Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: FDA Teleconferences and Cash Distributions…Oh, And A PDUFA Too…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (11/06/13)	$5.95
Target Price	**$9.00**

UPDATE

Pozen has a lot going on right now. The company is currently preparing for a teleconference with the U.S. FDA. The agency requested the meeting to discuss the existing pharmacology data on PA-81/40 prior to the PDUFA date of January 24, 2014. We are hoping this issue does not derail our thesis that PA-325/40 and PA-81/40 gets approved at that time. Besides this potential wildcard event, management is also looking at returning "surplus cash" to shareholders in the form of a distribution, potentially before the end of the year. We struggle to understand how this would impact the stock, but nevertheless still believe in our 'Outperform' rating and $9.00 price target.

SUMMARY DATA

52-Week High	**$6.50**
52-Week Low	**$4.50**
One-Year Return (%)	**13.91**
Beta	**1.21**
Average Daily Volume (sh)	**289,804**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$197**
Short Interest Ratio (days)	**14.12**
Institutional Ownership (%)	**59**
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 2013 Estimate	**N/M**
P/E using 2014 Estimate	**N/A**

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)
2012	1.3 A	1.4 A	0.9 A	1.4 A	5.3 A
2013	1.4 A	1.7 A	2.6 A	4.6 E	10.3 E
2014					29.9 E
2015					31.2 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.28 A	-$0.17 A	-$0.19 A	-$0.20 A	-$0.84 A
2013	-$0.19 A	-$0.13 A	-$0.16 A	-$0.05 E	-$0.53 E
2014					$0.12 E
2015					$0.05 E

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WHAT'S NEW

Recent Financial Results

On November 6, 2013, Pozen, Inc. (POZN) reported financial results for the third quarter ended September 30, 2013. Total revenues in the quarter were $2.6 million, and consisted of $1.6 million in royalties from AstraZeneca on worldwide sales of Vimovo totaling $23 million in the third quarter 2013, and $1 million in ratable recognition of the $15 million upfront payment from Sanofi-Aventis for the U.S. commercialization rights to the PA franchise struck on September 3, 2013. Pozen is recognizing this $15 million in revenue amortized over a 15 month period. We discuss this transaction in greater detail below.

Operating expenses in the quarter were $7.2 million, significantly higher than expected, but we note included roughly $1.6 million in one-time expenses associated with the Sanofi-Aventis transaction in September. Without this added expense, operating results would have been roughly in-line with our forecast. Net loss in the quarter totaled $4.8 million, or $0.16 per share based on 30.5 million shares outstanding.

The company's press release notes that management is currently focusing its efforts on obtaining FDA approval of PA-81/40 and PA-325/40, which includes transitioning all know-how to Sanofi-Aventis. The company's goals are to complete the remaining Phase 1 study and MAA filing for PA-100/40 in Europe, evaluate the possibility of a MAA filing using existing data for the use of PA in secondary cancer prevention in Europe, attempt to partner all un-partnered assets, and reduce staff and expenses as warranted by business conditions. In this regard, Liz Cermak, the company's Executive Vice President and Chief Commercial Officer will be retiring from Pozen at the end of the year. With PA now being transitioned over to Sanofi-Aventis, Pozen is no longer in need of a Chief Commercial Officer. The press release notes that Ms. Cermak led many facets of the PA program including Pozen's efforts to secure the best agreement possible for shareholders with Sanofi.

Pozen exited the third quarter 2013 with $89.7 million in cash on hand. The company's management team and board of directors are evaluating possible ways of returning value to shareholders, including cash distributions of surplus corporate cash. As Pozen winds down operations post PA approval, we believe the company can reach cash flow positive operations based on the royalties from Vimovo and PA alone. Assuming management has no further desire to bring new candidates into the clinic, we believe the company can dividend as much as $2.00 per share (approximately $60 million in cash) to shareholders. This would still leave them enough to push forward the MAA on PA-100/40 in the EU, as well as explore the possibility of filing an MAA for secondary cancer prevention. We remind investors that Pozen is entitled to $20 million in pre-commercialization milestones on PA from Sanofi-Aventis. On the company's third quarter conference call, CEO John Plachetka would not rule out the possibility of making a decision with respect to a cash distribution before the end of the year 2013.

…FDA Requests Teleconference On PA…

In Pozen's earning press release, the company noted that, "As part of Pozen's ongoing interactions and requests for information from the FDA during its review of the NDA for PA-81/40 and PA-325/40, the FDA has requested a teleconference, which has been scheduled for mid-November 2013 to discuss and address the FDA's request for information with respect to the existing clinical pharmacology data on PA8140."

On the third quarter call, management noted that they think all the necessary information the FDA would like clarity on is in the NDA filing, but that they need to do a better job in presenting it to the agency. We think the issue stems from a lack of pharmacology data on PA-81/40, not from the actual data itself. For example, the agency is not asking about PA-325/40, the dose in which Pozen conducted all the phase 2 and 3 studies. Pozen only conducted one bioequivalence study with PA-81/40. CEO John Plachetka noted that these types of pharmacology studies are inexpensive and quick to run, so if the worst-case scenarios arises and the company receives a complete response letter relating to this issue, we think Pozen could be in position to re-file in less than four months at pretty minimal cost. The company plans to provide an update to investors after the teleconference concludes. Although, we note this may include waiting for the minutes from the meeting, which usually takes around one month to receive.

Sanofi-Aventis To Commercialize PA in the U.S.

On September 3, 2013, Pozen Inc. entered into a licensing and collaboration agreement with Sanofi-Aventis for the commercialization of PA-325/40 and PA-81/40 in the U.S. PA-325/40 and PA-81/40 are Pozen's "safer aspirin" products current under U.S. FDA regulatory review with a PDUFA action date scheduled for January 24, 2014. Pozen has been promising a partnership for its PA franchise for over a year now, and it finally delivered with an impressive catch. Partnering with Sanofi-aventis is Pozen's fourth such impressive partnership based on internally-developed combination products. Prior to this licensing and collaboration agreement for PA, Pozen has previously licensed its "safer NSAID" drug, Vimovo, to AstraZeneca, and its dual-action migraine drug, Treximet / MT-400, to GlaxoSmithKline and Johnson & Johnson.

The PA licensing agreement came with $15 million in upfront cash. Pozen is also eligible for $20 million in pre-commercialization milestones, which we assume corresponds to U.S. FDA approval in late January 2014 and the transfer of the NDA to Sanofi (split evenly). Both the upfront and approval milestone were dead-on with our previous predictions on the potential deal. Pozen can earn additional milestone payments upon the achievement of specified sales thresholds for PA, and will receive a double-digit tiered royalty on sales in the U.S. at Sanofi-aventis. The exact terms of the back-end milestones have not been disclosed, only that the royalty rate is tiered between 12.5% and 22.5%. We expect that Pozen should be able to capture an additional $50 million in sales related milestone following commercialization by Sanofi.

Pozen will retain responsibility for obtaining FDA approval for PA. The duo has agreed to share costs up to certain limits with respect to any additional activities that might be required by the FDA to gain final approval for PA. This might include conducting some additional pharmacology work on PA-81/40 depending on how the teleconference with the U.S. FDA goes in the next few weeks. However, at this stage we believe approval in January 2014 seems a good bet considering Pozen completed two positive Phase 3 trials with highly statistically significant data and excellent safety. Both trials were run under a special protocol assessment (SPA) with the U.S. FDA, and Pozen has already been down a similar path gaining approval for Vimovo (formerly called PN-500/20) in April 2010. As noted above, if the agency does request additional work on PA-81/40, we believe Pozen could provide the necessary data in only a few months at a relatively insignificant cost.

Valuation

We see the shares fairly-valued at $9 based on Vimovo sales tapering off over the next few years down to a level of $50 million. We see PA peak global sales at $500 million. Our DCF model can be found below.

POZEN, INC.	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
U.S. Sales of Treximet (GSK)	$85.0	$90.0	$90.0	$90.0	$90.0	$25.0	$0	$0	$0	$0	$0
Royalties on Treximet (~18%)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YoY	-	-	-	-	-	-	-	-	-	-	-
WW Sales of Vimovo (AZN)	$95.0	$97.0	$95.0	$45.0	$40.0	$35.0	$30.0	$25.0	$25.0	$25.0	$25.0
Royalties on Vimovo (~10%)	$7.6	$7.8	$8.6	$4.1	$3.6	$3.2	$2.7	$2.5	$2.5	$2.5	$2.5
YoY	*48%*	*2%*	*10%*	*-53%*	*-11%*	*-13%*	*-14%*	*-7%*	*0%*	*0%*	*0%*
WW Sales of PA (SNY & ??)	$0.0	$50.0	$100.0	$200.0	$300.0	$400.0	$500.0	$500.0	$450.0	$400.0	$400.0
Royalties on PA (~20%)	$0.0	$6.3	$15.0	$35.0	$60.0	$80.0	$100.0	$100.0	$90.0	$80.0	$80.0
YoY	-	-	*140%*	*133%*	*71%*	*33%*	*25%*	*0%*	*-10%*	*-11%*	*0%*
Licensing & Collaborative	$15.0	$20.0	$0	$10.0	$0	$15.0	$20.0	$0.0	$0	$0	$0
Revenues (in Millions)	**$22.6**	**$34.0**	**$23.6**	**$49.1**	**$63.6**	**$98.2**	**$122.7**	**$102.5**	**$92.5**	**$82.5**	**$82.5**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
R&D	$9.9	$10.0	$10.0	$9.0	$8.0	$7.0	$6.0	$5.0	$5.0	$5.0	$5.0
SG&A	$15.1	$16.5	$17.0	$17.5	$18.0	$18.5	$19.0	$19.5	$20.0	$20.5	$21.0
EBITDA	($2.5)	$7.5	($3.5)	$22.6	$37.6	$72.7	$97.7	$78.0	$67.5	$57.0	$56.5
Depreciation and amortization	$0.8	$0.7	$0.6	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5
EBIT	**($3.3)**	**$6.8**	**($4.1)**	**$22.1**	**$37.1**	**$72.2**	**$97.2**	**$77.5**	**$67.0**	**$56.5**	**$56.0**
EBITDA margin	*-14.5%*	*20.0%*	*-17.2%*	*45.0%*	*58.3%*	*73.5%*	*79.2%*	*75.6%*	*72.4%*	*68.5%*	*67.9%*
Cash Taxes	$0	$0	$0	$0	($5.6)	($21.6)	($29.2)	($23.3)	($20.1)	($17.0)	($16.8)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*15%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*
Discounted Cash Flow											
Net Income	($3.3)	$6.8	($4.1)	$22.1	$31.5	$50.5	$68.0	$54.3	$46.9	$39.6	$39.2
Non-Cash Adjustment to NOI	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0
Depreciation and amortization	$0.8	$0.7	$0.6	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5
Post-Tax Operating Cash Flow	**$0.5**	**$10.5**	**($0.5)**	**$25.6**	**$35.0**	**$54.0**	**$71.5**	**$57.8**	**$50.4**	**$43.1**	**$42.7**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**$0.5**	**$10.5**	**($0.5)**	**$25.6**	**$35.0**	**$54.0**	**$71.5**	**$57.8**	**$50.4**	**$43.1**	**$42.7**

Assumptions	
Equity Risk Premium:	6.0%
Risk Free Rate:	2.0%
Terminal Growth:	1.0%
Discount Rate:	**15.0%**

Valuation	
10-Year Model:	$143.4
Terminal Value:	$65.6
Cash - Debt:	$76.9
Firm Value:	**$286**

Price Target	
Basic Outstanding:	30.4
Warrants / Options:	0.5
Fully Diluted:	30.9
Target Price:	**$9.25**

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

PROJECTED INCOME STATEMENT

INCOME STATEMENT

Pozen, Inc.	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
Vimovo (sales)	$33.8	$64.4	$19.7	$23.3	$23.0	$23.0	$89.0	$90.0	$85.0
Vimovo (royalty)	**$2.9**	**$4.8**	**$1.4**	**$1.7**	**$1.6**	**$1.6**	**$6.3**	**$6.4**	**$6.2**
YOY Growth	*533.0%*	*66.5%*	-	-	-	-	*29.1%*	*2.1%*	*-3.6%*
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$12.5**	**$25.0**
YOY Growth	-	-	-	-	-	-	-	-	*100.0%*
Licensing / Development	**$71.9**	**$0.5**	**$0**	**$0**	**$1.0**	**$3.0**	**$4.0**	**$11.0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	$87.0	$5.3	$1.4	$1.7	$2.6	$4.6	$10.3	$29.9	$31.2
YOY Growth	*26.8%*	*-93.8%*	*-71.1%*	*-97.7%*	*-97.0%*	*257.6%*	*91.8%*	*191.4%*	*4.3%*
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	$21.8	$19.0	$3.6	$3.7	$5.2	$4.0	$16.5	$16.5	$20.0
% SG&A	*25.0%*	*355.7%*	*256.8%*	*224.9%*	*200.6%*	*86.8%*	*161.1%*	*55.2%*	*64.2%*
R&D	$23.0	$11.9	$3.6	$1.9	$2.2	$2.3	$10.0	$10.0	$10.0
% R&D	*26.5%*	*221.8%*	*253.3%*	*117.6%*	*84.5%*	*49.9%*	*97.5%*	*33.5%*	*32.1%*
Operating Income	$42.2	($25.5)	($5.8)	($4.0)	($4.8)	($1.7)	($16.3)	$3.4	$1.2
Operating Margin	*48.5%*	*-477.5%*	*-410.1%*	*-242.5%*	*-185.1%*	*-36.7%*	*-158.7%*	*11.3%*	*3.7%*
Interest Income / Net	$0.2	$0.3	$0.0	$0.0	$0.0	$0.1	$0.2	$0.4	$0.4
Pre-Tax Income	$42.3	($25.3)	($5.8)	($4.0)	($4.8)	($1.6)	($16.1)	$3.8	$1.6
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$42.3	($25.3)	($5.8)	($4.0)	($4.8)	($1.6)	($16.1)	$3.8	$1.6
YOY Growth	*83.5%*	*-159.7%*	-	-	-	-	*-36.2%*	*-123.5%*	*-58.8%*
Net Margin	*48.7%*	*-472.7%*	*-408.3%*	*-241.6%*	*-184.6%*	*-34.5%*	*-157.2%*	*12.7%*	*5.0%*
Reported EPS	$1.40	($0.84)	($0.19)	($0.13)	($0.16)	($0.05)	($0.53)	$0.12	$0.05
Fully Diluted Shares	30.3	30.1	30.3	30.4	30.5	30.5	30.4	31.0	32.0

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

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