Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: PA PDUFA Set For December 30, 2014; Stock Remains Attractive…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (08/07/14)	$7.44
Target Price	**$11.50**

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 may look to do another cash-distribution to shareholders in 2015. We see the shares fairly-valued at $11.50.

SUMMARY DATA

52-Week High	**$9.77**
52-Week Low	**$5.00**
One-Year Return (%)	**37.41**
Beta	**1.95**
Average Daily Volume (sh)	**253,675**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$243**
Short Interest Ratio (days)	**9.63**
Institutional Ownership (%)	**64**
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	**18.1**
P/E using 2015 Estimate	**8.8**

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 E	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	$0.11 E	$0.12 E	$0.41 E
2015					$0.84 E
2016					$0.61 E

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WHAT'S NEW

Solid Second Quarter Financial Results

On August 7, 2014, Pozen, Inc. reported financial results for the second quarter ended June 30, 2014. Total revenues in the quarter were $7.4 million, comprised of $5.4 million in royalties on $42.4 million in sales of Vimovo at Horizon Pharma (HZNP) in the U.S. and $19.7 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 449% from the second quarter 2013 and handily beat our expectations of $6.3 million – with all the upside coming from higher royalties on Vimovo.

Vimovo Really Taking-Off

After four years of diddling around with AstraZeneca in the U.S., sales of Vimovo finally look like they on the upswing. Horizon reported $34 million in Vimovo sales in the first quarter 2014 and $42 million in the second quarter. 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 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. For 2014, we think it is likely that Horizon does roughly $150 million in Vimovo sales, putting Pozen's royalty at roughly $15 million from U.S. sales alone.

Meanwhile, Pozen continues to collect 6% royalty on Vimovo sales from AstraZeneca in territories outside the U.S. In 2013, Vimovo Ex-U.S. sales of Vimovo totaled $70 million. During the first six months of 2014, they totaled approximately $39 million, up slightly on last year's pace. We expect 2014 Ex-U.S. sales of Vimovo at AstraZeneca to be roughly $80 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.

…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 $7.6 million in royalties from Horizon during the first six months of 2014. For the full year, we expect the royalties to be roughly $15.0 million. As 20-30% hit to this number would bring Pozen's 2015 Vimovo royalties down to around $11 to $12 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.

Cutting Expenses

Over the past several months, Pozen has been aggressively working to reduce operating costs and increase profitability. The company has cut staff – currently they have 15 employees, down from 29 a year ago; and according to CEO John Plachetka, more cuts are coming. G&A costs in the second quarter 2014 totaled $2.5 million, the lowest quarterly overhead rate in six years. G&A in the second quarter 2013, for example, was $3.7 million. R&D in the second quarter 2014 totaled $1.9 million, the lowest we've ever seen (our model dates back to 2003). Total operating costs were reduced by $1.2 million from the second quarter 2013. We believe Pozen is trimming costs and getting as lean as possible, potentially setting the stage for an outright sale of the entire organization at some point in the not-too-distance future.

…Profitable Even Before PA Approval…

Thanks to the strong upside from Vimovo royalties and the lower G&A and R&D costs, Pozen reported a net gain in the quarter of $3.0 million. This equated to $0.09 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 six months of 2014, Pozen reported positive net income of $5.9 million.

PA – Back Under NDA Review

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 is unsure if the manufacturing facility will need to be re-inspected prior to approval. Pozen intends to seek an accelerated review period for PA with the FDA. The FDA has designated the response a "Class-2" response, which means a six-month review. Hence the PDUFA has been set as December 30, 2014. A "Class-1" response would have been a 60-day review. However, Pozen believes that once the FDA either re-inspects the facility or makes a decision that no re-inspection is necessary that the FDA will be ready to approve the product. Therefore, if re-inspection takes place in September or October, the potential exists that the agency may approve the product well before December 30, 2014. Pozen intends to pursue a dialogue with the agency on this topic and communicate back to investors once they know more.

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 sometime after the MAA has been filed. It is possible that an organization may want to wait for EU approval before providing a handsome upfront payment to Pozen, 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 $31.8 million in cash and investments as of June 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. The company made the strategic decision not to start new development programs that are not fully funded by a partner. The press release states, "*Our board of directors and management team continue to explore potential ways to return value to our stockholders, including future cash distributions when we accumulate surplus cash as a result of receiving milestones and royalties from our commercial partners*."

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 hit a minor hiccup, but we believe the issue was minor and with the application now back under review launch expectations by Sanofi remain the same. Therefore, we still expect PA approval 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).

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 31% 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 $11+ per share based on the future projected cash flows and return of capital to shareholders. We note this is only $1 per share lower than our previous estimate prior to Horizon's news on Vimovo coverage. Below we present a quick snap-shot of our DCF model.

	Vimovo		PA		Licsening	Cash				Free Cash
	WW Sales	Royalty	WW Sales	Royalty	Payments	Revenues	Op. Exps	Taxes	Cash Adjs	Flow
2014	$200	$17.0	$0	$0.0	$10	$27	($18)	$0	$2	$11
2015	$175	$26.0	$50	$8.8	$10	$45	($17)	$0	$2	$30
2016	$150	$14.5	$100	$20.0	$5	$40	($16)	$0	$2	$26
2017	$150	$14.5	$250	$50.0	$0	$65	($16)	$0	$2	$51
2018	$140	$14.0	$350	$78.8	$5	$98	($16)	($16)	$2	$67
2019	$130	$13.0	$400	$90.0	$0	$103	($16)	($26)	$2	$63
2020	$120	$12.0	$450	$101.3	$5	$118	($16)	($31)	$2	$74
2021	$110	$11.0	$450	$101.3	$0	$112	($16)	($29)	$2	$69
2022	$100	$10.0	$450	$101.3	$5	$116	($16)	($30)	$2	$72
2023	$100	$10.0	$400	$80.0	$0	$90	($16)	($22)	$2	$54

TGR:	0%	Net Present Value of Cash Flows	$223
Discont Rate:	15%	Term Value	$89
		Cash Projection As of Year-End 2014	$42.5
		Firm Value	$354
		Shares Outstanding	30.7
		Target Price	**$11.54**

Jason Napodano, CFA - Zacks/SCR

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 70% 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 the sell-off yesterday as a significant buying opportunity for investors.

PROJECTED INCOME STATEMENT

INCOME STATEMENT

Pozen, Inc.	2012 A	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E
Treximet / MT400 (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Vimovo (sales)	$64.4	$91.0	$53	$62	$49.0	$54.0	$218.1	$200.0	$180.0
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%*	*247.4%*	*234.7%*	*233.2%*	*-24.1%*	*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%*	*40.2%*	*437.1%*	*191.3%*	*39.7%*	*-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	$2.3	$2.2	$9.8	$8.5	$8.5
% SG&A	*355.7%*	*166.3%*	*37.4%*	*33.7%*	*30.7%*	*28.9%*	*32.7%*	*20.2%*	*24.1%*
R&D	$11.9	$9.9	$1.8	$1.9	$1.7	$1.5	$7.0	$6.0	$6.0
% R&D	*221.8%*	*96.3%*	*24.2%*	*26.0%*	*22.7%*	*19.7%*	*23.1%*	*14.3%*	*17.0%*
Operating Income	($25.5)	($16.8)	$2.9	$3.0	$3.5	$3.9	$13.3	$27.5	$20.7
Operating Margin	*-477.5%*	*-162.6%*	*38.4%*	*40.3%*	*46.7%*	*51.3%*	*44.2%*	*65.5%*	*58.8%*
Interest Income / Net	$0.3	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($25.3)	($16.7)	$2.9	$3.0	$3.5	$3.9	$13.3	$27.6	$20.8
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	$3.5	$3.9	$13.3	$27.6	$20.8
YOY Growth	*-159.7%*	*-33.9%*	-	-	-	-	*-179.9%*	*106.8%*	*-24.6%*
Net Margin	*-472.7%*	*-161.9%*	-	*40.4%*	*46.9%*	*51.6%*	*44.4%*	*65.7%*	*59.1%*
Reported EPS	($0.84)	($0.55)	$0.09	$0.09	$0.11	$0.12	$0.41	$0.84	$0.61
Fully Diluted Shares	30.1	30.4	30.7	32.6	32.6	32.7	32.2	33.0	34.0

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

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