Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Vimovo Sales Outshine Minor PA CRL, Stock Still Attractive…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (05/09/14)	$8.18
Target Price	**$12.50**

UPDATE

We believe Pozen represents a compelling valuation and catalyst play at this level. Despite the minor CRL issued by the FDA in April, 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 $12.50.

SUMMARY DATA

52-Week High	**$9.77**
52-Week Low	**$4.50**
One-Year Return (%)	**80.18**
Beta	**1.90**
Average Daily Volume (sh)	**734,674**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$252**
Short Interest Ratio (days)	**9.61**
Institutional Ownership (%)	**79**
Insider Ownership (%)	**4**
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	**13.5**
P/E using 2015 Estimate	**10.0**

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	6.3 E	6.7 E	16.1 E	36.6 E
2015					41.5 E
2016					54.0 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	$0.05 E	$0.08 E	$0.39 E	$0.62 E
2015					$0.81 E
2016					$1.19 E

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WHAT'S NEW

Solid First Quarter Financial Results

On May 8, 2014, Pozen, Inc. reported financial results for the first quarter ended March 31, 2014. Total revenues in the fourth quarter were $7.5 million, comprised of $4.5 million in royalties on $34 million in sales of Vimovo at Horizon Pharma (HZNP) in the U.S. and $19 million in sales at AstraZeneca (AZN) outside the U.S., and $3.0 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 703% from the first quarter 2013 and absolutely crushed our expectations of $5.0 million – with all the upside coming from higher royalties on Vimovo.

Vimovo Finally Starting To Take-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. We remind investors that on November 19, 2013, Pozen announced that Vimovo commercialization partner, AstraZeneca AB, has entered into an agreement with Horizon Pharma USA whereby Horizon acquired the U.S. rights for Vimovo. Under the terms of the agreement, Pozen will continue to receive a 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.

At the time of the agreement, we recall seeing the $5 million minimum royalty payment and thinking, "That's a pretty sweet deal for Pozen!" After all, 2013 U.S. Vimovo royalties totaled only $2.1 million on sales of $21 million. Well, based on the breakdown of royalties in the first quarter alone, Horizon will crush that $5 million minimum payment by the end of the second quarter. For 2014, we think it is likely that Horizon does over $100 million in Vimovo sales, putting Pozen's royalty at greater than $10 million from U.S. sales alone.

Meanwhile, AstraZeneca will continue to market Vimovo in territories outside the U.S., and Pozen will continue to collect 6% royalties on these sales. In 2013, Vimovo Ex-U.S. sales of Vimovo totaled $70 million. We expect 2014 sales to be similar. 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 too would be very good news for Pozen.

So far this looks like a "Homerun" for Pozen. Horizon is taking the re-launch of Vimovo seriously, having completed an expansion of its sales force to 250 representatives to promote the product, up from 150 earlier in the year. Horizon even increased is specialty rheumatology sales force to 40 reps. This has clearly lead to an increase in prescriptions for the product. Vimovo U.S. prescriptions grew by 10% in January, 18% in February and 15% in March versus the prior month, respectively. Total prescriptions in the first quarter were 69,368, greater than what AstraZeneca did in all of 2013.

Vimovo sales growth is coming from a combination of both strong prescription growth and a dramatically increased price. Under AstraZeneca, a 30-day supply of Vimovo cost around $68 ($2.25 per pill). Currently, a 30-day supply of Vimovo will run $720 ($12 per pill). This is in-line with other branded NSAID's. Following the price increase, Horizon then instituted a co-pay assistance program to ensure patients have access to Vimovo at a reasonable out-of-pocket cost – this is something that AstraZeneca never did in fear of damaging the pricing premium on Nexium versus generic omeprazole. Whatever else Horizon is doing seems to be working, and that's good news for Pozen.

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 16 employees, down from 29 a year ago. G&A costs in the first quarter 2014 totaled $2.8 million, the lowest quarterly overhead rate in six years. G&A in the first quarter 2013, for example, was $3.6 million. R&D in the first quarter 2014 totaled $1.8 million, the lowest we've ever seen (our model dates back to 2003). Total operating costs were reduced by $2.6 million from the first quarter 2013. On the company's first quarter earnings call, CEO John Plachetka noted that further cuts to overhead are expected in 2014. 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 overhead and R&D costs, Pozen reported a net gain in the quarter of $2.9 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.

Cash And Future Plans

Pozen exited March 31, 2014 with $27.1 million in cash on the books. The company also showed an Accounts Receivable line on the balance sheet of $4.549 million, equal exactly to the royalty line recorded on the income statement. We expect that this cash was paid to Pozen in April 2014 from Vimovo commercialization partners AstraZeneca and Horizon. 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.

As noted above, Pozen 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 (we discuss below), so approval did not come in late April 2014 as we expected. However, we believe the issues that lead to the complete response letter on April 25, 2014 seem minor. Therefore, we still expect PA approval in 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 third quarter 2014) and the second $10 million is for "commercial-readiness" (which we model in the first quarter 2015).

If all goes well, Pozen could exit 2014 with over $40 million on the books, and another $10 million coming early 2015. Pozen was very near cash flow positive in the first quarter 2014 based on Vimovo alone. We think by the end of 2014, Pozen will be cash flow positive based on Vimovo alone. Add in PA in 2015 and we see the company generating significant positive cash flow in the coming years. Therefore, we think Pozen can potentially look to distribute more cash to shareholders in 2015.

Did You Say Dividend Discount Model & Biotech In The Same Sentence?

For example, based on our current financial projections, Pozen could generate $25 million in positive cash flow from operating activities in 2015, along with having $50+ million in cash on the books. If the company wanted to have a payout ratio of 50%, this would equate to a cash dividend of around $12.5 million, or a yield on the stock of around 4.7%. However, if Pozen will truly have $50+ million in cash in 2015, we suspect that they will pay out – at least – 50% of this figure. This puts the total dividend payout more like $32.5 million, or $1.00 per share, or a yield on the current stock price of 11.5%.

PA CRL Seems Like Very Minor Issue

On April 25, 2014, Pozen announced receipt of a complete response letter (CRL) for PA8140/PA32540. In the CRL, the FDA noted that, "*During an inspection of the manufacturing facility of an active ingredient supplier that concluded earlier in the week, inspection deficiencies were found*." We note that these deficiencies were found at the manufacturing facility of a third-party supplier of the active ingredient for PA. On Pozen's first quarter conference call, CEO John Plachetka noted that the third-party supplier is already addressing these deficiencies and plans to respond to the FDA by the end of the week ending May 9, 2014.

As of now, we are unsure how long it will take for the FDA to respond back to the supplier. Pozen must submit a response to the FDA addressing the CRL. If all goes well, the third-party supplier has addressed these issues and Pozen can respond back to the FDA in June or July. With a two-month (Class-1) turnaround, we could be looking at a new PDUFA date for PA in September 2014. We note that Pozen has stated in both their press release and on the first quarter call that no other deficiencies, including clinical or safety issues, were noted in the CRL. Pozen also noted that draft labeling for the product was in-line with expectations.

Despite the minor delay, we continue to believe that Sanofi will be in position to launch PA in early 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 (SNY) 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.

Valuation

We've done some initial modeling on what Pozen will look like with PA on the market and a reinvigorated Vimovo selling at Horizon (see below). 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.

	Vimovo		PA		Licsening	Cash				Free Cash
	WW Sales	Royalty	WW Sales	Royalty	Payments	Revenues	Op. Exps	Taxes	Cash Adjs	Flow
2013	$91	$6.4	$0	$0	$15	$21	($27)	$0	$2	($4)
2014	$200	$17.0	$0	$0.0	$10	$27	($18)	$0	$2	$11
2015	$300	$26.0	$50	$8.8	$10	$45	($17)	$0	$2	$30
2016	$350	$35.0	$100	$20.0	$5	$60	($16)	$0	$2	$46
2017	$200	$20.0	$250	$50.0	$0	$70	($16)	$0	$2	$56
2018	$150	$15.0	$350	$78.8	$10	$104	($16)	($18)	$2	$72
2019	$150	$15.0	$400	$90.0	$0	$105	($16)	($27)	$2	$64
2020	$140	$14.0	$450	$101.3	$10	$125	($16)	($33)	$2	$78
2021	$130	$13.0	$450	$101.3	$0	$114	($16)	($29)	$2	$71
2022	$120	$12.0	$450	$101.3	$10	$123	($16)	($32)	$2	$77
2023	$110	$11.0	$400	$80.0	$0	$91	($16)	($23)	$2	$55

TGR:	1%	Net Present Value of Cash Flows	$247
Discont Rate:	15%	Term Value	$96
		Cash Projection As of Year-End 2014	$42.5
Jason Napodano, CFA - Zacks/SCR		**Firm Value**	$385
		Shares Outstanding	30.7
		Target Price	**$12.55**

At the current stock price, these dividends would equate to a 23% 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 $12+ per share based on the future projected cash flows and return of capital to shareholders. On a price to earnings ratio, Pozen is currently trading at 13.5x our 2014 estimate. For 2015, assuming PA approval, Pozen is trading at 10.0x earnings.

Now 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. 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.

PROJECTED INCOME STATEMENT

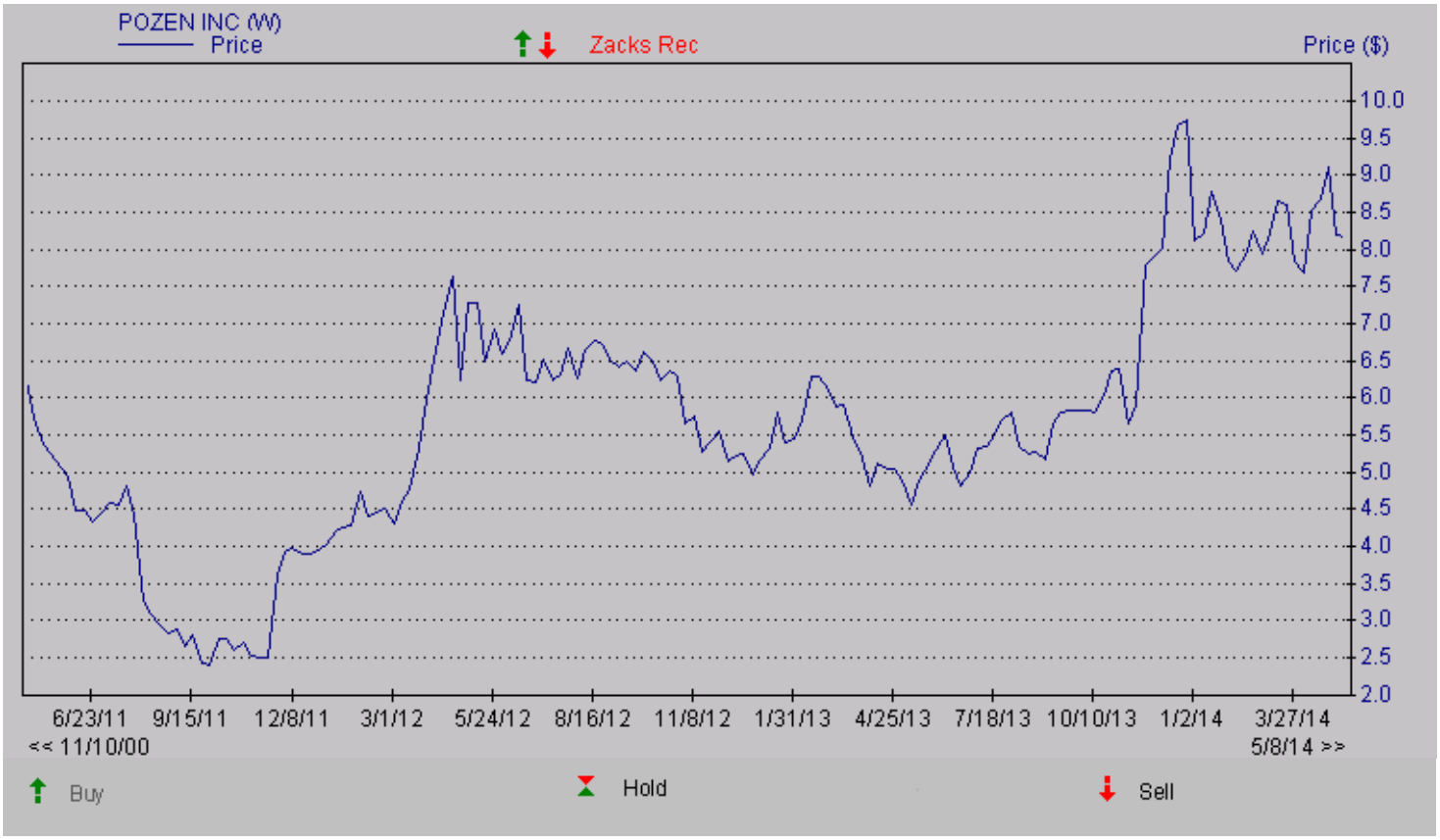
INCOME STATEMENT

Pozen, Inc.	2012 A	2013 A	Q1 A	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Vimovo (royalty)	**$4.8**	**$6.3**	**$4.5**	**$3.3**	**$3.7**	**$4.1**	**$15.6**	**$24.0**	**$31.5**
YOY Growth	*66.5%*	*30.4%*	*221.5%*	*99.9%*	*132.2%*	*142.1%*	*146.3%*	*54.1%*	*31.3%*
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$7.5**	**$17.5**
YOY Growth	-	-	-	-	-	-	-	-	*133.3%*
Licensing / Development	**$0.5**	**$4.0**	**$3.0**	**$3.0**	**$3.0**	**$12.0**	**$21.0**	**$10.0**	**$5.0**
Total Revenues	$5.3	$10.3	$7.5	$6.3	$6.7	$16.1	$36.6	$41.5	$54.0
YOY Growth	*-93.8%*	*93.0%*	*703.1%*	*366.0%*	*24.8%*	*1034.3%*	*254.3%*	*13.5%*	*30.1%*
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	$2.8	$2.6	$2.5	$10.7	$10.0	$10.0
% SG&A	*355.7%*	*166.3%*	*37.4%*	*44.4%*	*39.0%*	*15.6%*	*29.3%*	*24.1%*	*18.5%*
R&D	$11.9	$9.9	$1.8	$2.0	$1.7	$1.5	$7.0	$6.5	$6.0
% R&D	*221.8%*	*96.3%*	*24.2%*	*31.7%*	*25.5%*	*9.3%*	*19.2%*	*15.7%*	*11.1%*
Operating Income	($25.5)	($16.8)	$2.9	$1.5	$2.4	$12.1	$18.8	$25.0	$38.0
Operating Margin	*-477.5%*	*-162.6%*	*38.4%*	*23.8%*	*35.6%*	*75.1%*	*51.5%*	*60.2%*	*70.4%*
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	$1.5	$2.4	$12.1	$18.9	$25.1	$38.1
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	$1.5	$2.4	$12.1	$18.9	$25.1	$38.1
YOY Growth	*-159.7%*	*-33.9%*	-	-	-	-	*-213.1%*	*32.9%*	*51.8%*
Net Margin	*-472.7%*	*-161.9%*	-	*24.1%*	*35.9%*	*75.2%*	*51.6%*	*60.5%*	*70.6%*
Reported EPS	($0.84)	($0.55)	$0.09	$0.05	$0.08	$0.39	$0.62	$0.81	$1.19
Fully Diluted Shares	30.1	30.4	30.7	30.6	30.7	30.8	30.7	31.0	32.0

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

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