in part upon the availability of coverage and reimbursement from third-party payers. Such third-party payers include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates. Accordingly, EXPAREL, DepoCyt(e), DepoDur or any product candidates that we may develop, in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payers. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Third party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, results of operations, financial condition and prospects.

Table of Contents

*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;



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

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- 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. A number of states have challenged the constitutionality of certain provisions of the Health Care Reform Law, and many of these court challenges are still pending final adjudication. Congress has also proposed a number of legislative initiatives, including possible repeal of the Health Care Reform Law. At this time, it

Table of Contents

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.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. Most recently, 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.

***Public concern regarding the safety of drug products such as EXPAREL could result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.***

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to provide additional clinical or preclinical data for EXPAREL, the indications for which this product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize EXPAREL may be otherwise adversely impacted.

***Our product, DepoDur, is subject to regulation by the Drug Enforcement Agency and such regulation may affect the sale of DepoDur.***

Products used to treat and manage pain, especially in the case of opioids, are from time to time subject to negative publicity, including illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. DepoDur contains morphine, and it is regulated as a Schedule II controlled substance. Despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of morphine does occur. Thus, the marketing of DepoDur by our partners may generate public controversy that may adversely affect sales of DepoDur and decrease the revenue we receive from the sale of DepoDur.

Table of Contents

In addition, we and our contract manufacturers are subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

**Risks Related to Intellectual Property**

***The patents and the patent applications that we have covering our products are limited to specific injectable formulations, processes and uses of drugs encapsulated in our DepoFoam drug delivery technology and our market opportunity for our product candidates may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors.***

The active ingredients in EXPAREL, DepoCyt(e) and DepoDur are bupivacaine, cytarabine and morphine, respectively. Patent protection for the bupivacaine, cytarabine and morphine molecules themselves has expired and generic immediate-release products are available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as EXPAREL, DepoCyt(e) and DepoDur so long as the competitors do not infringe any process, use or formulation patents that we have developed for these drugs encapsulated in our DepoFoam drug delivery technology.

For example, we are aware of at least one long acting injectable bupivacaine product in development which utilizes an alternative delivery system to EXPAREL. Such a product is similar to EXPAREL in that it also extends the duration of effect of bupivacaine, but achieves this clinical outcome using a completely different drug delivery system compared to our DepoFoam drug delivery technology.

The number of patents and patent applications covering products in the same field as EXPAREL indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for EXPAREL could be significantly harmed if competitors are able to develop and commercialize alternative formulations of bupivacaine that are long acting but outside the scope of our patents.

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

Now that EXPAREL is approved by the FDA, one or more third parties may challenge the patents covering this product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing bupivacaine and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for EXPAREL; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for EXPAREL, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other

Table of Contents

proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

***Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection and all patents will eventually expire.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for EXPAREL, DepoCyt(e), DepoDur, DepoFoam and for any product candidates that we may develop, license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications will result in issued patents;
- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged by third parties;

- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

Patent applications in the United States are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, we cannot be certain we were the first to invent or the first to file patent applications on EXPAREL, our DepoFoam drug delivery technology or any product candidates that we may develop, license or acquire. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all United States and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

Some of our older patents have already expired. In the cases of DepoCyt(e) and DepoDur, key patents providing protection in Europe have expired. In the case of EXPAREL, while pending patent applications, if granted, would provide protection for EXPAREL in Europe and the United States through November 2018, an existing formulation patent for

Table of Contents

EXPAREL will expire in November 2013. Once our patents covering EXPAREL have expired, we are more reliant on trade secrets to protect against generic competition.

We also rely on trade secrets to protect our technology, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for EXPAREL, DepoCyt(e), DepoDur, DepoFoam or any product candidate that we may develop, license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability.

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.***

Our ability to develop, manufacture, market and sell EXPAREL, our DepoFoam drug delivery technology or any product candidates that we may develop, license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain management and cancer treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that EXPAREL, DepoCyt(e) or DepoDur may infringe. There could also be existing patents of which we are not aware that EXPAREL, DepoCyt(e) or DepoDur may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their products or technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;



- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

*We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.*

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Table of Contents

**Risks Related to Our Financial Condition and Capital Requirements**

*We believe certain matters raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.*

As of September 30, 2011, we believe certain matters raise substantial doubt about our ability to continue as a going concern. Such doubts are based on our recurring losses and our cash used in operating activities. We continue to experience losses. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including by the sale of our securities, obtaining loans from financial institutions or other financing arrangements, where possible. Our continued losses increase the difficulty of our meeting such goals and our efforts to continue as a going concern may not prove successful.

*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 \$27.1 million, \$31.7 million, and \$41.9 million for the years ended December 31, 2010, 2009, and 2008, respectively. As of September 30, 2011, we had an accumulated deficit of \$165.0 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.

*We may never become profitable.*

Our ability to become profitable depends upon our ability to generate revenue from EXPAREL and to continue to generate revenue from DepoCyt(e) and DepoDur. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- manufacture commercial quantities of EXPAREL, at acceptable cost levels;
- continue to manufacture DepoCyt(e) and DepoDur for sale by our commercial partners; and
- continue to develop a commercial organization and the supporting infrastructure required to successfully market and sell EXPAREL.

We anticipate incurring significant additional costs associated with the commercialization of EXPAREL. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

***Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.***

On March 23, 2007, we entered into the Amended and Restated Royalty Interests Assignment Agreement with affiliates of Paul Capital, pursuant to which we assigned to Paul Capital the right to receive a portion of our royalty payments from DepoCyt(e) and DepoDur. To secure our obligations to Paul Capital, we granted Paul Capital a security interest in collateral which includes the royalty payments we are entitled to receive with respect to sales of DepoCyt(e) and DepoDur, as well as to bank accounts to which such payments are deposited. Under our arrangement with Paul Capital, upon the occurrence of certain events, or the put events, including if we experience a change of control, we or our subsidiary undergo certain bankruptcy events, transfer any or substantially all of our rights in DepoCyt(e) or DepoDur, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Amended and Restated Royalty Interests Assignment Agreement, or sales of DepoCyt(e) or DepoDur are suspended due to an injunction or if we elect to suspend sales of DepoCyt(e) or DepoDur as a result of a lawsuit filed by certain third parties, Paul Capital may (i)

Table of Contents

require us to repurchase the rights we assigned to it at a cash price equal to (a) 50% of all cumulative payments made by us to Paul Capital under the Amended and Restated Royalty Interests Assignment Agreement during the preceding 24 months, multiplied by (b) the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.

***Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.***

We have a substantial level of debt. As of September 30, 2011, we had \$26.3 million in aggregate principal amount of indebtedness outstanding, not including our obligation under the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital. The level and nature of our indebtedness, among other things, could:

- make it difficult for us to make payments on our outstanding debt from time to time or to refinance it;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, product and company acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business including life cycle management;
- reduce funds available for use in our operations;
- impair our ability to incur additional debt because of financial and other restrictive covenants;
- make us more vulnerable in the event of a downturn in our business;
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources;
- restrict the operations of our business as a result of provisions in the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital that restrict our ability to (i) amend, waive any rights under, or terminate any material agreements relating to DepoCyt(e) and DepoDur, (ii) enter into any new agreement or amend or fail to exercise any of our material rights under existing agreements that would

materially adversely affect Paul Capital's royalty interest, and (iii) sell any material assets related to DepoCyt(e) or DepoDur; or

- impair our ability to merge or otherwise affect the sale of the Company due to the right of the holders of certain of our indebtedness to accelerate the maturity date of the indebtedness in the event of a change of control of the Company.

We will need to raise additional capital to pay our indebtedness as it comes due. If we are unable to obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. If we are unable to refinance or repay our indebtedness as it becomes due, we may become insolvent and be unable to continue operations.

For example, our loan and security agreement governing our \$26.3 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders, or the Hercules Credit Facility, contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the Hercules Credit Facility. Our failure to comply with the covenants in the loan and security agreement governing the Hercules Credit Facility could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets pledged to secure the debt.

Table of Contents

*Our short operating history makes it difficult to evaluate our business and prospects.*

We were incorporated in December 2006 and have only been conducting operations with respect to EXPAREL since March 2007. Our operations to date have been limited to organizing and staffing our company, conducting product development activities, including clinical trials and manufacturing development activities, for EXPAREL and manufacturing and related activities for DepoCyt(e) and DepoDur. Further, in 2010 and 2011 we began to establish our commercial infrastructure for EXPAREL. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

*We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.*

Developing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and continue our efforts to hire, and outsource through our relationship with Quintiles, additional personnel and build a commercial infrastructure to prepare for the commercialization of EXPAREL;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- in-license and develop additional product candidates.

We may not have sufficient financial resources to meet all of our objectives, which could require us to postpone, scale back or eliminate some, or all, of these objectives, including our launch activities for EXPAREL. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of establishing a commercial organization to sell, market and distribute EXPAREL;
- the success of the commercialization of EXPAREL;
- the cost and timing of manufacturing sufficient supplies of EXPAREL in preparation for commercialization;

- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of extended-release liposome injection of bupivacaine.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, product supply revenue and royalties, corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate, one or more of our development programs or our commercialization efforts.

Table of Contents

***Our quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- our ability to establish the necessary commercial infrastructure to launch EXPAREL without substantial delays, including engaging additional sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- maintaining our existing manufacturing facilities and expanding our manufacturing capacity, including installing specialized processing equipment for the manufacturing of EXPAREL;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting EXPAREL or the product candidates of our competitors; and
- the level of underlying hospital demand for EXPAREL and wholesaler buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***



To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments.

***We incur significant costs as a result of operating as a public company.***

As a public company, we incur significant legal, accounting, insurance and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with complying with the requirements of the Sarbanes-Oxley Act of 2002 and related rules implemented by the Securities and Exchange Commission and The NASDAQ Global Market. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain or maintain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Table of Contents

***Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to devote substantial time to compliance initiatives, and if our independent registered public accounting firm is required to provide an attestation report on our internal controls but is unable to provide an unqualified attestation report, our stock price could be adversely affected.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on the effectiveness of our internal control over financial reporting. The internal control report must contain (i) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (ii) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting and (iii) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire additional employees for our finance and audit functions, potentially engage outside consultants and adopt a detailed work plan to (i) assess and document the adequacy of internal control over financial reporting, (ii) continue steps to improve control processes where appropriate, (iii) validate through testing that controls are functioning as documented, and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. In addition, in connection with the attestation process by our independent registered public accounting firm, if required, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and our stock price could decline.

***The use of our net operating loss carryforwards and research tax credits may be limited.***

We have significant federal and state net operating loss carryforwards. Our net operating loss carryforwards and research and development tax credits may expire and not be used. Our net operating loss carryforwards will begin expiring in 2026 for federal purposes and 2016 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2027 unless previously used. Our state tax credits carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Internal Revenue

California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

***Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturns.***

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage

market and a declining residential real estate market in the United States have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

#### **Risks Related to Ownership of Our Common Stock**

##### ***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 October 28, 2011, the trading prices of our stock have ranged from \$6.16 to \$15.34 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;

Table of Contents

- 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 70% of our outstanding voting stock. As a result, these stockholders have significant influence and may be able to determine all 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.

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

***Because we do not intend to pay dividends on our common stock, your returns will be limited to any increase in the value of our stock.***

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not

Table of Contents

anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

*Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.*

Provisions in our restated certificate of incorporation and our bylaws, as well as provisions of the Delaware General Corporation Law, or DGCL, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

**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, 2011 covered by this report.

#### **Use of Proceeds**

In February 2011, we completed the initial public offering of our common stock pursuant to a registration statement on Form S-1, as amended (File No. 333-170245) that was declared effective on February 2, 2011.

There has been no material change in our planned use of proceeds from the initial public offering from that described in the final prospectus filed with the SEC on February 3, 2011. As of September 30, 2011, we invested \$20.7 million of the net proceeds into investment grade commercial paper and corporate bonds with maturities of less than one year. The remaining proceeds are currently held in a liquid operating account with a major bank.

#### **Item 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

#### **Item 4. [REMOVED AND RESERVED]**

[Table of Contents](#)

**Item 5. OTHER INFORMATION**

Not applicable.



Table of Contents

**Item 6. EXHIBITS**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.1*	Commercial Outsourcing Services Agreement, dated August 25, 2011, between the Registrant and Integrated Commercialization Solutions, Inc.
10.2*	Master Services Agreement, dated August 30, 2011, between the Registrant and Quintiles Commercial US, Inc.
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, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statement of Stockholders' Equity (Deficit), (iv) the Consolidated Statements of Cash Flows, and (v) the Condensed Notes to Consolidated Financial Statements, tagged as blocks of text.****

---

\* Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

\*\* 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: October 31, 2011

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

Dated: October 31, 2011

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