Zacks Small-Cap Research

May 5, 2011
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POZEN, Inc. (POZN-NASDAQ)

POZN: Confident in IP and Pipeline…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (05/05/11)	$5.95
Target Price	**$10.00**

UPDATE

We remain optimistic on Pozen.

We view the company as financially sound, with $57 million in cash to be on hand at the end of the first 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 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	**$10.39**
52-Week Low	**$4.51**
One-Year Return (%)	**-36.24**
Beta	**1.42**
Average Daily Volume (sh)	**114,371**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$177**
Short Interest Ratio (days)	**11.86**
Institutional Ownership (%)	**51**
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	**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	4.5 A	4.9 E	5.7 E	6.7 E	21.8 E
2012					29.5 E
2013					45.2 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	-$0.20 E	-$0.19 E	-$0.17 E	-$0.76 E
2012					-$0.74 E
2013					-$0.18 E

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

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WHAT'S NEW

First Quarter Financials

On May 5, 2011, Pozen reported financial results for the first quarter 2011. Pozen reported total revenues in the first quarter of $4.5 million. Revenues consisted of $4.0 million in royalties on sales of $22.0 million in sales of Treximet at GlaxoSmithKline and $0.4 million in royalties from $4.1 million in sales of Vimovo at AstraZeneca. This was in-line with expectations. Pozen did not record any collaboration payments from development partners during the first quarter 2011. Net loss for the quarter totaled $5.7 million, or $0.19 per diluted share. Pozen exited the first quarter ended March 31, 2011 with $56.8 million in cash and investments. We find this to be sufficient to fund operations for the foreseeable future.

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.

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 $5.95 per share today. 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.

…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 $93 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 June 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	$93.0	$96.0	$100.0	$104.0	$105.0	$104.0	$100.0	$20.0
Royalties	$2.3	$4.3	$15.7	$16.7	$17.3	$18.0	$18.7	$18.9	$18.7	$18.0	$3.6
Discount	10%										
NPV	$89.6	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, at least worldwide.

We see Vimovo posting sales of $450 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.

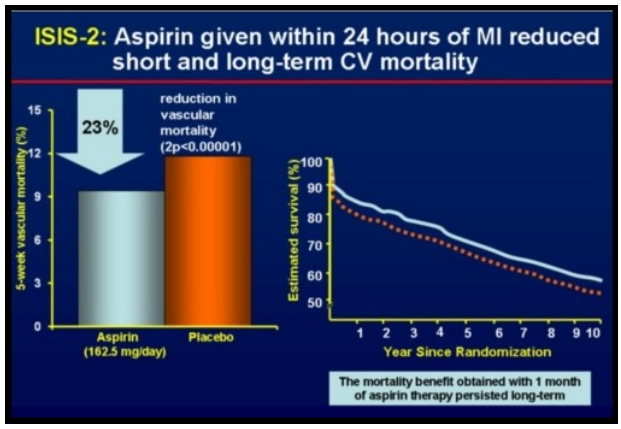
Our 2011 Vimovo sales forecast of $54 million assumes the drug captures less than 1% market share in the NSAID / Cox-II class. By 2018 we believe Vimovo can capture 4% market share of the daily NSAID / Cox-II class. Our assumptions clearly do not model Vimovo to be a blockbuster, but with 10% royalty to Pozen, it is still worth an estimated $80 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	$53.6	$121.7	$171.9	$227.3	$288.2	$354.7	$427.3	$450.0
Royalties	-	-	$0.5	$5.0	$12.2	$17.2	$22.7	$28.8	$35.5	$42.7	$45.0
Discount	20%										
NPV	$79.4	Million									

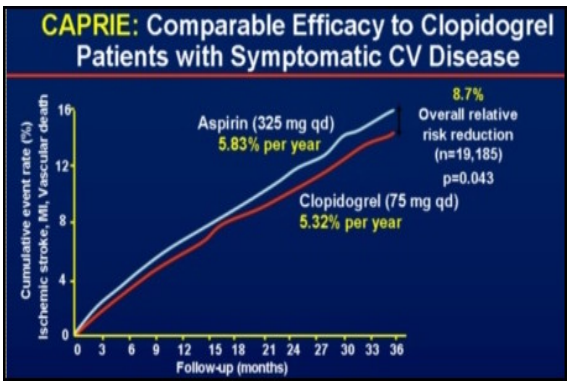
…What's PA Worth…

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, yet Plavix posted sales over $7 billion worldwide at its peak. Physicians are prescribing and patients are paying upwards of $5 per pill for Plavix vs. pennies for Aspirin to achieve only an 8.7% improvement. 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.

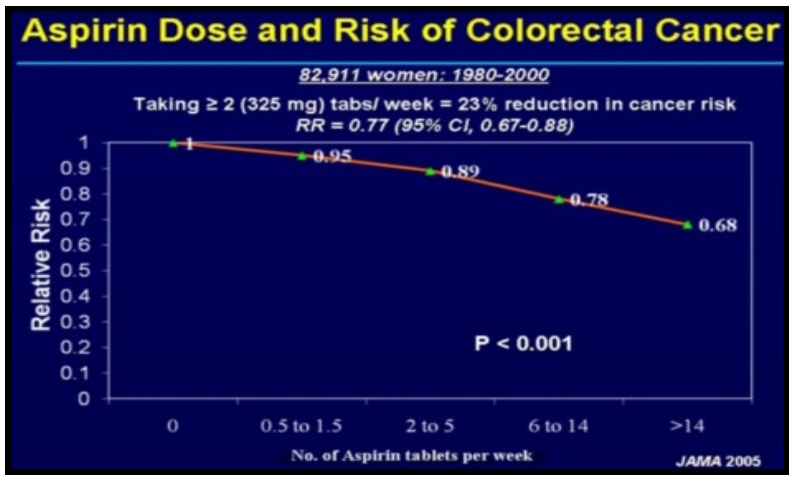
Pozen's phase 2 trial with PA-325/40 showed a 90% reduction in endoscopically diagnosed Lanza 3 & 4 GI-related damage compared to 325 mg of aspirin alone, and a 50% reduce when compare to 81 mg (baby) aspirin. The current phase 3 program is being conducted under a U.S. FDA Special Protocol Assessment (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.

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 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 $79 million, and PA worth $58 million, we arrive at a total of $230 million. We also note that Pozen held $57 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 $285 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.

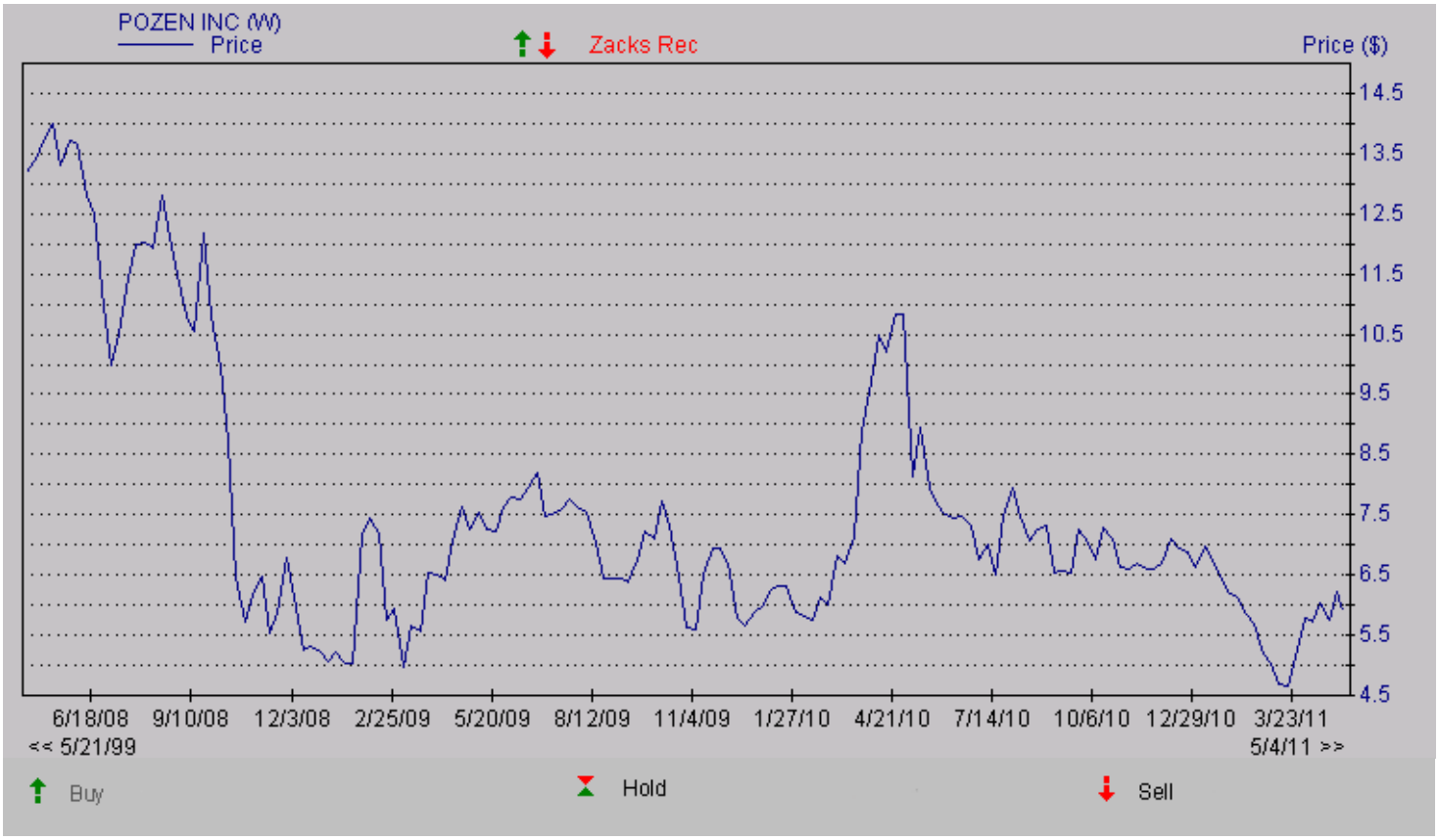
Income statement

	2009 A	2010 A	Q1 A	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Treximet (sales)	$86.1	$87.3	$22.0	$23.0	$24.0	$24.0	$93.0	$96.0	$100.0	$104.0
Treximet (royalty)	**$4.3**	**$15.7**	**$4.0**	**$4.1**	**$4.3**	**$4.3**	**$16.7**	**$17.3**	**$18.0**	**$18.7**
YOY Growth	*83.6%*	*265.0%*	*4.8%*	*1.0%*	*11.1%*	*7.9%*	*6.5%*	*3.2%*	*4.2%*	*4.0%*
Vimovo (sales)	$0	$4.6	$4.1	$8.0	$14.0	$24.0	$50.1	$121.7	$171.9	$227.3
Vimovo (royalty)	**$0**	**$0.5**	**$0.4**	**$0.8**	**$1.4**	**$2.4**	**$5.0**	**$12.2**	**$17.2**	**$22.7**
YOY Growth	-	-	-	-	-	-	*989.1%*	*143.0%*	*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	$4.5	$4.9	$5.7	$6.7	$21.8	$29.5	$45.2	$91.5
YOY Growth	*-51.3%*	*113.0%*	*-68.8%*	*17.0%*	*-82.2%*	*-3.0%*	*-68.3%*	*35.4%*	*53.4%*	*102.4%*
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%*	*96.7%*	*91.8%*
SG&A	$17.8	$23.8	$4.3	$4.5	$4.6	$4.6	$18.0	$22.5	$25.0	$30.0
% SG&A	*55.2%*	*34.7%*	*96.5%*	*91.1%*	*80.4%*	*68.5%*	*82.8%*	*76.4%*	*55.3%*	*32.8%*
R&D	$22.4	$22.6	$5.9	$6.5	$7.0	$7.5	$26.9	$30.0	$25.0	$25.0
% R&D	*69.7%*	*6+.%*	*132.5%*	*131.6%*	*122.4%*	*111.6%*	*123.7%*	*101.9%*	*55.3%*	*27.3%*
Operating Income	($8.0)	$22.1	($5.8)	($6.1)	($5.9)	($5.4)	($23.2)	($23.0)	($6.3)	$29.0
Operating Margin	*-24.9%*	*32.3%*	*-129.0%*	*-122.7%*	*-102.8%*	*-80.1%*	*-106.5%*	*-78.3%*	*-14.0%*	*31.7%*
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	($5.7)	($6.0)	($5.8)	($5.3)	($22.8)	($22.5)	$5.7	$29.6
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	($5.7)	($6.0)	($5.8)	($5.3)	($22.8)	($22.5)	($5.7)	$25.1
YOY Growth	-	-	-	-	-	-	*-198.8%*	*-1.1%*	*-74.7%*	*-540.0%*
Net Margin	*-21.3%*	*33.7%*	*-127.4%*	*-120.6%*	*-101.0%*	*-78.6%*	*-104.8%*	*-76.6%*	*-12.6%*	*27.5%*
Reported EPS	($0.23)	$0.76	($0.19)	($0.20)	($0.19)	($0.17)	($0.76)	($0.74)	($0.18)	$0.78
Fully Diluted Shares	29.9	30.2	29.9	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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