Salix's third quarter 2014 EPS of $1.37, up 69.1% y-o-y, were above the Zacks Consensus Estimate of $0.73. Revenues grew 49% y-o-y but declined sequentially and missed the Zacks Consensus Estimate of $393 million. Results were disappointing especially given the company's disclosure regarding the inventory levels. The higher wholesale inventory levels are a matter of concern – they indicate a gap in demand and actual sales. The inventory issues have also raised concerns about the company's ability to provide an accurate outlook about future sales. These issues will also lower Salix's chances of being acquired in the near future. Although Salix has progressed with its pipeline, we expect inventory management issues to remain the primary focus area for investors in the upcoming quarters. We remain Neutral on the stock.
OVERVIEW

Raleigh, NC-based Salix Pharmaceuticals, Ltd. is a specialty pharmaceutical company engaged in the acquisition, development, and commercialization of prescription drugs used for the treatment of a variety of gastrointestinal diseases. The company has several marketed products in its portfolio.

In Jan 2014, Salix acquired Santarus and added several products like Zegerid, Uceris and Glumetza to its portfolio.

<table>
<thead>
<tr>
<th>Product (Partner/Acquisition)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xifaxan 200 mg</td>
<td>Traveler’s diarrhea (treatment)</td>
</tr>
<tr>
<td>Xifaxan 550 mg</td>
<td>Reduction of the risk of the recurrence of overt hepatic encephalopathy (HE) in adults</td>
</tr>
<tr>
<td>Zegerid (Santarus acquisition)</td>
<td>Short-term treatment of active duodenal ulcer and active benign gastric ulcer, treatment of gastroesophageal reflux disease (GERD), maintenance of healing of erosive esophagitis and reduction of risk of upper GI bleeding in critically ill patients</td>
</tr>
<tr>
<td>Uceris (Santarus acquisition)</td>
<td>To control mild to moderate ulcerative colitis (UC)</td>
</tr>
<tr>
<td>Glumetza (Santarus acquisition)</td>
<td>Type II diabetes</td>
</tr>
<tr>
<td>Apriso</td>
<td>UC</td>
</tr>
<tr>
<td>OsmoPrep (InKine merger)</td>
<td>Colon cleansing prior to colonoscopy</td>
</tr>
<tr>
<td>MoviPrep (Norgine B.V.)</td>
<td>A liquid bowel cleansing agent</td>
</tr>
<tr>
<td>Pepcid Oral Suspension (Merck)</td>
<td>Gastrointestinal indications including the treatment of duodenal ulcer, benign gastric ulcer and GERD</td>
</tr>
<tr>
<td>Diuril Oral Suspension (Merck)</td>
<td>An adjunctive therapy in edema associated with several conditions including hepatic cirrhosis</td>
</tr>
<tr>
<td>Fulyzaq (Napo Pharmaceuticals)</td>
<td>Symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy</td>
</tr>
<tr>
<td>Relistor (Progenics Pharmaceuticals, Inc.)</td>
<td>Subcutaneous injection for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient</td>
</tr>
<tr>
<td>Solesta (Oceana acquisition)</td>
<td>A biocompatible tissue bulking agent approved for the treatment of fecal incontinence</td>
</tr>
<tr>
<td>Deflux (Oceana acquisition)</td>
<td>The only FDA–approved alternative to major ureteral reimplantation surgery for the treatment of vesicoureteral reflex</td>
</tr>
</tbody>
</table>
Other products include Colazal (balsalazide disodium) for the treatment of mild to moderate active ulcerative colitis, Azasan (azathioprine) immuno-suppressive therapy for renal homo-transplant rejection and rheumatoid arthritis, Anusol/Proctocort (hydrocortisone) for the relief of inflammatory dermatoses and hemorrhoids, Giazo, a tablet formulation of balsalazide disodium, and Metozolv ODT (metoclopramide–Zydis), indicated for short-term (4–12 weeks) therapy for adults with symptomatic documented GERD who fail to respond to conventional therapy and for the relief of symptoms associated with acute and recurrent diabetic gastric stasis.

Salix also acquired an exclusive license from Dr. Falk Pharma for the development and marketing of the latter’s budesonide family of products, including a rectal foam (phase III – U.S. regulatory filing slated shortly for the treatment of active mild or moderate ulcerative proctosigmoiditis) and a gastro-resistant capsule. In Oct 2010, Salix entered into a collaboration agreement with Norwegian specialty pharma company, Photocure, for the development and commercialization of Lumacan, which has the potential to be used for the early detection and diagnosis of colon cancer.

Salix reported $933.8 million in total revenues in 2013, up 27%.

**REASONS TO BUY**

- **Xifaxan Driving Growth:** Xifaxan is the primary growth driver at Salix. Xifaxan, a nonsystemic selective antibiotic taken orally in a 200 mg tablet, is indicated for the treatment of patients 12 years of age and older with travelers' diarrhea caused by non-invasive strains of E coli. A 550 mg dosage formulation of Xifaxan is also approved for hepatic encephalopathy (HE). We believe that the drug will continue experiencing solid growth. Salix has been pretty active in presenting abstracts on Xifaxan at several medical meetings. We believe the results presented in the abstracts will support the development of Xifaxan for additional indications, which in turn should spur sales growth of the product. Price increases together with presentation of additional data on Xifaxan at upcoming medical conferences should help drive growth going forward.

- **New Indications for Xifaxan:** We are pleased to see that Salix is working on developing new indications for the 550 mg dosage formulation of Xifaxan for ailments like non-constipation irritable bowel syndrome with diarrhea (IBS-D). We believe that the IBS-D indication represents significant commercial opportunity for the company. Meanwhile, the HE indication, for which Salix has orphan drug status, should also have excellent incremental potential. While Salix launched Xifaxan 550 mg for the HE indication in 2010, the company is yet to gain approval for the IBS-D indication. If all goes well, approval for the IBS indication could come by May 27, 2015. Xifaxan 550 for the HE indication is off to a good start with the product gaining strong formulary coverage. We are also encouraged by Salix is evaluating a next generation rifaximin, rifaximin soluble solid dispersion (SSD), which is currently in a phase II, double-blind, placebo-controlled, dose-ranging study for the prevention of complications of early decompensated liver cirrhosis. The company is also working on a delayed release formulation of rifaximin which is in a phase III program for the treatment of active moderate Crohn’s disease (peak sales potential of about $500 million). Xifaxan sales came in at $645.6 million in 2013, up 25.5%.

- **Boosting Pipeline through In-Licensing Deals and Acquisitions:** Salix has been working on expanding its product portfolio over the past few years through acquisitions and in-licensing of candidates in late stage clinical development. The company's acquisition of InKine Pharmaceutical in 2005 helped strengthen its position in the gastroenterology market.

Salix boosted its portfolio in Feb 2011 with the acquisition of worldwide (excluding Japan) rights to Relistor, a subcutaneous injection approved for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Salix is looking to drive Relistor sales through label expansions and focused
promotion efforts. Salix's presence in the gastroenterology space should increase awareness of the product. Salix plans to bring an oral formulation of Relistor to market. The company presented impressive phase III data from a study conducted in patients with chronic, non-cancer pain. Meanwhile, the Sep 2014 approval of Relistor SC for the treatment of OIC in patients taking opioids for chronic non-cancer pain has increased the addressable patient population from 1 million in advanced illness to 11 million patients suffering from chronic pain – as a result, Salix estimates the peak sales opportunity for this product has shot up from approximately $137 million to more than $300 million. Moreover, the approval of the oral formulation (filing expected in the second quarter of 2015) should significantly expand the sales potential for the Relistor franchise to approximately $1.3 billion.

The acquisition of Oceana Therapeutics has boosted Salix's portfolio by two more products - **Solesta** (launched in Sep 2011) and **Deflux** (marketed since 2001). Solesta is a biocompatible tissue bulking agent approved for the treatment of fecal incontinence and Deflux is the only FDA-approved alternative to major ureteral reimplantation surgery for the treatment of vesicoureteral reflux.

- **Positive on Santarus Acquisition:** In early 2014, Salix acquired specialty biopharmaceutical company, Santarus. This acquisition has expanded Salix's product portfolio as well as pipeline and will strengthen its position in the gastrointestinal market. With the addition of marketed products like Uceris, Glumetza (peak sales of $250 million by Feb 2016) and Zegerid (revenue target of $110 million) to its portfolio, Salix's product offering and revenue base has diversified. The Santarus acquisition will be significantly accretive in 2014. Additional synergies will lead to higher EPS accretion in 2015.

**REASONS TO SELL**

- **Inventory Issues a Major Overhang:** Salix revealed inventory issues at the time of releasing third quarter 2014 results. The company said that wholesaler inventory levels for its products (Xifaxan 550: approximately 9 months; Apriso: approximately 9 months; Glumetza: approximately 7 months; and Uceris: approximately 5 months) were higher than previously announced.

  The higher wholesale inventory levels may affect future sales of the company until inventory levels are worked down. The inventory issues have raised concerns about the company's future performance and will remain an overhang until fully resolved.

- **Additional Delays for Xifaxan IBS-D:** Salix has already faced a significant delay in getting Xifaxan 550 approved for the IBS-D indication. The FDA delayed the PDUFA date from Feb 28 to May 27. Additional delays would weigh heavily on the stock.

- **Generic Threats:** The entry of generic versions of Xifaxan, Salix's main growth driver, would be a huge setback for the company. Xifaxan accounted for 69% of 2013 revenues and will account for about 44% of 2014 revenues. Salix has already faced a major setback with the genericization of Colazal, which resulted in the company losing a major part of its revenues and earnings. Another product, Pepcid, started facing generic competition in 2010. Meanwhile, Lupin is looking to gain approval for its generic version of Apriso and Alvogen for Uceris.

- **Competition:** Several products in Salix's portfolio target highly competitive markets. While the OIC market has products like Sucampo's Amitiza and Cubist's Entereg, Uceris' target market has products like Shire's Lialda and Pentasa, Johnson & Johnson's Remicade and AbbVie's Humira among others. Zegerid's target market has OTC proton –pump inhibitors as well as AstraZeneca's Nexium, Eisai’s Aciphex and generics.
Audit Committee Findings to Lead to Restatement – Jan 28

The audit committee of Salix’s board of directors announced that the company’s consolidated financial statements for full year 2013 and the first three quarters of 2014 require certain corrections.

The committee said that the company’s total reported net product revenues of $933.8 million for 2013 will decrease by approximately $20.1 million. Also, the committee announced that the company’s diluted earnings per share will go down by approximately $0.18 per share.

Meanwhile, the company’s net product revenues of $384.4 million in the first quarter of 2014 shall be increased by approximately $18.6 million. Diluted net loss per share in the first quarter will reduce by $0.14 per share.

However, the audit committee determined that the company’s reported net product revenues for the second quarter (reported $382 million) and third quarter (reported $354.7 million) of 2014 will be cut by $6.5 million and $12.8 million, respectively. Diluted net income per share in the second quarter of 2014 shall reduce by $0.04 and diluted net loss per share in the third quarter will be reduced by $0.09.

Salix said that these audit reports are not expected to affect the company’s previously issued 2015 and 2016 guidance. The company had previously announced that it expects to earn $3.10–$4.10 per share on net product revenues of $1.25 billion to $1.35 billion in 2015. Earnings as per the Zacks Consensus Estimate stand at $1.13.

For 2016, the company expects to earn $8.50–$9.50 per share on total revenues of $1.9 billion to $2 billion.

Salix has been struggling with inventory issues for some time now. However, last month, the company announced that it plans to reduce inventory levels of three of its products – Xifaxan 550, Apriso and Uceris – to approximately three-month levels by the end of 2015, a year ahead of its previous expectation. We expect investor focus to stay on this issue going forward.

Salix CEO to Step Down, Inventory Issues Remain in Focus – Jan 5

Salix announced that its President and Chief Executive Officer (CEO), Carolyn Logan, has decided to step down from her position by the end of January.

Things were not looking good for the company lately. Salix has been struggling with inventory issues for some time now with third quarter results being adversely affected by inventory issues.

In Nov 2014, shares of the company sunk on inventory issues. At that time, the company’s Chief Financial Officer, Adam C. Derbyshire, also resigned.

However, last month, the company announced that it plans to reduce inventory levels of three of its products – Xifaxan 550, Apriso and Uceris – to approximately three-month levels by the end of 2015, a year ahead of its previous expectation. Per the plan, Salix has most likely sold lesser amounts of these products to its wholesalers in the fourth quarter.

The higher wholesale inventory levels may affect future sales of the company until inventory levels are worked down. The inventory issues have raised concerns about the company’s future performance.
Needless to say, Salix's search for finding a suitable leader for the company looks difficult at this point of time. The company announced that Tom D'Alonzo, chairman of the board of directors, will be the acting CEO from Jan 30, 2015, until Salix finds a suitable candidate for the post.

**Salix Gains on Destocking Initiatives, Gives 2-Year Outlook – Dec 16**

Salix’s shares gained 6.9% after the company announced that it would expedite its inventory issues related to three key drugs earlier than expected. The company also provided preliminary guidance for 2015 and 2016.

**Acceleration of Inventory Reduction by 2015 End**

Salix revealed plans to reduce inventory levels of 3 of its products, namely, Xifaxan 550, Apriso and Uceris, to approximately three-month levels by the end of 2015, which is about a year ahead of what it had initially guided. We remind investors that at the time of presenting third quarter results, Salix had announced its intention to cut wholesaler inventory levels of Xifaxan 550 (from approximately 9 months), Apriso (approximately 9 months) and Uceris (approximately 5 months) to approximately 3 months at or before the end of 2016.

Salix now intends to sell lesser amounts of Xifaxan 550, Apriso and Uceris to its wholesalers in the fourth quarter. As a result, the company withdrew its previously provided guidance for the fourth quarter and full year 2014. Meanwhile, the company continues to expect its distribution services agreements (DSAs) with its principal wholesalers to be finalized and become effective from the first quarter of 2015.

As per the company, Oct 2014 prescription demand for Xifaxan 550, Apriso, Relistor and Uceris increased approximately 24%, 12%, 31% and 64%, respectively, compared to Oct 2013.

**Xifaxan FDA Action Date Extended by Three Months**

Salix also informed that the FDA has extended the review date for the company’s resubmitted supplemental New Drug Application (sNDA) for Xifaxan 550 for the treatment of irritable bowel syndrome with diarrhea (IBS-D) by three months. The regulatory body will now announce its decision by May 27, 2015, instead of Feb 28, 2015.

**Preliminary Guidance for 2015 and 2016**

Based on its decision to fix inventory issues by the end of 2015 and the expectation of finalizing DSAs with principal wholesalers in the first quarter of 2015, the company provided a preliminary outlook for 2015 and 2016. The guidance does not include any contribution from Xifaxan 550 IBS-D.

The company expects to earn $3.10–$4.10 per share on total revenues of $1.25 billion to $1.35 billion in 2015. Revenue guidance was well below the Zacks Consensus Estimate of $1.49 billion.

For 2016, the company expects to earn $8.50–$9.50 per share on total revenues of $1.9 billion to $2 billion.

**Our Take**

We are encouraged by the company's efforts to work down inventory levels by year-end 2015, a year ahead of expectations. Meanwhile, the FDA’s extension of Xifaxan 550’s review period by 3 months should not be a matter of major concern considering the company did not say anything about the agency requiring additional studies.
Salix Pharmaceuticals, Ltd. (SLXP) posted third quarter 2014 earnings of $1.37 per share, above the Zacks Consensus Estimate of $0.73 and the year-ago earnings of 81 cents per share. Excluding the impact of depreciation and stock-based compensation expense, the company reported third quarter earnings of $1.53 per share, up 71.9% from the year-ago quarter.

Third quarter revenues increased 49% from the year-ago period to $354.7 million. However, revenues were down 7.1% on a sequential basis and missed the Zacks Consensus Estimate of $393 million and the company's guidance of $395 million.

Quarter in Detail

Xifaxan (rifaximin) posted sales of $159.7 million. Scrips for Xifaxan 550, which gained FDA approval in Mar 2010 for hepatic encephalopathy, grew 23% from the year-ago period.

Salix is working on the development of a next generation rifaximin - rifaximin soluble solid dispersion (SSD). The company is enrolling subjects for a phase II, double-blind, placebo-controlled, dose-ranging study for the prevention of complications of early decompensated liver cirrhosis. Enrollment is scheduled to complete by year end.

Salix is also looking to develop a delayed release version of rifaximin for Crohn's disease. The company is enrolling patients for the 52-week phase III study.

Salix's purgatives, MoviPrep and OsmoPrep, generated revenues of $(1.2) million. Apriso sales were $26.5 million, while scrips increased 15% during the quarter. Relistor sales were $10.8 million. Deflux sales were $7 million.

Santarus products like Uceris, Glumetza, Zegerid and Cycloset posted sales of $49.3 million, $62.9 million, $27 million and $6.7 million, respectively.

While research and development expenses increased 32.9% to $50.8 million during the quarter, Salix recorded a 78.7% increase in selling, general and administrative expenses which came in at $120.1 million. The inclusion of additional personnel and marketing costs led to higher SG&A spend.

Inventory Issues Revealed & Guidance Cut

Along with presenting third quarter results, Salix said that wholesaler inventory levels for its products (Xifaxan 550: approximately 9 months; Apriso: approximately 9 months; Glumetza: approximately 7 months; and Uceris: approximately 5 months) were higher than previously announced.

Salix is now working on entering into distribution services agreements with its principal wholesalers for the products in its portfolio. The target is to cut wholesaler inventory levels of Xifaxan 550, Apriso and Uceris to approximately 3 months at or before the end of 2016. The company expects to have these distribution services agreements in place in the first quarter of 2015.

Salix also intends to work with its wholesalers to reduce their inventory levels of Glumetza during 2015. Glumetza is expected to start facing generic competition in early 2016.

Salix also announced the resignation of its Chief Financial Officer, Adam C. Derbyshire.
Salix posted third quarter 2014 earnings of $1.37 per share, above the Zacks Consensus Estimate of $0.73 and the year-ago earnings of 81 cents per share. Third quarter revenues increased 49% from the year-ago period to $354.7 million. However, revenues were down 7.1% on a sequential basis and missed the Zacks Consensus Estimate of $393 million and the company's guidance of $395 million.

Salix's third quarter results were disappointing especially given the company's disclosure regarding the inventory levels. Revenues were also impacted by slower-than-expected prescription growth. The higher wholesale inventory levels are a matter of concern – they indicate a gap in demand and actual sales and this will affect future quarter sales until inventory levels are worked down.

The inventory issues have also raised concerns about the company's ability to provide an accurate outlook about future sales. These issues will also lower Salix's chances of being acquired in the near future. While the company is working on resolving the situation, we expect the inventory issues to remain an overhang.

Although the company has progressed with its pipeline, we expect inventory management issues to remain the primary focus area for investors in the upcoming quarters. We remain Neutral on Salix.

Salix's current trailing 12-month P/S multiple is 6.3, compared to the 5.6 average for the industry. The stock is currently trading at 6.4x our 2015 sales estimate. Our target price of $141 is based on 6.7x our 2015 sales estimate.

### Key Indicators

<table>
<thead>
<tr>
<th>Salix Pharmaceuticals, Ltd. (SLXP)</th>
<th>P/S F1</th>
<th>P/S F2</th>
<th>Est. 5-Yr EPS Gtr%</th>
<th>P/CF (TTM)</th>
<th>P/S (TTM)</th>
<th>P/E 5-Yr High (TTM)</th>
<th>P/E 5-Yr Low (TTM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer Group Average</td>
<td>5.2</td>
<td>4.7</td>
<td>18.6</td>
<td>28.1</td>
<td>6.3</td>
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<tr>
<td>Endo International (ENDP)</td>
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<td>Grifols, S.A. (GRFS)</td>
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<tr>
<td>United Therapeutics, Inc. (UTHR)</td>
<td>5.2</td>
<td>4.5</td>
<td>26.5</td>
<td>32.1</td>
<td>5.5</td>
<td>104.5</td>
<td>9.2</td>
</tr>
</tbody>
</table>

**TTM is trailing 12 months; F1 is 2014 and F2 is 2015, CF is operating cash flow**

<table>
<thead>
<tr>
<th>Salix Pharmaceuticals, Ltd. (SLXP)</th>
<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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</thead>
<tbody>
<tr>
<td>Industry Average</td>
<td>7.9</td>
<td>7.9</td>
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<td>S&amp;P 500</td>
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</table>
DISCLOSURES & DEFINITIONS

The analysts contributing to this report do not hold any shares of SLXP. 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 1117 companies covered: Outperform - 15.8%, Neutral - 77.2%, Underperform - 6.4%. 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.