Zacks Small-Cap Research

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Jason Napodano, CFA
Nisha Hirani, MD
312-265-9421
jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

POZEN, Inc. (POZN-NASDAQ)

POZN: Waiting For The FDA To Respond, Meanwhile Pozen Seeks An Alternative Supplier For PA…

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	03/07/2007
Current Price (05/08/15)	$6.85
Target Price	**$12.00**

UPDATE

On May 8, 2015, Pozen, Inc. reported financial results for the first quarter ended March 31, 2015. Total revenues in the quarter were $4.4 million, consisting of $3.3 million in royalties on $33.0 million in U.S. sales of Vimovo® at Horizon Pharma (HZNP) and approximately $1.1 million in royalties on $18.3 million in Ex-U.S. sales of Vimovo at AstraZeneca (AZN).

We are waiting for an update on the manfacutring facility and how the API supplier plans to address the issued noted in the February 2015 warning letter. At this time, we are not expecting YOSPRALA® commercializaton until 2016. Nevertheless, Pozen remains attractively valued and our target is $12 per share.

SUMMARY DATA

52-Week High	**$9.50**
52-Week Low	**$6.78**
One-Year Return (%)	**-2.93**
Beta	**1.82**
Average Daily Volume (sh)	**154,395**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$257**
Short Interest Ratio (days)	**13.41**
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	**N/M**
P/E using 2016 Estimate	**5.1**

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	4.4 A	4.8 E	5.3 E	6.5 E	20.1 E
2016					61.5 E
2017					63.8 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	-$0.00 A	$0.04 E	$0.06 E	$0.06 E	$0.18 E
2016					$1.43 E
2017					$1.53 E

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WHAT'S NEW

Financial Update

On May 8, 2015, Pozen, Inc. (POZN) reported financial results for the first quarter ended March 31, 2015. Total revenues in the quarter were $4.4 million, consisting of $3.3 million in royalties on $33.0 million in U.S. sales of Vimovo® at Horizon Pharma (HZNP) and approximately $1.1 million in royalties on $18.3 million in Ex-U.S. sales of Vimovo at AstraZeneca (AZN). Both numbers, down 3% year-over-year from the first quarter 2014, were below our expectations. For 2015, Pozen expects Vimovo® royalty income to be between $19 and $21 million. We model $20.1 million, down 5% from 2014 levels.

Unlike previous quarters, Pozen did not report any licensing and collaborative revenue in the first quarter 2015. The YOSPRALA® licensing agreement with Sanofi U.S. was terminated in December 2014, and management recognized all remaining unamortized revenue in the fourth quarter 2014. As a result, total revenues were down 42% year-over-year.

Operating expenses in the quarter totaled $4.3 million, consisting of $3.3 million in G&A and $1.0 million in R&D. G&A expense was higher than expected on IP litigation and YOSPRALA® pre-commercialization activities. In the first quarter of 2015, the company sold its Pernix Therapeutics Holdings, Inc. common stock warrants resulting in cash proceeds of $2.5 million. As the cash proceeds were less than the Black-Sholes value of the warrants listed on the balance sheet at December 31, 2014, Pozen recorded a loss on sale of the warrants in the Other Loss account totaling $0.2 million. This resulted in a net loss for the quarter of $0.03 million, or $0.00 per share.

Pozen exited the first quarter 2015 with $43.9 million in cash and investments. The company remains slightly 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 NDA approval. 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 at some point in the future. 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 to shareholders.

YOSPRALA® Update

On December 17, 2014, Pozen announced Yosprala had received a second complete response letter (CRL) from the U.S. FDA delaying approval. The issue holding up approval remains the same as the first CRL issued 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.

Pozen held a Type A meeting with the U.S. FDA's Office of Compliance in January 2015 to try to better understand the deficiences noted in the CRL. At Pozen's Type A meeting, the FDA confirmed again that there are no outstanding clinical efficacy or safety issues. In February 2015, the active ingredient supplier informed Pozen that they received a warning letter relating to the Form 483 inspection deficiencies. The supplier has submitted a comprehensive plan of corrective actions to address the matters raised in the warning letter to the FDA. According to Pozen, the warning letter contained far fewer items than from the original April 2014 inspection report and CRL, meaning the API supplier is making progress, but clearly more is still needed.

Once the FDA reviews the suppliers comprehensive corrective plan, they will inspects the facility. If cleared, supplier will receive a Good Manufacturing Practice (GMP) certification to make YOSPRALA®. Pozen believes that once the GMP certificate is issued they can re-file the NDA and hopefully receive a Class-1 (two month) review. This would be the most optimistic path forward, potentially still allowing for a new PDUFA late 2015.

In the meantime, Pozen has been working on a backup plan since last year to identify and qualify alternative suppliers of this API (the API is aspirin by the way) if the need arises for a secondary supplier to come into the picture. They company is already ording batches from this new supplier. However, receiving approval for a second supplier would have to come via filing an amendment to the NDA. This would likely be a Class-2 (six month) review.

In conclusion, Pozen believes YOSPRALA® will be available for commercialization in 2016. Management is currently exploring various strategic partnerships, supply chain activities and pre-market commercialization activities to get ready for the 2016 YOSPRALA® launch.

...New Deal Likely...

In the end, Sanofi's news to walk away may prove to be a blessing for Pozen. We believe YOSPRALA® will eventually be approved – we see it more as a mater of "when" not "if". 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, and investor should not have to wait all the way to commercial approval in 2016. We think once the original API supplier receives the GMP certificate its an "all clear" on the issued listed in the CRL; meaning the NDA goes quickly back under review and hopefully the turn-around time is only two months.

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.

Conclusion

Our valuation model remains largely unchanged from previous updates. Royalties on Vimovo®, estimated at $20.1 million in 2015 (smack in the middle of management guidance), are supporting the entire operations to slightly cash-flow positive right now. The net present value of all forecasted Vimovo® royalties is worth approximately $4 per share. We see YOSPRALA® as having $300 million peak sales potential in the U.S., with another $150 million peak potential outside the U.S. We assume Pozen can re-partner YOSPRALA® on similar terms to the Sanofi deal struck in September 2013 ($15 million upfront + $20 million approval + mid-teens royalties). Plugging this into our NPV model, we believe YOSPRALA® is worth $7 per share. Adding in another $1 per share for the current cash balance, we arrive at a fair-value target of $12 per share.

YOSPRALA® Peak Sales Assumption

24 Million American's with history of CV disease (secondary prevention)
- Approximately 90% on medication
- Approximately 60-80% take Apspirin
- Pozen's Market Research shows 30-40% physician acceptance
- Pozen's Market Research shows 36% patients willing to pay $1/day
- Payors coverage PA at Tier-2 (cost-neutral) at $1/day

This equates to 1.9 million patients @ $365/year = $695 Million Peak Sales

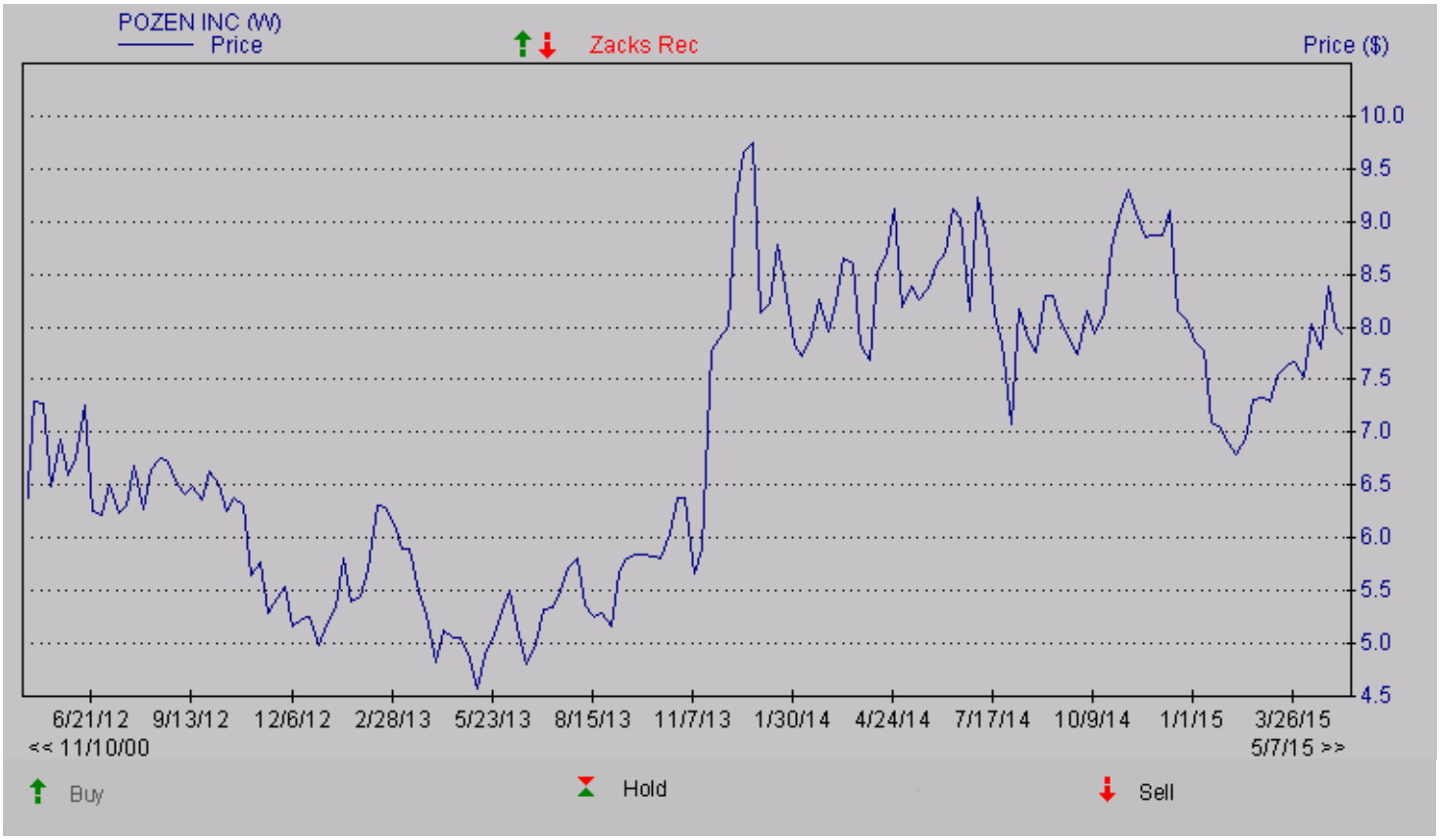
We cut this number if half (to be conservative) - Thus model $300 Million. Assume sales outside the U.S. is around half that, or around $150 Million. Thus, we model Peak WW sales of $450 Million for our vaulation model.

INCOME STATEMENT

Pozen, Inc.	2013 A	2014 A	Q1 A	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 (royalty)	$6.3	$21.1	$4.4	$4.8	$5.3	$5.6	$20.1	$22.5	$20.0
YOY Growth	*30.4%*	*234.3%*	*-3.2%*	*-12.3%*	*-3.6%*	*-0.9%*	*-5.0%*	*12.1%*	*-11.1%*
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	$4.4	$4.8	$5.3	$5.6	$20.1	$61.5	$63.8
YOY Growth	*93.0%*	*213.8%*	*-41.7%*	*-36.0%*	*-29.2%*	*-43.6%*	*-38.0%*	*206.3%*	*3.7%*
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	$3.3	$2.4	$2.3	$2.4	$10.4	$9.0	$8.0
% SG&A	*166.3%*	*31.1%*	*74.1%*	*50.5%*	*43.1%*	*43.0%*	*51.6%*	*14.6%*	*12.5%*
R&D	$9.9	$5.7	$1.0	$0.9	$0.9	$1.1	$3.9	$4.0	$4.0
% R&D	*96.3%*	*17.7%*	*22.3%*	*18.9%*	*16.9%*	*19.7%*	*19.3%*	*6.5%*	*6.3%*
Operating Income	($16.8)	$16.6	$0.2	$1.5	$2.1	$2.1	$5.8	$48.5	$51.8
Operating Margin	*-162.6%*	*51.2%*	*3.6%*	*30.6%*	*40.1%*	*37.3%*	*29.0%*	*78.9%*	*81.2%*
Interest Income / Net	$0.1	$3.1	($0.2)	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($16.7)	$19.7	($0.0)	$1.5	$2.2	$2.1	$5.9	$48.6	$51.9
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	($0.0)	$1.5	$2.2	$2.1	$5.9	$48.6	$51.9
YOY Growth	*-33.9%*	*-217.8%*	-	-	-	-	*-69.9%*	*719.5%*	*6.7%*
Net Margin	*-161.9%*	*60.7%*	*-0.6%*	*31.0%*	*40.4%*	*37.6%*	*29.5%*	*79.0%*	*81.3%*
Reported EPS	($0.55)	$0.60	($0.00)	$0.04	$0.06	$0.06	$0.18	$1.43	$1.53
Fully Diluted Shares	30.4	32.8	32.3	33.1	33.3	33.5	33.0	34.0	34.0

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

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