Zacks Small-Cap Research

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Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

POZEN, Inc. (POZN-NASDAQ)

POZN: Pozen To Distribute $1.75 In Cash To Shareholders…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (11/22/13)	$7.83
Target Price	**$9.00**

UPDATE

On November 21, 2013, Pozen announced it would issue a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with an expected payment date of December 30, 2013. On November 19, 2013, Pozen announced that U.S. Vimovo commercialization partner, AstraZeneca, has entered into an agreement with Horizon Pharma USA have entered into an agreement for Horizon to acquire the U.S. rights for Vimovo.

We continue to be positive on the Pozen story, and see $9.00 as fair-value prior to the cash distribution. This target assumes approval of PA in 2014.

SUMMARY DATA

52-Week High	**$7.79**
52-Week Low	**$4.50**
One-Year Return (%)	**43.46**
Beta	**1.21**
Average Daily Volume (sh)	**497,300**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$237**
Short Interest Ratio (days)	**14.12**
Institutional Ownership (%)	**15**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/M**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/M**
P/E using 2014 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)
2012	1.3 A	1.4 A	0.9 A	1.4 A	5.3 A
2013	1.4 A	1.7 A	2.6 A	4.6 E	10.3 E
2014					32.0 E
2015					36.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.28 A	-$0.17 A	-$0.19 A	-$0.20 A	-$0.84 A
2013	-$0.19 A	-$0.13 A	-$0.16 A	-$0.05 E	-$0.53 E
2014					$0.34 E
2015					$0.58 E

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WHAT'S NEW

Pozen To Issues Special Distribution

On November 21, 2013, Pozen announced it would issue a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with an expected payment date of December 30, 2013. This distribution represents a surplus of corporate cash and is expected to be treated as a return of capital to stockholders. In the simplest terms, shareholders on December 30, 2013 will see a reduced costs basis of $1.75 per share and receive $1.75 per share in cash. Pozen's issued the payment as a special return of capital and not a dividend so that the payment is tax free to shareholders. We expect Pozen's stock drop by $1.75 per share (assuming the market is 100% efficient) on December 30, 2013. The payout is analogous to a stock split, only instead of getting more shares at a lower price, investors will keep their Pozen stock with a new lower costs basis and receive $1.75 per share in cash.

Based on 30.5 million shares outstanding as of October 24, 2013 (Form-10Q), the special cash distribution equates to roughly $53.4 million being returned to shareholders. As of September 30, 2013, Pozen held cash and equivalents of $89.7 million. If we forecast an operating burn in the fourth quarter of around $3.0 million, the company will still exit 2013 with approximately $31.5 million in cash. We remind investors that Pozen is entitled to $20 million in pre-commercialization milestones on PA from Sanofi-Aventis. Therefore, following PA approval – should it come in January 2014 – Pozen could be back sitting with nearly $50 million on the books by the middle of 2014. And as Pozen winds down operations post PA approval, we believe the company can reach cash flow positive operations based on the royalties from Vimovo and PA alone. In fact, assuming PA approval in 2014, total operating burn at Pozen, the $20 million pre-commercialization payments from Sanofi notwithstanding, should only total around $6 million. Therefore, we think Pozen can potentially look to distribute more cash to shareholders at the end of 2014.

Horizon Pharma Acquires U.S. Rights To Vimovo

On November 19, 2013, Pozen announced that U.S. Vimovo commercialization partner, AstraZeneca, has entered into an agreement with Horizon Pharma USA have entered into an agreement for Horizon to acquire the U.S. rights for Vimovo. Under the terms of the agreement, Pozen will continue to receive a 10% royalty on net sales of products sold in the U.S., with guaranteed annual minimum royalty payments of $5 million in 2014, and $7.5 million each year thereafter, provided that the patents owned by Pozen which cover Vimovo are in effect and no generic forms of Vimovo are on the market.

Under the agreement, Horizon has assumed AstraZeneca's right to lead the on-going Paragraph IV litigation for Vimovo and will assume all patent-related defense costs relating to such litigation, including reimbursement for a specified amount of the cost of counsel retained by Pozen. AstraZeneca will continue to own rights to Vimovo outside the U.S.

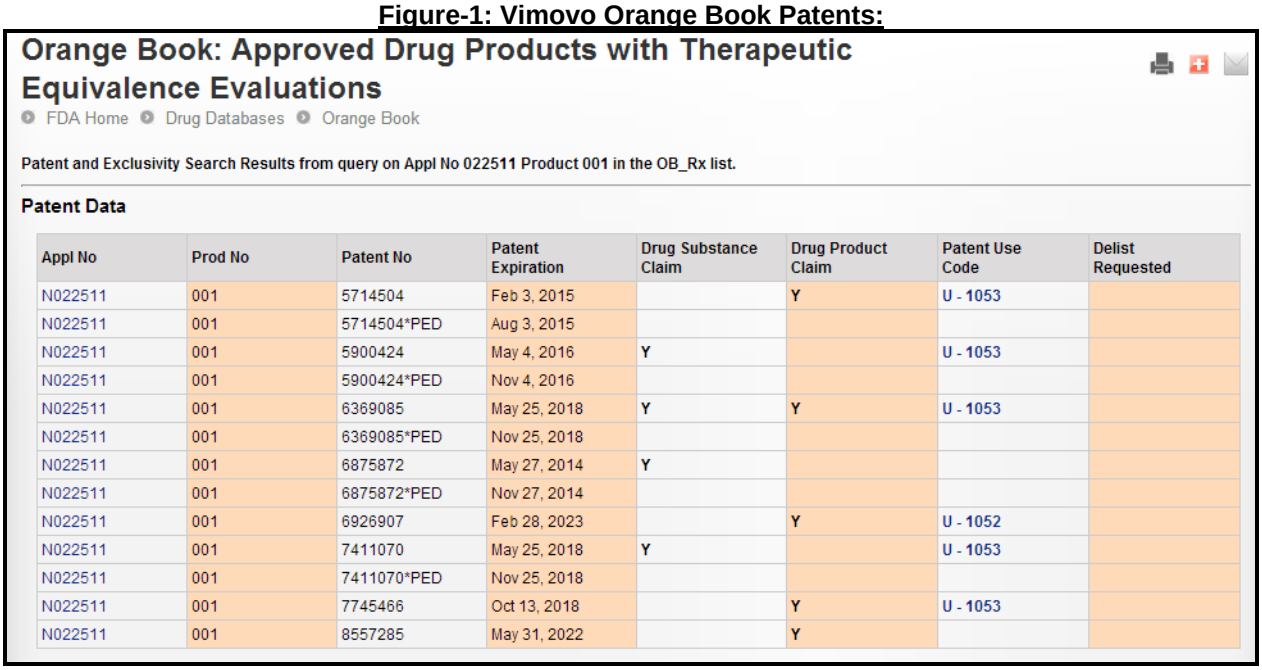
…Very Good News For Pozen…

Horizon taking over U.S. rights to Vimovo is a good thing for Pozen. AstraZeneca announced earlier in the year that they would cease all active promotion of the product in the U.S. U.S. sales of Vimovo during the first nine month of 2013 totaled only around $17 million. Ex-U.S. sales, where AstraZeneca seems to be committed to growing the product, totaled roughly $50 million. Pozen receives 10% royalty on U.S. sales. As such, Horizon's minimum commitment of $5.0 million in 2014 is a meaningful step-up in payment from what was previously expected. For instance, our financial model assumed only $20 million in U.S. Vimovo sales prior to the announcement. That equates to only a $2.0 million royalty payment to Pozen in 2014. The now $5.0 million guaranteed payment represents nice upside to our model.

…ANDA Challenges On Vimovo…

For 2015 and beyond, as long as there is no generic Vimovo on the market, Horizon guaranteed $7.5 million to Pozen each year. Again, that's a very nice bump from our previous financial modeling. That being said, there are several active generic challenges (Paragraph IV abbreviated new drug applications) on Vimovo that could impact the future payment structure from Horizon to Pozen. For example, there are eight patents listed on Vimovo in the FDA's Orange Book (see below). These patents begin to expire in November 2014 (with pediatric extension), with some going to as far out as February 2023.

Figure-1: Vimovo Orange Book Patents:



Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

FDA Home › Drug Databases › Orange Book

Patent and Exclusivity Search Results from query on Appl No 022511 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N022511	001	5714504	Feb 3, 2015		Y	U - 1053	
N022511	001	5714504*PED	Aug 3, 2015				
N022511	001	5900424	May 4, 2016	Y		U - 1053	
N022511	001	5900424*PED	Nov 4, 2016				
N022511	001	6369085	May 25, 2018	Y	Y	U - 1053	
N022511	001	6369085*PED	Nov 25, 2018				
N022511	001	6875872	May 27, 2014	Y			
N022511	001	6875872*PED	Nov 27, 2014				
N022511	001	6926907	Feb 28, 2023		Y	U - 1052	
N022511	001	7411070	May 25, 2018	Y		U - 1053	
N022511	001	7411070*PED	Nov 25, 2018				
N022511	001	7745466	Oct 13, 2018		Y	U - 1053	
N022511	001	8557285	May 31, 2022		Y		

If Pozen were to receive $5.0 million in 2014 and $7.5 million each year thereafter until the end of 2022, the total minimum net present value on the Horizon royalty payments to Pozen, using a 15% discount rate, would be nearly $36 million, or $1.18 per share (see Figure-2). However, if generic Vimovo shows up as early as 2016, the value drops significantly to Pozen (see Figure-3). Upside to our 'Best Case' scenario comes if Horizon can achieve sales in excess of $75 million in a calendar year – something we do not model at the current time.

Figure-2: Pozen 'Best Case' Scenario

	Vimovo	
	Royalty	NPV @ 15%
2014	$5.0	$5.0
2015	$7.5	$6.4
2016	$7.5	$5.4
2017	$7.5	$4.6
2018	$7.5	$3.9
2019	$7.5	$3.3
2020	$7.5	$2.8
2021	$7.5	$2.4
2022	$7.5	$2.0
	NPV	$35.9
	Shares Out	30.5
	Per Share	$1.18

Figure-3: Pozen 'Worst Case' Scenario

	Vimovo	
	Royalty	NPV @ 15%
2014	$5.0	$5.0
2015	$7.5	$6.4
2016	$1.0	$0.7
2017	$0.5	$0.3
2018	$0.0	$0.0
2019	$0.0	$0.0
2020	$0.0	$0.0
2021	$0.0	$0.0
2022	$0.0	$0.0
	NPV	$12.4
	Shares Out	30.5
	Per Share	$0.41

To date, there have been a number of challenges to the Vimovo intellectual property.

→ On March 14, 2011, Dr. Reddy filed a Paragraph IV challenging to the '907 patent noted above that expires in February 2023.
→ On September 19, 2011, Dr. Reddy amending that claim to include the '504, '085, '872, '070, and '466 patents.
→ On June 13, 2011, Lupin Pharma filed a Paragraph IV challenge to the '907, '504, '085, '872, '070, and '466 patents.
→ On March 29, 2013, Watson Labs filed a Paragraph IV challenge to the '907, '504, '085, '872, '070, and '466 patents.
→ On May 16, 2013, Mylan Pharma filed a Paragraph IV challenge to the '907, '504, '085, '872, '070, and '466 patents.

Pozen and AstraZeneca have aggressively fought the Paragraph IV challengers. On April 21, 2011, Pozen and AstraZeneca filed suit in the United States District Court for the District of New Jersey relating to the Paragraph IV challenge to the '907 patent. An amended was filed on October 28, 2011 to include the other six patents. This suit included Dr. Reddy, Anchen, and Lupin Pharma. On December 19, 2012, the District Court conducted a pre-trial "Markman" hearing to determine claim construction. On April 15, 2013 a Stipulation of Partial Dismissal was filed which sought dismissal of all infringement claims relating to all seven patent challenges. On April 18, 2013, the District Court issued a Stipulation and Order dismissing with prejudice those claims and defenses. On May 1, 2012, the Court issued a Markman Order construing the claim terms disputed by the parties.

On October 15, 2013, the U.S. Patent Office issued to Pozen, U.S. Patent No. 8,557,285. The '285 patent entitled, "Pharmaceutical compositions for the coordinated delivery of NSAIDs." This patent is related to the '907 patent. This was a key patent victory for Pozen. On October 23, 2013, Pozen and AstraZeneca filed patent infringement lawsuits against Dr. Reddy's, Lupin, Watson and Mylan in the U.S. District Court of New Jersey alleging that their ANDA products infringe the '285 patent. Dr. Reddy's, Lupin, Watson and Mylan have yet to answer in those cases. We suspect that the generic filers are current reviewing the new '285 patent and will be filing Paragraph IV challenges over the next several months. However, any victory by Pozen and Horizon with respect to the '907 or '285 patent would seemingly protect Vimovo until 2022 or slightly beyond.

Pozen will continue to receive a 6% royalty on Vimovo sales outside the U.S. at AstraZeneca. Assuming AstraZeneca can maintain the current $60 million per year run-rate for Vimovo, this equates to roughly $3.6 million in royalties to Pozen. We note this royalty rate jumps to 10% starting in 2016.

Sanofi-Aventis To Commercialize PA in the U.S.

On September 3, 2013, Pozen Inc. entered into a licensing and collaboration agreement with Sanofi-Aventis for the commercialization of PA-325/40 and PA-81/40 in the U.S. PA-325/40 and PA-81/40 are Pozen's "safer aspirin" products current under U.S. FDA regulatory review with a PDUFA action date scheduled for January 24, 2014. Pozen has been promising a partnership for its PA franchise for over a year now, and it finally delivered with an impressive catch. Partnering with Sanofi-aventis is Pozen's fourth such impressive partnership based on internally-developed combination products. Prior to this licensing and collaboration agreement for PA, Pozen has previously licensed its "safer NSAID" drug, Vimovo, to AstraZeneca, and its dual-action migraine drug, Treximet / MT-400, to GlaxoSmithKline and Johnson & Johnson.

The PA licensing agreement came with $15 million in upfront cash. Pozen is also eligible for $20 million in pre-commercialization milestones, which we assume corresponds to U.S. FDA approval in late January 2014 and the transfer of the NDA to Sanofi (split evenly). Both the upfront and approval milestone were dead-on with our previous predictions on the potential deal. Pozen can earn additional milestone payments upon the achievement of specified sales thresholds for PA, and will receive a double-digit tiered royalty on sales in the U.S. at Sanofi-aventis. The exact terms of the back-end milestones have not been disclosed, only that the royalty rate is tiered between 12.5% and 22.5%. We expect that Pozen should be able to capture an additional $50 million in sales related milestone following commercialization by Sanofi.

…FDA Requests Teleconference On PA…

In Pozen's earning press release on November 6, 2013, the company noted that, "As part of Pozen's ongoing interactions and requests for information from the FDA during its review of the NDA for PA-81/40 and PA-325/40, the FDA has requested a teleconference, which has been scheduled for mid-November 2013 to discuss and address the FDA's request for information with respect to the existing clinical pharmacology data on PA8140."

On the third quarter call, management noted that they think all the necessary information the FDA would like clarity on is in the NDA filing, but that they need to do a better job in presenting it to the agency. We think the issue stems from a lack of pharmacology data on PA-81/40, not from the actual data itself. For example, the agency is not asking about PA-325/40, the dose in which Pozen conducted all the phase 2 and 3 studies. Pozen only conducted one bioequivalence study with PA-81/40. CEO John Plachetka noted that these types of pharmacology studies are inexpensive and quick to run, so if the worst-case scenarios arises and the company receives a complete response letter relating to this issue, we think Pozen could be in position to re-file in less than four months at pretty minimal cost. The company plans to provide an update to investors after the teleconference concludes. Although, we note this may include waiting for the minutes from the meeting, which usually takes around one month to receive.

We remind investors that Pozen retains responsibility for obtaining FDA approval for PA. Sanofi and Pozen have agreed to share costs up to certain limits with respect to any additional activities that might be required by the FDA to gain final approval for PA. This might include conducting some additional pharmacology work on PA-81/40 depending on how the teleconference with the U.S. FDA goes in the next few weeks. However, at this stage we believe approval at some point in 2014 seems a good bet considering Pozen completed two positive Phase 3 trials with highly statistically significant data and excellent safety. Both trials were run under a special protocol assessment (SPA) with the U.S. FDA, and Pozen has already been down a similar path gaining approval for Vimovo (formerly called PN-500/20) in April 2010. As noted above, if the agency does request additional work on PA-81/40, we believe Pozen could provide the necessary data in only a few months at a relatively insignificant cost.

Valuation

We have made a number of changes to our financial model since the third quarter earnings call. Firstly, we have significantly increased the minimum U.S. royalty on Vimovo payable to Pozen from Horizon Pharma. We have increased 2014 revenues by $3.0 million and 2015 revenues by $5.5 million. Beyond 2015, it becomes difficult to forecast the Vimovo royalty line given the number of active patent challenges ongoing. However, if Pozen and Horizon are to stave off all challengers on Vimovo until 2023, U.S. Vimovo royalties are worth $1.18 per share at a minimum. Throw in Ex-U.S. royalties and Vimovo is worth around $2.00 per share to Pozen. The entry of generic Vimovo has about a $1.00 negative impact on our valuation. Upside to the $2.00 figure comes from Horizon being able to increase U.S. Vimovo sales beyond $75 million in a calendar year, which given Horizon's aggressive guidance issued last week, seems like something Horizon management believes it can accomplish.

After the special cash distribution is paid on December 30, 2013, we estimate Pozen will still have roughly $31.5 million in cash on the books, burning very little on a quarterly basis. This equates to $1.00 per share. Following PA approval, Pozen nets a $20 million pre-commercialization milestone, and then begins to collect sales milestones and royalties on U.S. sales of PA at Sanofi US.

In the past we've outlined our belief that PA is a $260 million drug in the U.S. We think that Pozen should be able to capture as much as $50 million in backend milestones, along with royalties between 12.5% and 22.5%. That pegs the U.S. PA valuation to Pozen at around $3 to $4 per share. Therefore, on a "sum-of-parts" valuation, Pozen's stock is worth $6 to $8 per share post the $1.75 cash distribution. Our previous target was $9.00 per share, which is now adjusted down to $7.25 given the cash pay-out coming on December 30, 2013. Upside to our valuation comes from moving PA forward in Europe, or the ramping-up of new applications for higher or lower doses of PA for cancer prevention.

PROJECTED INCOME STATEMENT

INCOME STATEMENT

Pozen, Inc.	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
Vimovo (sales)	$33.8	$64.4	$19.7	$23.3	$23.0	$23.0	$89.0	$90.0	$85.0
Vimovo (royalty)	**$2.9**	**$4.8**	**$1.4**	**$1.7**	**$1.6**	**$1.6**	**$6.3**	**$8.5**	**$11.0**
YOY Growth	*533.0%*	*66.5%*	-	-	-	-	*29.1%*	*35.8%*	*29.4%*
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$12.5**	**$25.0**
YOY Growth	-	-	-	-	-	-	-	-	*100.0%*
Licensing / Development	**$71.9**	**$0.5**	**$0**	**$0**	**$1.0**	**$3.0**	**$4.0**	**$11.0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	$87.0	$5.3	$1.4	$1.7	$2.6	$4.6	$10.3	$32.0	$36.0
YOY Growth	*26.8%*	*-93.8%*	*-71.1%*	*-97.7%*	*-97.0%*	*257.6%*	*91.8%*	*211.9%*	*12.5%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
SG&A	$21.8	$19.0	$3.6	$3.7	$5.2	$4.0	$16.5	$14.0	$12.0
% SG&A	*25.0%*	*355.7%*	*256.8%*	*224.9%*	*200.6%*	*86.8%*	*161.1%*	*43.8%*	*33.3%*
R&D	$23.0	$11.9	$3.6	$1.9	$2.2	$2.3	$10.0	$8.0	$6.0
% R&D	*26.5%*	*221.8%*	*253.3%*	*117.6%*	*84.5%*	*49.9%*	*97.5%*	*25.0%*	*16.7%*
Operating Income	$42.2	($25.5)	($5.8)	($4.0)	($4.8)	($1.7)	($16.3)	$10.0	$18.0
Operating Margin	*48.5%*	*-477.5%*	*-410.1%*	*-242.5%*	*-185.1%*	*-36.7%*	*-158.7%*	*31.3%*	*50.0%*
Interest Income / Net	$0.2	$0.3	$0.0	$0.0	$0.0	$0.1	$0.2	$0.4	$0.4
Pre-Tax Income	$42.3	($25.3)	($5.8)	($4.0)	($4.8)	($1.6)	($16.1)	$10.4	$18.4
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$42.3	($25.3)	($5.8)	($4.0)	($4.8)	($1.6)	($16.1)	$10.4	$18.4
YOY Growth	*83.5%*	*-159.7%*	-	-	-	-	*-36.2%*	*-164.5%*	*76.9%*
Net Margin	*48.7%*	*-472.7%*	*-408.3%*	*-241.6%*	*-184.6%*	*-34.5%*	*-157.2%*	*32.5%*	*51.1%*
Reported EPS	$1.40	($0.84)	($0.19)	($0.13)	($0.16)	($0.05)	($0.53)	$0.34	$0.58
Fully Diluted Shares	30.3	30.1	30.3	30.4	30.5	30.5	30.4	31.0	32.0

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

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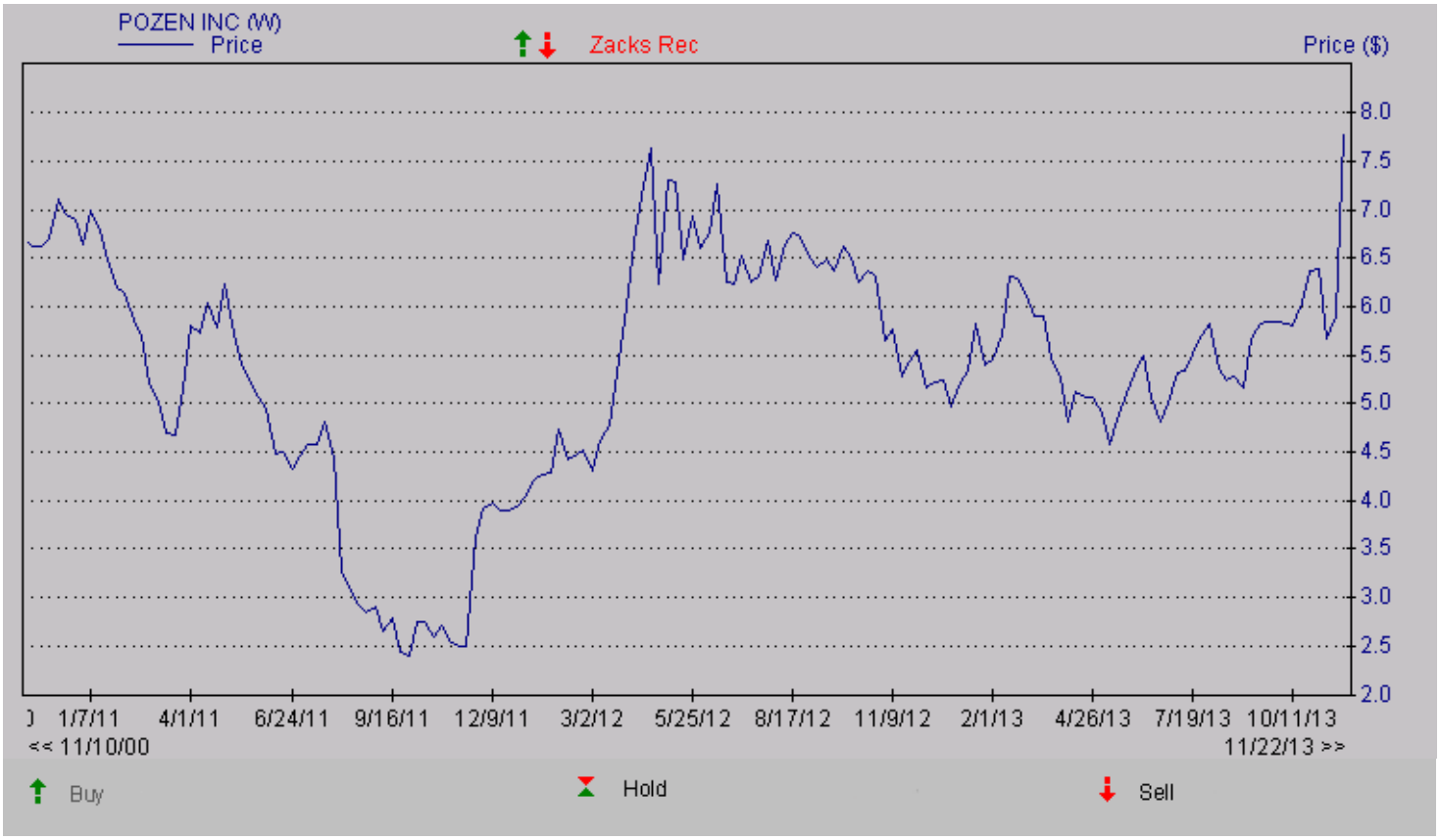
HISTORICAL ZACKS RECOMMENDATIONS



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