Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Pozen Is Worth More Than $5 Bucks!

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (03/09/11)	$5.02
Target Price	**$10.00**

UPDATE

We remain optimistic on Pozen.

We view the company as financially sound, with $64 million in cash to be on hand at the end of 2010. 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 month. This could be a major catalyst to drive Pozen shares higher. We think the market has yet to come to grips with the potential for PA-325/40.

Based on our sum-of-parts analysis, we see Pozen fairly valued at $10 per share.

SUMMARY DATA

52-Week High	**$12.08**
52-Week Low	**$4.88**
One-Year Return (%)	**-25.54**
Beta	**1.39**
Average Daily Volume (sh)	**95,474**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$154**
Short Interest Ratio (days)	**15.82**
Institutional Ownership (%)	**54**
Insider Ownership (%)	**16**
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	**1**

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	4.4 E	5.4 E	6.1 E	6.7 E	22.7 E
2012					31.9 E
2013					48.6 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	-$0.23 E	-$0.20 E	-$0.20 E	-$0.20 E	-$0.82 E
2012					-$0.74 E
2013					-$0.23 E

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

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WHAT'S NEW

Recent Financials

On March 9, 2011, Pozen reported financial results for the fourth quarter and full year 2010. Pozen reported total revenues in the fourth quarter of $29.0 million. Revenues consisted of $4.0 million in royalties on sales of Treximet at GlaxoSmithKline and $25 million in a one-time milestone payment from AstraZeneca on the Ex-U.S. approval and pricing of Vimovo in Europe. This was in-line with expectations. Total revenues for 2010 were $68.5 million, and consisted of $15.7 million in royalties on sales of Treximet at Glaxo, $0.5 million in royalties on sales of Vimovo at AstraZeneca, $45 million in milestone payments from AstraZeneca on the U.S. and Ex-U.S. approval of Vimovo, and $7.3 million in collaboration payments from development partners.

Net income for the fourth quarter 2010 totaled $18.4 million, or $0.61 per diluted share. Net income for the full year 2010 totaled $23.1 million, or $0.76 per diluted share. Operating expenses in 2010 included legal and professional fees associated with the company's patent infringement case of $9.3 million. The trial wrapped-up in the fourth quarter 2010, so we are not expecting significant legal costs in 2011, perhaps around $1 million. Pozen exited 2010 with $64.1 million in cash and investments. We find this to be sufficient to fund operations for the foreseeable future.

INVESTMENT THESIS

Pozen Is Worth More Than $5 / Share

Pozen's stock has been on a precipitous decline since the beginning of the year, down from $7.10 on January 1st to roughly $5 today. The current market capitalization based on today's price and roughly 30 million shares outstanding is $150 million. We think this vastly undervalues the company based on a sum-of-parts discounted cash flow (DCF) calculation.

…What's Weighing On The Stock…

Pozen's stock decline has been driven by two forces since the beginning of the year. The first is lingering patent infringement trial against three generic pharmaceutical companies (Par Pharmaceuticals, Alphapharm Pty, and Dr. Reddy's) on Treximet, the company's combination sumatriptan / naproxen sodium tablet for the treatment of migraines, and sold in the U.S. by partner, GlaxoSmithKline (GSK). Pozen previously guided on its third quarter conference call, held in October 2010, that a decision from Judge Leonard Davis from the United States District Court for the Eastern District of Texas would be out before the end of the year. December 31, 2010 came and went, and management has since backed-off giving guidance on when the outcome will be released. We are hoping that a decision will be out by the end of April 2011. We note that Pozen has filed an injunction against Par under Hatch-Waxman, which precludes the launch of an alternative sumatriptan / naproxen product until April 2011.

Nevertheless, Pozen remains decidedly confident in the outcome of the case. CEO John Plachetka stated on the third quarter call that there were, "No surprises" from the generic firms. On the fourth quarter call Mr. Plachetka noted being "patient and confident". We remind investors that Teva Pharmaceuticals previously bailed-out of this lawsuit, potentially hinting that Pozen's IP looked too strong to challenge. If upheld, the two patents will protect Treximet exclusivity until August 2017. Recent news that the U.S. FDA rejected the pediatric extension on Treximet is a non-issue in our view. This would have only extended the patient from August 2017 to February 2018.

The second issue that is weighing on Pozen share is the weak launch of Vimovo, Pozen's esomeprazole / naproxen tablet for osteoarthritis pain, by partner AstraZeneca (AZN). Weak might be an understatement after AstraZeneca reported only $5 million in sales in the third quarter 2010 and $0 sales in the fourth quarter 2010. AstraZeneca has reported that prescriptions for Vimovo are growing "on plan". Those prescriptions are not generating revenues because they are all being fulfilled by free samples and deep discounting coupons. If patients like the drug, they will eventually come back for refills at full price. We expect that sales in the coming quarters will start to track prescriptions, and that should help turn Pozen's stock around.

…What's Treximet Worth…

Our first assumption is that Pozen will win the patent infringement case and Treximet will be patent protected until August 2017. Under this scenario, we see Treximet alone with $90 million in market value. Treximet posted sales of $86.1 million in 2009 and $87.3 million in 2010. For 2011, assuming full exclusivity, we expect Treximet sales of $92 million, with low-single digit growth until August 2017 when the patent expires. Pozen collects an 18% royalty on U.S. sales of Treximet by GlaxoSmithKline. Our DCF analysis of these future cash flows yields an NPV of $90 million based on a 10% discount rate (beta of 1.45, a 4% risk-free rate, 0% debt). Obviously if Pozen loses the case and a generic Treximet hits the market in May 2011 we will need to adjust our valuation, but as of now we remain confident in a favorable outcome.

Treximet	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sales	$46.2	$86.1	$87.3	$92.0	$96.0	$100.0	$104.0	$105.0	$104.0	$100.0	$20.0
Royalties	$2.3	$4.3	$15.7	$16.6	$17.3	$18.0	$18.7	$18.9	$18.7	$18.0	$3.6
Discount	10%										
NPV	$89.5	Million									

…What's Vimovo Worth…

Sales forecasts for Vimovo are a little harder to forecast given the slow ramp since the launch in the third quarter 2010. However, we take confidence in the fact that AstraZeneca thinks this could be a $500 million drug in the U.S., and the company recently paid Pozen a $25 million milestone for approval in Europe. Between the U.S. and Europe approvals, AstraZeneca paid Pozen $45 million in cash in 2010. We do not believe that AstraZeneca would have made this level of commitment if they do not see Vimovo as having $500 million potential.

We see Vimovo posting sales of $600 million in 2018. Vimovo is designed to provide a safer gastrointestinal (GI) approach to daily NSAID therapy. Cox-II drugs such as Vioxx and Celebrex, designed to provide safer gastrointestinal profile, peaked sales at over $7 billion worldwide in 2004 before Vioxx was pulled from the market for cardiovascular risk. According to Pozen management, approximately 50% of OA / RA patients are at risk for gastrointestinal damage. Some 37 million Americans suffer from OA or RA. Several large clinical studies have confirmed that 20-40% of those who take NSAIDs regularly have one or more ulcers in their stomach or intestines. In the U.S., there are an estimated 16,500 deaths each year due to NSAID-induced GI complications (primarily from GI hemorrhage). Given the lack of treatment options and the withdrawal of Vioxx and Bextra, only about 25% of these patients are co-prescribed a gastro-protectant.

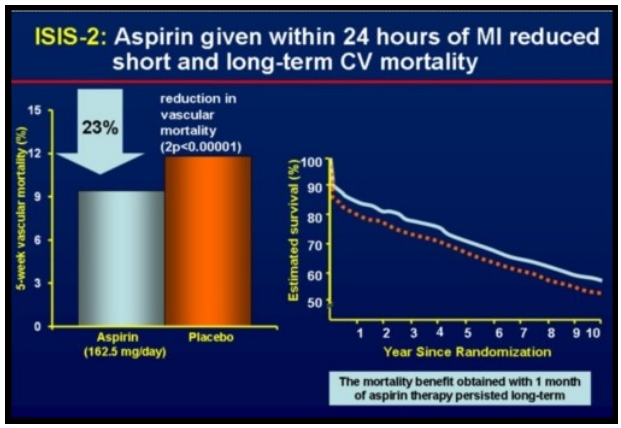
Our 2011 Vimovo sales forecast of $61 million assumes only 1% market share in the NSAID / Cox-II class. By 2018 we believe Vimovo can capture 4% market share of the daily NSAID / Cox-II class. Our assumptions clearly do not model Vimovo to be a blockbuster, but with 10% royalty to Pozen, it is still worth an estimated $90 million in market value, even if we bump the discount rate to 20% to account for the added risk of the recent launch.

Vimovo	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Sales	-	-	$4.6	$61.2	$146.1	$206.3	$272.8	$336.2	$405.4	$427.3	$450.0
Royalties	-	-	$0.5	$6.1	$14.6	$20.6	$27.3	$33.6	$40.5	$42.7	$45.0
Discount	20%										
NPV	$89.8	Million									

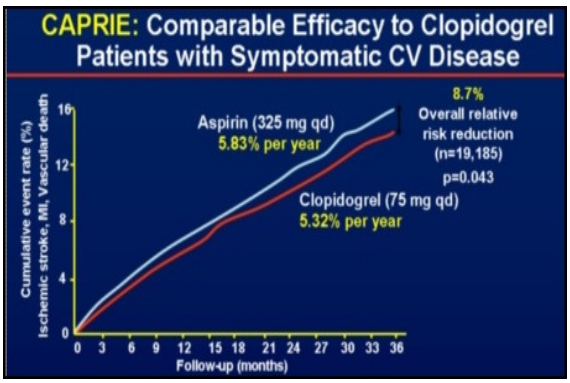
…What's PA Worth…

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%

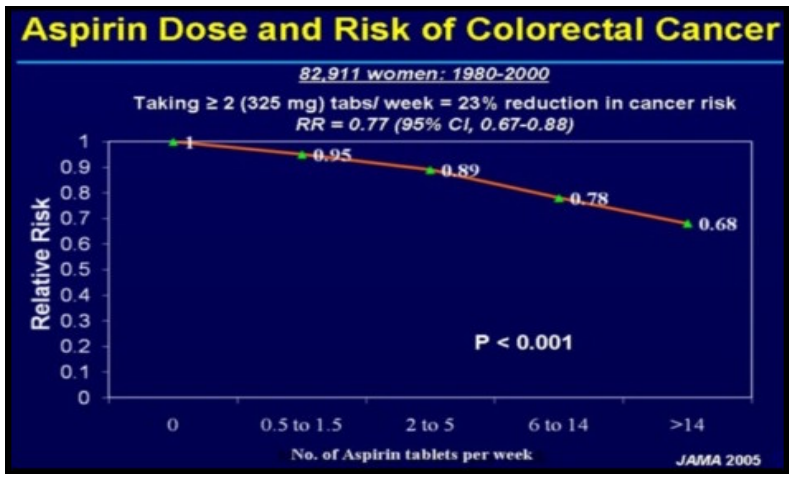
The AHA and ACC recommend daily aspirin use at 75mg to 162mg per day. The European Society of Cardiology recommends 75mg to 150mg per day. These guidelines were put into place to reduce the potential for GI-related bleeding events. Data published in the *American Journal of Cardiology* shows a 2-fold 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 think the PA-325/40 product, along with potential follow-on products with various doses (650mg and 81mg) of aspirin, is worth $58 million. We are using a steeper 20% discount rate here to account for the added risk of being in phase 3 trials. Upside to this figure could come from initiating another phase 3 program with PA-650/20 or PA-81/20. We see PA-650/20 for pain and cancer prevention and PA-81/20 for secondary prevention as bringing the peak sales potential for the entire PA franchise in the U.S. to $500+ million.

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	-	-	-	$0.0	$0.0	$0.0	$5.0	$16.5	$40.0	$59.1	$84.0
Discount	20%										
NPV	$58.5	Million									

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.

Sum of Parts

Summing up the three products at Pozen, Treximet worth $90 million, Vimovo worth $90 million, and PA worth $58 million, we arrive at a total of $240 million. We also note that Pozen will hold still $58 million in cash at the end of the first quarter 2011. Adding in this cash value and we arrive at a total firm value of $296 million. Based on 30 million shares outstanding, we see $10 as fair-value.

(DCF Assumptions: Beta – 1.45, Rf – 4%, 100% Equity, 0% Debt, Shares Outstanding – 30 million)

PROJECTED INCOME STATEMENT

POZEN INC.

Income statement

	2009 A	2010 A	Q1 E	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Treximet (sales)	$86.1	$87.3	$21.0	$23.0	$24.0	$24.0	$92.0	$96.0	$100.0	$104.0
Treximet (royalty)	**$4.3**	**$15.7**	**$3.8**	**$4.1**	**$4.3**	**$4.3**	**$16.6**	**$17.3**	**$18.0**	**$18.7**
YOY Growth	*83.6%*	*265.0%*	*0.0%*	*1.0%*	*11.1%*	*7.9%*	*5.4%*	*4.3%*	*4.2%*	*4.0%*
Vimovo (sales)	$0	$4.6	$6.0	$13.0	$18.0	$24.0	$61.0	$146.1	$206.3	$272.8
Vimovo (royalty)	**$0**	**$0.5**	**$0.6**	**$1.3**	**$1.8**	**$2.4**	**$6.1**	**$14.6**	**$20.6**	**$27.3**
YOY Growth	-	-	-	-	-	-	*1226.1%*	*139.5%*	*41.2%*	*32.2%*
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	$4.4	$5.4	$6.1	$6.7	$22.7	$31.9	$48.6	$96.0
YOY Growth	*-51.3%*	*113.0%*	*-69.3%*	*28.8%*	*-81.0%*	*-3.0%*	*-66.9%*	*40.7%*	*52.5%*	*97.4%*
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%*	*96.9%*	*92.2%*
SG&A	$17.8	$23.8	$5.5	$5.0	$5.2	$5.3	$21.0	$25.0	$30.0	$35.0
% SG&A	*55.2%*	*34.7%*	*125.6%*	*91.9%*	*85.0%*	*78.9%*	*92.7%*	*78.4%*	*61.7%*	*36.5%*
R&D	$22.4	$22.6	$6.0	$6.5	$7.0	$7.5	$27.0	$30.0	$25.0	$25.0
% R&D	*69.7%*	*6+.%*	*137.0%*	*119.5%*	*114.4%*	*111.6%*	*119.2%*	*94.1%*	*51.4%*	*26.0%*
Operating Income	($8.0)	$22.1	($7.1)	($6.1)	($6.1)	($6.1)	($25.3)	($23.1)	($7.9)	$28.5
Operating Margin	*-24.9%*	*32.3%*	*-162.6%*	*-111.4%*	*-99.3%*	*-90.5%*	*-111.8%*	*-72.5%*	*-16.2%*	*29.7%*
Interest Income / Net	$0.5	$0.9	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.6	$0.6
Pre-Tax Income	($7.5)	$23.1	($7.0)	($6.0)	($6.0)	($6.0)	($24.9)	($22.6)	$7.3	$29.1
Taxes	($0.63)	$0	$0	$0	$0	$0	$0	$0	$0	$4.4
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*15.0%*
Net Income	($6.9)	$23.1	($7.0)	($6.0)	($6.0)	($6.0)	($24.9)	($22.6)	($7.3)	$24.7
YOY Growth	-	-	-	-	-	-	*-208.1%*	*-9.3%*	*-67.8%*	*-440.2%*
Net Margin	*-21.3%*	*33.7%*	*-160.3%*	*-109.6%*	*-97.7%*	*-89.0%*	*-110.1%*	*-70.9%*	*-14.9%*	*25.8%*
Reported EPS	($0.23)	$0.76	($0.23)	($0.20)	($0.20)	($0.20)	($0.82)	($0.74)	($0.23)	$0.77
Fully Diluted Shares	29.9	30.2	30.2	30.2	30.3	30.3	30.3	30.5	31.0	32.0

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

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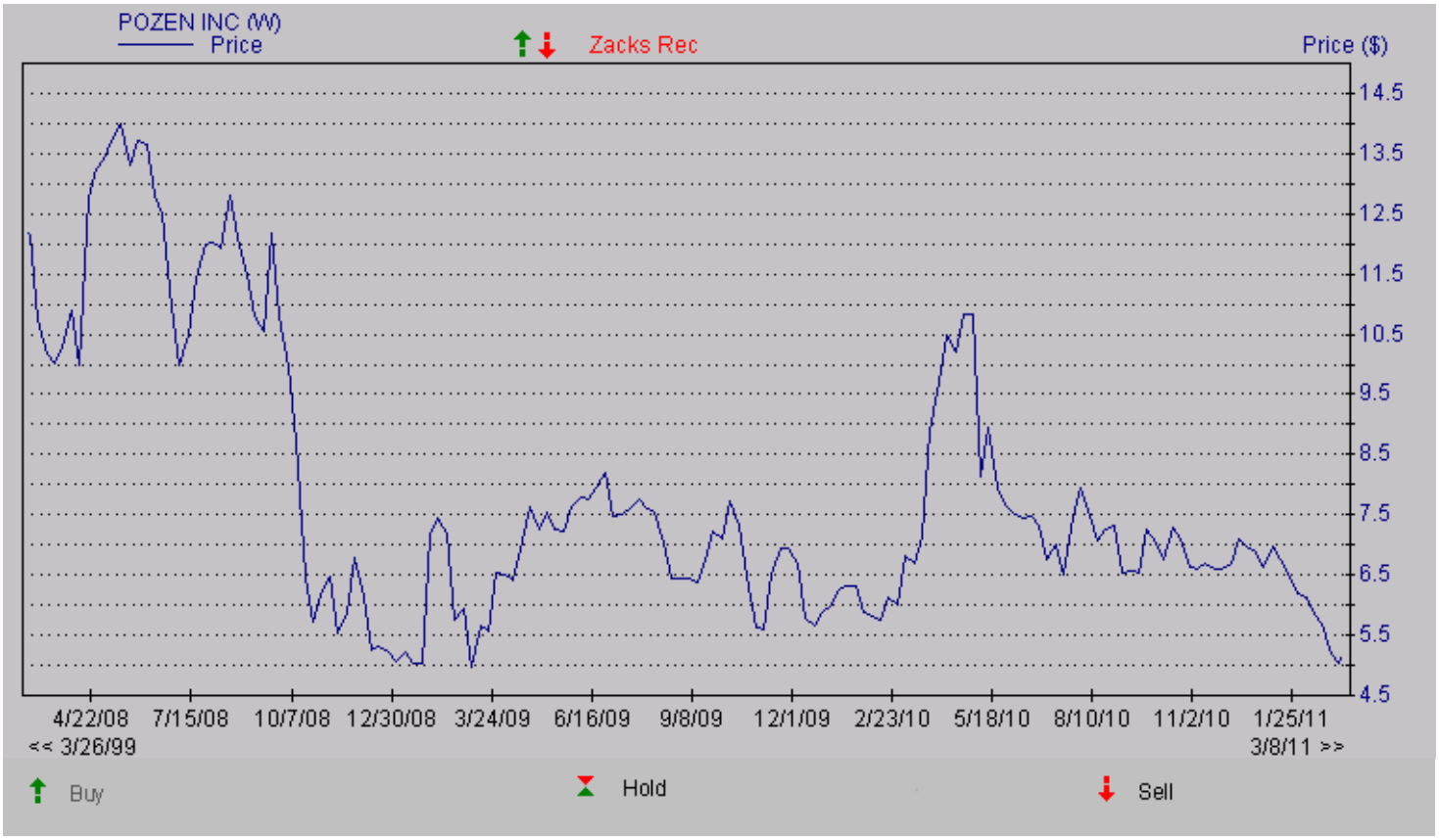

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