Zacks Small-Cap Research

September 5, 2013
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POZEN, Inc. (POZN-NASDAQ)

POZN: Pozen Partners With Sanofi For U.S. Commercialization of PA-325/40.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (09/05/13)	$5.84
Target Price	**$9.00**

UPDATE

On September 3, 2013, Pozen Inc. entered into a licensing and collaboration agreement with Sanofi-aventis U.S. (SNY) 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. We view the deal is a great strategic fit for Pozen (and Sanofi).

We continue to be optimistic on the story and believe the stock is under-valued today. Our rating is 'Outperform' and our target is $9.00.

SUMMARY DATA

52-Week High	**$6.68**
52-Week Low	**$4.50**
One-Year Return (%)	**-17.73**
Beta	**1.39**
Average Daily Volume (sh)	**125,912**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$161**
Short Interest Ratio (days)	**13.98**
Institutional Ownership (%)	**54**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**4.1**
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	16.8 E	2.9 E	21.7 E
2014					39.4 E
2015					31.9 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	$0.36 E	-$0.14 E	-$0.10 E
2014					$0.43 E
2015					$0.07 E

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WHAT'S NEW

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 U.S. (SNY) 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 the licensing and collaboration agreement yesterday 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 comes 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.

Pozen will retain responsibility for obtaining FDA approval for PA. The duo has 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. However, at this stage we believe approval in January 2014 seems likely given that Pozen completed two positive Phase III 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.

...Hoping The Third Time Is A Charm...

Despite Pozen's impressive history of gaining approval for its products and finding big-name pharmaceutical partners to commercialize them, sales of both Treximet (at GSK) and Vimovo (at AZN) have disappointed. Both products faced stiff competition from their generic components and both Glaxo and AstraZeneca over-priced the drugs in the face of the cheaper alternatives. That being said, we expect things with PA to be different. Pozen has spoken in great length about the desire to launch PA at around $1 per day, a low enough cost that should greatly facilitate broad tier-2 formulary coverage. This affordable pricing strategy may actually reduce the out-of-pocket cost for millions of Americans taking daily aspirin therapy for secondary prevention indications. We have written in the past that this pricing and go-to-market strategy for PA is what should separate the product from the past failures of Vimovo.

Nevertheless, Pozen, having been burned in the past by lackluster efforts from Glaxo on Treximet and unwise pricing strategies on Vimovo from AstraZeneca, has added a clause to the above agreement with Sanofi for PA, noting that Pozen can seek to acquire the U.S. rights to PA back in two years after the launch if sales are less than a specified (undisclosed) amount. In return, Sanofi has agreed to use commercially reasonable efforts to sell PA, specifying advertising and promotional expense levels and sales details for the first two years under this agreement.

We Think PA Will Do Just Fine

Any pending FDA approval is a wildcard event, but we believe odds strongly favor approval of PA-325/40 and PA-81/40 in January 2014. We find it interesting that the Pozen earnings press release on August 6, 2013 even contained the proposed label for PA:

Proposed PA Indications and Usage (Pending FDA Review and Approval)

PA8140/PA32540 Tablets contain 81 mg or 325 mg delayed release aspirin and 40 mg immediate-release omeprazole and are indicated for patients who require aspirin (1) to reduce the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, (2) to reduce the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, (3) to reduce the combined risk of MI and sudden death in patients with chronic stable angina pectoris, (4) in patients who have undergone revascularization procedures (CABG, PTCA) when there is a pre-existing condition for which aspirin is already indicated, and to decrease the risk of developing gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers.

Under this proposed label, we see PA as a $365 million drug in the U.S. Below is a "back-of-the-envelope" calculation on how we arrive at this figure - with additional details available in our report below.

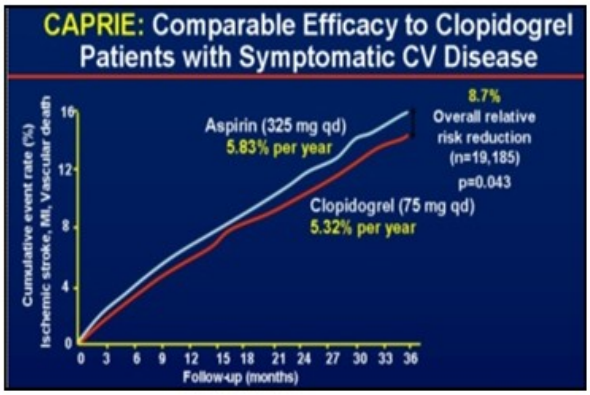
24 Million American's with history of CV disease (secondary prevention)
- Approximately 95% on medication
- Approximately 60-80% take Apspirin
- Pozen's Market Research shows 30-40% physician acceptance
- Pozen's Market Research shows 36% patients willing to pay $1/day
- Payors coverage PA at Tier-2 (cost-neutral) at $1/day

This equates to 2·0 million patients @ $365/year = $734 Million Peak Sales

We cut this number if half (to be conservative) - Thus model $365 Million·
Assume sales outside the U·S· is around half that, or around $180 Million·
Thus, we model Peak WW sales of $500 Million for our vaulation model·

Two things we find encouraging from the licensing agreement yesterday give us confidence in our previous forecast. Firstly, probably no company in the world knows the secondary prevention market better than Sanofi-aventis. The company spent 15 years from 1997 to 2012 marketing and promoting Plavix (clopidogrel) for indications like acute coronary syndrome and prevention of ST-elevation myocardial infarction. Plavix has been shown to reduce cardiovascular death, re-infarction, and stroke.

Data from the CAPRIE trial (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events) shows Plavix and aspirin have pretty darn similar efficacy in reducing the incidence of a major adverse cardiovascular event. Plavix offers only a modest 8.7% efficacy improvement over aspirin, and Plavix posted sales over $7 billion worldwide at its peak. Evidence shows 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%

So the fact that Sanofi, a company that spent 15 years talking-up and promoting Plavix as superior to enteric-coated aspirin, is now on board with Pozen's PA "safer aspirin" product says a lot. No one knows this market better than Sanofi, and it's hard to imagine them throwing away $35 million upfront to Pozen for a drug they don't see as a contributor to their top-line.

The second encouraging point from the deal is the $35 million upfront and approval milestone. Although not set in stone, 10% of the peak sales in that region is often what is agreed upon by the two partners for upfront and pre-commercialization milestones. Under that scenario, Pozen and Sanofi may have agreed that PA is a $350 million drug in the U.S. That's darn near what we calculated above in our back-of-the-envelope analysis.

One final point worth noting, Pozen is in the process of preparing to file for PA in Europe. Pozen recently gained clarity from the Medicines Evaluation Board (MEB) regarding what is required for the approval of PA-325/40 and a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA-100/40). MEB confirmed that no Phase III trial was necessary for PA-100/40. Instead, Pozen recently conducted two Phase 1 studies to satisfy the MEB requests prior to filing the Marketing Authorization Application (MAA). These included one Phase 1 pharmacodynamic (PD) study demonstrating appropriate gastric pH control with PA-100/40 and one bioequivalence (BE) study comparing PA-100/40 to a currently marketed enteric-coated aspirin 100mg product. On a side note, The Netherlands has agreed to be the Reference Member State (RMS) in a decentralized filing procedure of PA-325/40 and PA-100/40. We think this is good news, as The Netherlands was the RMS for the European Vimovo application. To date, Vimovo has been approved in over 65 countries around the world. We anticipate that Pozen will look to push forward with the EU filing for PA in 2014. Sanofi would certainly be a nice partner for Europe as well. Above we noted that the EU represents another $180 million peak sales opportunity for the drug.

Conclusion

Pozen shares should be up nicely today. Investors have been waiting for a partnership on PA for a long time now. We first started getting interested in PA and the potential for a deal in 2010 shortly after Vimovo was approved. But the Vimovo soft launch by AstraZeneca muddied the waters, and Pozen has been a relatively boring investment for the past two years as a result. Above we've outlined our case that we believe sales of PA will be meaningfully better than Vimovo, and that Sanofi was an ideal partner to announce. Below we post a snap-shot of our DCF model on Pozen, which includes only the disclosed terms from the U.S. PA deal with Sanofi. Investors can see we are not expecting much from Vimovo in the next several years. We see PA as a $500 million product worldwide. This brings up to a fair-value target for Pozen of $9 per share. Pozen should exit the third quarter with nearly $90 million in cash on hand. The market value of only $180 million is too low in our view. Thus, we are maintaining our ‘Buy’ rating.

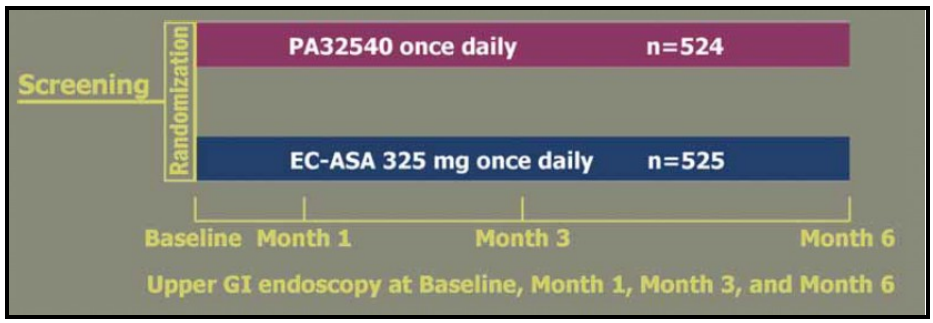
INVESTMENT OVERVIEW

Impressive Phase 3 Data On PA-325/40

Full data analysis from the integrated results of the two phase 3 trials with PA-325/40 has now been presented at numerous medical meetings. Management broke up the data between the American College of Gastroenterology (ACG) meeting in late October 2012, the American Heart Association (AHA) meeting in early November 2012, and most recently the American Heart Association International Stroke (AHA-Stroke) conference in early February 2013.

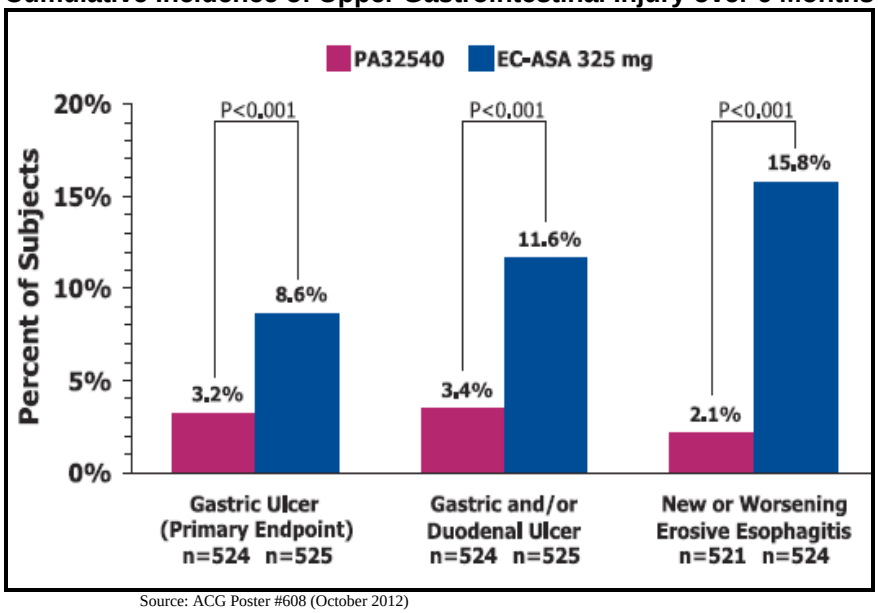
As a reminder, the two phase 3 studies compared PA-325/40 (EC-ASA 325 mg + IR omeprazole 40 mg) to enteric-coated aspirin (EC-ASA) 325 mg in patients requiring aspirin (ASA) for secondary cardiovascular prophylaxis who were at risk for ASA-associated gastric ulceration. In the two phase 3 trials, 1,049 subjects were randomized to either PA-325/40 or EC-ASA 325 mg, taken once daily in the morning on an empty stomach, approximately 1 hour before breakfast.

At baseline, subjects were required to be *H. pylori* stool-antigen negative and have no endoscopic ulcers. Subsequent endoscopies were performed at months 1, 3, and 6. Both trials were run under a special protocol assessment (SPA) with the U.S. Food and Drug Administration (FDA). The design can be seen below:



The primary endpoint of the study was cumulative proportion of subjects with endoscopically-confirmed gastric ulceration (defined as a mucosal break of at least 3 mm in diameter with depth) at any time throughout 6 months. Results below show an impressive separation for PA-325/40 vs. EC-ASA:

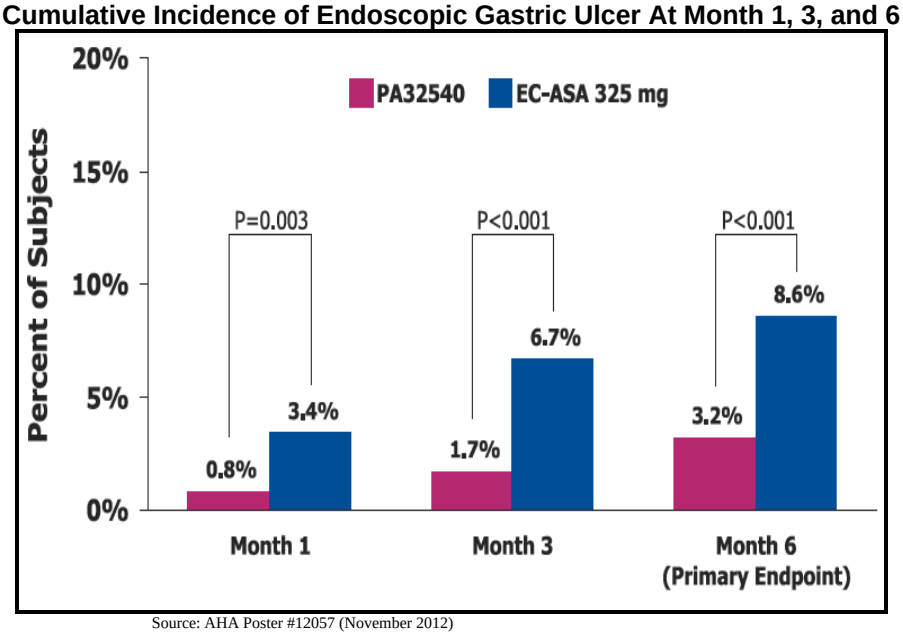
Cumulative Incidence of Upper Gastrointestinal Injury over 6 Months



Source: ACG Poster #608 (October 2012)

Results were even statistically significant as soon as one month after the start of the trial, and held (actually separated from EC-ASA 325 mg) as the trial progressed.

Cumulative Incidence of Endoscopic Gastric Ulcer At Month 1, 3, and 6



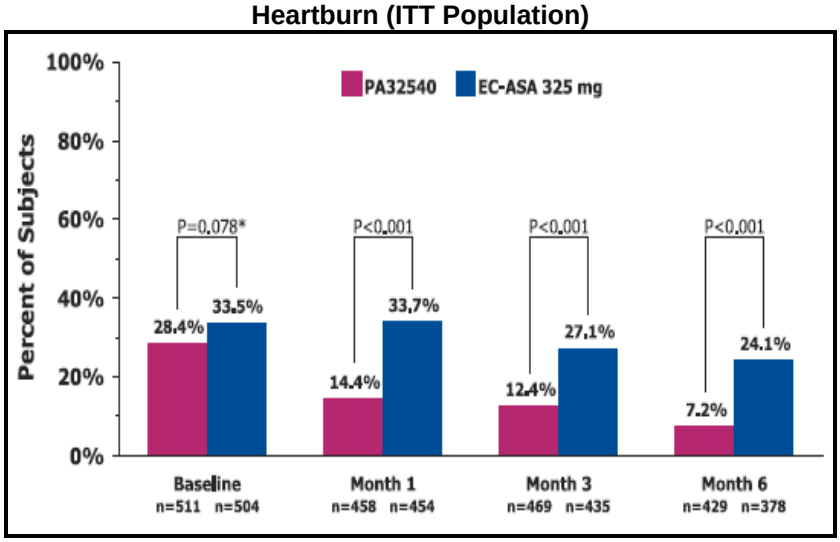
Source: AHA Poster #12057 (November 2012)

The data equate to an impressive 63% reduction in gastric ulcer. The results were remarkably consistent between the two studies, with PA-325/40 yielding 3.8% in Study-1 and 2.7% in Study-2 vs. 8.5% and 8.7%, respectively for EC-ASA 325 mg. Both trials were statistically significant on a stand-alone basis.

These results are consistent with our expectations and show the powerful efficacy of Pozen's drug. When duodenal ulcers were included in the analysis, the reduction increased to 71%. Data on new or worsening erosive esophagitis showed an astonishing 87% reduction in favor of Pozen's PA-325/40 verse EC-ASA 325 mg.

Secondary analysis also show statistically significant reductions in the presence of heartburn as reported on a standardized questionnaire at month 1, 3, and 6. A post-hoc esophageal mucosal assessment showed a meaningful and statistically significant reduction in new esophageal erythema (2.7% vs. 7.6%, p<0.001) and new esophageal erythema or new or worsening erosive esophagitis (4.8% vs. 22.5%, p<0.001).

Heartburn (ITT Population)

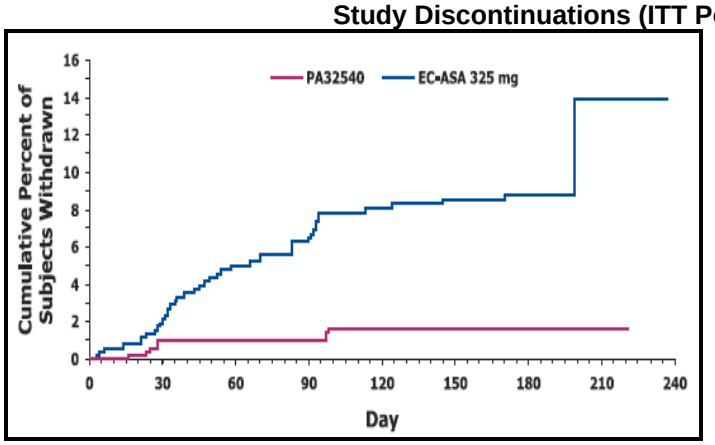


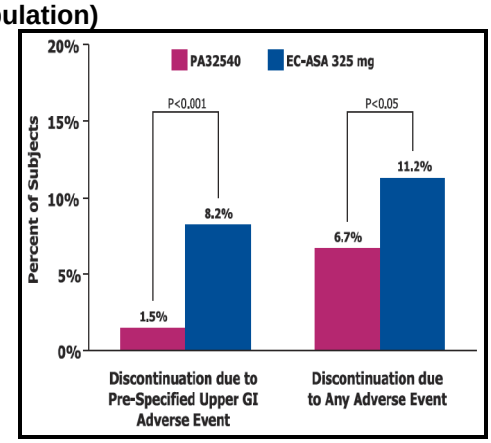
Additional post-hoc analysis of subjects with a history of transient ischemic attack (TIA) or stroke was recently analyzed and presented in February 2013 at AHA-Stroke. The data shows that long-term (6 months) treatment with PA-325/40, compared to EC-ASA (325 mg), was associated with a significantly reduced rate of endoscopic

gastroduodenal ulcers (2.0% vs. 12.4% respectively; p=0.005), and study discontinuation due to adverse pre-specified upper GI events (0% vs. 8.0% respectively; p=0.006). The incidence of adjudicated major adverse cardiac events was similar for PA32540 (2.9%) and EC-ASA (325 mg) (4.4%).

Discontinuation rates and treatment success at six months also showed strong statistical significance in favor of Pozen's PA-325/40 versus EC-ASA 325 mg. At six months, the observed incidence of discontinuations due to pre-specified upper-gastrointestinal events was significantly lower with PA-325/40 vs. EC-ASA 325 mg, 1.5% vs. 8.2%, p<0.001. Study discontinuations due to any adverse event showed a 40% reduction in favor of Pozen's drug, 6.7% vs. 11.2% (p<0.05).

Study Discontinuations (ITT Population)





Treatment success at six months was 95.2% for PA-325/40 vs. 83.2% for EC-ASA 325 mg, a 14% improvement in outcome based on intent to treat (p<0.001). However, if we flip that analysis and instead look at treatment failures, the ratios get even more impressive. A 95.2% success rate means a 4.8% failure rate, and an 83.2% success rate means at 16.8% failure rate. Compare 4.8% to 16.8% failure and investors will see that Pozen's drug yields a 71% reduction in treatment failure, with statistical significance. We see that as highly impressive clinical data; and data that should grab the attention of cardiologists as they are looking to effectively treat patients for the secondary prevention of cardiovascular events.

Treatment-emergent adverse events, included GERD, esophagitis, erosive esophagitis, or reflex esophagitis was 6.1% for PA-325/40 versus 23.9% for EC-ASA 325 mg (p<0.001).

Treatment-Emergent Adverse Events

Parameter	PA32540 (n=521)	EC-ASA 325 mg (n=524)
	Number of Subjects (%)	
Gastritis	91 (17.5)	84 (16.0)
Gastritis erosive	60 (11.5)	138 (26.3)
Dyspepsia	59 (11.3)	158 (30.2)
Hiatus hernia	46 (8.8)	56 (10.7)
Duodenitis	29 (5.6)	70 (13.4)
Nausea	17 (3.3)	12 (2.3)
Esophagitis	17 (3.3)	63 (12.0)
Erosive duodenitis	7 (1.3)	37 (7.1)
GERD	7 (1.3)	20 (3.8)
Reflux esophagitis	6 (1.2)	17 (3.2)
Erosive esophagitis	2 (0.4)	33 (6.3)
Duodenal ulcer	1 (0.2)	19 (3.6)

However, potentially the most impressive data from the two posters was the reductions in MACE. Specifically, patients on Pozen's PA-325/40 had a MACE rate of 1.7% vs. 2.5% for EC-ASA 325 mg.

Incidence of Major Adverse Cardiovascular Events

Major Adverse Cardiovascular Event (MACE)	PA32540 (N=521)	EC-ASA 325 mg (N=524)
	Number of Subjects (%)	
Cardiovascular death	0 (0%)	1 (0.19%)
Nonfatal myocardial infarction	5 (0.96%)	3 (0.57%)
Confirmed ischemic stroke	0 (0%)	0 (0%)
Acute coronary syndrome[2]	0 (0%)	4 (0.76%)
Transient ischemic attack	1 (0.19%)	4 (0.76%)
Congestive heart failure	1 (0.19%)	1 (0.19%)
Other, mild CAD	1 (0.19%)	0 (0%)
Other, planned CABG	1 (0.19%)	0 (0%)
Subjects with any MACE	9 (1.7%)	13 (2.5%)
	Total = 22 (2.1%)	

U.S. NDA Filed / EU Up Next

Pozen filed the U.S. new drug application (NDA) on March 27, 2013. The filing to include data from a total of 2,100 subjects over 16 studies, including the 1,049 subjects from the two phase 3 studies outlined above. The filing also included additional pharmacokinetic, clinical pharmacology, and in vitro dissolution data. The NDA included all the necessary data to gain approval for PA-81/40 as well. The U.S. FDA accepted the application by on May 29, 2013 and established January 24, 2014 as the PDUFA action date.

Pozen is in the process of preparing to file for PA in Europe. Pozen recently gained clarity from the Medicines Evaluation Board (MEB) regarding what is required for the approval of PA-325/40 and a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA-100/40). Similar to the FDA, MEB confirmed that no phase 3 trial was necessary. Pozen recently conducted two phase 1 studies to satisfy the MEB requests prior to filing the Marketing Authorization Application (MAA). These included one phase 1 pharmacodynamic (PD) study demonstrating appropriate gastric pH control with PA-100/40 and one bioequivalence (BE) study comparing PA-100/40 to a currently marketed enteric-coated aspirin 100mg product. We expect the MAA filing in the next few months. On a side note, The Netherlands has agreed to be the Reference Member State (RMS) in a decentralized filing procedure of PA-325/40 and PA-100/40. We think this is good news. The Netherlands was the RMS for the European Vimovo application. To date, Vimovo has been approved in over 65 countries around the world

The path to approval for PA closely models that of Vimovo. For Vimovo (formerly PN-500/20), Pozen ran two parallel phase 3 trials under and SPA in similar design (actually smaller at around 800 patients total) to the PA-325/40 trials. Pozen submitted additional bioequivalence, clinical pharmacology, and CMC data on PN-375/20 with the PN-500/20 NDA filing. The FDA approved both PN-500/20 and PN-375/20 after the first NDA filing. In our view, this gives clear precedent for both agencies to approve PA-325/40 and PA-81/40 (or PA-100/40) in one application.

Commercial Potential – Bigger Than You Think

Given the failures of Vimovo, the sales potential for PA has been called into question by investors. But we are far more confident in the commercial success of PA than Vimovo for two reasons.

1. Firstly, the market opportunity is much larger for aspirin vs. naproxen. Data from the FDA shows that about one-quarter of all adult American's use NSAIDs, with the majority of the use OTC. Over half of the NSAID use in the U.S. is acetaminophen. In fact, according to FDA data, only 17% of all NSAID use is naproxen (another 17% is ibuprofen). That's around 13 million individuals – a decent market size, no doubt. However, further analysis of the data shows the average length of treatment is only 13.5 days.

According to the American Heart Association and Pozen market research, an estimated 17 million Americans take daily aspirin therapy (24 million secondary prevention patients in the U.S. with roughly 60-80% compliance to daily aspirin recommendation). The market is bigger, and these patients are taking their medication every day of their lives, versus intermittent two-week regimens of naproxen. Both PA and Vimovo are designed to provide safer chronic use, specifically with respect to GI toxicity. However, the average intermittent naproxen user, taking the drug for 13.5 days, is not concerned with GI toxicity.

We know this is not the case for users of daily aspirin. A Meta-analysis and peer-reviewed research concludes that 20% of all patients on daily-aspirin are at risk for upper GI adverse events such as gastric or duodenal ulcers. Pozen's phase 3 trial showed that 8.2% of secondary prevention patients on 325 mg enteric-coated aspirin discontinue after six months. A systematic review and meta-analysis on the hazards of discontinuing or not adhering to daily aspirin therapy shows a greater-than 3-fold increased risk of a potentially fatal cardiovascular event. It is clear to us, the market Pozen is going after with PA absolutely dwarfs that of Vimovo.

2. The pricing of PA will be cost neutral for the patient. Vimovo is primarily covered as a Tier-3 drug, similar to Pfizer's Celebrex (celecoxib). The average patient co-pay for Vimovo ranges between $75 and $200 per month. This is far more expensive than re-creating the drug by buying comparable generic components over-the-counter. A box of 60 tablets of naproxen sodium might cost between $10 and $15, and we found a one-month supply of OTC Prilosec (omeprazole) for around $20. Thus, the average monthly cost of re-creating an equivalent product to Vimovo OTC is around $30 to $35. AstraZeneca is charging $5 to $6 per pill, or upwards of $165 per month for Vimovo, mainly because the Nexium (esomeprazole) component remains exclusive.

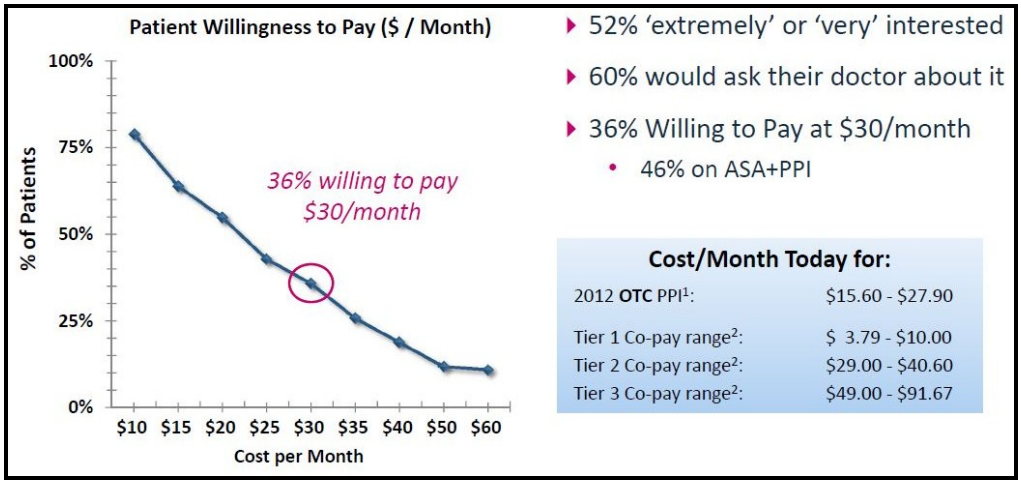
   We believe Sanofi plans to make PA available at around $1 per pill, or $30 per month. Pozen has had extensive conversations with payers, health care providers, and patients.



At this level of pricing, the company has received extremely favorable feedback from formularies noting broad-scale Tier-2 coverage. This would put the patient out-of-pocket at around $25 to $30 per month. Similar to re-creating PA by buying its generic components OTC, a prescription of PA costs the patient and healthcare system roughly the same as the majority of patients are spending now. This type of cost-neutral / reasonable pricing gives us confidence that the hurdles to use and low acceptance by patients and physicians that has dogged Vimovo may not be an issue with PA.

Pozen's extensive market research finds that 40 - 60% of physicians recommend using gastro-protective agents, such as proton pump inhibitors (e.g. omeprazole) to 35 - 50% of their patients. The interesting thing is Pozen found that over 80% of physicians would prescribe PA instead of the separate components of OTC aspirin and OTC proton pump inhibitor if the cost was comparable because it allows the physician to track the usage of PA and make sure the patient in staying on therapy. No such prescription tracking exists for OTC aspirin. Physicians have to trust that their patients are buying and taking the medication, and they see no orders or re-orders each month to confirm the patient is maintaining the regimen. We think the market dramatically under-appreciates this concept.

The slide below is from Pozen's investor presentation in April 2013. It shows that 36% of patients are willing to pay $30 per month for PA:



The following is our "back-of-the-envelope" calculation on potential PA peak sales in the U.S.

24 Million American's with history of CV disease (secondary prevention)
- Approximately 95% on medication
- Approximately 60-80% take Apspirin
- Pozen's Market Research shows 30-40% physician acceptance
- Pozen's Market Research shows 36% patients willing to pay $1/day
- Payors coverage PA at Tier-2 (cost-neutral) at $1/day

This equates to 2·0 million patients @ $365/year = $734 Million Peak Sales

We cut this number if half (to be conservative) - Thus model $365 Million·
Assume sales outside the U·S· is around half that, or around $180 Million·
Thus, we model Peak WW sales of $500 Million for our vaulation model·

Valuation

We see the shares fairly-valued at $9 based on Vimovo sales tapering off over the next few years down to a level of $50 million. We see PA peak global sales at $500 million. Our DCF model can be found below.

PROJECTED INCOME STATEMENT

DCF MODEL

POZEN, INC.	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
U.S. Sales of Treximet (GSK)	$85.0	$90.0	$90.0	$90.0	$90.0	$25.0	$0	$0	$0	$0	$0
Royalties on Treximet (~18%)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YoY	-	-	-	-	-	-	-	-	-	-	-
WW Sales of Vimovo (AZN)	$95.0	$97.0	$95.0	$45.0	$40.0	$35.0	$30.0	$25.0	$25.0	$25.0	$25.0
Royalties on Vimovo (~10%)	$7.6	$7.8	$8.6	$4.1	$3.6	$3.2	$2.7	$2.5	$2.5	$2.5	$2.5
YoY	*48%*	*2%*	*10%*	*-53%*	*-11%*	*-13%*	*-14%*	*-7%*	*0%*	*0%*	*0%*
WW Sales of PA (SNY & ??)	$0.0	$50.0	$100.0	$200.0	$300.0	$400.0	$500.0	$500.0	$450.0	$400.0	$400.0
Royalties on PA (~20%)	$0.0	$6.3	$15.0	$35.0	$60.0	$80.0	$100.0	$100.0	$90.0	$80.0	$80.0
YoY	-	-	*140%*	*133%*	*71%*	*33%*	*25%*	*0%*	*-10%*	*-11%*	*0%*
Licensing & Collaborative	$15.0	$20.0	$0	$10.0	$0	$15.0	$20.0	$0.0	$0	$0	$0
Revenues (in Millions)	**$22.6**	**$34.0**	**$23.6**	**$49.1**	**$63.6**	**$98.2**	**$122.7**	**$102.5**	**$92.5**	**$82.5**	**$82.5**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
R&D	$9.9	$10.0	$10.0	$9.0	$8.0	$7.0	$6.0	$5.0	$5.0	$5.0	$5.0
SG&A	$15.1	$16.5	$17.0	$17.5	$18.0	$18.5	$19.0	$19.5	$20.0	$20.5	$21.0
EBITDA	($2.5)	$7.5	($3.5)	$22.6	$37.6	$72.7	$97.7	$78.0	$67.5	$57.0	$56.5
Depreciation and amortization	$0.8	$0.7	$0.6	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5
EBIT	**($3.3)**	**$6.8**	**($4.1)**	**$22.1**	**$37.1**	**$72.2**	**$97.2**	**$77.5**	**$67.0**	**$56.5**	**$56.0**
EBITDA margin	*-14.5%*	*20.0%*	*-17.2%*	*45.0%*	*58.3%*	*73.5%*	*79.2%*	*75.6%*	*72.4%*	*68.5%*	*67.9%*
Cash Taxes	$0	$0	$0	$0	($5.6)	($21.6)	($29.2)	($23.3)	($20.1)	($17.0)	($16.8)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*15%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*
Discounted Cash Flow											
Net Income	($3.3)	$6.8	($4.1)	$22.1	$31.5	$50.5	$68.0	$54.3	$46.9	$39.6	$39.2
Non-Cash Adjustment to NOI	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0	$3.0
Depreciation and amortization	$0.8	$0.7	$0.6	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5
Post-Tax Operating Cash Flow	**$0.5**	**$10.5**	**($0.5)**	**$25.6**	**$35.0**	**$54.0**	**$71.5**	**$57.8**	**$50.4**	**$43.1**	**$42.7**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**$0.5**	**$10.5**	**($0.5)**	**$25.6**	**$35.0**	**$54.0**	**$71.5**	**$57.8**	**$50.4**	**$43.1**	**$42.7**

Assumptions	
Equity Risk Premium:	6.0%
Risk Free Rate:	2.0%
Terminal Growth:	1.0%
Discount Rate:	**15.0%**

Valuation	
10-Year Model:	$143.4
Terminal Value:	$65.6
Cash - Debt:	$76.9
Firm Value:	**$286**

Price Target	
Basic Outstanding:	30.4
Warrants / Options:	0.5
Fully Diluted:	30.9
Target Price:	**$9.25**

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

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INCOME STATEMENT

	2011 A	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E
Vimovo (royalty)	**$2.9**	**$4.8**	**$1.4**	**$1.7**	**$1.8**	**$1.9**	**$6.7**	**$6.9**	**$6.9**
YOY Growth	*533.0%*	*66.5%*	-	-	-	-	*38.3%*	*2.7%*	*0.0%*
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**	**$15.0**	**$0.0**	**$0.0**	**$20.0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	$87.0	$5.3	$1.4	$1.7	$16.8	$1.9	$21.7	$39.4	$31.9
YOY Growth	*26.8%*	*-93.8%*	*-71.1%*	*-97.7%*	*-80.7%*	*46.6%*	*305.8%*	*81.5%*	*-19.0%*
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	$3.8	$4.0	$15.1	$16.5	$20.0
% SG&A	*25.0%*	*355.7%*	*256.8%*	*224.9%*	*22.7%*	*211.6%*	*69.8%*	*41.9%*	*62.7%*
R&D	$23.0	$11.9	$3.6	$1.9	$2.1	$2.3	$9.9	$10.0	$10.0
% R&D	*26.5%*	*221.8%*	*253.3%*	*117.6%*	*12.5%*	*121.7%*	*45.7%*	*25.4%*	*31.4%*
Operating Income	$42.2	($25.5)	($5.8)	($4.0)	$10.9	($4.4)	($3.4)	$12.9	$1.9
Operating Margin	*48.5%*	*-477.5%*	*-410.1%*	*-242.5%*	*64.8%*	*-233.3%*	*-15.5%*	*32.7%*	*5.9%*
Interest Income / Net	$0.2	$0.3	$0.0	$0.0	$0.1	$0.1	$0.2	$0.4	$0.4
Pre-Tax Income	$42.3	($25.3)	($5.8)	($4.0)	$11.0	($4.3)	($3.1)	$13.3	$2.3
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)	$11.0	($4.3)	($3.1)	$13.3	$2.3
YOY Growth	*83.5%*	*-159.7%*	-	-	-	-	*-87.6%*	*-525.1%*	*-82.8%*
Net Margin	*48.7%*	*-472.7%*	*-408.3%*	*-241.6%*	*65.4%*	*-228.0%*	*-14.4%*	*33.7%*	*7.2%*
Reported EPS	$1.40	($0.84)	($0.19)	($0.13)	$0.36	($0.14)	($0.10)	$0.43	$0.07
Fully Diluted Shares	30.3	30.1	30.3	30.4	30.4	30.5	30.4	31.0	32.0

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

HISTORICAL ZACKS RECOMMENDATIONS



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