Zacks Small-Cap Research

November 6, 2014
Jason Napodano, CFA
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 PA PDUFA On December 30, 2014…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (11/06/14)	$9.20
Target Price	**$14.00**

UPDATE

We believe Pozen represents a compelling valuation and catalyst play at this level. Despite the minor CRL issued by the FDA in April, the application is now back under review and we continue to believe PA is approved in 2014. Once PA is approved, we think Pozen becomes cash flow positive on an operating basis through a combination of growing royalties on both PA and Vimovo. Pozen is also sitting on enough cash that the company will look to do another cash-distribution to shareholders in 2015. We see the shares fairly-valued at $14.

SUMMARY DATA

52-Week High	**$9.77**
52-Week Low	**$5.67**
One-Year Return (%)	**51.38**
Beta	**2.13**
Average Daily Volume (sh)	**358,323**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$278**
Short Interest Ratio (days)	**11.03**
Institutional Ownership (%)	**56**
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 2014 Estimate	**18.0**
P/E using 2015 Estimate	**11.2**

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)
2013	1.4 A	1.7 A	2.6 A	4.7 A	10.3 A
2014	7.5 A	7.4 A	7.5 A	7.6 E	30.1 E
2015					42.0 E
2016					35.2 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.19 A	-$0.13 A	-$0.16 A	-$0.07 A	-$0.55 A
2014	$0.09 A	$0.09 A	$0.20 E	$0.12 E	$0.51 E
2015					$0.82 E
2016					$0.58 E

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Solid Third Quarter Financial Results

On November 6, 2014, Pozen, Inc. reported financial results for the third quarter ended June 30, 2014. Total revenues in the quarter were $7.5 million, comprised of $5.5 million in royalties on $43.2 million in sales of Vimovo at Horizon Pharma (HZNP) in the U.S. and $20.3 million in sales at AstraZeneca (AZN) outside the U.S., and $2.0 million in licensing revenue relating to amortization of the $15 million upfront payment from Sanofi U.S. on the PA licensing agreement in September 2013. Revenues for quarter were up 41% from the third quarter 2013 and dead-on with our expectations.

Operating expenses in the quarter totaled $3.7 million, comprised of $2.6 million in SG&A and $1.1 million in R&D. Operating income totaled $3.9 million, ahead of our expectations on lower R&D costs. Net income totaled $6.8 million, and included a record gain of $2.8 resulting from the company's 500,000 warrants to purchase Pernix Therapeutics Holdings, Inc. (PTX) common stock. 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 in May 2014. Pozen took ownership of the warrants in August 2014 and recorded the value as other income during the third quarter. Net income of $6.8 million equated to $0.20 per share.

…Vimovo Chugging Along…

After four years of diddling around with AstraZeneca in the U.S., sales of Vimovo finally look like they on the upswing. Horizon reported $43.2 million in sales the third quarter 2014. The $76.4 million U.S. Vimovo sales by Horizon in the first six months of 2014 eclipsed all previous sales by AstraZeneca in the prior four years the drug was on the market. Under the terms of the agreement with Horizon, Pozen gets 10% royalty on net sales in the U.S., with guaranteed annual minimum royalty payments of $5.0 million in 2014, and $7.5 million each year thereafter, provided that the patents owned by Pozen which cover Vimovo are in effect and no generic forms of Vimovo are on the market. U.S. Vimovo royalties in the third quarter totaled $4.3 million.

Total Vimovo royalties in the quarter were $5.5 million, meaning that Ex-U.S. sales at AstraZeneca were roughly $20.3 million based on 6% royalty. Total Vimovo sales of $63.5 million were up slightly from the $62.1 million in the second quarter 2014. 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.

…But 2015 May See Slight Declines…

Things are going beautifully for Pozen with respect to Vimovo, at least for now. We expect things to change in 2015 because on July 28, 2014 Horizon filed a Form 8-K with the SEC disclosing that the nation's two largest pharmacy benefit managers, CVS Caremark (CVS) and Express Scripts, Inc. (ESRX), will add Duexis and Vimovo to their formulary exclusion list effective January 1, 2015. Horizon estimates 20-30% of its Duexis and Vimovo prescriptions could be at risk by being excluded from these formularies.

Exclusion from formulary listing means patients will have to cover the full cost of the drug out-of-pocket. One month of Vimovo costs around $425, or $14+ per day. This news is clearly going to have an impact on Pozen's financials. Pozen collected $11.9 million in royalties from Horizon during the first nine months of 2014. For the full year, we expect the royalties to be roughly $16.5 million. As 20-30% hit to this number would bring Pozen's 2015 Vimovo royalties down to around $12 to $13 million. Not an enormous impact, but a hit nonetheless. We remind investors that even if additional PBM's follow on and place Vimovo on their exclusion list for 2015, the absolute minimum that Pozen will collect from Horizon in 2015 is $7.5 million based on their agreement. So while the impact of these formularies dropping coverage of Vimovo is negative, the actual financial impact to Pozen is muted based on minimum guaranteed payments, steady sales of the drug outside the U.S., and the up-tick in royalty rate from AstraZeneca from 6% to 10% in 2016.

Another Profitable Quarter

Thanks to the strong Vimovo royalties and the lower R&D costs, Pozen reported a net gain in operating income during the quarter of $3.9 million. Actual net income totaled $6.8 million due to the $2.8 million gain recorded on the Pernix warrants. This equated to $0.20 per share in positive EPS. We are impressed that Pozen can report positive EPS even before the approval and commercial launch of PA. We had previously believed that PA was necessary to drive Pozen to profitability, but it seems clear now with accelerating Vimovo royalties and a lean operating budget that Pozen can be cash flow positive on just Vimovo alone. During the first nine months of 2014, Pozen reported positive net income of $12.7 million. Cash has been increased from $32.8 million as of December 30, 2014 to the current balance of $38.4 million. This includes approximately $2.8 million in value for the Pernix warrants. At September 30, 2014, Pernix stock was $7.72 per share. Today it is $9.22 per share, so the investment will likely be marked up at year-end 2014.

PA PDUFA Set For December 30, 2014

On July 1, 2014, Pozen Inc (POZN) announced it had resubmitted the New Drug Application (NDA) for PA8140 and PA32540 to the U.S. FDA. On July 16, 2014, Pozen announced that the U.S. FDA had accepted the application and established a new PDUFA date of December 30, 2014. Pozen reported that the API supplier has been working to respond to the deficiencies noted in the FDA inspector's report. In fact, the company completed its own onsite audit and management believes the issues have been adequately addressed. At this time, management at Pozen does not believe the FDA will re-inspect the facility. We believe approval could come at any time between now and December 30, 2014.

Pozen is preparing a filing for the European Union with PA-100/40. The company recently held discussions with the Dutch Medicines Evaluation Board in July 2014. The DMED is Pozen's representative state under the European decentralized process. Based on recent and previous discussions with the DMEB, Pozen recently conducted two Phase 1 studies with PA-100/40. The first was a bioequivalence study comparing PA-100/40 to a commercially available 100 mg aspirin product in the EU. The other Phase 1 study was designed to show that the 40 mg omeprazole component provided adequate gastrointestinal support over a 24 hour period. Pozen intends to use the data from these studies to file a Marketing Authorization Application (MAA) under a decentralized process. The DMEB notified Pozen that no other clinical assessment is required and that a complete benefit / risk analysis should be included as part of the submission.

We believe Pozen has a very good chance at approval in the EU based on all the available data. We expect that the company will seek to partner PA-100/40 for commercial sale in the EU. Management is waiting to file the MAA to see if potential partners have input into the application. That being said, at some point Pozen will stop waiting for partner feedback and submit the application – assuming they don't close a deal first. We believe potential EU partners are likely waiting for U.S. approval before paying Pozen a big upfront payment for PA. Although we note that was not the case with Sanofi in the U.S. We've noted in the past, Sanofi-aventis (SNY) would be an outstanding EU partner for Pozen. The company has already licensed the U.S. right to the drug and it seems logical to believe they would be interested in PA for Europe as well.

…Optimistic on PA…

We continue to believe that Sanofi will be in position to launch PA during the first half of 2015. We model peak sales of PA in the U.S. at around $300 million. Pozen management expects Sanofi U.S. to put forth a first class effort with PA, piggy-backing off the success in this area by the company with mega-blockbuster Plavix®. We remind investors that besides the $20 million in pre-commercialization milestones, Pozen is entitled to sales milestones and royalties from Sanofi U.S. ranged between 12.5% and 22.5% on sales.

We think the opportunity for PA outside the U.S. is around $150 to $200 million. We suspect that Sanofi-aventis is the ideal EU commercialization partner for PA, but chose to model the path to market conservatively. Thus, a commercialization deal for Europe represents nice upside to our financial model in terms of bringing in new upfront and sales cash milestones.

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
- Assume 40% market penetration on above metrics

This equates to 800,000 patients @ $365/year ~ $300 Million Peak Sales

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.

Fundamentals Remain Strong

Pozen reported $38.4 million in cash and investments as of September 30, 2014. 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 second quarter conference call, Pozen noted that has been working to reduce operating expenses to maximize profitability and reduce cash burn ahead of PA approval. Management reiterated their goal to return cash to shareholders in 2015.

Pozen is basically telling us – once PA gets approved, expect more cash distributions (or dividends if distributed in a year with positive net income). The approval of PA should come in December 2014; this entitles Pozen to $20 million in combined pre-launch milestones from Sanofi U.S. that would further strengthen the cash position. The first $10 million is for approval (which we model in the first quarter 2015) and the second $10 million is for "commercial-readiness" (which we model in the second quarter 2015). As such, by June 30, 2015, Pozen should report over $60 million in cash and investment.

Valuation

We've done some initial modeling on what Pozen will look like with PA on the market in 2015 along with our best estimate for what Vimovo royalties will look like in the coming years. We think Pozen could generate as much as $60+ million in free cash flow starting a few years. Based on the current share count, with equates to over $2.00 in potential free cash flow per share earmarked for future cash distributions.

At the current stock price, these dividends would equate to a 21% yield, and that includes no payment of surplus cash currently on the books. You can't find that kind of "high-income yield" anywhere in the market! Pozen's stock should be trading at $15+ per share based on the future projected cash flows and return of capital to shareholders.

We understand there is risk based on the fact that PA has yet to be approved, but we think this is a low hurdle to overcome given the only issue outlined in the CRL was a small deficiency at the third party manufacturing facility and it looks like that has been resolved. Pozen stated in its press release that they have substantial agreement with the FDA on the product labeling. We think approval for PA in December 2014 will be a major catalyst for the shares, and investors can buy Pozen today with roughly 55% upside to our DCF-derived price target.

We also note that our modeling above has Pozen paying taxes starting in 2017. Our assumptions could be increased by 1/3rd if Pozen decides to sell to a tax advantaged organization, similar to what the company did when it monetized the Treximet royalty to Canada's CPPIB Credit Investments in November 2011. That sales price of Treximet royalty for $75 million was around 35% higher than we factored in our DCF model due to tax implications. As such, we see today as a significant buying opportunity for investors.

PROJECTED INCOME STATEMENT

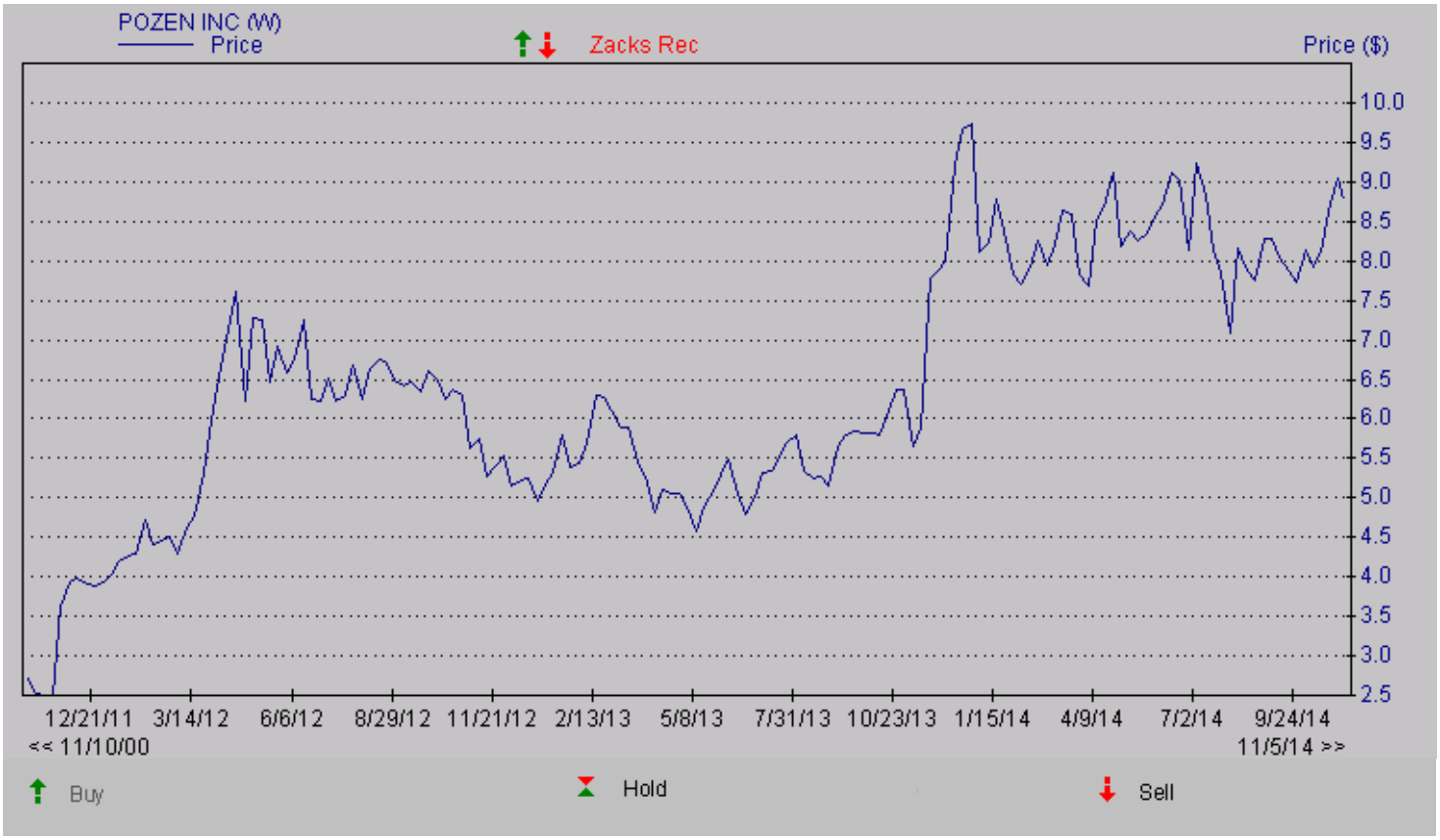
INCOME STATEMENT

Pozen, Inc.	2012 A	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
Treximet / MT400 (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Vimovo (royalty)	**$4.8**	**$6.3**	**$4.5**	**$5.4**	**$5.5**	**$5.6**	**$21.1**	**$16.0**	**$16.2**
YOY Growth	*66.5%*	*30.4%*	*221.5%*	*228.2%*	*250.0%*	*234.7%*	*233.9%*	*-24.2%*	*1.3%*
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$6.0**	**$14.0**
YOY Growth	-	-	-	-	-	-	-	-	*133.3%*
Licensing / Development	**$0.5**	**$4.0**	**$3.0**	**$2.0**	**$2.0**	**$2.0**	**$9.0**	**$20.0**	**$5.0**
Total Revenues	$5.3	$10.3	$7.5	$7.4	$7.5	$7.6	$30.1	$42.0	$35.2
YOY Growth	*-93.8%*	*93.0%*	*703.1%*	*448.8%*	*41.0%*	*437.1%*	*191.7%*	*39.5%*	*-16.2%*
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	$19.0	$17.2	$2.8	$2.5	$2.6	$2.5	$10.4	$9.0	$9.5
% SG&A	*355.7%*	*166.3%*	*37.4%*	*33.7%*	*34.1%*	*32.9%*	*34.5%*	*21.4%*	*27.0%*
R&D	$11.9	$9.9	$1.8	$1.9	$1.1	$1.2	$6.0	$6.0	$6.0
% R&D	*221.8%*	*96.3%*	*24.2%*	*26.0%*	*14.0%*	*15.8%*	*20.0%*	*14.3%*	*17.0%*
Operating Income	($25.5)	($16.8)	$2.9	$3.0	$3.9	$3.9	$13.7	$27.0	$19.7
Operating Margin	*-477.5%*	*-162.6%*	*38.4%*	*40.3%*	*51.9%*	*51.3%*	*45.5%*	*64.3%*	*56.0%*
Interest Income / Net	$0.3	$0.1	$0.0	$0.0	$2.8	$0.0	$2.9	$0.1	$0.1
Pre-Tax Income	($25.3)	($16.7)	$2.9	$3.0	$6.8	$3.9	$16.6	$27.1	$19.8
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($25.3)	($16.7)	$2.9	$3.0	$6.8	$3.9	$16.6	$27.1	$19.8
YOY Growth	*-159.7%*	*-33.9%*	-	-	-	-	*-199.2%*	*63.5%*	*-26.9%*
Net Margin	*-472.7%*	*-161.9%*	-	*40.4%*	*89.6%*	*51.6%*	*55.1%*	*64.5%*	*56.3%*
Reported EPS	($0.84)	($0.55)	$0.09	$0.09	$0.20	$0.12	$0.51	$0.82	$0.58
Fully Diluted Shares	30.1	30.4	30.7	32.6	32.9	32.7	32.2	33.0	34.0

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

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2014, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Jason Napodano, CFA, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1110 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 17.2%, Hold/Neutral- 76.6%, Sell/Underperform – 5.5%. Data is as of midnight on the business day immediately prior to this publication.