

# Pacira Pharmaceuticals Reports Fourth Quarter and 2010 Financial Results

March 31, 2011

## Continued Progress in Pre-Commercial Activities; 2011 Financial Guidance Established

PARSIPPANY, N.J., March 31, 2011 /PRNewswire via COMTEX/ --

Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX), an emerging specialty pharmaceutical company, today announced financial results for the fourth quarter and full-year ended December 31, 2010, provided an update on the execution of its pre-commercial and launch strategies for EXPAREL™ and established 2011 financial guidance.

"Since our initial public offering in February, we have continued to make significant progress in educating healthcare professionals and other decision makers on the advantages of EXPAREL, including multiple recent data presentations at medical meetings and the formation of several clinical advisory boards led by key opinion leaders," said David Stack, president and chief executive officer of Pacira Pharmaceuticals, Inc. "We have received encouraging feedback from these health care providers regarding the need fora safe, long-acting, easy to use analgesic to manage postsurgical pain. As we continue to advance our pre-launch strategy, we are planning to conduct a number of health outcomes studies focused on the potential for EXPAREL to control pain with reduced reliance on opioid (morphine) analgesics. The health outcomes program is designed in collaboration with our acute health care customers in order to define postsurgical patient and procedure needs where reduced opioid (morphine) consumption provides the opportunity for enhanced patient care and hospital economics."

### **Financial Highlights**

- Net loss for the quarter ended December 31, 2010 was \$7.0 million, or \$12.27 per share, compared with \$9.0 million, or \$15.63 per share, for the quarter ended December 31, 2009. Net loss for the year ended December 31, 2010 was \$27.1 million, or \$47.29 per share, compared with \$31.7 million, or \$55.32 per common share, for the year ended December 31, 2009. In February 2011, the company sold 6 million shares of common stock at \$7.00 per share in its initial public offering (IPO). On a pro forma basis, reflecting the issuance of shares of common stock in the IPO, and the conversion of outstanding preferred stock and promissory notes into an aggregate of approximately 10.7 million shares of common stock, net loss per share was \$1.58 for the year ended December 31, 2010. As the closing of the IPO occurred in February 2011, it is not included in the fourth quarter 2010 financial results, except in certain designated pro forma calculations.
- Total revenues for the quarter ended December 31, 2010 were \$2.2 million compared with \$4.3 million for the fourth quarter of 2009. The \$2.1 million decrease was primarily attributable to a decline in supply revenue of \$1.5 million in the fourth quarter of 2010 that reflects the variable nature of product orders from Pacira's commercial partners and Pacira's practice of running periodic manufacturing campaigns of several lots at a time to increase manufacturing efficiency, which results in supply revenue not falling uniformly within quarters; and a \$0.4 million decrease in collaborative licensing and development revenue resulting from lower reimbursable development activity in the fourth quarter of 2010 compared with the same period of 2009. Total revenues for the year ended December 31, 2010 were \$14.6 million compared with \$15.0 million for the year ended December 31, 2009. The \$0.4 million decrease was primarily due to decreases in collaborative licensing and development revenues of \$1.4 million and royalties of \$0.3 million, partially offset by an increase in supply revenue of \$1.3 million.
- Total operating expenses for the quarter ended December 31, 2010 were \$7.9 million compared with \$12.1 million for the same period of 2009. The \$4.2 million decrease was primarily attributable to the completion of pivotal Phase 3 placebo controlled studies in 2009. Total operating expenses for the year ended December 31, 2010 were \$36.9 million compared with \$43.6 million for the year ended December 31, 2009. The \$6.7 million decrease in expenses for the full year was also attributable to the completion of pivotal Phase 3 placebo controlled studies in 2009.
- As of December 31, 2010, Pacira had unrestricted cash and cash equivalents of \$26.1 million compared with \$7.1 million on December 31, 2009. As of December 31, 2010, the company had pro forma cash, including the proceeds from the IPO, net of underwriters' discounts and commissions and estimated offering expenses, of \$64.6 million. As the closing of the IPO occurred in February 2011, it is not included in the fourth quarter 2010 financial results, except in certain designated pro forma calculations.

shares of common stock in the IPO, and the conversion of outstanding preferred stock and promissory notes, approximately 17.2 million shares of common stock were outstanding.

#### **Full Year 2011 Financial Guidance**

Pacira currently expects to achieve the following financial results for the full-year ending December 31, 2011:

- Excluding the impact of potential sales of EXPAREL should it be approved by the U.S. Food and Drug Administration
  (FDA) in the third quarter of 2011 and commercialized by Pacira in the fourth quarter of 2011, revenue is expected to
  range between \$14 and \$16 million in 2011. Revenue expectations include anticipated DepoCyt and DepoDur supply
  revenue and royalties, and collaborative licensing and development revenues resulting from DepoFoam based
  partnerships.
- Excluding the impact of any future partnerships, asset monetizations or other cash generating activities unrelated to its current operations, Pacira expects cash used in operating activities and for the purchase of fixed assets used in investing activities ("cash burn") to be approximately \$30 million cumulatively through the third quarter of 2011. Based upon the assumption of FDA approval for EXPAREL in the third quarter of 2011 and EXPAREL commercialization in the fourth quarter of 2011, Pacira expects cash burn in the fourth quarter of 2011 to be approximately \$25 million, which would include a \$10 million milestone payment to Skye Pharmaceuticals due upon the first commercial sale of EXPAREL.

## **Recent Developments**

- Presented new Phase 3 EXPAREL data at two medical meetings: Data from Pacira's Phase 3 multicenter, randomized, double-blind, parallel group, placebo-controlled bunionectomy trial was presented at the 2011 American Academy of Orthopaedic Surgeons (AAOS) Annual Meeting and the Orthopaedic Research Society's 57th Annual Meeting. The data demonstrated that the median time to first use of opioid rescue medication was 7.2 hours for patients treated with EXPAREL compared with 4.3 hours for patients on placebo (p<0.0001) and that patients treated with EXPAREL had comparable safety in wound healing and significantly improved efficacy in pain reduction compared to patients treated with placebo. Pacira's poster at AAOS was awarded the best poster in the "foot and ankle" category. Data from this Phase 3 trial was included in the new drug application (NDA) accepted for filing by the FDA in December 2010.
- Presented new Phase 1 study data on subjects with hepatic impairment: Data from Pacira's Phase 1 study evaluating EXPAREL in subjects with moderate, stable hepatic impairment was presented at the 2011 American Society for Clinical Pharmacology and Therapeutics 112th Annual Meeting. Results from the Phase 1 open-label, parallel group volunteer study demonstrated that the differences in plasma exposure of EXPAREL between subjects with moderate, stable hepatic impairment compared to subjects with normal hepatic function were small and unlikely to require a dose adjustment of EXPAREL. Data from this Phase 1 trial was also included in the new drug application (NDA) accepted for filing by the FDA in December 2010.
- Acceptance of EXPAREL NDA filing: In December 2010, the FDA accepted Pacira's NDA filing for EXPAREL, a
  long-acting bupivacaine for postsurgical pain management. The FDA also notified Pacira that its Prescription Drug User
  Fee Act (PDUFA) target date is July, 28, 2011. Data from Pacira's two Phase 3 clinical trials in hemorrhoidectomy and
  bunionectomy, respectively, were included in the NDA filing.

If granted a broad postsurgical pain label by the FDA, Pacira would be positioned to address a U.S. market opportunity of approximately 25 million infiltration and elastomeric bag procedures per year. Based upon the current PDUFA date and potential FDA approval timeline, Pacira plans to commercialize EXPAREL in the U.S. in the fourth quarter of 2011. Beyond infiltration, the company expects to develop EXPAREL for use in nerve block and epidural administration procedures, which collectively represent an additional 14 million annual opportunities per year. Pacira believes there are multiple product opportunities for EXPAREL in the future as well as significant potential for its DepoFoam(R) technology platform, which supports an additional pipeline of development assets and partnering opportunities.

# **Upcoming Activities**

Pacira expects to present at the following investor conferences:

- 18th Annual Future Leaders in the Biotech Industry Conference, April 15, in New York City
- UBS Global Specialty Pharmaceuticals Conference, May 24-25, in London, UK

Pacira expects to have a presence at the following medical meetings:

- Experimental Biology/American Society for Pharmacology and Experimental Therapeutics (EB/ASPET), April 13, in Washington, DC
- 36th Annual Meeting of American Society of Regional Anesthesia (ASRA), May 5-8, in Las Vegas, Nev.
- 26th Annual Meetingof the Society for Ambulatory Anesthesia (SAMBA), May 5-8, in San Antonio, Texas
- 2011 Annual Meeting of American Society of Colon & Rectal Surgeons (ASCRS), May 14-18, in Vancouver, BC
- 2011 Annual Meeting of International Anesthesia Research Society (IARS), May 21-24, in Vancouver, BC
- American Association of Pharmaceutical Scientists: National Biotechnology Conference, May 17, in San Francisco

#### Today's Conference Call and Webcast Reminder

The Pacira management team will host a conference call discussing the company's fourth quarter financial results, recent developments and 2011 financial guidance today at 9:00 a.m. (ET). The call can be accessed by dialing 1-866-831-6270 (domestic) or 1-617-213-8858 (international) five minutes prior to the start of the call and providing the passcode 94842804. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-888-286-8010 (domestic) or 1-617-801-6888 (international), providing the passcode 43508327. The replay of the call will be available for two weeks from the date of the live call.

The live, listen-only webcast of the conference call can be accessed by visiting the investors section of the Pacira's website at <a href="www.pacira.com">www.pacira.com</a>. A replay of the webcast will be archived on the company's website for two weeks following the call.

#### **About Pacira**

Pacira Pharmaceuticals, Inc. is an emerging specialty pharmaceutical company focused on the development, manufacture, and commercialization of novel pharmaceutical products, based on its proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. In December 2010, Pacira announced that its New Drug Application (NDA) for EXPAREL, the company's most advanced investigational product candidate, had been accepted for filing by the U.S. Food and Drug Administration (FDA). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of July 28, 2011 for the review of the EXPAREL NDA. EXPAREL is a bupivacaine-based product and has completed extensive Phase 3 clinical development for postoperative analgesia by infiltration. EXPAREL consists of bupivacaine encapsulated in DepoFoam, which is designed to address the limitations of widely used medications by enhancing their dosing and/or administration profile. Additional information about Pacira is available at <a href="http://www.pacira.com/">http://www.pacira.com/</a>.

#### About EXPAREL™

EXPAREL is Pacira's proprietary drug candidate consisting of bupivacaine encapsulated in DepoFoam(R), both of which are currently used separately in FDA-approved products. Bupivacaine is a well-characterized anesthetic/analgesic that has an established safety profile with more than 20 years of use in the United States. Several Phase 2 and Phase 3 clinical trials have been completed for EXPAREL and demonstrate statistically significant reduction of pain in soft tissue and orthopedic surgery in different surgical models. Clinical data from phase 3 trial 316 demonstrates that EXPAREL provides analgesia for up to 72 hours post-surgery, the primary endpoint for the trial. The package insert for bupivacaine indicates it provides anesthesia for up to 7 hours. The safety of EXPAREL was evaluated in 10 randomized, double-blind, local administration into the surgical wound clinical studies involving 823 patients; the most common adverse events following EXPAREL administration were nausea, constipation, and vomiting.

## Safe Harbor

This press release contains forward-looking statements of Pacira Pharmaceuticals that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the company's plans to develop and commercialize EXPAREL; the Company's plans to continue to manufacture and provide support services for its commercial partners who have licensed DepoCyt(e) and DepoDur; the timing of, and the Company's ability to obtain, regulatory approval of EXPAREL; the timing of the Company's anticipated commercial launch of EXPAREL; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and the Company's ability to serve those markets; the Company's plans to expand the indications of EXPAREL to include nerve block and epidural administration; ands our commercialization and marketing capabilities Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements; and those risks discussed in "Risk Factors" and elsewhere in Pacira Pharmaceuticals' final prospectus dated February 2, 2011 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent Pacira Pharmaceutical's views as of the date of this press release. The Company anticipates that subsequent events and

development will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it has 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 Pacira Pharmaceutical's views as of any date subsequent to the date of this press release.

# Pacira Pharmaceuticals, Inc. Consolidated Statement of Operations (in thousands, except shares and per share data)

	ThreeMonthsEndedDec31, TwelveMonthsEndedDec31,			
	<u>2010</u>	2009	<u>2010</u>	<u>2009</u>
Revenues:				
Supply revenue	\$ 513	\$2,051	\$ 7,640	\$ 6,324
Royalties	1,012	1,138	3,705	4,044
Collaborative licensing and development revenue	<u>666</u>	1,095	3,217	<u>4,638</u>
Total revenues	<u>2.191</u>	4.284	<u>14.562</u>	<u>15.006</u>
Operating expenses:				
Cost of revenues	2,108	3,478	12,276	12,301
Research and development	3,674	7,516	18,628	26,233
Selling, general and administrative	2,089	1,100	6,030	5,020
Total operating expenses	<u>7.871</u>	<u>12.094</u>	<u>36.934</u>	<u>43.554</u>
Loss from operations	(5,680)	(7,810)	(22,372)	(28,548)
Other income	50	14	150	367
Loss on early extinguishment of debt	(184)		(184)	-
Interest:				
Interest income	34	31	146	77
Interest expense	(1,382)	(733)	(3,959)	(1,723)
Royalty interest obligation	<u>118</u>	<u>(473)</u>	<u>(930)</u>	<u>(1.880)</u>
Net loss	\$ (7,044)	\$ (8,971)	\$ (27,149)	\$ (31,707)
Basic and diluted net loss per common share	\$ (12.27)	\$ (15.63)	\$ (47.29)	\$ (55.32)
Weighted average common shares outstanding - basic and diluted	573,989	573,870	574,072	573,118
Proforma loss per common share - Basic and diluted (unaudited)			\$ (1.58)	
Shares used in computing proforma loss per common share - Basic and diluted (unaudited) (1)			17,232,917	

<sup>(1)</sup> Pro forma includes the impact of the conversion of all of our outstanding shares of Series A convertible preferred stock and our secured and unsecured notes (including the notes issued upon the first closing of the December 2010 Convertible Notes) and accrued interest thereon into common stock and proceeds from initial public offering, completed in February 2011, net of underwriters' discounts and commissions and estimated offering expenses.

# Pacira Pharmaceuticals, Inc. Condensed Consolidated Balance Sheets (in thousands)

_	at December 31,				
_	2010	2010 Pro forma (1)	2009		
Cash and cash equivalents	\$26,133	\$ 64,568	\$ 7,077		
Other current assets	4,922	4,922	5,472		
Fixed assets, net	23,950	23,950	19,560		
Intangibles and other assets, net	11,557	10,150	11,845		
Total assets	\$ 66,562	\$ 103,590	\$ 43,954		
Current liabilities	\$16,322	\$ 16,322	\$14,417		
Related party debt, including accrued interest	49,795	-	22,173		
Long term debt	21,869	21,869	-		

Deferred revenue and other long term liabilities	26,959	26,959	30,313
Stockholders' equity	(48,383)	38,440	(22,949)
Total liabilities and stockholders' equity	\$ 66,562	\$ 103,590	\$ 43,954

(1) Pro forma includes the impact of the conversion of all of our outstanding shares of Series A convertible preferred stock and our secured and unsecured notes (including the notes issued upon the first closing of the December 2010 Convertible Notes) and accrued interest thereon into common stock and proceeds from initial public offering, completed in February 2011, net of underwriters' discounts and commissions and estimated offering expenses.

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