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Related Companies: Share Price: DRRX 1.18
PCRX 8.60

# Pacira Pharmaceuticals Overweight

(PCRX - \$8.60)

## **Specialty Pharmaceuticals**

# Posidur Miss Translates Into An Improved Competitive Landscape for Exparel

#### **CONCLUSION:**

Last night, DURECT/Hospira announced that its Phase III study evaluating its extended release formulation of bupivicaine for in post-operative pain did not meet its primary endpoints versus placebo. Though DURECT is planning discussions with the FDA regarding the path forward, we would be surprised if the FDA deemed the current body of data to be acceptable for an NDA filing. As such, last night's news likely points to the absence of significant competition for the foreseeable future. We continue to believe that peak Exparel sales north of \$200M are realistic, and further believe that the barriers to a potential generic version of the product are exceedingly high, translating into a sustainable cash flow stream for Pacira. We reiterate our Overweight rating and \$11 price target on PCRX.

- DRRX/Hospira's Posidur fails to meet co-primary endpoints. The pivotal Phase III trial tested Posidur in 305 patients undergoing general abdominal surgical procedures. Posidur failed to show a statistically significant reduction in pain scores at 72 hours as measured by area under the curve (AUC), and also failed to show superiority in terms of opioid usage.
- Exparel did show clear benefit over placebo in Phase III. Recall that in a Phase III study evaluating Exparel in patients undergoing a hemorrhoidectomy, the 300 mg dose was superior to placebo on pain scores at 72 hours, per AUC measurement (p<0.0001). Further, 28% of patients on Exparel were opioid-free through 72 hours versus 10% of patients on placebo (p<0.0007). In a second Phase III study in patients undergoing a bunionectomy, a dose of 120 mg of Exparel was superior to placebo on pain scores at 24 hours, also per AUC (p=0.0005). We would keep in mind that initial Phase III studies testing Exparel failed to show superiority, and PCRX had to go back to the drawing board even though earlier data showed encouraging results. We would expect a similar situation to unfold for Posidur given the Phase III setback.
- Competitive landscape for Exparel now looks more favorable. With an estimated 24 million surgical procedures using a local/regional anesthetic (i.e., a sodium channel blocker like bupivacaine), we believe the market is certainly large enough to accommodate multiple long-acting products (i.e. Exparel and Posidur). That said, with the future of Posidur murky, the potential threat of Hospira entering the market in the 2013 timeframe and competing on price has been mitigated significantly in our view.

### PRICE TARGET AND JUSTIFICATION:

We believe the risk/reward profile for PCRX is favorable given Exparel's value proposition. We base our \$11 PT on our 2014 EPS of \$1.41, times a P/E of 9x discounted at 15%.

#### **RISKS TO ACHIEVEMENT OF TARGET PRICE:**

Risks include competitive and reimbursement risks associated with Exparel.

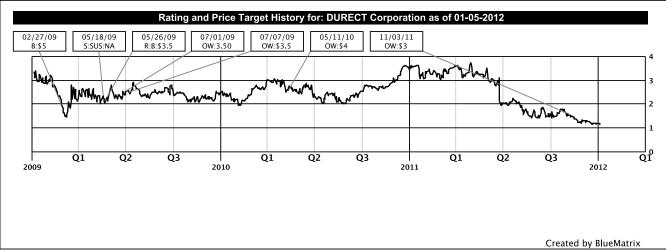
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DURECT Corporation is rated Overweight with a price target of \$3, based on 10x FY14E EPS of \$0.31, disc at 15%. The main risk is significant delays related to pipeline products.

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Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

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S: Suspending Coverage

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N: Neutral

UW: Underweight

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Analyst Certification — David Amsellem, Sr. Research Analyst

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