Zacks Small-Cap Research

November 8, 2012
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POZEN, Inc. (POZN-NASDAQ)

POZN: Data At ACG & AHH Highlights Potential For Pozen's Drug…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (10/23/12)	$5.38
Target Price	**$9.00**

NOTE

On October 22, 2012, Pozen presented a full analysis of the integrated results of the two phase 3 studies comparing PA-325/40 (EC-ASA 325 mg + IR omeprazole 40 mg) to enteric-coated aspirin (EC-ASA) 325 mg in patients requiring aspirin (ASA) for secondary cardiovascular prophylaxis who were at risk for ASA-associated gastric ulceration at the American College of Gastroenterology meeting. Pozen follow-up with additional data at the American Heart Association (AHA) meeting in early November 2012. Below we highlight the data and how we believe it could drive meaningful uptake for Pozen's drug once approved.

Our rating is 'Outperform' and our target is $9.

SUMMARY DATA

52-Week High	$7.91
52-Week Low	**$2.35**
One-Year Return (%)	**122.63**
Beta	**1.39**
Average Daily Volume (sh)	**76,627**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$163**
Short Interest Ratio (days)	**13.37**
Institutional Ownership (%)	**61**
Insider Ownership (%)	**11**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**4.1**
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	0.9 A	1.2 E	5.4 E
2013					25.9 E
2014					40.0 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	-$0.19 A	-$0.21 E	-$0.84 E
2013					-$0.20 E
2014					$0.17 E

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WHAT'S NEW

Recent Financials

On November 8, 2012, Pozen reported financial results for the third quarter 2012. Pozen reported revenues in the quarter of $0.940 million, driven entirely by royalties on $13.4 million in worldwide sales of Vimovo at AstraZeneca.

Pozen reported a net loss in the third quarter 2012 of $5.7 million, or $0.19 per share. This was slightly better than our model which estimated the net loss at $0.21 per share. Both SG&A and R&D were lower than expected. In fact, R&D was the lowest we've seen (at $2.3 million) in nearly a decade. We expect that Pozen will be conducting a phase 1 bioequivalence, pk / pd study on PA-100/40 for the European application later this year. Pozen is also wrapping up U.S. bioequivalence to ASA data prior to filing the U.S. NDA expected in early 2013.

Pozen exited the third quarter ended September 30, 2012 with $92.3 million in cash and investments. We expect that Pozen will exit 2012 with an estimated $87 million in cash and investment. This includes no upfront payment from a commercialization partnership on PA, which we have pushed into 2013 given the delay in NDA filing. In 2013, we think PA could command an upfront payment of $15 to $20 million for the U.S.

…Vimovo Baffles…

Vimovo sales of $13.4 million were far shy of our forecast at $17.5 million. Sales declined 19% sequentially from the $16.6 million reported in the second quarter 2012. U.S. sales of Vimovo were only $4 million. The product is a commercial flop in the U.S., and sales outside the U.S. have yet to accelerate as Pozen management has been guideline to all year. This is despite the fact that AstraZeneca has undertaken regulatory filings in 80 countries. Vimovo has been approved in 60 countries and launched in 40. AstraZeneca received two country approvals on Vimovo and launched in ten new territories in just the last three months alone. However, despite 40 country approvals, ten alone in the third quarter 2012, sales of the drug were flat outside the U.S. The weak sales of Vimovo, no doubt, are hurting the market perception for PA.

We see some key differences between Vimovo and PA that give us confidence PA will succeed where Vimovo has not. Namely, these include a much larger patient populations (50 million American's take daily ASA versus only a few million on naproxen) and a lower projected market price. We believe launching PA at roughly $1 per day will be key to its uptake. AstraZeneca is trying to sell Vimovo at a $4 per pill.

…Treximet Patents Upheld…

On October 1, 2012, the United States Court of Appeals for the Federal Circuit has affirmed the August 5, 2011 decision of the United States District Court for the Eastern District of Texas that had issued a favorable verdict in the litigation between Pozen and several generic pharmaceutical companies which had filed abbreviated new drug applications (ANDAs) seeking approval from the FDA to market generic copies of Treximet (sumatriptan / naproxen). Treximet is marketed by GlaxoSmithKline in the U.S. We remind investors that Pozen sold substantially all the royalties on Treximet to Canada's CPPIB Credit Investments in November 2011 for $75 million in cash.

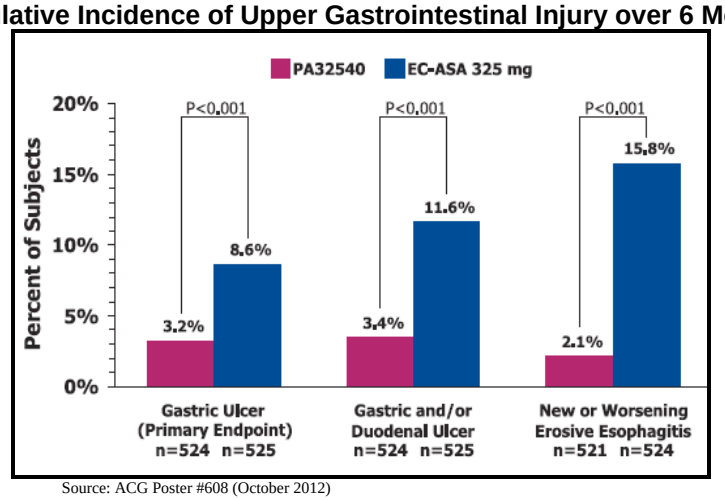
Phase 3 Data Impresses At ACG & AHA

Full data analysis from the integrated results of the two phase 3 trials with PA-325/40 has now been presented. Management broke up the impressive data between the American College of Gastroenterology (ACG) meeting in late October 2012 and the American Heart Association (AHA) meeting in early November 2012.

As a reminder, the two phase 3 studies compared PA-325/40 (EC-ASA 325 mg + IR omeprazole 40 mg) to enteric-coated aspirin (EC-ASA) 325 mg in patients requiring aspirin (ASA) for secondary cardiovascular prophylaxis who were at risk for ASA-associated gastric ulceration. In the two phase 3 trials, subjects were randomized to either PA-325/40 or EC-ASA 325 mg, taken once daily in the morning on an empty stomach, approximately 1 hour before breakfast. At baseline, subjects were required to be *H. pylori* stool-antigen negative and have no endoscopic ulcers. Subsequent endoscopies were performed at months 1, 3, and 6. Both trials were run under a special protocol assessment (SPA) with the U.S. Food and Drug Administration (FDA).

The primary endpoint of the study was cumulative proportion of subjects with endoscopically-confirmed gastric ulceration (defined as a mucosal break of at least 3 mm in diameter with depth) at any time throughout 6 months. Results below show an impressive separation for PA-325/40 vs. EC-ASA:

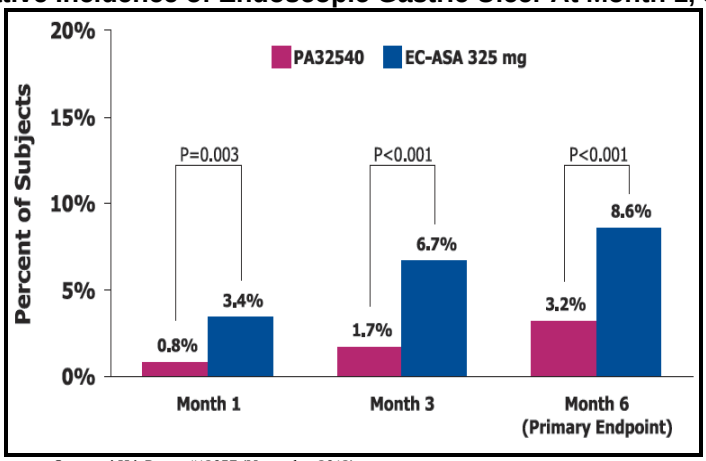
Cumulative Incidence of Upper Gastrointestinal Injury over 6 Months



Source: ACG Poster #608 (October 2012)

Results were even statistically significant as soon as one month after the start of the trial, and held (actually separated from EC-ASA 325 mg) as the trial progressed.

Cumulative Incidence of Endoscopic Gastric Ulcer At Month 1, 3, and 6



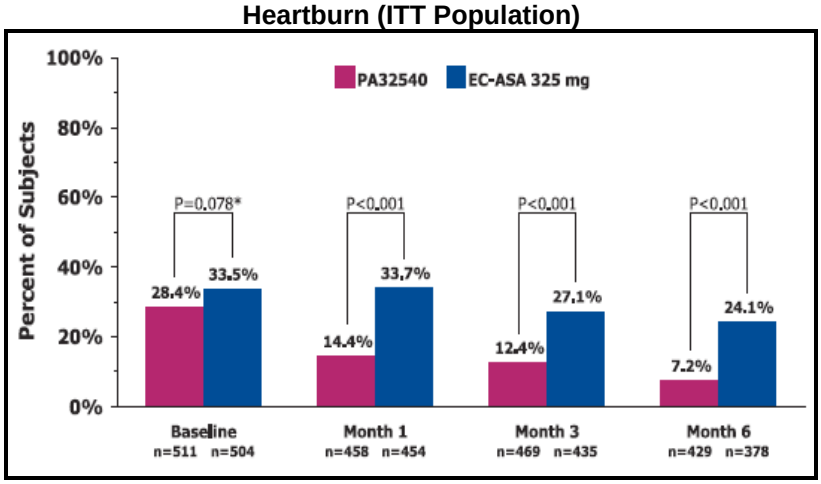
Source: AHA Poster #12057 (November 2012)

The data equate to an impressive 63% reduction in gastric ulcer. The results were remarkably consistent between the two studies, with PA-325/40 yielding 3.8% in Study-1 and 2.7% in Study-2 vs. 8.5% and 8.7%, respectively for EC-ASA 325 mg. Both trials were statistically significant on a stand-alone basis.

These results are consistent with our expectations and show the powerful efficacy of Pozen's drug. When duodenal ulcers were included in the analysis, the reduction increased to 71%. Data on new or worsening erosive esophagitis showed an astonishing 87% reduction in favor of Pozen's PA-325/40 verse EC-ASA 325 mg.

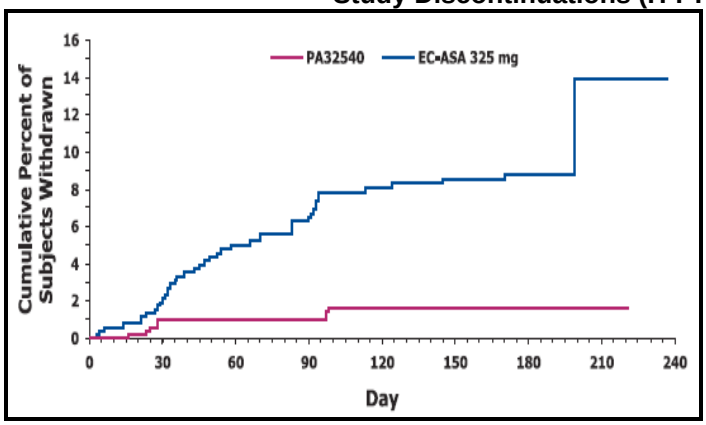
Secondary analysis also show statistically significant reductions in the presence of heartburn as reported on a standardized questionnaire at month 1, 3, and 6. A post-hoc esophageal mucosal assessment showed a meaningful and statistically significant reduction in new esophageal erythema (2.7% vs. 7.6%, p<0.001) and new esophageal erythema or new or worsening erosive esophagitis (4.8% vs. 22.5%, p<0.001).

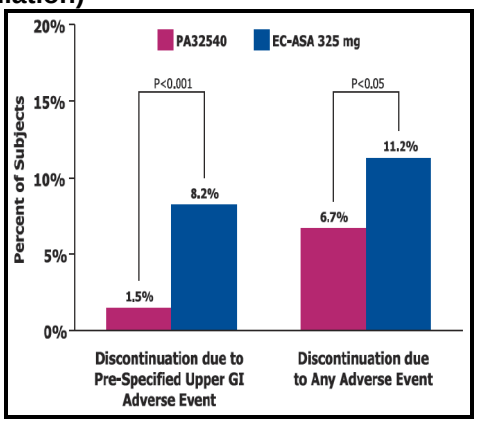
Heartburn (ITT Population)



Discontinuation rates and treatment success at six months also showed strong statistical significance in favor of Pozen's PA-325/40 versus EC-ASA 325 mg. At six months, the observed incidence of discontinuations due to pre-specified upper-gastrointestinal events was significantly lower with PA-325/40 vs. EC-ASA 325 mg, 1.5% vs. 8.2%, p<0.001. Study discontinuations due to any adverse event showed a 40% reduction in favor of Pozen's drug, 6.7% vs. 11.2% (p<0.05).

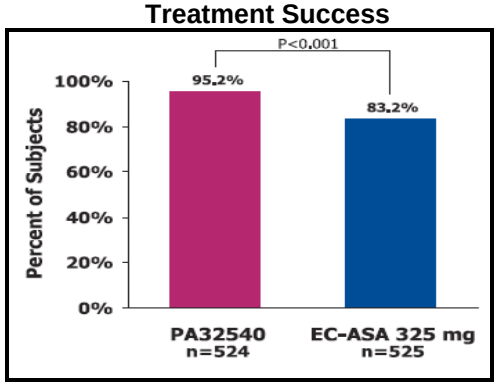
Study Discontinuations (ITT Population)





Treatment success at six months was 95.2% for PA-325/40 vs. 83.2% for EC-ASA 325 mg, a 14% improvement in outcome based on intent to treat (p<0.001). However, if we flip that analysis and instead look at treatment failures, the ratios get even more impressive. A 95.2% success rate means a 4.8% failure rate, and an 83.2% success rate means at 16.8% failure rate. Compare 4.8% to 16.8% failure and investors will see that Pozen's drug yields a 71% reduction in treatment failure, with statistical significance. We see that as highly impressive clinical data; and data that should grab the attention of cardiologists as they are looking to effectively treat patients for the secondary prevention of cardiovascular events.

Treatment Success



Treatment-emergent adverse events, included GERD, esophagitis, erosive esophagitis, or reflex esophagitis was 6.1% for PA-325/40 versus 23.9% for EC-ASA 325 mg (p<0.001).

Treatment-Emergent Adverse Events

Parameter	PA32540 (n=521)	EC-ASA 325 mg (n=524)
	Number of Subjects (%)	
Gastritis	91 (17.5)	84 (16.0)
Gastritis erosive	60 (11.5)	138 (26.3)
Dyspepsia	59 (11.3)	158 (30.2)
Hiatus hernia	46 (8.8)	56 (10.7)
Duodenitis	29 (5.6)	70 (13.4)
Nausea	17 (3.3)	12 (2.3)
Esophagitis	17 (3.3)	63 (12.0)
Erosive duodenitis	7 (1.3)	37 (7.1)
GERD	7 (1.3)	20 (3.8)
Reflux esophagitis	6 (1.2)	17 (3.2)
Erosive esophagitis	2 (0.4)	33 (6.3)
Duodenal ulcer	1 (0.2)	19 (3.6)

However, potentially the most impressive data from the two posters was the reductions in MACE. Specifically, patients on Pozen's PA-325/40 had a MACE rate of 1.7% vs. 2.5% for EC-ASA 325 mg.

Incidence of Major Adverse Cardiovascular Events

Major Adverse Cardiovascular Event (MACE)	PA32540 (N=521)	EC-ASA 325 mg (N=524)
	Number of Subjects (%)	
Cardiovascular death	0 (0%)	1 (0.19%)
Nonfatal myocardial infarction	5 (0.96%)	3 (0.57%)
Confirmed ischemic stroke	0 (0%)	0 (0%)
Acute coronary syndrome[2]	0 (0%)	4 (0.76%)
Transient ischemic attack	1 (0.19%)	4 (0.76%)
Congestive heart failure	1 (0.19%)	1 (0.19%)
Other, mild CAD	1 (0.19%)	0 (0%)
Other, planned CABG	1 (0.19%)	0 (0%)
Subjects with any MACE	9 (1.7%)	13 (2.5%)
	Total = 22 (2.1%)	

NDA Expected 1H-2013

We believe Pozen remains on track to file the new drug application (NDA) on PA during the first half of 2013. We remind investors that back in August 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 and PA-81/40. Talks at that meeting centered on the recently completed phase 1 study (Study 115) to assess the bioequivalence and bioavailability of PA-325/40 to enteric-coated aspirin 325 mg using acetylsalicylic acid (ASA) as the analyte.

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 NDA. Pozen plans to compile this data over the next several months and file the NDA in the first half of 2013. Management has not gotten 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 is current underway 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 March 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 CMC work on the new formulation. The FDA requires 12 months of "real time" product stability to be included in the NDA. Pozen believes it has an agreement in place with the FDA to file for approval with 6 months of stability and then supplement the application with the 12 month data after the filing. We note this data is already 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.

…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 60 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 believe that Pozen will be able to secure a U.S. commercialization partner for PA in after the NDA filing. 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. 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.

Valuation

We are maintaining our 'Outperform' rating but adjusting our target down to $9 per share target on the stock. This is based on the delay in the PA NDA filing and the poor sales of Vimovo. 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 $9 per share.

PROJECTED INCOME STATEMENT

Income statement:

	2010 A	2011 A	Q1 A	Q2 A	Q3 A	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 (sales)	$4.6	$33.8	$16.0	$16.6	$13.4	$15.0	$61.0	$65.0	$75.0	$85.0
Vimovo (royalty)	**$0.5**	**$2.9**	**$1.3**	**$1.3**	**$0.9**	**$1.2**	**$4.9**	**$5.9**	**$7.5**	**$8.5**
YOY Growth	-	*533.0%*	-	-	-	-	*67.6%*	*19.9%*	*28.2%*	*13.3%*
PA Franchise (sales)	$0	$0	$0	$0	$0	$0	$0	$0	$50.0	$100.0
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$12.5**	**$25.0**
YOY Growth	-	-	-	-	-	-	-	-	-	*100.0%*
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	$0.9	$1.2	$5.4	$25.9	$40.0	$33.5
YOY Growth	*113.0%*	*26.8%*	*-70.3%*	*-93.9%*	*-98.6%*	*-73.1%*	*-93.8%*	*380.5%*	*54.7%*	*-16.3%*
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	$4.4	$4.5	$18.7	$20.0	$21.0	$22.0
% SG&A	*34.7%*	*25.0%*	*438.2%*	*230.2%*	*472.8%*	*375.0%*	*346.9%*	*77.4%*	*52.5%*	*65.7%*
R&D	$22.6	$23.0	$4.1	$2.9	$2.3	$3.0	$12.2	$12.5	$14.0	$15.0
% R&D	*6+.%*	*26.5%*	*318.4%*	*162.6%*	*240.0%*	*250.0%*	*227.4%*	*48.4%*	*35.0%*	*44.8%*
Operating Income	$22.1	$42.2	($8.5)	($5.2)	($5.8)	($6.3)	($25.5)	($6.7)	$5.0	($3.5)
Operating Margin	*32.3%*	*48.5%*	*-656.6%*	*-292.8%*	*-612.8%*	*-525.0%*	*-474.3%*	*-25.7%*	*12.5%*	*-10.4%*
Interest Income / Net	$0.9	$0.2	$0.1	$0.1	$0.1	$0.1	$0.3	$0.4	$0.4	$0.4
Pre-Tax Income	$23.1	$42.3	($8.4)	($5.1)	($5.7)	($6.2)	($25.3)	($6.3)	$5.4	$3.1
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)	($5.7)	($6.2)	($25.3)	($6.3)	$5.4	($3.1)
YOY Growth	-	*83.5%*	-	-	-	-	*-159.6%*	*-75.2%*	*-186.4%*	*-157.4%*
Net Margin	*33.7%*	*48.7%*	*-651.3%*	*-288.7%*	*-605.9%*	*-520.0%*	*-469.4%*	*-24.2%*	*13.5%*	*-9.3%*
Reported EPS	$0.76	$1.40	($0.28)	($0.17)	($0.19)	($0.21)	($0.84)	($0.20)	$0.17	($0.10)
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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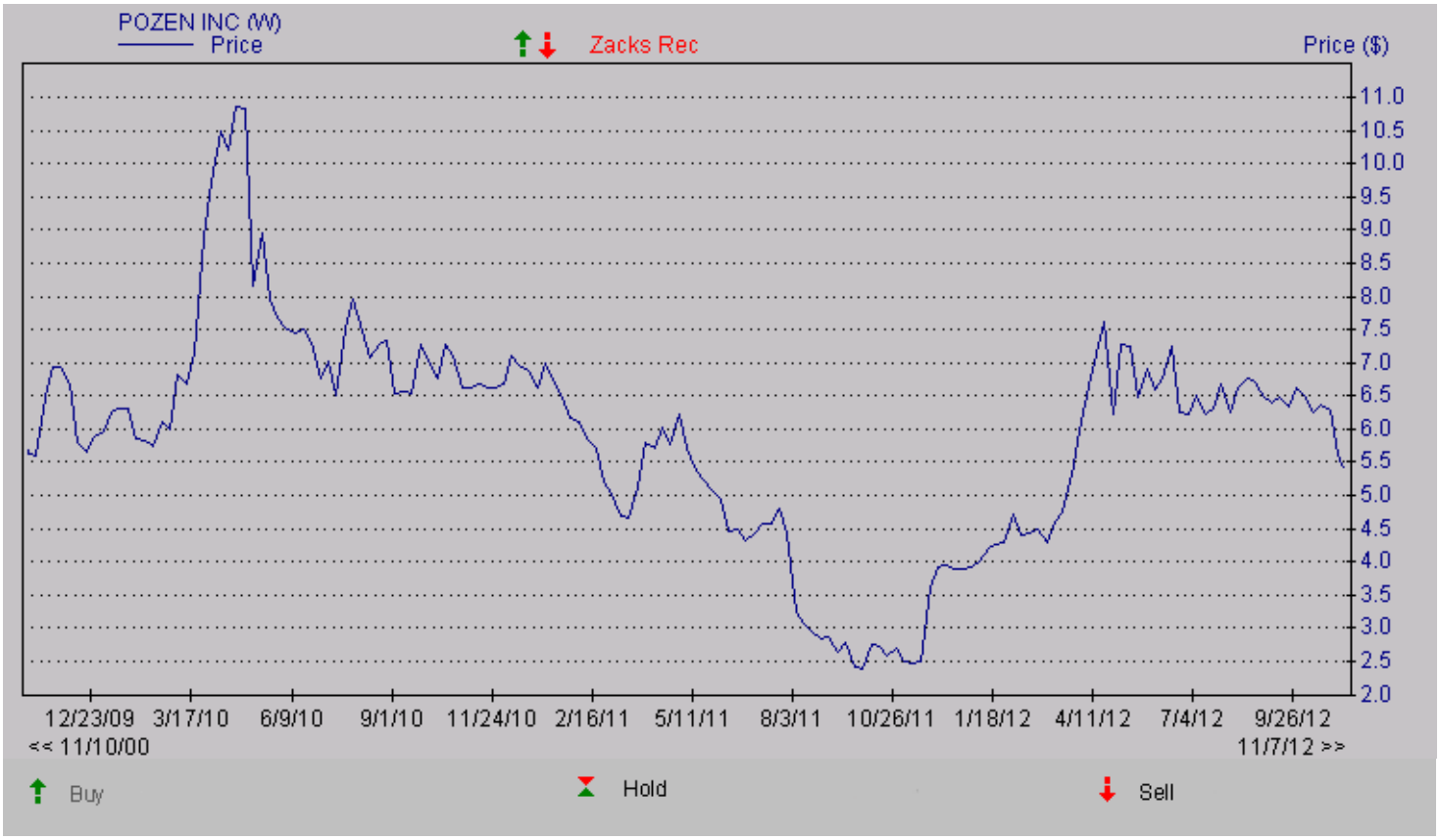
HISTORICAL ZACKS RECOMMENDATIONS



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