Zacks Small-Cap Research

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# POZEN, Inc. (POZN-NASDAQ)

## *POZN: Yosprala Remains High Priority As We Wait For API Supplier To Rectify Deficiencies…*

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | Neutral |
| Date of Last Change | 03/07/2007 |
| Current Price (03/10/15) | $7.30 |
| **Target Price** | **$14.00** |

## UPDATE

On March 9, 2015, Pozen announced financial results for the fourth quarter and full year ended December 31, 2014. For the full year, Pozen reported $32.4 million in total revenues, and net income of $19.7 million, or $0.60 per share. We still believe Pozen represents a compelling valuation and catalyst play at this level. Despite the two CRLs issued by the FDA last year in April and December, and current warning letter received by the API supplier regarding inspection deficiencies, we believe Yosprala will be approved in 2015 with commercialization in 2016. Once approved, we think Pozen will remain cash flow positive on an operating basis through a combination of growing royalties on both Yosprala and Vimovo. We believe Pozen is also sitting on enough cash that they will look to do another cash-distribution to shareholders in 2015. We see the shares fairly-valued at $14.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$9.60** |
| **52-Week Low** | **$6.78** |
| **One-Year Return (%)** | **-13.21** |
| **Beta** | **2.13** |
| **Average Daily Volume (sh)** | **220,506** |
| **Shares Outstanding (mil)** | **32** |
| **Market Capitalization ($mil)** | **$226** |
| **Short Interest Ratio (days)** | **10.75** |
| **Institutional Ownership (%)** | **58** |
| **Insider Ownership (%)** | **18** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/M** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2015 Estimate** | **7.1** |
| **P/E using 2016 Estimate** | **8.1** |

| | |
|---|---|
| **Risk Level** | **Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Drugs** |

## ZACKS ESTIMATES

### Revenue

(In millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | 7.5 A | 7.4 A | 7.5 A | 9.9 A | 32.4 A |
| 2015 | 5.8 E | 5.9 E | 6.1 E | 6.2 E | 23.9 E |
| 2016 | | | | | 65.5 E |
| 2017 | | | | | 68.8 E |

### Earnings per Share

(EPS is operating earnings before non-recurring items)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | $0.09 A | $0.09 A | $0.20 E | $0.21 A | $0.60 A |
| 2015 | $0.08 E | $0.09 E | $0.09 E | $0.09 E | $0.34 E |
| 2016 | | | | | $1.52 E |
| 2017 | | | | | $1.67 E |

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## WHAT'S NEW

**Fourth Quarter & Year End Financial Results**

On March 9, 2015, Pozen, Inc. reported financial results for the fourth quarter and year ended December 31, 2014. Total revenues in the fourth quarter were $9.9 million, consisting of $5.6 million in royalties on $43.3 million in sales of Vimovo at Horizon Pharma (HZNP) in the U.S. and approximately $21.7 million in sales at AstraZeneca (AZN) outside the U.S., $4.0 million in licensing revenue relating to the remaining amortization of the $15 million upfront payment from Sanofi U.S. on the Yosprala licensing agreement in September 2013, and $0.3 million deferred revenue recognized on the termination of the Cilag GmbH agreement. Revenues for quarter were up 112% from the fourth quarter 2013 and nicely above our expectations.

For the full year 2014, Pozen reported revenues of $32.4 million, an increase of 214% over the full year 2013. Revenues in 2014 consisted of $21.1 million in royalties on $163 million in sales of Vimovo at Horizon Pharma (HZNP) in the U.S. and $81 million in sales at AstraZeneca (AZN) outside the U.S., $11.0 million in licensing revenue relating to the amortization of the $15 million upfront payment from Sanofi U.S, and $0.3 million deferred revenue relating to the Cilag GmbH agreement termination of MT400 in certain Latin America countries. We remind investors in December 2014, Pozen and Sanofi U.S. terminated their agreement on Yosprala (formerly called PA), which accelerated Pozen's recognition of the outstanding unamortized amount from the upfront payment.

Operating expenses in the fourth quarter totaled $3.1 million, consisting of $2.2 million in SG&A and $0.9 million in R&D. The decrease in operating expenses in the fourth quarter was primarily due to reduced staff, decreased non-cash compensation expense and lower costs related to Yosprala. Operating expenses for the year were $15.8 million in 2014 compared to $27.1 million in 2013. Operating income totaled $6.8 million in the fourth quarter, compared to an operating loss of $(2.2) million in the fourth quarter of 2013. For the full year 2014, operating income totaled $16.6 million compared to an operating loss of $16.8 million in 2013.

Pozen recorded other income of $3.1 million in 2014, which included a valuation gain of $2.7 million resulting from the company's 500,000 warrants to purchase Pernix Therapeutics Holdings, Inc. (PTX) common stock and $0.4 million "related to the disgorgement of short-swing profits arising from trades by a Pozen shareholder under Section 16(b) of the Securities Exchange Act of 1934." As a reminder, Pozen was awarded 500,000 PTX warrants at $4.28 per share back in May 2014 when Pernix acquired Treximet U.S. commercial rights. Pozen took ownership of the warrants in August 2014 and recorded the value as other income during the third quarter. The company adjusted that amount slightly for the fourth quarter. According to Management, Pozen sold the Pernix warrants and realized approximately $2.5 million in 2015.

Net income for the fourth quarter totaled $7.0 million, and equated to $0.21 per share, compared to a net loss of $(2.2) million for the fourth quarter 2013. For the full year, Pozen reported net income of $19.7 million, or $0.60 per share, compared to a net loss of $(16.7) million for the year ended 2013. Pozen's profitability was the highest it has ever been (excluding one-time revenues) primarily due to strong Vimovo royalties and expense control activities as mentioned above.

Pozen exited 2014 with $43.3 million in cash and investments. The company remains strongly cash flow positive based on royalties from Vimovo and has the potential to generate significant cash flow in 2015 based on re-partnering Yosprala either before or after the re-submission of the NDA. We remind investors that back in December 2013, Pozen paid a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 30, 2013. On its quarterly conference call, Pozen noted that has been working to reduce operating expenses to maximize profitability and reduce cash burn ahead of Yosprala approval. Management reiterated their goal to return cash to shareholders in 2015. Pozen is basically telling us – once Yosprala gets approved, expect more cash distributions (or dividends if distributed in a year with positive net income). For example, if Pozen can re-partner Yosprala later in 2015 for another $15-20 million upfront, the company will have close to $60 million in cash on the books ahead of approval. We would not be surprised to see them return half that amount before the end of the year.

***…Quick Vimovo Update…***

After four years of diddling around with AstraZeneca in the U.S., sales of Vimovo finally look like they on the upswing. Horizon reported $163.0 million in sales of Vimovo during 2014. That was nearly quadruple what

AstraZeneca did with the drug in the U.S. during 2013. U.S. sales of Vimovo in the fourth quarter at $43.3 million were flat with the third quarter 2014 of $43.2 million. From a prescription standpoint, Vimovo growth has leveled out. Prescriptions were up only 3% sequentially from the third quarter to the fourth quarter 2014. Horizon's strategy is to continue to take aggressive price increases on the drug to maintain growth. Vimovo is now incredibly expensive, at roughly $25 per day; but Horizon has instituted a "prescriptions made easy" program to offer co-pay and cost-assistance. Horizon has also increase the size of the sales force promoting the drug by 75 reps to 325. However, we would not be surprised to see Vimovo U.S. sales stall at around $175-200 million simply based on pricing pressure and competition. Nevertheless, Pozen's 10% royalty on U.S. Vimovo sales is still providing meaningful cash flow to the company. Vimovo sales outside the U.S. have been fairly consistent at around $20 million per quarter. We anticipate that this level will be maintained in 2015. As such, for 2015 we model worldwide Vimovo sales at $270 million. We note the royalty rate on Ex-U.S. sales jumps to 10% starting in 2016. We would also not be surprised to see AstraZeneca sell Vimovo rights outside the U.S. to a smaller organization that can do with sales what Horizon is doing in the U.S. This would be very good news for Pozen. The company just received another patent on Vimovo that will protect exclusivity out until October 2031.

**Still Waiting For Guidance On Yosprala Re-File**

It was a rough December 2014 for Pozen. On December 1st, Pozen announced that the company and Sanofi U.S. have mutually agreed to terminate their agreement for the commercialization of Yosprala in the U.S. Pozen held a conference call to discuss the surprising news. Although the title of the press release noted the partners "mutually agree" to terminate the agreement, it was clear from the call that Pozen's CEO, John Plachetka, would have liked to seen Sanofi commercialize the product. Two weeks later, Pozen announced Yosprala had received a second complete response letter (CRL) from the U.S. FDA delaying approval.

The issue holding up approval remained the same as the first CRL back in April 2014. In fact, the wording was identical, noting, "During an inspection of the foreign manufacturing facility of an active ingredient supplier on April 25, 2014, a FDA field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved." Pozen management noted that there were no clinical or safety deficiencies noted with respect to either YOSPRALA 81/40 or YOSPRALA 325/40 and no other deficiencies were noted in the CRL.

The facility's original response to the inspectional observations did not convince the FDA to clear the facility. Pozen announced yesterday that the active ingredient supplier received a warning letter regarding the Form 483 inspection deficiencies, which according to John Plachetka, highlights far fewer items than from the April 2014 inspection. Pozen has been in recent communication with the supplier and is confident that the resolution of this issue remains a high-priority for all involved parties. Nevertheless, Pozen has been working on a backup plan since last year to identify and qualify alternative suppliers of this API if the need arises for a secondary supplier to come into the picture. However, Pozen strongly believes that resubmission of the NDA after the current facility is cleared still remains the most likely route for progression. Management finally has better clarity of the situation and will have more information in about 35-45 days after the facility files their initial response letter.

Pozen believes Yosprala will be available for commercialization in 2016. Although Pozen believes a 2015 commercialization date is achievable, they would much rather invest some extra time in focusing on items that would ensure a highly successful launch. They are currently exploring various strategic parternships, supply chain activities and pre-market commercialization activities to get ready for the 2016 Yosprala launch.

***…Some Quick Thoughts…***

It looks like the issue isn't that the foreign manufacturing tried and failed to fix the problem, it simply looks like the FDA just hasn't been back to the facility to re-inspect. In fact, in February 2015, Pozen filed a Form 8K with the U.S. SEC noting that the review to the manufacturer's response to the deficiencies noted in the first inspection where still under review. Pozen held a face-to-face (Type-A) meeting with the agency in January 2015 to gain clarity on the issue. According to the Company, the outcome of the meeting is that the FDA said it would be on the fast-track. We note the facility is still actively producing this exact API for direct sale into the U.S., and shut-down of this facility seems highly unlikely. We believe there are clearly politics involved and that Pozen is being held hostage – for lack of a better word between the FDA and the manufacturing facility.

We also think Sanofi's decision to drop Yosprala has less to do with the product or the peak sales opportunity and more to do with internal changes at the company. We remind investors that Sanofi's Board of Directors decided

unanimously to remove its CEO in late October 2014. In November 2014, Sanofi held an R&D day highlighting the company's late-stage pipeline and pending drug launches. The company is forecasting they will launch 18 new drugs between now and 2020, with cumulative sales estimated at $37.5 billion. We believe Pozen's Yosprala has peak U.S. sales around $300 million - a nice specialty pharma product no doubt, but perhaps not quite worth the effort for a global pharmaceutical company under heavy Board and shareholder pressure like Sanofi-aventis.

***...New Deal Likely Post Approval...***

In the end, Sanofi's news to walk away may prove to be a blessing for Pozen. We believe Yosprala will eventually be approved. If Pozen is able to pull in $20 to $25 million upfront for a new deal, it's a win for the company. As a reminder, Sanofi gave Pozen $15 million upfront and agreed to $20 million in approval / pre-commercialization milestones back in September 2013. We think a new deal can easily duplicate these economics.

Pozen investors may feel disappointed that the company lost a household name in big pharma giant Sanofi to commercialize Yosprala, but finding big pharma partners to promote specialty pharma drugs like Yosprala is overrated in our view. For example, AstraZeneca was never a good U.S. partner for Pozen's Vimovo product. Now that Vimovo is in the hands of Horizon Pharma sales have increased nearly eight-fold! Getting dumped by AstraZeneca and hooking-up with Horizon was the best thing to happen to Pozen's Vimovo. The same can be said for Pozen's Treximet product, which languished in the bottom of the sales rep's bag at Glaxo for years until the U.S. rights were recently sold to Pernix in May 2014**.** From a specialty standpoint, Yosprala would be a nice addition to the product suite for companies like The Medicines Company (MDCO), Bayer, Kowa, Daiichi Sankyo, or Takeda.

## PROJECTED INCOME STATEMENT

### INCOME STATEMENT

| Pozen, Inc. | 2013 A | 2014 A | Q1 E | Q2 E | Q3 E | Q4 E | 2015 E | 2016 E | 2017 E |
|---|---|---|---|---|---|---|---|---|---|
| **Treximet / MT400 (royalty)** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| Vimovo (sales) | $91.0 | $243.6 | $66.0 | $67.0 | $68.0 | $69.0 | $270.0 | $265.0 | $250.0 |
| **Vimovo (royalty)** | **$6.3** | **$21.1** | **$5.8** | **$5.9** | **$6.1** | **$6.2** | **$23.9** | **$26.5** | **$25.0** |
| *YOY Growth* | *30.4%* | *234.3%* | *27.0%* | *8.8%* | *9.2%* | *10.3%* | *13.2%* | *10.7%* | *-5.7%* |
| **PA-Franchise (royalty)** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$14.0** | **$43.8** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| **Licensing / Development** | **$4.0** | **$11.3** | **$0** | **$0** | **$0** | **$0** | **$0** | **$25.0** | **$0.0** |
| Total Revenues | $10.3 | $32.4 | $5.8 | $5.9 | $6.1 | $6.2 | $23.9 | $65.5 | $68.8 |
| *YOY Growth* | *93.0%* | *213.8%* | *-23.5%* | *-20.5%* | *-19.7%* | *-37.2%* | *-26.1%* | *173.7%* | *5.0%* |
| Cost of Goods Sold | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | *100.0%* | *100.0%* | - | - | - | - | *100.0%* | *100.0%* | *100.0%* |
| SG&A | $17.2 | $10.1 | $2.2 | $2.2 | $2.3 | $2.4 | $9.1 | $9.0 | $8.0 |
| *% SG&A* | *166.3%* | *31.1%* | *38.1%* | *37.3%* | *38.0%* | *38.6%* | *38.0%* | *13.7%* | *11.6%* |
| R&D | $9.9 | $5.7 | $0.9 | $0.9 | $0.9 | $0.9 | $3.6 | $5.0 | $4.0 |
| *% R&D* | *96.3%* | *17.7%* | *15.6%* | *15.3%* | *14.9%* | *14.5%* | *15.0%* | *7.6%* | *5.8%* |
| Operating Income | ($16.8) | $16.6 | $2.7 | $2.8 | $2.9 | $2.9 | $11.2 | $51.5 | $56.8 |
| *Operating Margin* | *-162.6%* | *51.2%* | *46.3%* | *47.4%* | *47.1%* | *46.9%* | *46.9%* | *78.6%* | *82.5%* |
| Interest Income / Net | $0.1 | $3.1 | $0.0 | $0.0 | $0.0 | $0.0 | $0.1 | $0.1 | $0.1 |
| Pre-Tax Income | ($16.7) | $19.7 | $2.7 | $2.8 | $2.9 | $2.9 | $11.3 | $51.6 | $56.9 |
| Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Net Income | ($16.7) | $19.7 | $2.7 | $2.8 | $2.9 | $2.9 | $11.3 | $51.6 | $56.9 |
| *YOY Growth* | *-33.9%* | *-217.8%* | - | - | - | - | *-42.4%* | *355.3%* | *10.2%* |
| *Net Margin* | *-161.9%* | *60.7%* | *46.7%* | *47.8%* | *47.5%* | *47.2%* | *47.4%* | *78.8%* | *82.7%* |
| Reported EPS | ($0.55) | $0.60 | $0.08 | $0.09 | $0.09 | $0.09 | $0.34 | $1.52 | $1.67 |
| Fully Diluted Shares | 30.4 | 32.8 | 32.9 | 33.1 | 33.3 | 33.5 | 33.2 | 34.0 | 34.0 |

*Source: Jason Napodano, CFA - Zacks Investment Research, Inc.*

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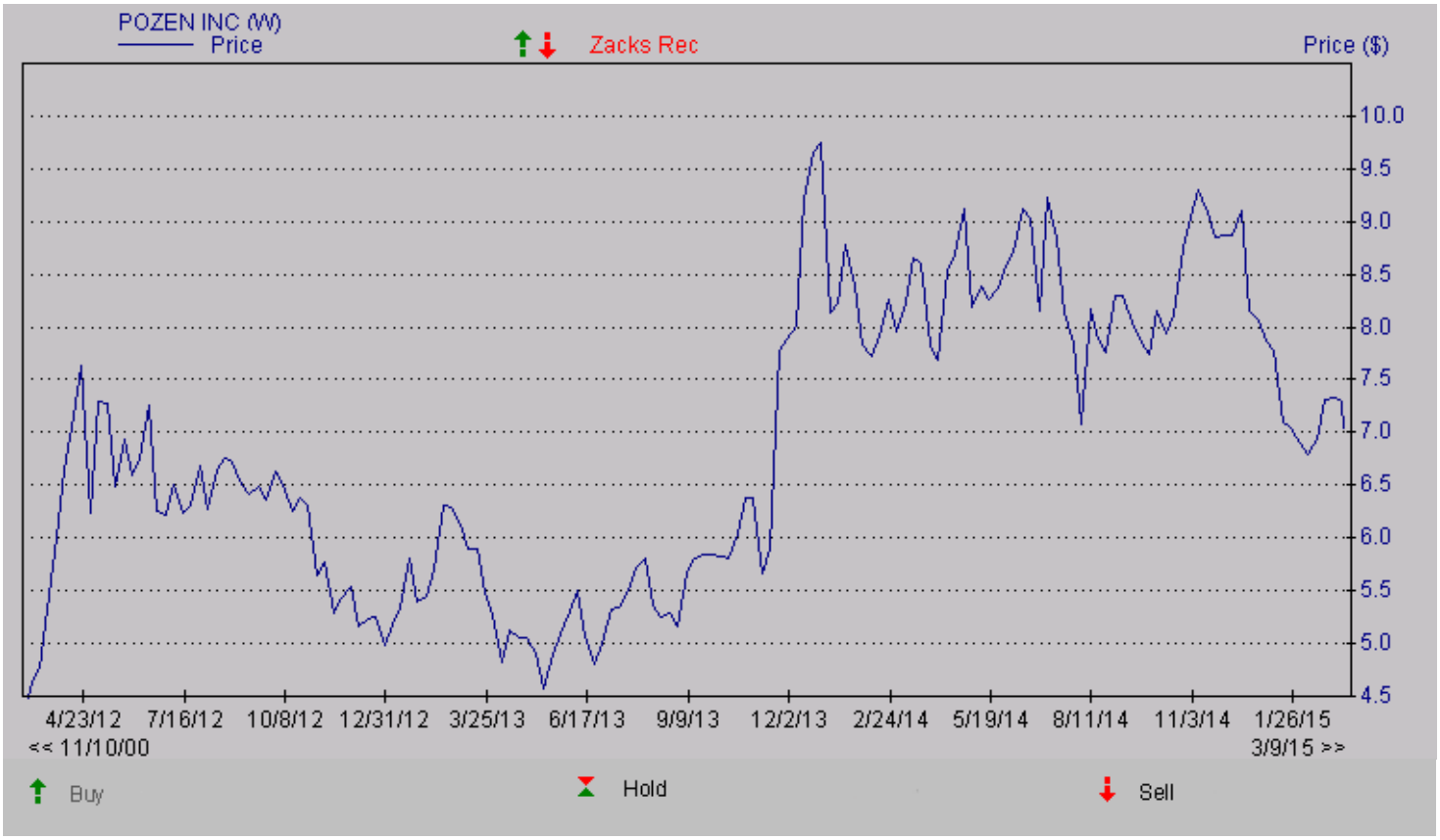
## HISTORICAL ZACKS RECOMMENDATIONS

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