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**September 26, 2011** 

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Pacira Pharmaceuticals, Inc. (PCRX - OUTPERFORM): Exparel Use in Plastic Surgery Highlighted at Medical Conference. Plastic Surgery Market Offers Potential for Early Sales, in our View. Reiterate OUTPERFORM

Price: \$10.26 Fair Value Estimate: \$20

- Two presentations related to Exparel were highlighted at the 2011 Annual Meeting of the American Society of Plastic Surgeons (ASPS; September 23 27; Denver, CO). An overview of Exparel, including efficacy and safety data to date, was presented in the "Hot Topics in Plastic Surgery" panel by Richard A. Baxter, M.D., a practicing plastic surgeon in the Seattle area and former president of the Washington Society of Plastic Surgeons and the Northwest Society of Plastic Surgeons, on Friday, September 23<sup>rd</sup>. In addition, an oral presentation titled "Long-Term Safety of Exparel (Bupivacaine Extended Release Liposome Injection) Reveals No Impact on Silicone Breast Implants at up to Two Years Follow-up" was presented by Harold Minkowitz, M.D., a staff anesthesiologist at Memorial Hermann Memorial City Medical Center in Houston, Texas, on Saturday, September 24<sup>th</sup>. The new data presented was from a two-year observational study of Exparel following breast augmentation using silicone implants in a total of 94 patients enrolled in prior Phase 2 and Phase 3 trials who received either Exparel or regular bupivacaine. The new key findings from the study include 1) Exparel did not have an impact on normal healing. 2) There was no negative interaction between Exparel and the silicone breast implant material.

  3) There was no meaningful difference in impact on breast appearance or implant material between the Exparel and bupivacaine groups. And 4) Exparel was not associated with any serious adverse events, deaths, or withdrawals, and no drug-related clinical sequelae (decreased breast size, hard knots, uneven appearance, and swelling) was found.
- We believe plastic surgeries, mainly breast augmentation and abdominoplasty (tummy tuck), offer a market opportunity of about one million annual procedures where Exparel could be used before hospital formulary approval given that plastic surgery is generally an all-cash business. In our opinion, the presentations at ASPS and other medical conferences go a long way toward increasing physician awareness and comfort with Exparel ahead of a potential launch and should help drive early adoption. While the hospital formulary process which typically takes 6 to 12 months is normally the gating factor in hospital drug launches, we believe the launch of Exparel could be somewhat differentiated given the opportunity in plastic surgery as well as a replacement for elastomeric bags (additional ~1 million opportunities annually), both of which may not require formulary approval prior to sales. We anticipate that the initial launch strategy will focus on high volume hospitals in the areas of soft tissue surgery, plastic surgery, and elastomeric bag replacement. To support the launch, Pacira expects to have data from both retrospective and prospective health outcome studies which are likely to show the cost benefit of Exparel use versus treating opioid-related adverse events. Furthermore, the company plans to publish data in numerous medical journals and participate in several upcoming medical meetings to increase awareness. In our opinion, these pre-launch activities should help position Exparel for a successful launch with early adoption, driven by key opinion leaders.
- We anticipate the next major catalyst for Pacira is the PDUFA date of October 28, 2011, for Exparel treatment of postsurgical pain management. We estimate a 75% chance that Exparel is approved on its PDUFA date and think the stock could double on approval. With the recent pullback in PCRX shares, we see a favorable risk/reward scenario and remain confident in approval for three main reasons. First, the efficacy evidence for the NDA is based on two positive Phase 3 trials of Exparel which the FDA acknowledged at a pre-NDA meeting in February 2010 to be appropriately designed to evaluate safety and efficacy. Second, the safety profile of Exparel seems adequate for approval and while the FDA typically requires a 500 patient safety database for pain drugs, Pacira submitted data for over 1300 patients. Third, the FDA is already familiar with bupivacaine, the active ingredient in Exparel, as well as Pacira's DepoFoam technology. Furthermore, the hemorrhoidectomy (soft-tissue surgery) and bunionectomy (orthopedic surgery) indications were selected to support a broad label for use as a single dose local administration into the surgical wound to produce postsurgical analgesia. We believe Exparel is likely to receive this broad label, given that other pain drugs such as OFIRMEV, Caldolor, and Zipsor were all recently approved with broad labels for pain.
- We reiterate our OUTPERFORM rating and fair value of \$20. Our fair value is calculated based on the sum-of-parts for
  each drug/indication, combination using a 30% annual discount from our peak annual revenues projections and 1-10x
  multiple, depending on stage of development to reflect risk.

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## POTENTIAL UPCOMING MILESTONES (\*OUR ESTIMATES)

October 16-19, 2011 Participation at American College of Clinical Pharmacy (ACCP; Pittsburgh, PA)
October 23-27, 2011 Participation at American College Surgeons (ACS; San Francisco, CA)

October 28, 2011 Exparel (infiltration) PDUFA date

2011\* Select clinical candidate from DepoNSAID program
2011/2012\* Potential partnership for ex-US rights of Exparel
2011/2012\* Potential additional technology partnerships

Q1:12 US launch of Exparel (infiltration)

H1:12\* Initiate pivotal trial of Exparel in nerve block H2:12\* Pivotal trial data for Exparel in nerve block

Risks to our fair value include regulatory and commercial risk for Pacira's lead drug candidate Exparel. The PDUFA date for Exparel is October 28, 2011 and there is always risk that the FDA could delay approval. On the commercial front, Exparel will compete with generic forms of regular bupivacaine and, although we believe Exparel offers therapeutics advantages, some physicians may opt for the cheaper alternative.



#### **Analyst Certification**

I, Richard Lau, Liana Moussatos, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Company	Disclosure
Pacira Pharmaceuticals, Inc.	1,3,4,5,7

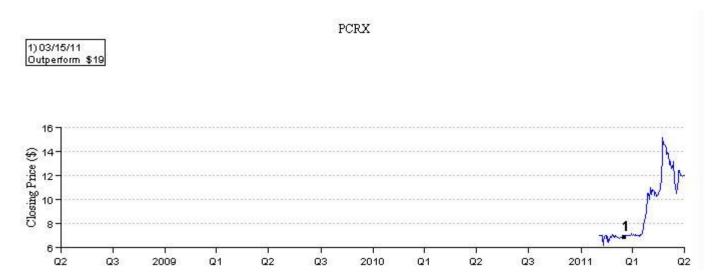
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