Zacks Equity Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Vimovo Approved! Let The Good Times Roll…

UPDATE

Pozen is one of our top-picks for small-cap biotech. We see the fundamentals as strong and the valuation as low.

With Vimovo now approved, Pozen is set to collect a $20 million milestone payment from AstraZeneca here in the second quarter 2010. Another potential $25 million could come late 2010 or early 2011 on the first Ex-U.S. approval. We see Vimovo as a $500 million product in the U.S. alone, with Pozen entitled to 10% royalty on net sales. The royalty payments off Vimovo and Treximet should drive the company to cash flow positive operations in 2011. The Vimovo approval also validates the pathway for Pozen's phase III PA-325/40 product.

We see the stock fairly-valued at $15 per share.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (05/03/10)	$10.85
Six- Month Target Price	**$15.00**

SUMMARY DATA

52-Week High	**$12.08**
52-Week Low	**$5.28**
One-Year Return (%)	**48.83**
Beta	**1.50**
Average Daily Volume (sh)	**1,084,376**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$324**
Short Interest Ratio (days)	**4.96**
Institutional Ownership (%)	**47**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**31.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**39.4**
P/E using 2011 Estimate	**11.9**
Zacks Rank	**3**

Risk Level	**Average,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**
Zacks Rank in Industry	**18 of 79**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	8.8 A	4.9 A	14.3 A	4.2 A	32.2 A
2010	6.9 A	26.7 E	7.4 E	8.1 E	49.1 E
2011					69.1 E
2012					$65.6 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.12 A	-$0.14 A	$0.22 A	-$0.19 A	-$0.23 A
2010	-$0.10 A	$0.55 E	-$0.13 E	-$0.15 E	$0.16 E
2011					$0.54 E
2012					$0.24 E

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

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WHAT'S NEW

Vimovo Approved!!!!

On April 30, 2010, Pozen and its partner, AstraZeneca, announced that the U.S. Food and Drug Administration (FDA) has approved Vimovo (naproxen and esomeprazole magnesium) delayed-release tablets for the relief of signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), and ankylosing spondylitis (AS), and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. Based on FDA approval, Pozen has earned a $20 million milestone payment from AstraZeneca. We expect that this milestone will be recognized in full in the second quarter 2010. AstraZeneca should be in position to launch Vimovo early in the third quarter 2010. Pozen is entitled to 10% royalty on net Vimovo sales.

AstraZeneca submitted a Marketing Authorization Application (MAA) to the European Medicines Association (EMEA) for Vimovo in October 2009. In total, AstraZeneca has filed applications in over 25 countries outside of the U.S. We expect the first responses to start coming back toward the end of the year. Pozen is entitled to a $25 million milestone payment from AstraZeneca for Vimovo's first approval outside the U.S. To be conservative, we do not model recognition of this payment until early 2010.

…A Potential Blockbuster Product…

We see Vimovo as a $500+ million product in the U.S. alone. 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 management, approximately 50% of OA / RA patients are at risk for gastrointestinal (GI) damage. In the U.S., 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. The Vimovo "safer naproxen" product looks to have efficacy on par with Vioxx and Celebrex, with low-risk GI damage thanks to the esomeprazole component, and a cardiovascular risk profile determined to be no greater than placebo (risk ratio = 0.97, 95%: 0.87-1.07, McGettigan et al., JAMA, September 12, 2006).

We remind investors that drugs such as Prilosec and Nexium are already approved for daily use with naproxen. Nexium is a $5 billion product worldwide. We estimate approximately 10% of the Nexium sales are coming from patients co-prescribed the drug as a gastro-protectant. Even during the Cox-II market peak, physicians often recommended patients take a PPI such as esomeprazole as a safety precaution with Celebrex and Vioxx. The combination into one pill will greatly improve patient compliance and ease of use. We believe there is significant unmet prescription need caused by the removal of the Cox-II drugs. A sizable number of patients are still taking enteric-coated naproxen. Over half of these patients are at high risk for gastric ulcers. We believe Vimovo represents a safer option for patients than Cox-II drugs or enteric-coated naproxen. In fact, we would not be surprised to see AstraZeneca and Pozen develop a lower-dose version of PN seeking a potential move to over-the-counter (OTC) once the prescription candidate loses patent protection in 2023.

First Quarter 2010 Financials…

On April 29, 2010, Pozen reported financial results for the first quarter 2010. Total revenues for the quarter were $6.9 million and consisted of $3.1 million in amortization of upfront payments from AstraZeneca and $3.8 million in royalty payments from GlaxoSmithKline on $21.0 million in U.S. sales of Treximet. For the first quarter 2010, Pozen reported a net loss of $3.0 million, or $0.10 per share. The company exited the first quarter ended March 31, 2010 with $36.7 million in cash and investments. Thanks to the receipt of the $20 million milestone from AstraZeneca on the U.S. approval of Vimovo, we expect that Pozen will exit the second quarter 2010 with roughly $50 million in cash on the books. We believe this is enough to fund operations to cash flow positive in 2011, including the future development and commercialization of PA-325/40.

INVESTMENT THESIS

Pozen is one of our top picks in the small-to-mid cap biotechnology industry. We view the company as financially sound, with now over $50 million in cash on hand and another potential $25 million coming in early 2011 from the first Ex-U.S. approval of Vimovo. The royalty line should begin to dramatically accelerate over the next few quarter as sales of both Treximet and Vimovo ramp at Glaxo and AstraZeneca, respectively. Based on our financial model, Pozen should turn cash flow positive in 2011 based on the royalties off the Treximet and Vimovo ramp. Plus, Pozen still offers shareholders significant opportunity for upside with the currently ongoing phase III program on PA-325/40. We are adjusting our price target higher on the approval of Vimovo from $12 to $15 per share to account for the lower risk profile and the significant cash influx from the approval milestone.

OVERVIEW

Treximet Ramping Slowly…

Sales of Treximet in the first quarter 2010 totaled only $21.0 million at Glaxo. This resulted in a royalty payment from Glaxo to Pozen of approximately $3.8 million. Sales continue to track far below expectations since the launch almost two years ago. Sales in 2008 were hampered by the lack of approved marketing material. Sales in 2009 were hampered by significant sampling and widespread misconception that the product had poor reimbursement (tier-3 vs. the actual tier-2) status. In the first quarter 2010, sales were negatively impacted by increased co-pays and confusion around potential big changes coming to the prescription drug market with healthcare reform. This seemed to be a systemic trend in the first quarter 2010, as total U.S. prescriptions were down for the quarter by 1.3% according to IMS Health. Treximet prescriptions were down 5.1% in the first quarter sequentially, in-line with the broader migraine triptan market, which was down 5.3%.

On a year-over-year basis, Treximet sales were up 3% from the first quarter 2009. Total prescriptions grew by 8%. However, the royalty payment to Pozen was up 272% in the first quarter 2010 thanks to the jump in royalty rate from 5% to now 18% at the start of 2010. Sales in the second quarter should give us a sense on where Treximet is going in 2010.

We think it is safe to say that Glaxo significantly botched the launch of Treximet over the past two years. The question is can Glaxo get it turned around and ramp the drug to the $250 million product in the U.S. we think it can still be? The company is back with a new plan for Treximet. The sales force has been once again realigned and incentivized to drive sales. The number of reps detailing Treximet is over 650, including 500 to the primary care market and 150 to migraine specialists. Paramount to driving uptake for Treximet is to rectify the still widespread misconception that Treximet is a poorly reimbursed product, or a line-extension of the now generic Imitrex. Treximet has greater than 50% tier-2 status and Glaxo is currently providing a coupon to narrow the co-pay gap between generic sumatriptan and Treximet to help drive uptake. Based on market research, 98% of the patients that try Treximet give the product a favorable rating, and 75% believe Treximet to be superior to their current migraine prevention therapy.

For 2010 we forecast Treximet sales of $96 million, up 12% from 2009. However, as noted above, the reason to be bullish on Pozen with respect to Treximet in 2010 is that the royalty rate has now increased from 5% to 18%. Sales of $96 million will provide Pozen will $17 million in cash in 2010. This provides significant non-dilutive capital into Pozen, enough to cover the underlying SG&A expense.

…Pozen Defending Its IP…

Late in 2008, Pozen learned that generic drug manufacturer Par Pharmaceuticals has submitted an abbreviated new drug application (ANDA) for approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets, a generic version of Treximet. Including in the ANDA is a “paragraph IV” certification claim that Par believes its version of Treximet either does not infringe on Pozen’s patent, or that the patient is invalid. We view this filing as normal, and at this time we have confidence in Pozen’s intellectual property and do not believe a generic Treximet will launch

until the patent expires in 2017. Pozen has filed an injunction against Par under Hatch-Waxman, which precludes the launch of an alternative sumatriptan / naproxen product until October 2011 – assuming a pediatric extension.

These pediatric studies are currently underway at Glaxo. In the meantime, Pozen intends to vigorously defend its intellectual property against Par. The company is gearing up a lawsuit to start in the fourth quarter of 2010. Legal fees in the first quarter 2010 were approximately $2.2 million. For the full year 2010, we expect that legal fees will total roughly $6 to 8 million to defend the Treximet intellectual property. We note that in mid-April 2010, Teva Pharmaceuticals came to a settlement agreement with Pozen on Treximet, exiting the consolidated litigation. We would not be surprised to see either Dr. Reddy or AlphaPharm also look exit the lawsuit prior to the start of the trial. We expect Par to push the litigation to trial, as Par has the first-to-file exclusivity on Treximet should they win.

Vimovo Approved!

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Vimovo is a combination of 500mg enteric coated naproxen (ECN) and 20mg immediate release esomeprazole. Previous clinical work at Pozen and AstraZeneca proved bioequivalence to naproxen, so the drug can be used for the treatment of chronic pain in the enormous market opportunities, including the 25-30 million Americans that suffer from osteoarthritis (OA), rheumatoid arthritis (RA), or other instances of pain such as ankylosing spondylitis. The phase III data demonstrated a significant reduction in the risk of gastrointestinal (GI) adverse events (below):

PN-400 Phase III	Study 301: (n=434)		Study 302: (n=420)	
	Vimovo	ECN	Vimovo	ECN
Reported Incidence of Gastric Ulcers (GU)	4.1%	23.1%	7.1%	24.3%
	(p<0.001)		(p<0.001)	
Endoscopic Confirmed Duodenal Ulcers (DU)	0.5%	5.1%	1.0%	5.7%
	(p=0.003)		(p<0.007)	
Severity of Dyspepsia Assessment (SODA)	-5.51	-0.15	-2.64	-0.47
	(p<0.001)		(p<0.001)	
Overall Treatment Evaluation for Dyspepsia (OTE-DP)	+45.6%	+27.8%	+42.9%	+34.4%
	(p<0.001)		(p=0.017)	
Discontinuation Due to Upper Gastrointestinal Events	3.2%	12.0%	4.8%	11.0%
	(p<0.001)		(p=0.009)	

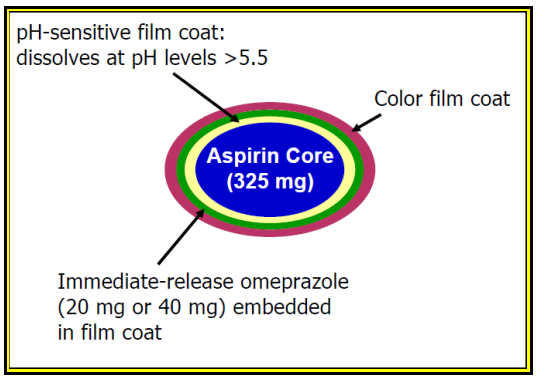
We see Vimovo as a potential $500+ million product. Cox-II drugs such as Vioxx and Celebrex, designed to provide safer gastrointestinal profile, peaked sales at over $7 billion worldwide in 2004 before Vioxx was pulled from the market for cardiovascular risk. According to management, approximately 60% of the OA / RA patients worldwide are at risk for gastrointestinal (GI) damage. 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. The Vimovo "safer naproxen" product looks to have efficacy on par with Vioxx and Celebrex, with low-risk GI damage thanks to the esomeprazole component, and a cardiovascular risk profile determined to be no greater than placebo (risk ratio = 0.97, 95%: 0.87-1.07, McGettigan et al., JAMA, September 12, 2006).

We remind investors that drugs such as Prilosec and Nexium are already approved for daily use with naproxen. Physicians that prescribed Celebrex and Vioxx often recommended patients also take a PPI such as esomeprazole as a safety precaution. The combination into one pill will greatly improve patient compliance and ease of use. We believe there is significant unmet prescription need caused by the removal of the Cox-II drugs. A sizable number of patients are still taking enteric-coated naproxen. Over half of these patients are at high risk for gastric ulcers. We believe Vimovo represents a safer option for patients than Cox-II drugs or enteric-coated naproxen. In fact, we would not be surprised to see AstraZeneca and Pozen develop a lower-dose version of PN seeking a potential move to over-the-counter (OTC) once the prescription candidate loses patent protection.

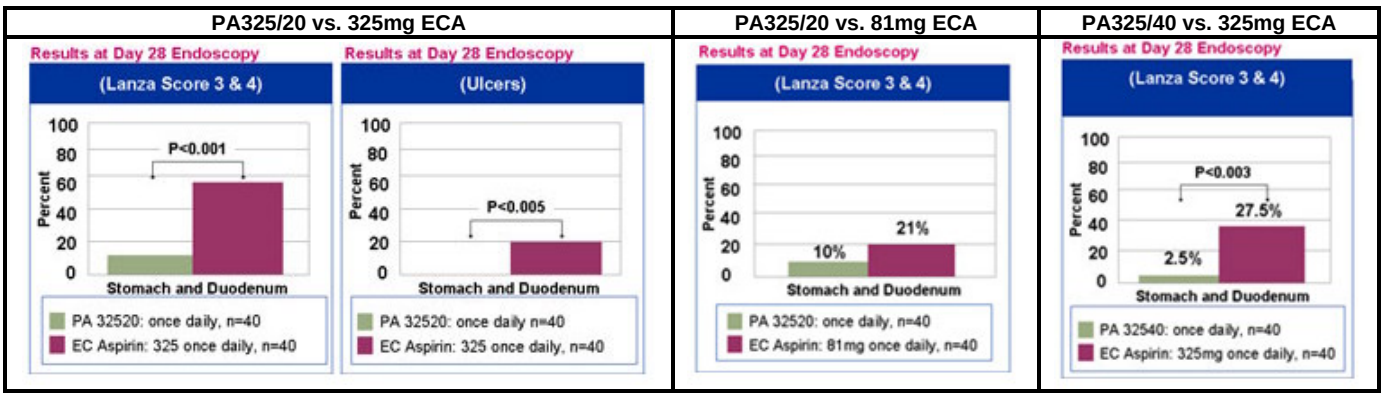
Bulling On PA-325…

On December 8, 2009, Pozen held an analyst and investor meeting in New York highlighting the potential for the company's phase III candidate, PA-325/40. The meeting featured prominent medical experts touting the potential benefits of aspirin therapy for the treatment of cardiovascular disease and colon cancer, while outlining the challenges that the PA product overcomes with respect to gastrointestinal safety. We think this is easily a $500+ million product in the U.S. alone.

Pozen has designed the PA-325/40 product to be a "safer aspirin" for daily use. PA-325/40 is 325mg of aspirin surrounded by a film coating of a 40mg immediate-release omeprazole. The PPI omeprazole provides gastrointestinal (GI) protection from the potential harmful effects of high-dose aspirin, including GI bleeding and ulcers. In addition, in-between the omeprazole and aspirin is a thin pH-sensitive film that only dissolves when the stomach is at pH >5.5, ensuring that no aspirin is released until the omeprazole has taken effect. Below is a cartoon representation of the PA product:



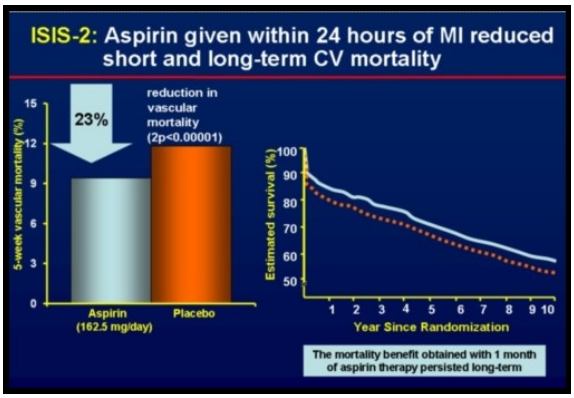
In June 2008, Pozen announced that it had filed a Special Protocol Assessment (SPA) with the U.S. FDA for pivotal phase III program on PA-325/40. As part of the SPA filing Pozen provided data proving the bioequivalence of PA-325/40 to 325mg of enteric-coated aspirin (ECA) with significant improvement in GI protection. By demonstrating bioequivalence to enteric coated aspirin, management believes PA-325/40, if approved, will receive all of aspirin's claims for the secondary prevention of cardiovascular events, including heart attacks and strokes. Below are graphical representations of the proof-of-concept data on PA. These results show significant GI protection for Pozen's PA product relative to enteric coating. In fact, Pozen's PA-325/20 product offered less GI-related damage (Lanza 3 / 4 scores) than 81mg "baby" aspirin.



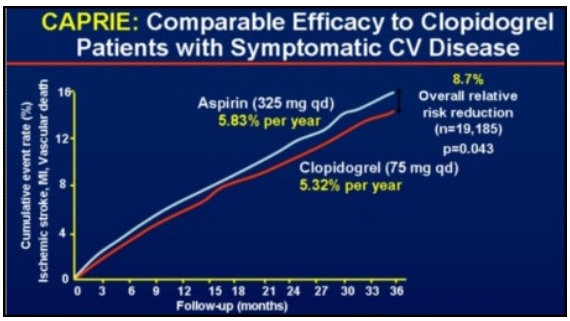
Pozen began the phase III product under U.S. FDA Special Protocol Assessment in October 2009. Enrollment in the two pivotal programs should continue through the end of the year. The design for the phase III program mirrors that of the Vimovo program, with the patient population skewed a little older and potentially more prone to cardiovascular disease. Two phase III trials will enroll around 500 patients each, with the primary endpoint being cumulative incidence of gastric ulcers over a six-month treatment period. Bioequivalence will also be confirmed. There will also be a long-term safety program that plans to enroll roughly 400 patients that will study patients on PA-324/40 for a period of 12 months. Enrollment in this program should be completed shortly. We expect Pozen will have all the necessary data from the phase III PA trials in hand by the third quarter of 2011 and look to file the new drug application (NDA) late 2011 or early 2012. Management is also in discussions with various European authorities working through potential dosing issues that are necessary to meet European regulatory standards.

…PA for Cardiovascular Disease…

No market in the pharmaceutical industry is larger than cardiovascular disease (CVD) prevention. CVD is the leading cause of death worldwide with over 50% mortality. Roughly 50% of newborns in the U.S. will eventual die from CVD, with about half of those due to coronary artery disease. An American has a heart attack roughly every 26 seconds. It is truly an enormous market for which the pharmaceutical industry has spent hundreds of billions of dollars on over the past twenty years. 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.



Aspirin clearly is an effective drug for the reduction in risk of a future CVD event. However, what's more interesting is the direct comparison of aspirin, a drug that costs pennies a day and is available OTC, to Bristol-Myers and Sanofi's Plavix. Data from the CAPRIE (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events) in 1996 shows that Plavix (clopidogrel) offers only a modest 8.7% efficacy improvement over aspirin.



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 stronger efficacy and with the improved GI safety profile of Plavix has allowed Bristol-Myers and Sanofi to turn Plavix into the world's second best selling pharmaceutical product with sales over $7 billion worldwide in 2008. But most cardiologists agree aspirin is not being used to its full potential. Aspirin's limitations of GI intolerance and bleeding are what keep the daily recommended dose far below 325mg. 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.

Both the AHA and ACG recommend gastro-protective therapy in patients that take daily aspirin. Aspirin is the backbone of many cardiovascular therapies, including in combination use with Plavix. However, a VA Hospital study showed that less than 30% of the patients taking daily aspirin, either for pain or for secondary cardiovascular prevention, are co-prescribed a GI-protectant. And, even in patients that are co-prescribed the GI-protectant, only half comply. That means potentially 85% of patients that are at risk for developing GI-related complications due to aspirin therapy (ulcers / bleedings) are not taking a gastro-protective. Instead of taking 325mg per day, patients and physicians are migrating down to less-effective doses at 81mg.

Pozen's PA-325/40 delivers the effective dose of 325mg aspirin while offering substantial GI-protection. PA-325/40 is designed to have less GI-related adverse events than Plavix. We think this narrowing of the perceived safety gap between Plavix and aspirin, knowing that Pozen will price PA-325/40 far cheaper than Plavix, will allow for the drug to capture sizable market share gains in the daily aspirin or co-prescribed Plavix+aspirin population.

…Plavix + PPI Issue…

Recent data from a meta-analysis from MEDCO demonstrated that use of PPI, such as omeprazole, negatively impacts the effectiveness of Plavix. Data from 16k patients on Plavix analyzed the effects of a PPI and found a higher survival rate for patients not on PPI (event rate: 25.1% for PPI vs. 17.9% for no PPI; hazard ratio = 1.51) than those on PPI. Sanofi has placed a voluntary warning on the label for Plavix cautioning against use of a concurrent PPI. We believe this has negatively impacted Pozen's stock over the past few months as investors fear the PA-325/40 product will not use allowed for use with Plavix. We believe this is premature, as the meta-analysis conducted by MEDCO was not a randomized program and patient populations were not identical. Additionally, use of the commercially available PPI, omeprazole (Prilosec) is not comparable to Pozen's PA formulation. AstraZeneca's Prilosec is a delayed release formulation with the majority of daily use taken at the same time as Plavix. The omeprazole used by Pozen in the PA product is an immediate-release, and patients can be instructed to dose PA-325/40 in the morning and Plavix at night. Pozen is actually doing a Plavix-PPI interaction study with data expected in 2010. We do not believe that use of Pozen's PA-325/40 will be contraindicated for use with Plavix.

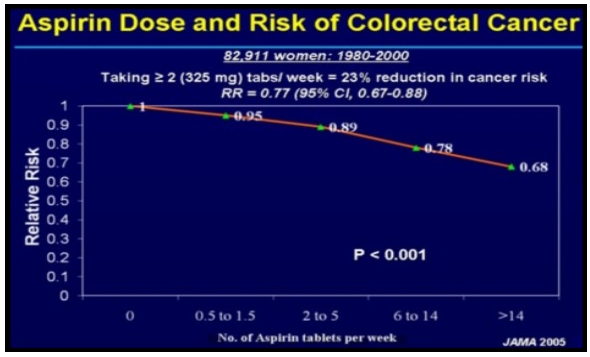
…PA for Pain...

Pozen believes that there is a point of differentiation between a safer aspirin concept and all other products in the arthritis space, including the recently approved Vimovo. As such, management is looking to develop an even higher dose PA product, PA-650/20, for the potential treatment of pain. Management has been in discussion with the U.S. FDA on an investigation new drug (IND) application for this indication and hopes to begin a phase I program with PA-650/20 later this year. If the trial proceeds as planned, Pozen should be in position to begin a phase III program with PA-650/20 in pain in late 2010 or early 2011.

All NSAIDs, including Vimovo, have a black box warning for cardiovascular risk. And, even though naproxen is believed to be the safest of all available NSAIDs, the FDA still requires a bolded risk on the label for contraindication in patients at risk for cardiovascular thrombotic events, myocardial infarction, and stroke, or for patients undergoing at coronary artery bypass graft (CABG) surgery.

…PA for Cancer Prevention...

Besides the potential for high-dose daily aspirin in cardiovascular disease prevention, Pozen and key opinion leaders in oncology believe that significant potential exists in colorectal cancer prevention. There are an estimated 150k cases of colon or rectal cancer in the U.S each year, with 50k deaths. Colon cancer develops as the normal epithelium cells of the colon began to hyperproliferate into the formation of a small adenoma. If not treated, the small adenoma grows larger and can eventually turns cancerous. Diet, alcohol and smoking lead to increased risk factors for the development of colon cancer. 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." Similar to cardiovascular disease, aspirin, a proven effective drug for prevention, is not being used to the full potential because of the negative GI-related side effects.

This is why we think Pozen's PA-325/40 product has significant sales potential. It is aspirin without the harmful side effects. PA-325/40 "safer aspirin" could be a blockbuster drug. We expect Pozen to price PA-325/40 between a branded pharmaceutical product like Plavix ($3-4/day) and OTC/generic aspirin ($0.10/day).



RECOMMENDATION

We continue to be very positive on the Pozen story. With Vimovo now approved, Pozen is set to collect a $20 million milestone payment from AstraZeneca here in the second quarter 2010. Another potential $25 million could come late 2010 or early 2011 on the first Ex-U.S. approval. We see Vimovo as a $500 million product in the U.S. alone, with Pozen entitled to 10% royalty on net sales. Treximet sales have been a disappointment, but the product is slowly ramping and with the royalty rate increasing to 18% in 2010, the cash to Pozen is significant. The royalty payments off Vimovo and Treximet should drive the company to cash flow positive operations in 2011.

But perhaps the most exciting product at Pozen is PA. Millions of people are taking daily aspirin for cardiovascular secondary prevention, the majority without a gastro-protectant. PA offers significantly improved GI tolerability to enteric-coated aspirin, and the potential to increase the dose to therapeutic levels that can also treat pain and may reduce the risk of pre-cancerous colon adenomas. We see Pozen fairly-valued at $15 per share.

PROJECTED INCOME STATEMENT

POZEN INC.

Income statement

	2009 A	Q1 A	Q2 E	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E	2014 E
Treximet (sales)	$86.1	$21.0	$23.5	$25.0	$26.5	$96.0	$128.0	$152.0	$168.0	$178.0
Treximet (royalty)	**$4.3**	**$3.8**	**$4.2**	**$4.5**	**$4.8**	**$17.3**	**$23.0**	**$27.4**	**$30.2**	**$32.0**
YOY Growth	*83.6%*	*272.4%*	*345.3%*	*273.4%*	*320.3%*	*301.4%*	*33.3%*	*18.8%*	*10.5%*	*6.0%*
Vimovo (sales)	$0	$0	$0	$18.8	$28.4	$47.1	$160.5	$282.3	$410.2	$544.1
Vimovo (royalty)	**$0**	**$0**	**$0**	**$1.9**	**$2.8**	**$4.7**	**$16.1**	**$28.2**	**$41.0**	**$54.4**
YOY Growth	-	-	-	-	-	-	*240.5%*	*75.8%*	*45.3%*	*32.6%*
PA-325/40 (Sales)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$100.0**	**$200.0**
YOY Growth	-	-	-	-	-	-	-	-	-	*100.0%*
Licensing / Development	**$27.9**	**$3.1**	**$22.5**	**$1.0**	**$0.5**	**$27.1**	**$30.0**	**$10.0**	**$5.0**	**$5.0**
YOY Growth	*-56.3%*	*-59.4%*	*467.3%*	*-92.4%*	*-83.8%*	*-2.6%*	*10.5%*	*-66.7%*	*-50.0%*	*0.0%*
Total Revenues	$32.2	$6.9	$26.7	$7.4	$8.1	$49.1	$69.1	$65.6	$176.3	$291.4
YOY Growth	*-51.3%*	*-50.7%*	*-59.6%*	*-88.8%*	*-7.4%*	*52.7%*	*40.6%*	*-5.1%*	*168.7%*	*65.3%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$15.0	$30.0
Product Gross Margin	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*91.2%*	*89.5%*
SG&A	$17.8	$5.2	$5.3	$5.4	$5.5	$21.4	$25.5	$30.0	$40.0	$50.0
% SG&A	*55.2%*	*75.2%*	*19.8%*	*73.2%*	*67.9%*	*43.6%*	*36.9%*	*45.7%*	*22.7%*	*17.2%*
R&D	$22.4	$4.7	$5.5	$6.5	$7.5	$24.2	$30.0	$30.0	$25.0	$25.0
% R&D	*69.7%*	*68.1%*	*20.6%*	*88.1%*	*92.5%*	*6+.%*	*43.4%*	*45.7%*	*14.2%*	*8.6%*
Operating Income	($8.0)	($3.0)	$15.9	($4.5)	($4.9)	$3.5	$13.6	$5.6	$96.3	$186.4
Operating Margin	*-24.9%*	*-43.3%*	*59.6%*	*-61.3%*	*-60.4%*	*7.2%*	*19.7%*	*8.5%*	*54.6%*	*64.0%*
Interest Income / Net	$0.5	$0.0	$0.4	$0.5	$0.4	$1.3	$2.8	$3.1	$3.6	$4.1
Pre-Tax Income	($7.5)	($3.0)	$16.3	($4.0)	($4.5)	$4.8	$16.4	$8.7	$99.9	$190.5
Taxes	($0.63)	$0	$0	$0	$0	$0	$0	$1.3	$32.0	$61.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*15.0%*	*32.0%*	*32.0%*
Net Income	($6.9)	($3.0)	$16.3	($4.0)	($4.5)	$4.8	$16.4	$7.4	$67.9	$129.6
YOY Growth	-	-	-	-	-	-	*238.2%*	*-55.0%*	*819.6%*	*90.8%*
Net Margin	*-21.3%*	*-42.8%*	*61.1%*	*-54.5%*	*-55.4%*	*9.9%*	*23.7%*	*11.3%*	*38.5%*	*44.5%*
Reported EPS	($0.23)	($0.10)	$0.55	($0.13)	($0.15)	$0.16	$0.54	$0.24	$2.16	$4.05
FAS-123R Expense	$5.1	$0.8	$1.4	$1.3	$1.4	$4.9	$6.0	$6.5	$7.0	$7.5
EPS Impact of FAS-123R	($0.17)	($0.03)	($0.05)	($0.04)	($0.05)	($0.16)	($0.20)	($0.21)	($0.22)	($0.23)
Fully Diluted Shares	29.9	29.8	29.9	30.0	30.1	30.0	30.5	31.0	31.5	32.0

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

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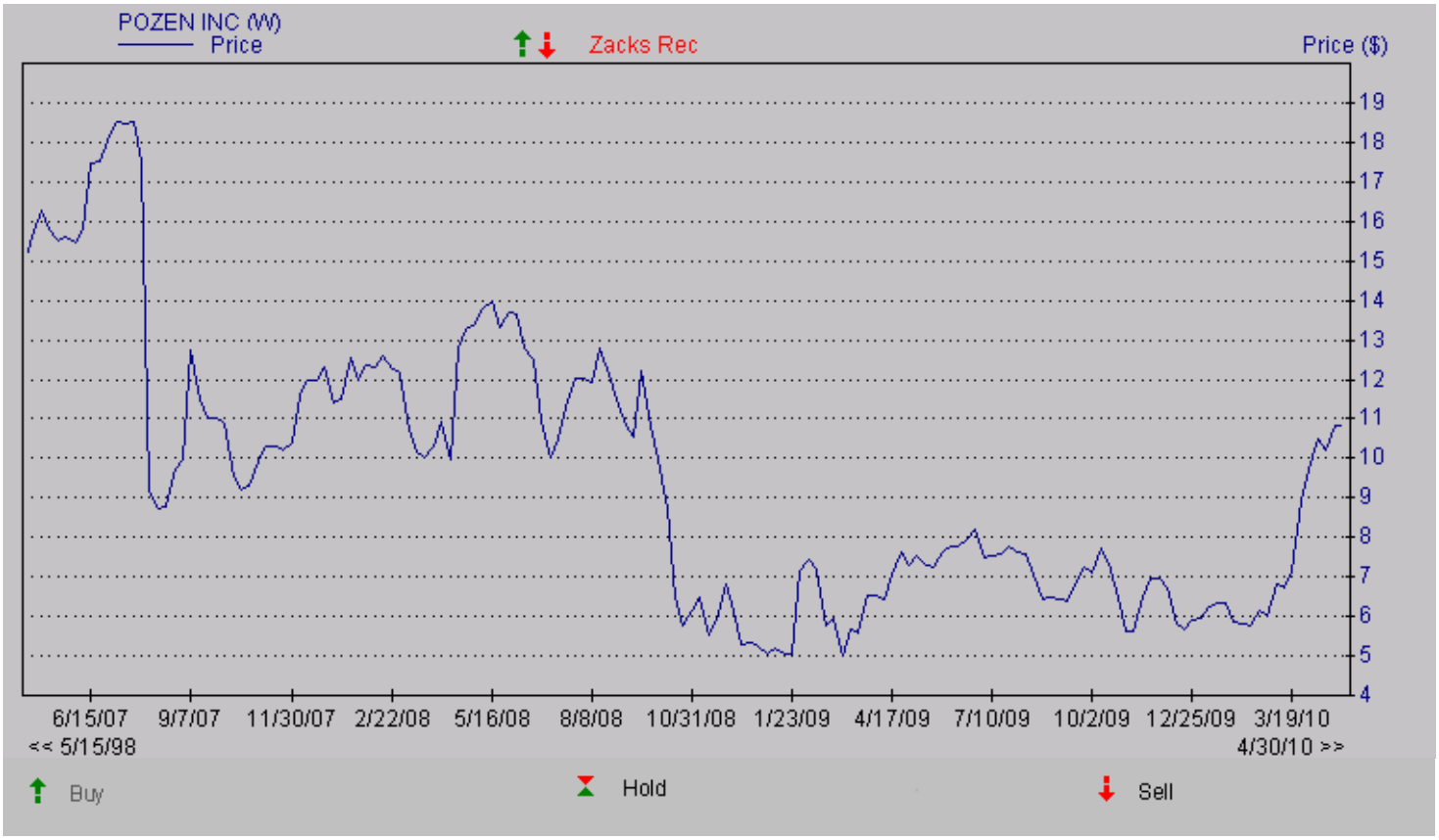
HISTORICAL ZACKS RECOMMENDATIONS



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