Zacks Small-Cap Research

July 28, 2011
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POZEN, Inc. (POZN-NASDAQ)

POZN: Vimovo Launch Continues To Disappoint, Will PA Be Any Different?

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (07/28/11)	$4.53
Target Price	**$6.50**

UPDATE

We view the company as financially sound, with $53 million in cash to be on hand at the end of the second quarter. The royalty line should begin to accelerate over the next few quarter as sales of both Treximet and Vimovo ramp at Glaxo and AstraZeneca, respectively. We are expecting news on the Treximet patent infringement case in the next few months. This could be a major catalyst to drive Pozen shares higher.

Based on our sum-of-parts analysis, we see Pozen fairly valued at $6.50 per share.

SUMMARY DATA

52-Week High	**$8.10**
52-Week Low	**$4.20**
One-Year Return (%)	**-43.45**
Beta	**1.44**
Average Daily Volume (sh)	**173,591**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$135**
Short Interest Ratio (days)	**10.76**
Institutional Ownership (%)	**52**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**15.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**2**

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)
2010	6.9 A	28.2 A	4.3 A	29.0 A	68.5 A
2011	4.5 A	4.6 A	5.0 E	5.7 E	19.9 E
2012					22.1 E
2013					33.6 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.10 A	$0.53 A	-$0.29 A	$0.61 A	$0.76 A
2011	-$0.19 A	-$0.21 A	-$0.20 E	-$0.20 E	-$0.80 E
2012					-$0.98 E
2013					-$0.52 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Second Quarter Financials

On July 28, 2011, Pozen reported financial results for the second quarter 2011. Pozen reported total revenues in the second quarter of $4.6 million. Revenues consisted of $4.0 million in royalties on $23.0 million in sales of Treximet at GlaxoSmithKline and $0.6 million in royalties from $6.3 million in sales of Vimovo at AstraZeneca. Treximet was dead-on with our expectations, whereas Vimovo continues to disappoint. Pozen did not record any collaboration payments from development partners during the second quarter 2011. Net loss for the quarter totaled $6.4 million, or $0.21 per diluted share. Pozen exited the second quarter ended June 30, 2011 with $52.6 million in cash and investments. We find this to be sufficient to fund operations for the foreseeable future.

R&D Update

Pozen expects that enrollment in the ongoing PA-325/40 phase 3 pivotal studies will complete here in the third quarter 2011. As a reminder, the primary endpoint of the trials is, "Cumulative incidence of gastric ulcers following administration of either PA32540 or 325 mg enteric-coated aspirin in subjects at risk for developing aspirin-associated ulcers." Based on previous data from phase 2, and data from the Vimovo pivotal programs, we think hitting statistical significance is a slam dunk. We expect the trials to complete in the first quarter 2012, and then offer data shortly thereafter. We expect the U.S. NDA filing to take place in the third quarter 2012.

The 12-month safety study with PA-325/40 to evaluate the long-term safety of the drug in patients who are at risk for developing aspirin-associated gastric ulcers has been completed. Pozen is reviewing the data and we expect a presentation shortly. This will give excellent insight into the outcome of the phase 3 programs discussed above.

INVESTMENT UPDATE

J&J Licenses MT-400 for South America

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 (sumatriptan/naproxen, sold in the U.S. as Treximet) 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. The deal expires after 15 years. We are expecting that J&J will be in position to file with NHSAB in 2012.

Co-Rx Study Show Potential For PA-325/40

In March 2011, Pozen announced positive top-line results from a phase 1 study of PA-325/40 used in conjunction with clopidogrel (sold as branded Plavix). The data from the Co-Rx Study suggest that PA-325/40 given in conjunction with clopidogrel, dosed at least 10 hours apart, resulted in an approximate 20% improvement inhibition of ADP-induced platelet aggregation (anti-clotting) when compared to a current standard of care (81 mg of EC aspirin, EC omeprazole 40 mg and clopidogrel). This suggests that the dosing combination of Plavix and PA-325/40 could offer a promising new option for the secondary prevention of heart attacks and strokes in cardiovascular patients who require aspirin therapy, but are at risk for gastric ulcers. We expect to see additional data from this study at an upcoming scientific meeting later in the year.

As a reminder, The Co-Rx study was a phase 1, randomized, open-label, two-arm crossover study in which 30 healthy subjects were treated with one of the following:

A) PA-325/40 in the morning plus 300mg clopidogrel over 10 hours later on day 1, and PA-325/40 in the morning plus 75mg clopidogrel 10 hours later on days 2-7,
B) 81mg enteric-coated aspirin plus 300mg clopidogrel plus 40mg enteric-coated omeprazole (Prilosec) all in the morning on day 1 followed by 81mg enteric-coated aspirin plus 75mg clopidogrel plus 40mg enteric-coated omeprazole all in the morning on days 2-7

Subjects were first randomized to treatment A or treatment B and then crossed over to the alternate treatment. Each treatment was separated by a 14 day washout period. The primary objective of the study was to assess the effects of PA-325/40 and enteric-coated omeprazole on clopidogrel activity as measured by *ex-vivo* platelet aggregation using 20 uM adenosine diphosphate (ADP), a commonly used platelet assay of clopidogrel effect. The primary endpoint was the percent inhibition of platelet aggregation (IPA) after morning dosing on day seven of each period. In the study, PA-325/40 in the morning, plus clopidogrel 10 hours later, resulted in a significantly greater IPA than 81 mg enteric-coated aspirin plus 40mg enteric-coated omeprazole plus clopidogrel all dosed in the morning.

INVESTMENT THESIS

Stock Remains Under-Valued

We continue to believe that Pozen is under-valued at $4.55 per share. We base this belief on a sum-of-parts analysis looking at the cash flows expected to be generated from the royalties on Treximet (from Glaxo) and Vimovo (from AstraZeneca), and the future earnings potential of PA-325/40.

Pozen is trading with a market capitalization of only $135 million. We also note that Pozen held nearly $53 million in cash at the end of the second quarter 2011. We believe royalties from Treximet alone are worth another $80 million in value. Vimovo has clearly been a big disappointment, but we note that AstraZeneca recently launched the product in five new countries in Europe in the second quarter 2011, and we believe sales will improve in the coming quarters. We have dramatically reduced our expectations for Vimovo, but we still believe the drug is worth $45 million in value to Pozen shareholders.

Treximet	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sales	$46.2	$86.1	$87.3	$92.0	$96.0	$98.0	$100.0	$100.0	$100.0	$100.0	$100.0
Royalties	$2.3	$4.3	$15.7	$16.6	$17.3	$17.6	$18.0	$18.0	$18.0	$18.0	$18.0
Discount	15%										
NPV	$78.7	Million									

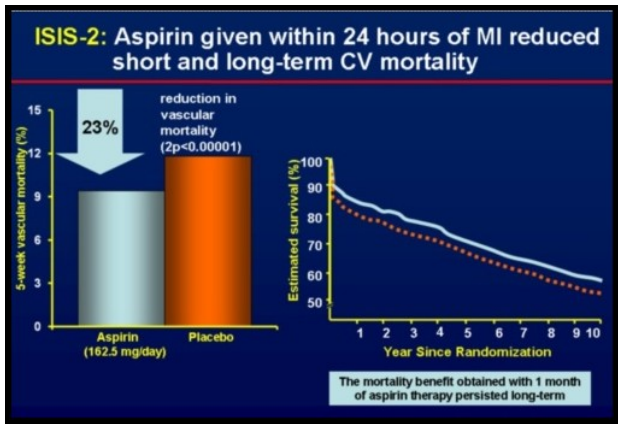
Vimovo	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sales	-	-	$4.6	$33.7	$53.6	$78.2	$101.8	$129.7	$152.0	$176.3	$196.1
Royalties	-	-	$0.5	$3.4	$5.4	$7.8	$10.2	$13.0	$15.2	$17.6	$19.6
Discount	15%										
NPV	$44.0	Million									

Summing in the values for the Treximet and Vimovo royalties streams, which we note are cash payments with little ongoing expenses, we arrive at a market value of $123 million. This is only $12 million below the current market value. If we add in the $53 million in cash, we arrive at a value of $176 million. We believe at the current stock price, investors are getting PA-325/40 for free. That begs the question:

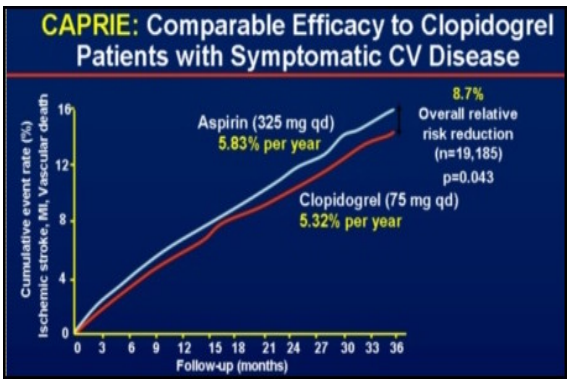
What's PA Worth??

Pozen is currently in 2 phase 3 trials for PA-325/40, a "safer aspirin" product that combines 325mg of enteric coated aspirin with the PPI 40mg omeprazole (sold as branded Prilosec). It's a novel formulation and a simple idea that builds off the already approved pathway defined by Vimovo. We expect that once approved Pozen's "safer aspirin" will find its way into daily aspirin therapy for cardiovascular disease. The potential label will be for secondary prevention of cardiovascular or cerebrovascular events in patients at risk for gastric or esophageal ulcers. This is an enormous market. Cardiovascular disease is the leading cause of death in the U.S., with over 50% mortality. An American has a heart attack roughly every 26 seconds!

Aspirin has been used to prevent recurrent myocardial infarction (MI) since the 1940's when the drugs anti-platelet activation properties where first discovered. In 1988, the U.S. FDA approved the use of aspirin for the prevention of recurrent MI. Since that time, data reported in *The Lancet* from the ISIS-2 (2nd International Study of Infract Survival of MI) demonstrates that daily use of 162.5mg aspirin reduces the potential for vascular mortality by 23% (p<0.00001) vs. placebo in the first five weeks following a myocardial infarction. Long-term follow-up data suggest the benefit of daily aspirin use persists in the prevention of recurrent MI as long as 10 years post event.



Over 50 million American's use daily aspirin therapy. Unfortunately, of the 50+ million Americans that take daily aspirin therapy, as many as 50% are at risk for 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. Market research shows a significant opportunity for Pozen's product. Data published from the CAPRIE (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events) study in 1996 shows that Plavix (clopidogrel) offers only a modest 8.7% efficacy improvement over aspirin, and Plavix posted sales over $7 billion worldwide at its peak. It is clear that Aspirin use is limited by gastrointestinal intolerance and bleeding.



Cumulative Event Rate
(Ischemic Stroke, MI, CV-Death)

Plavix = 5.32%
Aspirin = 5.83%

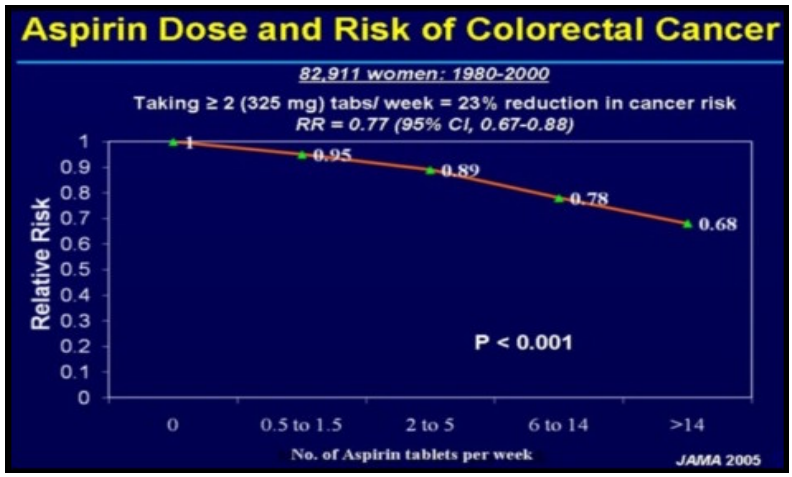
+8.7% Overall risk reduction for Plavix

Severe Adverse Events…	**Plavix**	**Aspirin**
…Overall Hemorrhage	9.27%	9.28%
…Intracranial Hemorrhage	0.31%	0.42%
…GI Hemorrhage	1.99%	2.66%
…Severe GI Bleeding	0.49%	0.71%
…GI Adverse Events	27.1%	29.8%

The AHA and ACC recommend daily aspirin use at 75mg to 162mg per day. The European Society of Cardiology recommends 75mg to 150mg per day. These guidelines were put into place to reduce the potential for GI-related bleeding events. Data published in the *American Journal of Cardiology* shows a 2-fold reduction in major bleeding events and a 3-fold reduction in total bleeding events on daily aspirin use <100mg when compared to use >200mg. Pozen's "safer aspirin" product, a drug that is designed to provide a full 325 mg dose of aspirin while greatly reducing the risk for GI-bleeding and ulcers, could find significant use among the 50+ million American's at risk for recurrent MI and GI-related side-effects. Management has conducted market research yielding encouraging statistics. At about $1/day, roughly 30% of physicians would prescribe PA-325/40 to their patients in need of secondary prevention aspirin therapy. We see this as a $300-400 million opportunity in the U.S. alone.

Pozen's phase 2 trial with PA-325/40 showed a 90% reduction in endoscopically diagnosed Lanza 3 & 4 GI-related damage compared to 325 mg of aspirin alone, and a 50% reduce when compare to 81 mg (baby) aspirin. The current phase 3 program is being conducted under a U.S. FDA Special Protocol Assessment (SPA). Management expects enrollment to complete in the second half of 2011, offer data in the second half of 2012, and filing for approval shortly thereafter. Assuming these timelines hold, PA-325/40 could be on the market late 2013 / early 2014. Pozen plans to market the product itself.

We are intrigued by the significant meta-analysis data showing aspirin use as a potential to reduce incidence of colon cancer. There are an estimated 150k cases of colon or rectal cancer in the U.S each year, with 50k deaths. Data from a prospective analysis of nearly 83k women from 1980 to 2000 published in JAMA in 2005 shows a significant risk reduction when on daily aspirin 325mg.



In total, there have been four randomized clinical programs demonstrating a significant risk reduction in patients with confirmed adenomas taking aspirin vs. placebo. The pooled analysis shows a 20% to 40% reduction in risk of cancer development for patients taking that high-dose aspirin (325mg). Unfortunately, the same increased risk of GI bleeding and gastric ulcers was seen in the trials as discussed above for cardiovascular disease prevention. There is a 2-fold increase in risk of a major GI bleed for patients taking 325mg aspirin per day vs. placebo. Therefore, despite the reduction in risk of cancer progression, the U.S. Preventive Services Task Force stated in 2007 that, "The harms outweigh the benefits of aspirin and NSAID use for prevention of colorectal cancer." Pozen's PA-325/40 could see sizable off-label use in this indication following approval.

Pozen will fund development of PA-325/40 through its existing cash balance and the royalty payments from Treximet and Vimovo. We have forecasted future PA-325/40 sales, and at this stage we believe the drug is worth another $30+ million in market value (net of negative cash flow through 2013).

PA	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sales	-	-	-	$0.0	$0.0	$10.0	$50.0	$110.0	$160.0	$215.0	$280.0
Cash	-	-	-	($22.0)	($22.0)	($15.0)	$5.0	$16.5	$40.0	$59.1	$84.0
Discount	15%										
NPV	$32.4	Million									

…Sum of Parts…

Through our sum of parts analysis, we arrive at a target market value of around $200 million. Based on 29.9 million shares outstanding, this equates to price of $6.50 per share.

Valuation Method	Projected Market Cap.
Value for Treximet	~ $79 Million
Value for Vimovo	~ $44 Million
Value for PA	~ $31 Million
Year-End Cash Balance	~ $45 Million
Estimated Fair Value	~$200 Million

APPENDIX – LEGAL ISSUES

Preliminary Injunction Ordered in Treximet Patent Case

On April 15, 2011, Pozen announced that the U.S. District Court for the Eastern District of Texas had granted a preliminary injunction ordering Par Pharmaceutical Inc. not to make, use, sell, offer to sell, or import into the U.S. a generic version of sumatriptan/naproxen sodium that competes with Treximet sold by GlaxoSmithKline.

As a reminder, we are currently awaiting the decision of the court in the patent infringement lawsuit pending between Pozen and Par, Alphapharm, and Dr. Reddy's relating to Abbreviated New Drug Application (ANDA) submissions seeking approval for a generic sumatriptan/naproxen product in the U.S. We find is encouraging that Judge Davis granted the preliminary injunction while the final decision is still pending. In Judge Davis' decision, he concludes that Pozen had shown "that it is likely to succeed against Par on the merits of its infringement claim of the '458 patent." The Court further concluded that Pozen "is likely to succeed against Defendants' invalidity claims" concerning the '458 patent and that it "does not find that Defendants' arguments raise a substantial question regarding the enforceability of the '458 patent." The injunction will remain in effect until a final decision is issued in the pending patent litigation. We continue to believe that the Treximet patents are valid and enforceable, and will be upheld by the court.

AstraZeneca & Pozen File Patent Infringement Against Dr. Reddy's

On April 25, 2011, Pozen and AstraZeneca announced that they have filed a lawsuit against Dr. Reddy's Laboratories in the U.S. District Court for the District of New Jersey, for infringement of U.S. Patent No. 6,926,907 relating to Vimovo (naproxen / esomeprazole magnesium) delayed-release tablets. The news follows Dr. Reddy's filing an ANDA seeking U.S. FDA approval to market a generic version of Vimovo prior to expiration of the '907 patient in 2023. We remind investors that this is only one of seven patents listed in the FDA's Orange Book for Vimovo. Pozen spent an estimated $10 million defending the Treximet patent in 2010, so we are pleased that AstraZeneca has exercised its right to defend the patent at issue and will take the leading role in prosecuting the infringement suit against Dr. Reddy's. Because Pozen and AstraZeneca filed the patent infringement lawsuit within 45 days of receipt of Dr. Reddy's ANDA, under Hatch-Waxman, the FDA now automatically institutes a 30 month stay (or until a final court decision) before approval the ANDA. We feel confident in the Vimovo intellectual property. A positive verdict in the Treximet case should strengthen market perception around Vimovo's exclusivity.

PROJECTED INCOME STATEMENT

POZEN INC.

Income statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Treximet (sales)	$86.1	$87.3	$22.0	$23.0	$23.0	$24.0	$92.0	$96.0	$98.0	$100.0
Treximet (royalty)	**$4.3**	**$15.7**	**$4.0**	**$4.0**	**$4.1**	**$4.3**	**$16.6**	**$17.3**	**$17.6**	**$18.0**
YOY Growth	*83.6%*	*265.0%*	*4.8%*	*-3.5%*	*6.5%*	*7.9%*	*5.4%*	*4.3%*	*2.1%*	*2.0%*
Vimovo (sales)	$0	$4.6	$4.1	$6.3	$9.5	$13.8	$33.7	$53.6	$78.2	$101.8
Vimovo (royalty)	**$0**	**$0.5**	**$0.4**	**$0.6**	**$1.0**	**$1.4**	**$3.4**	**$5.4**	**$7.8**	**$10.2**
YOY Growth	-	-	-	-	-	-	*631.7%*	*59.1%*	*46.0%*	*30.2%*
PA-325/40 (Sales)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$10.0**	**$50.0**
YOY Growth	-	-	-	-	-	-	-	-	-	*400.0%*
Licensing / Development	**$27.9**	**$52.3**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*-56.3%*	*87.6%*	-	-	-	-	-	-	-	-
Total Revenues	$32.2	$68.5	$4.5	$4.6	$5.1	$5.7	$19.9	$22.6	$35.5	$78.2
YOY Growth	*-51.3%*	*113.0%*	*-68.8%*	*8.6%*	*-84.2%*	*-17.8%*	*-70.9%*	*13.6%*	*56.7%*	*120.5%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$1.5	$7.5
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*95.8%*	*90.4%*
SG&A	$17.8	$23.8	$4.3	$4.8	$4.7	$4.8	$18.6	$22.5	$25.0	$30.0
% SG&A	*55.2%*	*34.7%*	*96.5%*	*103.8%*	*92.3%*	*84.3%*	*93.2%*	*99.4%*	*70.5%*	*38.4%*
R&D	$22.4	$22.6	$5.9	$6.3	$6.5	$7.0	$25.7	$22.0	$20.0	$20.0
% R&D	*69.7%*	*6+.%*	*132.5%*	*136.7%*	*127.7%*	*122.9%*	*128.9%*	*97.2%*	*56.4%*	*25.6%*
Operating Income	($8.0)	$22.1	($5.8)	($6.4)	($6.1)	($6.1)	($24.3)	($21.9)	($11.0)	$20.7
Operating Margin	*-24.9%*	*32.3%*	*-129.0%*	*-140.6%*	*-120.0%*	*-107.2%*	*-122.1%*	*-96.6%*	*-31.1%*	*26.5%*
Interest Income / Net	$0.5	$0.9	$0.1	$0.0	$0.1	$0.1	$0.3	$0.5	$0.6	$0.6
Pre-Tax Income	($7.5)	$23.1	($5.7)	($6.4)	($6.0)	($6.0)	($24.0)	($21.4)	($10.4)	$21.3
Taxes	($0.63)	$0	$0	$0	$0	$0	$0	$0	$0	$3.2
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*15.0%*
Net Income	($6.9)	$23.1	($5.7)	($6.4)	($6.0)	($6.0)	($24.0)	($21.4)	($10.4)	$18.1
YOY Growth	-	-	-	-	-	-	*-204.1%*	*-11.0%*	*-51.1%*	*-273.3%*
Net Margin	*-21.3%*	*33.7%*	*-127.4%*	*-139.6%*	*-118.1%*	*-105.4%*	*-120.5%*	*-94.4%*	*-29.4%*	*23.1%*
Reported EPS	($0.23)	$0.76	($0.19)	($0.21)	($0.20)	($0.20)	($0.80)	($0.70)	($0.34)	$0.57
Fully Diluted Shares	29.9	30.2	29.9	29.9	29.9	30.0	29.9	30.5	31.0	32.0

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

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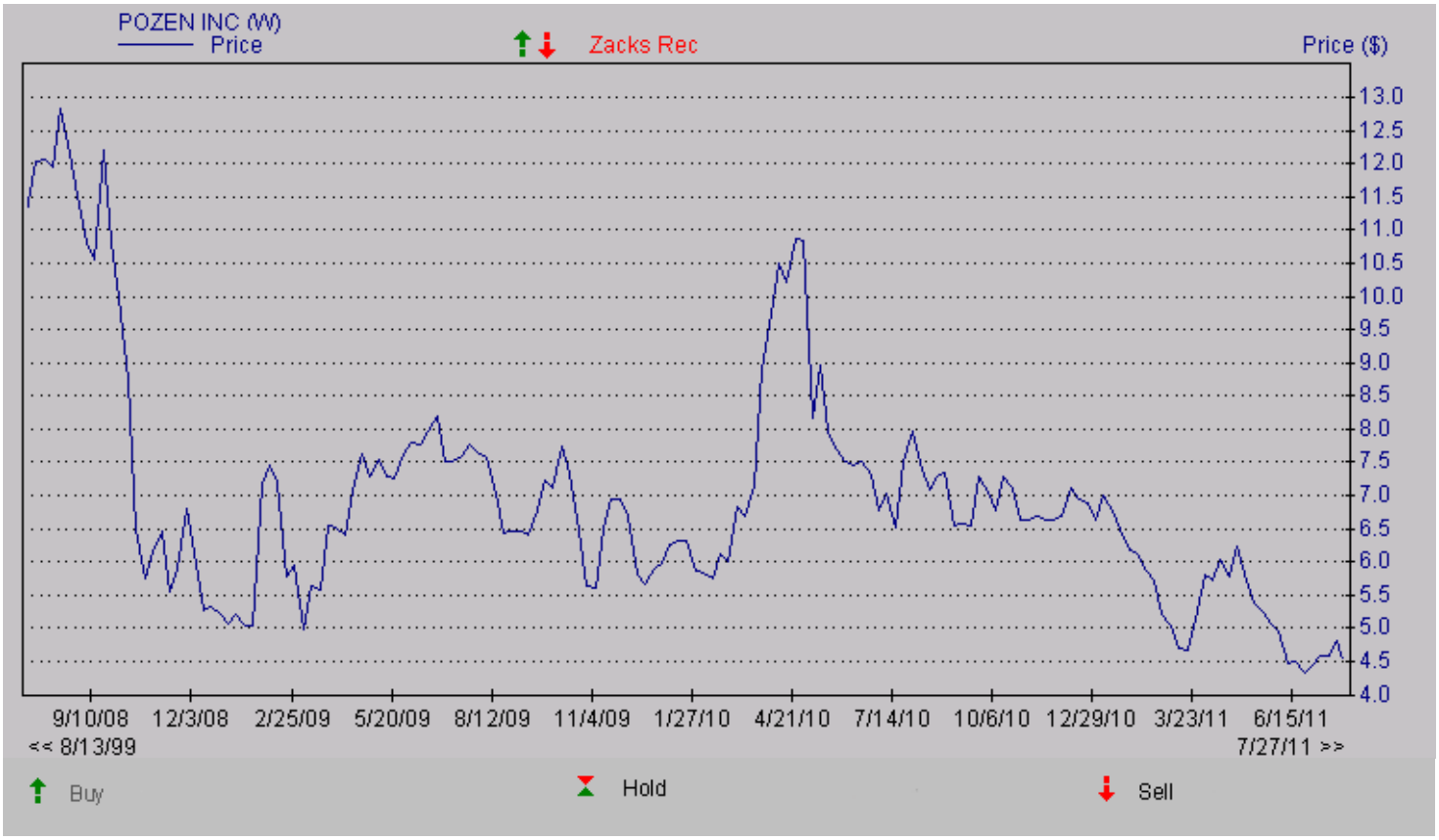
HISTORICAL ZACKS RECOMMENDATIONS



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