Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Expecting PA Approval In April 2014…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (03/05/14)	$8.10
Target Price	**$11.00**

UPDATE

We believe Pozen represents a compelling valuation and catalyst play at this level. The PDUFA for PA is approaching and we see limited risk at this stage given the small requirement from the agency on a required Phase 1 pharmacokinetic study. Once PA is approved, we think Pozen will rapidly approach cash flow positive operations 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.

SUMMARY DATA

52-Week High	**$9.77**
52-Week Low	**$4.50**
One-Year Return (%)	**26.44**
Beta	**1.88**
Average Daily Volume (sh)	**197,066**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$247**
Short Interest Ratio (days)	**12.05**
Institutional Ownership (%)	**80**
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	**N/M**
P/E using 2015 Estimate	**N/M**

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	5.0 E	15.1 E	5.2 E	14.9 E	40.2 E
2015					21.5 E
2016					33.5 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	-$0.06 E	$0.28 E	-$0.02 E	$0.31 E	$0.50 E
2015					$0.07 E
2016					$0.53 E

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WHAT'S NEW

Recent Financial Results

On March 5, 2014, Pozen, Inc. reported financial results for the fourth quarter and full year ended December 31, 2013. Total revenues in the fourth quarter were $4.7 million, comprised of $1.7 million in royalties on roughly $25 million in sales of Vimovo at AstraZeneca AB 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 the fourth quarter were essentially dead-on with our forecast. Revenues for the full year 2013 totaled approximately $10.3 million, which included $6.3 million in royalties from roughly $91 million in worldwide sales of Vimovo at AstraZeneca AB and $4.0 million in amortized recognition of the PA upfront licensing fee from Sanofi U.S.

Net loss in the fourth quarter 2013 totaled $2.2 million, or $0.07 per share. Operating expenses included $4.6 million in G&A and $2.2 million in R&D. Both were in-line with expectations. For the full year 2013, net loss totaled $16.7 million, or $0.55 per share. Operating expenses included $17.2 million in G&A and $9.9 million in R&D.

Pozen exited 2013 with $32.8 million in cash on the books. We remind investors that back in November 2013, Pozen announced it would issue a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with an expected payment date of December 30, 2013. Based on 30.6 million shares outstanding, the special cash distribution equated to roughly $53.6 million returned to shareholders. We believe the current cash position of $32.8 million is sufficient to fund operations for the foreseeable future given the low burn rate of only $1.0 million per month ahead of the pending PA approval on April 25, 2014.

Assuming PA approval, Pozen is entitled 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 second quarter 2014) and the second $10 million is for "commercial-readiness" (which we model in the fourth quarter 2014). We believe with a growing royalty payment now emerging from resurgent U.S. sales of Vimovo, now in the hands of Horizon Pharma, USA, continued solid ex-U.S. sales of Vimovo at AstraZeneca, and PA approval and launch at Sanofi U.S., Pozen will be cash flow positive on an operating basis in 2015. If all goes well, Pozen could exit 2014 with $45 million on the books. Therefore, we think Pozen can potentially look to distribute more cash to shareholders in 2015.

PA PDUFA Approaching

As a reminder, Pozen announced in November that the FDA requested a teleconference to discuss the new drug application for PA-325/40 and PA-81/40. Late last year, Pozen announced that the FDA had extended the PDUFA goal to April 25, 2014 to allow Pozen to conduct a comparative Phase 1 pharmacokinetic study. According to management, this study has been completed and the data analysis is ongoing, with an expected submission to the U.S. FDA before the end of March 2014. This should provide the agency enough time to review the information and make a decision by the posted PDUFA date of April 25, 2014.

The study compared the dissolution of the 40mg immediate release omeprazole component between PA-325/40 and PA-81/40. Pozen did the initial pharmacokinetic work for the drug on the PA-325/40 compound and the FDA wants to be sure that the characteristics of PA-81/40 are similar. Given that PA-325/40 contains 325mg of aspirin compared to only 81mg of aspirin for PA-81/40, the surface area of the 40mg omeprazole component differs between the two formulations. Management tells us that the initial pk curves between the two compounds do differ slightly, but that the overall characteristics should be similar enough (usually the FDA gives a window of ±20% on these types of things) to sail through review with no issues.

We think PA is a $300 million product in the U.S. 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.

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·

We think the opportunity for PA outside the U.S. is around $150 to $200 million, and we note our valuation model includes no commercialization deal for Europe at this time. 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.

Expecting Uptick In Vimovo

On November 19, 2013, Pozen announced that U.S. Vimovo commercialization partner, AstraZeneca AB, has entered into an agreement with Horizon Pharma USA have entered into an agreement for Horizon to acquire the U.S. rights for Vimovo. Under the terms of the agreement, Pozen will continue to receive a 10% royalty on net sales of products sold 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. AstraZeneca will continue to market Vimovo in territories outside the U.S. In 2013, Vimovo U.S. sales totaled only $21 million, dwarfed by ex-U.S. sales of $70 million.

We see this event as very good news for Pozen. AstraZeneca announced earlier in 2013 that they would cease all active promotion of the product in the U.S. based on weak sales. U.S. sales of Vimovo have been abysmal under AstraZeneca, no doubt due to the company's lackluster promotional effort and difficult pricing environment. Ex-U.S. sales, where AstraZeneca seems to be committed to growing the product, outpaced U.S. sales by over 3-1. Horizon believes with a renewed promotional effort and co-pay assistance, U.S. sales can be turned around and approach $100 million in the next few years.

In fact, Horizon provided a brief update on Vimovo in late January 2014. Horizon stated that all required FDA transfers with respect to Vimovo NDA and IND have been completed complete. This is important because under the agreement, Horizon assumed AstraZeneca's right to lead the on-going Paragraph IV litigation for Vimovo and will assume all patent-related defense costs relating to such litigation, including reimbursement for a specified amount of the cost of counsel retained by Pozen. Management at Horizon also noted that labeled inventory has been manufactured, shipped and sold into the wholesale and pharmacy channel as of late January 2014. Horizon seems to be taking the launch of Vimovo seriously, as the company has recently completed an expansion of its field sales force to promote the product. Horizon even 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. Horizon reported that this co-pay assistance program should bring the out-of-pocket cost for Vimovo down to $0 for the first month for 96% of all insured patients. The renewed effort seems to be working for Horizon, as new prescriptions in January 2014 were up 10% sequentially from December 2013.

Pozen receives 10% royalty on U.S. sales. As such, Horizon's minimum commitment of $5.0 million in 2014 is a meaningful step-up in payment from what was previously expected. Remember, AstraZeneca sold only $21 million of Vimovo in the U.S. in 2013. That equated to only a $2.1 million royalty payment to Pozen. The now $5.0 million minimum guaranteed payment represents nice upside to our model in 2014. In 2014 and beyond, the minimum payment rises to $7.5 million, meaning Horizon must be confident it can turn Vimovo into at least a $75 million product in the U.S.

Pozen will continue to receive a 6% royalty on Vimovo sales outside the U.S. at AstraZeneca, which totaled $70 million in 2013, with sales up 69% year-over-year in the fourth quarter 2013. Assuming AstraZeneca can maintain the current $70 million per year run-rate for Vimovo, this equates to roughly $4.2 million in royalties to Pozen. We note this royalty rate jumps to 10% starting in 2016. Things are clearly looking up for Vimovo!

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 $60-70 million in free cash flow starting in 2017. 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	$115	$9.0	$15	$2.3	$20	$31	($25)	$0	$2	$8
2015	$125	$12.5	$70	$12.3	$0	$25	($20)	$0	$2	$7
2016	$135	$13.5	$100	$20.0	$5	$39	($17)	$0	$2	$24
2017	$140	$14.0	$250	$50.0	$0	$64	($16)	($5)	$2	$45
2018	$150	$15.0	$350	$78.8	$10	$104	($16)	($18)	$2	$72
2019	$150	$15.0	$450	$101.3	$0	$116	($16)	($30)	$2	$72
2020	$140	$14.0	$450	$101.3	$15	$130	($16)	($34)	$2	$82
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	$211
Discont Rate:	15%	Term Value	$96
		Cash Projection As of Year-End 2013	$32.8
Jason Napodano, CFA		**Firm Value**	$340
		Shares Outstanding	30.6
		Target Price	**$11.11**

At the current stock price, these dividends would equate to a 20-25% yield. 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. Now we understand there is a discount based on the fact that PA has yet to be approved and Horizon has yet to demonstrate it can grow Vimovo; but we think both caveats are low hurdles 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	Q1 A	Q2 A	Q3 A	Q4 A	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Vimovo (sales)	$64.4	$19.7	$23.3	$23.0	$25.0	$91.0	$26.5	$27.5	$29.0	$32.0	$115.0	$125.0	$135.0
Vimovo (royalty)	**$4.8**	**$1.4**	**$1.7**	**$1.6**	**$1.7**	**$6.3**	**$2.0**	**$2.1**	**$2.2**	**$2.2**	**$8.5**	**$11.0**	**$11.0**
YOY Growth	*66.5%*	-	-	-	-	*30.4%*	*41.3%*	*27.2%*	*39.0%*	*33.9%*	*35.1%*	*28.8%*	*0.0%*
PA Franchise (sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5.0	$5.0	$70.0	$100.0
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.6**	**$0.6**	**$10.5**	**$17.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*1580.0%*	*66.7%*
Licensing / Development	**$0.5**	**$0**	**$0**	**$1.0**	**$3.0**	**$4.0**	**$3.0**	**$13.0**	**$3.0**	**$12.0**	**$31.0**	**$0**	**$5.0**
Total Revenues	$5.3	$1.4	$1.7	$2.6	$4.7	$10.3	$5.0	$15.1	$5.2	$14.9	$40.2	$21.5	$33.5
YOY Growth	*-93.8%*	*-71.1%*	*-97.7%*	*-97.0%*	*262.5%*	*93.0%*	*431.9%*	*1016.9%*	*-2.8%*	*950.5%*	*289.1%*	*-46.5%*	*55.8%*
Cost of Goods Sold	$0	$0	$0	$0	$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	$3.6	$3.7	$5.2	$4.6	$17.2	$3.9	$4.1	$3.6	$3.4	$15.0	$12.0	$10.0
% SG&A	*355.7%*	*256.8%*	*224.9%*	*200.6%*	*99.1%*	*166.3%*	*78.0%*	*27.2%*	*69.2%*	*22.9%*	*37.3%*	*55.8%*	*29.9%*
R&D	$11.9	$3.6	$1.9	$2.2	$2.2	$9.9	$3.1	$2.5	$2.2	$2.0	$9.8	$7.5	$6.5
% R&D	*221.8%*	*253.3%*	*117.6%*	*84.5%*	*47.9%*	*96.3%*	*62.0%*	*16.6%*	*42.3%*	*13.5%*	*24.4%*	*34.9%*	*19.4%*
Operating Income	($25.5)	($5.8)	($4.0)	($4.8)	($2.2)	($16.8)	($2.0)	$8.5	($0.6)	$9.5	$15.4	$2.0	$17.0
Operating Margin	*-477.5%*	*-410.1%*	*-242.5%*	*-185.1%*	*-47.0%*	*-162.6%*	*-40.0%*	*56.3%*	*-11.5%*	*63.7%*	*38.3%*	*9.3%*	*50.7%*
Interest Income / Net	$0.3	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($25.3)	($5.8)	($4.0)	($4.8)	($2.2)	($16.7)	($2.0)	$8.5	($0.6)	$9.5	$15.4	$2.1	$17.1
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($25.3)	($5.8)	($4.0)	($4.8)	($2.2)	($16.7)	($2.0)	$8.5	($0.6)	$9.5	$15.4	$2.1	$17.1
YOY Growth	*-159.7%*	-	-	-	-	*-33.9%*	-	-	-	-	*-192.4%*	*-86.4%*	*714.3%*
Net Margin	*-472.7%*	*-408.3%*	*-241.6%*	*-184.6%*	*-46.5%*	*-161.9%*	-	*56.4%*	*-11.2%*	*63.8%*	*38.5%*	*9.8%*	*51.0%*
Reported EPS	($0.84)	($0.19)	($0.13)	($0.16)	($0.07)	($0.55)	($0.06)	$0.28	($0.02)	$0.31	$0.50	$0.07	$0.53
Fully Diluted Shares	30.1	30.3	30.4	30.5	30.6	30.4	30.6	30.6	30.7	30.8	30.7	31.0	32.0

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

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