Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Bioequivalence Hiccup Does Not Change Our Views on PA, or Pozen…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (06/21/12)	$5.83
Target Price	**$7.00**

NOTE

After the market closed on June 20, 2012, Pozen announced that the U.S. FDA had provided the company with an Advice / Information Request letter indicating that the FDA has made a preliminary review of the study results and Pozen's summary analyses of a phase 1 study (115 Study) to assess the bioequivalence of PA-325/40 to enteric-coated (EC) aspirin 325 mg using acetylsalicylic acid (ASA) as the analyte.

We see this as only a minor hiccup with respect to the NDA filing. Pozen will reconduct the study, this time with more patients and better sampling. We have made no material changes to our financial model.

SUMMARY DATA

52-Week High	**$7.91**
52-Week Low	**$2.26**
One-Year Return (%)	**65.19**
Beta	**1.37**
Average Daily Volume (sh)	**293,646**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$223**
Short Interest Ratio (days)	**8.15**
Institutional Ownership (%)	**49**
Insider Ownership (%)	**11**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**14.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/M**
P/E using 2013 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)
2011	4.5 A	4.6 A	4.9 A	73.0 A	87.0 A
2012	1.3 A	1.4 E	1.6 E	16.6 E	20.9 E
2013					28.3 E
2014					30.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.19 A	-$0.21 A	-$0.24 A	$2.04 A	$1.40 A
2012	-$0.28 A	-$0.28 E	-$0.28 E	$0.27 E	-$0.57 E
2013					-$0.24 E
2014					-$0.21 E

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WHAT'S NEW

Minor Hiccup For Pozen

After the market closed on June 20, 2012, Pozen announced that the U.S. FDA had provided the company with an Advice / Information Request letter indicating that the FDA has made a preliminary review of the study results and Pozen's summary analyses of a phase 1 study (115 Study) to assess the bioequivalence of PA-325/40 to enteric-coated (EC) aspirin 325 mg using acetylsalicylic acid (ASA) as the analyte.

According to the letter, the FDA does not agree that bioequivalence of PA-325/40 to EC aspirin 325 mg was demonstrated. It seems as though the phase 1 data Pozen submitted had substantial variability with respect to the blood levels tested in the ASA group. The trial was not adequately powered for such variation in the data, and as a result the phase 1 study came up short of demonstrating statistically significant bioequivalence. The FDA does not seem to have any issues with the approach Pozen took to collect or analyze the data, known as a reference-scaled bioequivalence approach. The data simply was not sufficient as submitted.

We remind investors that Pozen had previously demonstrated bioequivalence of PA-325/40 to EC aspirin 325 mg using salicylic acid (SA) as the analyte. Salicylic acid is the main metabolite of acetylsalicylic acid. Generic aspirin manufacturers must show bioequivalence to SA prior to OTC approval. It seems as though for ethical use the FDA is taking the approval hurdle one-step higher, requesting bioequivalence to ASA.

Pozen plans to hold a follow-up call with the U.S. FDA in the next few weeks to clarify the next steps in satisfying the bioequivalence requirement prior to filing the new drug application (NDA) on PA-325/40. Positive phase 3 data was announced in March 2012. These two trials enrolled 1,049 patients under a special protocol assessment (SPA). In May 2012, the FDA threw Pozen a curveball with respect to the planned NDA filing, asking for data on a lower dose using 81 mg of aspirin. As it turns out, this may actually work to the company's benefit, allowing for the potential approval of PA-81/40 without having to do a pivotal program.

…What's Next For Pozen…

Pozen plans to hold a follow-up call with the U.S. FDA in the next few weeks. We believe the company plans to conduct another phase 1 bioequivalence study, only this time enrolling more patients and collecting more blood samples. The new trial should have higher statistical powering, allowing Pozen to account for the blood variability levels typically seen with ASA. We believe this trial will start sometime in August 2012 and cost around $1 million. We expect results in October 2012. Pozen's second quarter conference call will most likely take place in early August 2012. We expect an update at that time.

Plans with respect to the PA-81/40 product have yet to be determined. Ideally, Pozen would like to file for a biowaiver (clinical exemption) based on the strength of the PA-325/40 data they generate. Collecting bioequivalence data on EC 325 mg ASA has proved difficult enough. We see challenges to demonstrating bioequivalence to EC 81 mg ASA. In theory, the biowaiver should be approved if the data is sufficient with PA-325/40. However, if Pozen needs to conduct a phase 1 (in vivo) bioequivalence study to EC 81 mg ASA, it would delay the planned NDA filing, which we currently model in the first quarter of 2013.

In the meantime, the only change we are making to our financial model is to add in $1 million in costs in the third quarter 212. We have made no changes to our expectations on the timing of the NDA (Q1-2013), FDA approval (Q1-2014), or peak sales for PA-325 and PA-81 ($350 million in 2020). We still believe that Pozen will be able to secure a commercialization partner for PA around the NDA filing.

Valuation

We have previously written that we believe Pozen, pre a commercialization partnership on PA-325/40, is worth $7 per share. The stock traded briefly above $8 per share on April 26th, as investors clearly believe a partnership is near. With a narrowed indication to include only CABG patients, we think Pozen's stock is worth around $5-6 per share. Full approval of both PA-325/40 and PA-81/40 and Pozen is worth as much as $10 per share.

We believe Pozen can still close a deal on PA in 2012, but management will most likely have to give up some of the upfront payment in lieu of backend milestones contingent on sales levels and label expansion. Still however, we see the sales opportunity with PA-81/40 as doubling the market opportunity to Pozen's partner. Therefore, giving up some modest upfront payment in lieu of more sales related payments may be the smart thing to do.

For now, we are maintaining our 'Outperform' rating on the shares and not adjusting our $7 target. Our DCF model is currently "in flux" – meaning we can justify virtually any price between $5 and $10 based on the final verdict of the FDA on the NDA filing.

- ⇨ Approval of PA-325/40 with limited indication to include CABG & Stroke patients only = Pozen is worth $5 per share.
- ⇨ Approval of PA-325/40 will full label to include secondary prevention, delay in approval of PA-81/40 while Pozen conducts additional analysis = Pozen is worth $7 per share.
- ⇨ Approval of both PA-325/40 and PA-81/40 to include the full label for secondary prevention of cardiovascular disease = Pozen worth $10 per share.
- ⇨ EU approval of PA-100/40 and/or PA-300/40 following comprehensive phase 3 program (MAA filing in 2015) = Pozen worth $11 per share.
- ⇨ EU approval of PA-100/40 and/or PA-300/40 following simple PK/PD + BE + CMC data (MAA filing in 2013) = Pozen worth $13 per share.

At this point, we are going to leave our target at $7 per share while we wait for improved visibility on both the timing and content of the U.S. NDA. A partnership later in 2012 remains the single biggest catalyst ahead. We think a partnership alone could send the shares above $10.

PROJECTED INCOME STATEMENT

Income statement:

	2010 A	2011 A	Q1 A	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Treximet / MT400 (royalty)	**$15.7**	**$12.2**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*265.0%*	*-22.6%*	-	-	-	-	*-100.0%*	-	-	-
Vimovo (royalty)	**$0.5**	**$2.9**	**$1.3**	**$1.4**	**$1.6**	**$1.6**	**$5.9**	**$8.3**	**$11.2**	**$14.5**
YOY Growth	-	*533.0%*	-	-	-	-	*103.3%*	*39.9%*	*35.3%*	*29.5%*
PA Franchise (sales)	$0	$0	$0	$0	$0	$0	$0	$0	$75.0	$125.0
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$18.8**	**$31.3**
YOY Growth	-	-	-	-	-	-	-	-	-	*66.7%*
Licensing / Development	**$52.3**	**$71.9**	**$0**	**$0.5**	**$0**	**$15.0**	**$15.0**	**$20.0**	**$0**	**$0**
YOY Growth	*87.6%*	-	-	-	-	-	-	-	-	-
Total Revenues	$68.5	$87.0	$1.3	$1.9	$1.6	$16.6	$20.9	$28.3	$30.0	$45.8
YOY Growth	*113.0%*	*26.8%*	*-70.3%*	*-93.3%*	*-97.7%*	*272.1%*	*-75.9%*	*35.2%*	*5.9%*	*52.8%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$23.8	$21.8	$5.6	$6.0	$5.2	$5.0	$21.8	$21.0	$22.0	$22.5
% SG&A	*34.7%*	*25.0%*	*438.2%*	*309.3%*	*325.0%*	*30.1%*	*104.4%*	*74.3%*	*73.5%*	*49.2%*
R&D	$22.6	$23.0	$4.1	$4.0	$5.0	$3.4	$16.5	$15.0	$15.0	$15.0
% R&D	*6+.%*	*26.5%*	*318.4%*	*206.2%*	*312.5%*	*20.5%*	*78.9%*	*53.0%*	*50.1%*	*32.8%*
Operating Income	$22.1	$42.2	($8.5)	($8.1)	($8.6)	$8.2	($17.4)	($7.7)	($7.1)	$8.3
Operating Margin	*32.3%*	*48.5%*	*-656.6%*	*-415.5%*	*-537.5%*	*49.4%*	*-83.3%*	*-27.3%*	*-23.5%*	*18.0%*
Interest Income / Net	$0.9	$0.2	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5	$0.5
Pre-Tax Income	$23.1	$42.3	($8.4)	($8.0)	($8.5)	$8.3	($17.1)	($7.2)	$6.6	$8.8
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$23.1	$42.3	($8.4)	($8.0)	($8.5)	$8.3	($17.1)	($7.2)	($6.6)	$8.8
YOY Growth	-	*83.5%*	-	-	-	-	*-140.3%*	*-57.7%*	*-9.3%*	*-233.6%*
Net Margin	*33.7%*	*48.7%*	*-651.3%*	*-410.3%*	*-531.3%*	*50.0%*	*-81.6%*	*-25.5%*	*-21.9%*	*19.1%*
Reported EPS	$0.76	$1.40	($0.28)	($0.26)	($0.28)	$0.27	($0.57)	($0.24)	($0.21)	$0.27
Fully Diluted Shares	30.2	30.3	30.0	30.1	30.2	30.3	30.1	30.5	31.0	32.0

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

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