Pacira Pharmaceuticals, Inc. (PCRX-NASDAQ)

**SUMMARY**

Pacira reported fourth-quarter net income of $0.14 per share, missing the Zacks Consensus Estimate of $0.19. The company had reported a loss of $0.36 per share in the year-ago quarter. Fourth-quarter 2014 revenues soared 84.1% year over year to $61.8 million, in line with the Zacks Consensus Estimate. Earnings estimates for 2015 have gone down significantly ever since the company missed on earnings in the fourth quarter. Pacira suffered a major setback when the company received a CRL from the FDA following a review of its sNDA for Exparel. The company was seeking to expand the label of its lead product Exparel in the U.S. in femoral nerve block in total knee arthroplasty. We are not certain if the company will meet its targets for 2015. Consequently, we downgrade our recommendation to Underperform.

**SUMMARY DATA**

- **52-Week High**: $119.27
- **52-Week Low**: $62.95
- **One-Year Return (%)**: 30.33
- **Beta**: 1.24
- **Average Daily Volume (sh)**: 659,693
- **Shares Outstanding (mil)**: 36
- **Market Capitalization ($mil)**: $3,344
- **Short Interest Ratio (days)**: 8.33
- **Institutional Ownership (%)**: N/A
- **Insider Ownership (%)**: 9
- **Annual Cash Dividend**: $0.00
- **Dividend Yield (%)**: 0.00
- **5-Yr. Historical Growth Rates**:
  - Sales (%): 107.1
  - Earnings Per Share (%): N/A
  - Dividend (%): N/A
- **P/E using TTM EPS**: N/A
- **P/E using 2015 Estimate**: 108.0
- **P/E using 2016 Estimate**: 34.8
- **Zacks Rank**: 5 - Strong Sell
- **Risk Level ***: Above Average
- **Type of Stock**: Mid-Growth
- **Industry**: Med-Drugs
- **Zacks Industry Rank ***: 106 out of 267

**ZACKS CONSENSUS ESTIMATES**

**Revenue Estimates**

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Year</th>
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<tbody>
<tr>
<td>(Mar)</td>
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<td>2013</td>
<td>12 A</td>
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<td>2015</td>
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<td>2016</td>
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Note: Quarterly revenues may not add up to the annual figures due to rounding off.

**Earnings Per Share Estimates**

(EPS is operating earnings before non-recurring items, but including employee stock options expenses)

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Year</th>
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<tr>
<td>(Mar)</td>
<td>(Jun)</td>
<td>(Sep)</td>
<td>(Dec)</td>
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<tr>
<td>2013</td>
<td>-$0.61 A</td>
<td>-$0.42 A</td>
<td>-$0.41 A</td>
<td>-$0.36 A</td>
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<tr>
<td>2014</td>
<td>-$0.31 A</td>
<td>-$0.11 A</td>
<td>-$0.05 A</td>
<td>$0.14 A</td>
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<tr>
<td>2015</td>
<td>$0.06 E</td>
<td>$0.17 E</td>
<td>$0.20 E</td>
<td>$0.43 E</td>
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<tr>
<td>2016</td>
<td></td>
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<td>$2.67 E</td>
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Note: Quarterly EPS may not add up to the annual figures due to rounding off.

**Projected EPS Growth - Next 5 Years %**

30
OVERVIEW

Pacira Pharmaceuticals, Inc. is a specialty pharmaceutical company that focuses on the development, commercialization and manufacture of proprietary pharmaceutical products. These products are developed using the company’s proprietary DepoFoam drug delivery technology for use primarily in hospitals and ambulatory surgery centers.

Pacira currently has two products – Exparel and DepoCyt(e). Pacira’s prime product, Exparel, was approved by the FDA in 2011 and launched in 2012. Exparel is a liposome injection of bupivacaine, which is indicated for administration into the surgical site to produce postsurgical analgesia. DepoCyt(e) is indicated for intrathecal treatment of lymphomatous meningitis.

Total revenue in 2014 was $193.5 million, up from $81.9 million in 2013.

REASONS TO SELL

- **Earnings Estimates Down Significantly:** Earnings estimates for 2015 have gone down significantly ever since the company missed on earnings in the fourth quarter. With the company’s plan to expand Exparel's label suffering a major blow, we are not certain if the company will meet its targets for 2015.

- **CRL regarding sNDA for Exparel:** Pacira suffered a major setback when the company received a complete response letter (CRL) from the FDA following a review of its supplemental new drug application (sNDA) for Exparel. Pacira was seeking to expand the label of its lead product Exparel in the U.S. in femoral nerve block in total knee arthroplasty. Consequently, Pacira intends to schedule an End-of-Review meeting with the Division of Anesthesia, Analgesia and Addiction Products of the Center for Drug Evaluation and Research to discuss the contents of the CRL on an immediate basis. A label expansion of the drug would have further boosted its sales.

- **Exclusive Dependence on Exparel:** Pacira is entirely dependent on Exparel for growth. Exparel accounted for 95% of total sales in 2014. The company’s top line will be adversely impacted by a drop in Exparel sales. Moreover, increasing completion might also impact Exparel's sales. Exparel competes with elastomeric pump/catheter devices, which are designed to provide bupivacaine over several days. Exparel faces competition from I-FLOW Corporation which has been marketing these medical devices in the U.S. since 2004. Exparel also faces intense competition from currently marketed bupivacaine and opioid analgesics such as morphine.

RISKS

- **Exparel, the Growth Driver:** Demand for Exparel has been strong since its launch in Apr 2012, driven by growth within existing accounts along with increasing acceptance by major hospitals and orthopedic centers as it continues to be used in orthopedic procedures. Exparel sales in 2014 came in at $188.5 million, up from $85.5 million in 2013. Moreover, continued adoption of Exparel for transversus abdominis plane, infiltration procedures for abdominal and genitourinary surgeries has positively impacted sales. Moreover, Pacira is looking to expand Exparel's label to boost its sales – oral surgery and chronic pain. The company expects that a label expansion of Exparel into oral surgery will benefit oral and maxillofacial surgeons, prosthodontists and endodontists by giving them the ability to produce analgesia with a single-dose administration during the days following surgery. The successful development of Exparel for additional indications will boost sales and we might revisit our recommendation in such a scenario.
Expansion into the Animal Health Market: Meanwhile, Pacira is looking to expand Exparel's label in the animal health market as well. The company had entered into an exclusive license, development and commercialization agreement and related supply agreement with Aratana Therapeutics, Inc. in Dec 2012. As per the agreement, Pacira granted an exclusive royalty-bearing license to Aratana for the development and commercialization of Exparel for animal health indications. Subsequently, Aratana agreed to develop and seek approval for the use of the product in veterinary surgery to manage postsurgical pain, focusing initially on developing it for cats, dogs and other companion animals. In Dec 2014, Aratana initiated a pivotal field effectiveness study in dogs undergoing knee surgery. Expansion into the animal health market will diversify Exparel's franchise and might offset the decline in sales in the prime markets.

RECENT NEWS

Pacira Plunges on FDA’s CRL on Exparel – Mar 2, 2015

Pacira announced the receipt of a complete response letter (CRL) from the FDA following a review of its supplemental new drug application (sNDA) for Exparel.

We note that Exparel is a liposome injection of bupivacaine indicated for single-dose administration into the surgical site to produce postsurgical analgesia. Pacira was seeking to expand the label of its lead product Exparel in the U.S. in femoral nerve block in total knee arthroplasty.

Consequently, Pacira intends to schedule an End-of-Review meeting with the Division of Anesthesia, Analgesia and Addiction Products of the Center for Drug Evaluation and Research to discuss the contents of the CRL on an immediate basis.

Our Take

The CRL for Exparel's sNDA was disappointing. We note that Exparel is Pacira's only approved product, making the company solely dependent on it for growth.

Exparel revenues came in at $188.5 million in 2014, up from $76.2 million in 2013. Demand for Exparel has been strong since its launch in Apr 2012, driven by growth within existing accounts and higher adoption by major hospitals and medical centers as its use in orthopedic procedures is increasing. A label expansion of the drug would have further boosted its sales.

We expect investor focus on further updates on the CRL.

Pacira Misses Earnings Estimates in Q4, Revenues in Line – Feb 24, 2015

Pacira reported fourth-quarter net income of $0.14 per share, missing the Zacks Consensus Estimate of $0.19. The company had reported a loss of $0.36 per share in the year-ago quarter.

Fourth-quarter 2014 revenues soared 84.1% year over year to $61.8 million, in line with the Zacks Consensus Estimate. The year-over-year increase in revenues was primarily driven by higher demand for Exparel.

Pacira's net revenue comprises product revenues, collaborative licensing and development revenues, and royalty revenues. Exparel revenues were $59.0 million, up from $30.5 million in the year-ago quarter, primarily driven by higher demand. Collaboration and license agreement revenues, and royalty revenues were $0.3 million and $0.6 million, respectively.
Meanwhile, Pacira is working on the label expansion of Exparel. The company is currently seeking FDA approval for Exparel in femoral nerve block in total knee arthroplasty with a response due by Mar 5, 2015.

Research and development expenses decreased 19.6% to $3.9 million from the year-ago quarter. Selling, general and administrative expenses however increased 53.8% year over year to $31.0 million.

**Annual Results**

Revenues came in at $197.7 million, up 131% from 2013, in line with the Zacks Consensus Estimate. Loss per share came in at $0.39 in 2014 compared to a loss of $1.93 per share in 2013.

**2015 Outlook**

Exparel revenues are projected in the range of $310 million to $330 million in 2015. Earlier in the month, Pacira announced that it has resolved its issue with the FDA related to the promotional aspects of its lead product Exparel. The company had received a warning letter from the FDA's Office of Prescription Drug Promotion (OPDP) regarding certain promotional materials on Exparel. The letter from the agency had accused the company of making misleading statements related to Exparel in educational technique flashcards (administration guides) and a journal advertisement submitted under Form FDA-2253. The resolution of the matter with OPDP will remove a major overhang on Pacira's shares as Exparel is its lead product.

**Pacira Resolves Promotion Issues Related to Exparel – Feb 12, 2015**

Pacira announced that it has resolved its issue with the FDA related to the promotional aspects of its lead product Exparel.

We note that Pacira had received a warning letter from the FDA’s Office of Prescription Drug Promotion (OPDP) regarding certain promotional materials on Exparel. The letter from the agency had accused the company of making misleading statements related to Exparel in educational technique flashcards (administration guides) and a journal advertisement submitted under Form FDA-2253.

According to the OPDP, the administration guides show that Exparel is intended for indications for which it has not been approved. Additionally, the product label does not provide adequate directions for use in these indications.

The OPDP claimed that according to the Federal Food, Drug and Cosmetic (FD&C) Act, Pacira's activities misbranded Exparel and violated the approved rules. The OPDP therefore requested the company to take immediate actions to stop violation of the FD&C Act.

As per the resolution, Pacira will now accurately communicate to its customers that Exparel is indicated for administration into the surgical site to produce postsurgical analgesia. The approval was based on pivotal trials conducted in excisional hemorrhoidectomy and bunionectomy surgical models. Hence, the basis of assessment of safety and efficacy has been limited to these two procedures.

Moreover, Exparel demonstrated a significant reduction in pain intensity scores compared to placebo for up to 24 hours in both the trials in the context of duration of efficacy.

The resolution of the matter with OPDP will remove a major overhang on Pacira's shares as Exparel is its lead product.

**Pacira Announces Changes to Exparel Label – Dec 12, 2014**
Pacira announced that the FDA approval of changes to the Exparel packaging and label proposed by the company as part of a routine label supplement application are limited to revisions of the product's storage, instructions of use and use in special populations, and do not impact the approved indication whatsoever.

**Pacira Announces Encouraging Data on Exparel – Nov 6, 2014**

Pacira announced encouraging results of an independent, physician-initiated study which was designed to evaluate the difference in postsurgical pain and opioid consumption between patients who received Exparel versus a multi-drug analgesic cocktail (ketorolac, morphine, epinephrine and ropivacaine) for pain management following total knee arthroplasty (TKA).

The results showed that patients treated with Exparel reported significantly lower patient-perceived pain scores and morphine sulfate equivalence consumption, and reported higher satisfaction with pain control and overall experience, compared with patients who received the multi-drug analgesic cocktail.

**VALUATION**

Pacira reported fourth-quarter net income of $0.14 per share, missing the Zacks Consensus Estimate of $0.19. The company had reported a loss of $0.36 per share in the year-ago quarter. Fourth-quarter 2014 revenues soared 84.1% year over year to $61.8 million, in line with the Zacks Consensus Estimate. The year-over-year increase in revenues was primarily driven by higher demand for Exparel.

Earnings estimates for 2015 have gone down significantly after ever since the company missed on earnings in the fourth quarter. Pacira suffered a major setback when the company received a CRL from the FDA following a review of its sNDA for Exparel. The company was seeking to expand the label of its lead product Exparel in the U.S. in femoral nerve block in total knee arthroplasty. We are not certain if the company will meet its targets for 2015.

The stock is currently trading at 108.0x our 2015 earnings estimate, compared with the industry average of 72.8x and the S&P 500’s 16.3x. We believe the stock is grossly overvalued at such levels. Consequently, we downgrade our recommendation to Underperform. Our target price of $84.00 is based on 97.7x our 2015 earnings estimate of $0.86 per share.
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<tr>
<th></th>
<th>P/E F1</th>
<th>P/E F2</th>
<th>Est. 5-Yr EPS Gr%</th>
<th>P/CF (TTM)</th>
<th>P/E 5-Yr High (TTM)</th>
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<td>TTM is trailing 12 months; F1 is 2015 and F2 is 2016, CF is operating cash flow</td>
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<th>P/B Last Qtr.</th>
<th>P/B 5-Yr High</th>
<th>P/B 5-Yr Low</th>
<th>ROE (TTM)</th>
<th>D/E Last Qtr.</th>
<th>Div Yield Last Qtr.</th>
<th>EV/EBITDA (TTM)</th>
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DISCLOSURES & DEFINITIONS

The analysts contributing to this report do not hold any shares of PCRX. The EPS and revenue forecasts are the Zacks Consensus estimates. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts' personal views as to the subject securities and issuers. Zacks certifies that no part of the analysts' compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report. Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed herein are subject to change. This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. Zacks uses the following rating system for the securities it covers. Outperform: Zacks expects that the subject company will outperform the broader U.S. equity market over the next six to twelve months. Neutral: Zacks expects that the company will perform in line with the broader U.S. equity market over the next six to twelve months. Underperform: Zacks expects the company will underperform the broader U.S. Equity market over the next six to twelve months. The current distribution of Zacks Ratings is as follows on the 1109 companies covered: Outperform - 15.3%, Neutral - 78.4%, Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.

Our recommendation for each stock is closely linked to the Zacks Rank, which results from a proprietary quantitative model using trends in earnings estimate revisions. This model is proven most effective for judging the timeliness of a stock over the next 1 to 3 months. The model assigns each stock a rank from 1 through 5. Zacks Rank 1 = Strong Buy. Zacks Rank 2 = Buy. Zacks Rank 3 = Hold. Zacks Rank 4 = Sell. Zacks Rank 5 = Strong Sell. We also provide a Zacks Industry Rank for each company which provides an idea of the near-term attractiveness of a company's industry group. We have 264 industry groups in total. Thus, the Zacks Industry Rank is a number between 1 and 264. In terms of investment attractiveness, the higher the rank the better. Historically, the top half of the industries has outperformed the general market. In determining Risk Level, we rely on a proprietary quantitative model that divides the entire universe of stocks into five groups, based on each stock's historical price volatility. The first group has stocks with the lowest values and are deemed Low Risk, while the 5th group has the highest values and are designated High Risk. Designations of Below-Average Risk, Average Risk, and Above-Average Risk correspond to the second, third, and fourth groups of stocks, respectively.