Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: PA NDA Expected 1H-2013…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (08/27/12)	$6.62
Target Price	**$10.00**

NOTE

Visibility around the NDA for Pozen's PA "safer aspirin" product is starting to improve. What the market originally interpreted as negative news with respect to the FDA's request on inclusion of PA-81/40 now seems like a good thing – a market expanding opportunity. T

he path to approval outside the U.S. looks clear as well. Recent meetings with the U.S. FDA and European MEB seem to allow for a filing without a large-scale phase 3 study. This saves Pozen both time and money. We now expect the U.S. FDA in the first half of 2012 (our best guess is May 2013).

Our rating is 'Outperform' and our target is $10.

SUMMARY DATA

52-Week High	**$7.91**
52-Week Low	**$2.26**
One-Year Return (%)	**135.79**
Beta	**1.35**
Average Daily Volume (sh)	**123,790**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$201**
Short Interest Ratio (days)	**10.56**
Institutional Ownership (%)	**67**
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 A	1.4 E	1.6 E	6.1 E
2013					28.3 E
2014					50.0 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	-$0.17 A	-$0.21 E	-$0.27 E	-$0.94 E
2013					-$0.24 E
2014					$0.43 E

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WHAT'S NEW

PA NDA Expected 1H-2013

On August 23, 2012, Pozen provided an update on its Type-A meeting with the FDA. The key topic for discussion at the meeting was to define a path forward for both PA-325/40, Pozen's high dose "safer aspirin", and PA-81/40, the company's low dose version. We assume that talks at the meeting centered on the recently completed phase 1 study (Study 115) to assess the bioequivalence / bioavailability of PA-325/40 to enteric-coated aspirin (Ecotrin) 325 mg using acetylsalicylic acid (ASA) as the analyte.

We remind investors that in June 2012, the FDA provided Pozen with an Advice / Information Request letter indicating that the FDA has made a preliminary review of the results from Study 115 and concluded that bioequivalence of PA-325/40 to Ecotrin 325 mg, the Reference Listed Drug ("RLD") for the 505(b)(2) application, was not demonstrated. Pozen noted that data from Study 115 had substantial variability with respect to the blood levels tested in the ASA group, and that the trial was not adequately powered for such variation in the data.

At the meeting, the FDA confirmed that, although it still believes the data from Study 115 did not strictly establish bioequivalence, a bridge to Ecotrin 325 mg can be established by the submission of additional data in the new drug applications ("NDA"). Pozen plans to compile this data over the next several months and file the NDA in the first half of 2013. On the company's update conference call, held on August 24, 2012, management would not get specific on what additional data it plans to include in the NDA, only that no additional bioequivalence studies will be conducted with the PA-325/40 dose formulation. We assume the additional data will be pharmacokinetic, clinical pharmacology, and in vitro dissolution data.

We remind investors that Pozen had previously demonstrated bioequivalence of PA-325/40 to enteric-coated 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.

…Good News On PA-81/40…

During the Type-A meeting, Pozen and the FDA also came to an agreement on a path forward for the company's low dose formulation, PA-81/40. The FDA confirmed that no phase 3 trial for PA-81/40 is necessary – a big win for Pozen and a decision that saves two years and $40 million in expense. Instead, the FDA would like to see Pozen demonstrate bioequivalence / bioavailability to Ecotrin 81 mg. We expect that Pozen will conduct a similar study to the Study 115 conducted with PA-325/40, only making small changes to improve the outcome. We expect these changed to include enrolling more patients and collecting more blood samples during the study. This should result in higher statistical powering, allowing Pozen to account for the blood variability levels typically seen with ASA. We believe this trial will start sometime in September 2012 and cost around $1 million.

We believe Pozen will have this data in hand by the end of the year. We previously modeled the NDA in late 2012. The delay in filing the NDA to the first half of 2013 (our best guess is May 2012) stems from a lack of stability data required for the NDA on the PA-81/40 formulation. Pozen originally planned to file for approval of only the 325 mg dose. When the FDA asked Pozen to include both the 325 mg and 81 mg dose in the PA NDA back in April 2012, Pozen immediately began Chemistry, Manufacturing and Controls ("CMC") work on the new formulation. The FDA requires 12 months of "real time" product stability to be included in the NDA. This data is in hand for PA-325/40. Pozen still needs to generate the data for PA-81/40. We expect the CMC data on PA-81/40 will be in hand in April 2012, allowing Pozen to file the NDA in May 2012. The six-month delay, although clearly disappointing, is inconsequential from a valuation standpoint.

…European Application In 2013…

Pozen is also in the process of preparing to file for PA in Europe. Pozen recently gained clarity from the Medicines Evaluation Board ("MEB") in the Netherlands regarding what is required for the approval of PA-325/40 and a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA-100/40). Similar to the FDA, MED confirmed that no phase 3 trial was necessary. We expect that the bioequivalence / bioavailability data necessary for the EU approval of PA-325/40 and PA-100/40 can mirror the work being done for the U.S. NDA application. We expect the MAA filing during the second half of 2013.

The path to approval for PA closely models that of Vimovo. For Vimovo (formerly PN-500/20), Pozen ran two parallel phase 3 trials under and SPA in similar design (actually smaller at around 800 patients total) to the PA-325/40 trials. Pozen submitted additional bioequivalence, clinical pharmacology, and CMC data on PN-375/20 with the PN-500/20 NDA filing. The FDA approved both PN-500/20 and PN-375/20 after the first NDA filing. In our view, this gives clear precedent for both agencies to approve PA-325/40 and PA-81/40 (or PA-100/40) in one application.

On a side note, MEB has agreed to be the Reference Member State (RMS) in a decentralized filing procedure of PA-325/40 and PA-100/40. We think this is good news. The Netherlands was the RMS for the European Vimovo application. To date, Vimovo has been approved in 58 countries around the world.

…A Simple Concept…

PA is such a simple product concept. Over 50 million American's use daily aspirin therapy, with 50% of those patients at risk of developing major complications due to gastric bleeding. Roughly 25% of the people that start a daily aspirin therapy will discontinue or reduce frequency or dose due to serious gastrointestinal side-effects. Roughly 65% of the market is taking 81 mg "baby" aspirin, and we estimate that half of these patients are being under-dosed because of the potential GI toxicity.

We believe that PA-325/40, at $1/day, is about a $250 million product in the U.S., and that's with only 5% penetration. We think that PA-81/40, also at $1/day, essentially doubles the market opportunity to the company. Gaining approval of a low dose PA opens the door to allow millions access to the drug. We think our sales forecasts are easily achievable. We think a similar opportunity exists in Europe. Aspirin is used pretty commonly all around the world. We peg the E.U. opportunity at around $150 million, bringing peak global sales of PA to around $400 million. Again, we believe these forecasts are conservative.

…Partnership Could Drive Shares Higher…

We still believe that Pozen will be able to secure a U.S. commercialization partner for PA in the near future. Management has previously stated they would like to have a deal signed by the end of the year. However, that was when the NDA was also planned at the end of the year. Pozen would not give specifics on a timeline for a deal, but we are not expecting a deal until the first half of 2013.

That being said, we believe an upfront payment on PA could be in the area of $15 to $20 million, along with over $150 million in back-end milestones and royalties on sales. A deal that includes countries outside the U.S. presents upside (perhaps a doubling) to these figures. We remind investors that in October 2011, Pozen retained Keelin Reeds LLC to assist in the strategic partner search for PA. Keelin Reeds is a global expert in helping life science companies value assets, develop business development strategies and execute partnership transactions.

As a point of reference, the Vimovo transaction with AstraZeneca provided $40 million upfront, $45 million in approval milestones, and $290 million in sales milestones plus roughly 10% royalties on sales. Pulling in a deal of this magnitude has the potential to double the stock.

Vimovo Sales On Track

Vimovo sales of $16.6 million were shy of our forecast at $17.5 million. To date, Vimovo has been approved in 58 countries and launched in 30. AstraZeneca received eight country approvals on Vimovo and launched in two of those in the last three months alone. Our sales number may have been a tad too high, as we expected launches to be north of 35 by the end of the second quarter. Sales in the U.S. have been disrupted by sales force streamlining at AstraZeneca. Despite the longer-than-expected lag between approvals and launches and some disruption in the U.S., we believe Vimovo remains on track for peak sales in $200 million range worldwide. Applications have been filed in a total of 78 countries to date. For 2012, we see Vimovo sales totaling $70 million, which should provide a net royalty to Pozen of nearly $6 million.

MT-400 Offers Upside Potential

May 2012, Pozen announced that it has entered into a license agreement with Desitin Arzneimittel GmbH, for the development and commercialization of MT-400 for the 27 countries of the European Union, as well as Switzerland and Norway. MT-400 is Pozen's internal code name for Treximet (85 mg sumatriptan / 500 mg naproxen), sold in the U.S by GlaxoSmithKline. We remind investors that in November 2011, Pozen entered into an agreement with CPPIB Credit Investments (CIT) whereby the company sold the U.S. royalty rights to Treximet for $75 million.

Desitin made an initial upfront payment to Pozen of $0.5 million (booked in the second quarter 2012). Pozen is eligible for milestone payments related to the development and launch of MT-400 in certain specified countries totaling $2.5 million. Following approval, Desitin will pay Pozen a double digit royalty on net sales of MT-400 that increases based on annual sales volume.

This was not the first Ex-U.S. deal Pozen struck on MT-400. In March 2011, Pozen announced that had entered into a licensing agreement with Cilag GmbH International, a division of J&J, for the development and commercialization of MT-400 in Brazil, Colombia, Ecuador, and Peru. Under terms of the deal, J&J made an initial upfront payment to Pozen (undisclosed). Cilag will pay a milestone to Pozen upon the approval of MT-400 by the National Health Surveillance Agency of Brazil (NHSAB). During the first 10 years of sales, Cilag will pay Pozen a high single digit royalty on net sales of MT-400, followed by a low single digit royalty during the next 5 years. We are expecting that J&J will be in position to file with NHSAB in 2012.

Valuation

We are maintaining our 'Outperform' rating and $10 per share target on the stock. We are comfortable with the filing strategy on PA-325/40 and PA-81/40 in the U.S. We suspect that the application will include all the necessary data to gain approval during the first half of 2014. Additionally, we are pleased with the company's progress with PA outside the U.S. Guidance from the MED in the Netherlands suggest that no phase 3 trial is necessary for approval in Europe. We have conducted a discounted cash flow (DCF) analysis on Pozen and arrived at a fair value of $10 per share.

PROJECTED INCOME STATEMENT

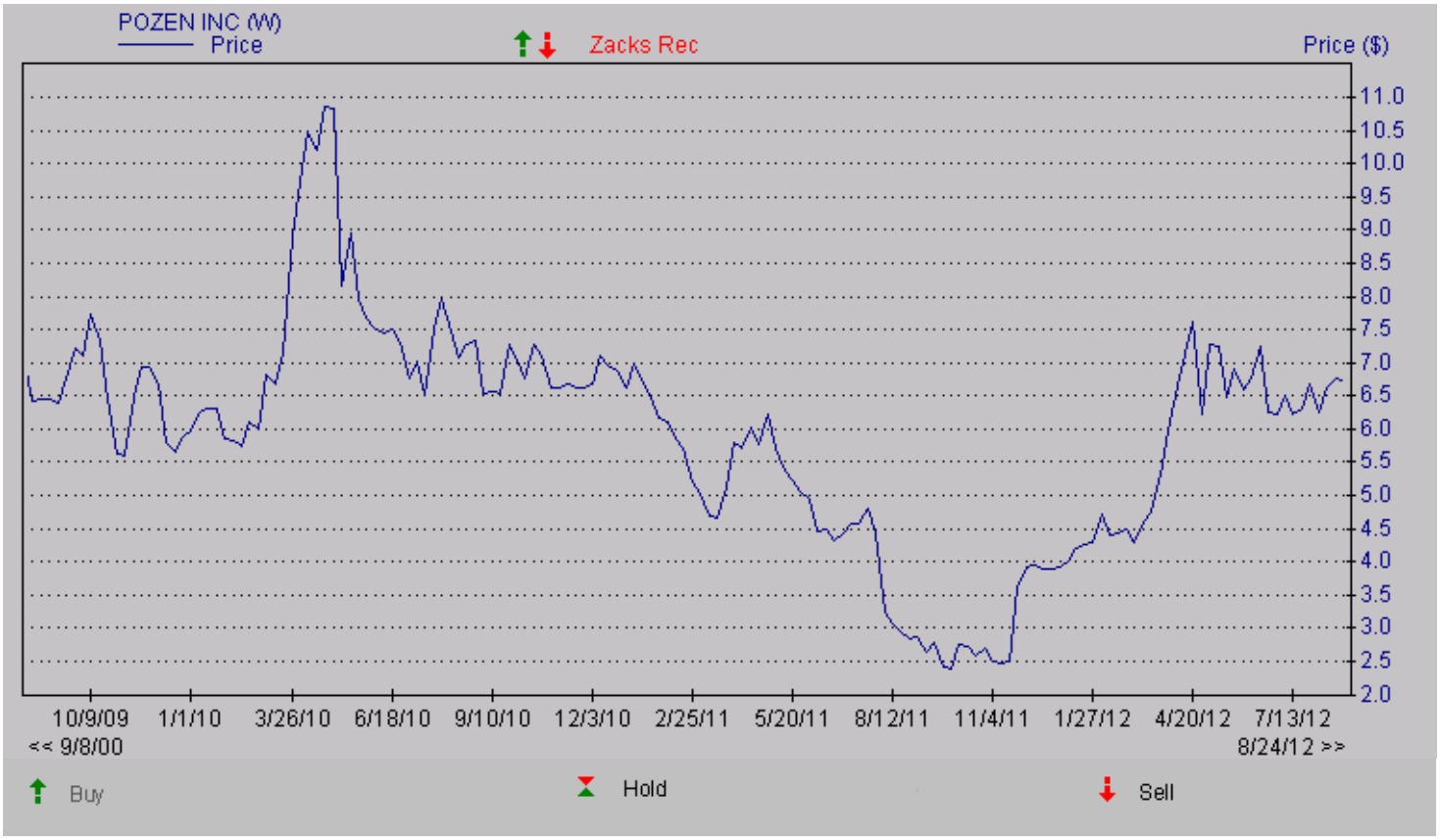
Income statement:

	2010 A	2011 A	Q1 A	Q2 A	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**	**$1.3**	**$1.4**	**$1.6**	**$5.6**	**$8.3**	**$11.2**	**$14.5**
YOY Growth	-	*533.0%*	-	-	-	-	*94.0%*	*46.6%*	*35.3%*	*29.5%*
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**	**$0**	**$0.5**	**$20.0**	**$20.0**	**$0**
YOY Growth	*87.6%*	-	-	-	-	-	-	-	-	-
Total Revenues	$68.5	$87.0	$1.3	$1.8	$1.4	$1.6	$6.1	$28.3	$50.0	$45.8
YOY Growth	*113.0%*	*26.8%*	*-70.3%*	*-93.9%*	*-97.9%*	*-64.1%*	*-92.9%*	*360.0%*	*76.6%*	*-8.4%*
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	$4.1	$4.8	$5.0	$19.5	$21.0	$22.0	$22.5
% SG&A	*34.7%*	*25.0%*	*438.2%*	*230.2%*	*333.3%*	*312.5%*	*317.5%*	*74.3%*	*44.0%*	*49.2%*
R&D	$22.6	$23.0	$4.1	$2.9	$3.2	$5.0	$15.2	$15.0	$15.0	$15.0
% R&D	*6+.%*	*26.5%*	*318.4%*	*162.6%*	*222.2%*	*312.5%*	*246.9%*	*53.0%*	*30.0%*	*32.8%*
Operating Income	$22.1	$42.2	($8.5)	($5.2)	($6.6)	($8.4)	($28.5)	($7.7)	$13.0	$8.3
Operating Margin	*32.3%*	*48.5%*	*-656.6%*	*-292.8%*	*-455.6%*	*-525.0%*	*-464.4%*	*-27.3%*	*25.9%*	*18.0%*
Interest Income / Net	$0.9	$0.2	$0.1	$0.1	$0.1	$0.1	$0.3	$0.5	$0.5	$0.5
Pre-Tax Income	$23.1	$42.3	($8.4)	($5.1)	($6.5)	($8.3)	($28.2)	($7.2)	$13.5	$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)	($5.1)	($6.5)	($8.3)	($28.2)	($7.2)	$13.5	$8.8
YOY Growth	-	*83.5%*	-	-	-	-	*-166.6%*	*-74.4%*	*-286.3%*	*-34.9%*
Net Margin	*33.7%*	*48.7%*	*-651.3%*	*-288.7%*	*-448.6%*	*-518.8%*	*-458.8%*	*-25.5%*	*26.9%*	*19.1%*
Reported EPS	$0.76	$1.40	($0.28)	($0.17)	($0.21)	($0.27)	($0.94)	($0.24)	$0.43	$0.27
Fully Diluted Shares	30.2	30.3	30.0	30.0	30.1	30.2	30.1	30.5	31.0	32.0

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

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