Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Expecting Visibility On PA Soon…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (08/01/12)	$6.31
Target Price	**$8.00**

NOTE

Visibility around the NDA for Pozen's PA "safer aspirin" product is starting to improve. What the market originally interpreted as negative news with respect to the FDA's request on inclusion of PA-81/40 now seems like a good thing – a market expanding opportunity. The path to approval outside the U.S. looks clear as well. Recent meetings with a European regulatory authority seem to allow for a filing without a large-scale phase 3 study. This saves Pozen both time and money. The final path in the U.S. should become clear after the scheduled Type A meeting later in August 2012. We now expect the U.S. FDA in the fourth quarter 2012. Our rating is 'Outperform' and our target is $10.

SUMMARY DATA

52-Week High	**$7.91**
52-Week Low	**$2.26**
One-Year Return (%)	**53.90**
Beta	**1.35**
Average Daily Volume (sh)	**163,061**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$189**
Short Interest Ratio (days)	**10.56**
Institutional Ownership (%)	**50**
Insider Ownership (%)	**11**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**14.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/M**
P/E using 2013 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)
2011	4.5 A	4.6 A	4.9 A	73.0 A	87.0 A
2012	1.3 A	1.4 A	1.4 E	16.6 E	20.6 E
2013					28.3 E
2014					30.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.19 A	-$0.21 A	-$0.24 A	$2.04 A	$1.40 A
2012	-$0.28 A	-$0.17 A	-$0.21 E	$0.22 E	-$0.46 E
2013					-$0.24 E
2014					-$0.21 E

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WHAT'S NEW

Recent Financials

On August 1, 2012, Pozen reported financial results for the second quarter 2012. Pozen reported revenues in the second quarter of $1.8 million, driven by $1.3 million royalties on $16.6 million in worldwide sales of Vimovo at AstraZeneca and full recognition of a $0.5 million payment from Desitin Arzneimittel GmbH for the license, development and commercialization of Pozen's MT-400 for the 27 countries of the European Union, as well as Switzerland and Norway.

Vimovo sales of $16.6 million were shy of our forecast at $17.5 million. To date, Vimovo has been approved in 58 countries and launched in 30. AstraZeneca received eight country approvals on Vimovo and launched in two of those in the last three months alone. Ex-U.S. sales now exceed U.S. sales. Our sales number may have been a tad too high, as we expected launches to be north of 35 by the end of the second quarter. AstraZeneca's recent streamlining of the U.S. salesforce may have caused a disruption in the second quarter U.S. sales as well. Despite the longer-than-expected lag between approvals and launches and minor sales force disruptions in the U.S., we believe Vimovo remains on track for peak sales in $200 million range worldwide. Applications have been filed in a total of 78 countries to date. For 2012, we see Vimovo sales totaling $70 million, which should provide a net royalty to Pozen of nearly $6 million.

Pozen reported a net loss in the second quarter 2012 of $5.1 million, or $0.17 per share. This was slightly better than our model which estimated the net loss at $0.26 per share. Both SG&A and R&D were lower than expected. In fact, R&D was the lowest we've seen in (at $2.9 million) in nearly a decade. We expect that Pozen will be conducting a phase 1 bioequivalence, pk / pd study on PA-100/40 for the European application later this year. Pozen may also have to redo the U.S. bioequivalence to ASA study prior to filing the U.S. NDA, although management sees this as unlikely. Assuming the U.S. NDA in the fourth quarter 2012, we expect a jump in R&D based on the filing fee (around $1.5 million). These should lead to higher R&D in the coming quarters.

Pozen exited the second quarter ended June 30, 2012 with $95.3 million in cash and investments. We expect that Pozen will exit 2012 with over $80 million in cash and investment. This estimate includes no upfront payment from a commercialization partnership on PA. Management has reiterated its goal to have a partnership in place before the end of the year. We think PA could command an upfront payment of $15 to $20 million for the U.S.

PA Bumps In The Road

On April 26, 2012, Pozen filed an 8K updating investors on the status of the planned New Drug Application (NDA) for its PA-325/40 product. As a reminder, PA-325/40 is Pozen's fixed-dose "safer aspirin" product comprised of 325 mg enteric-coated aspirin and 40 mg omeprazole. Pozen previously successfully completed two parallel phase 3 trials in 1,049 patients with PA-325/40 demonstrating a statistically significant reduction in the cumulative incidence of gastric ulcers following administration of PA-325/40 vs. 325 mg enteric-coated aspirin over six months. The phase 3 trial also demonstrated a reduction in gastroduodenal ulceration as well as a reduction in discontinuation due to upper gastrointestinal adverse events in favor of PA-325/40 compared to 325 mg enteric-coated aspirin.

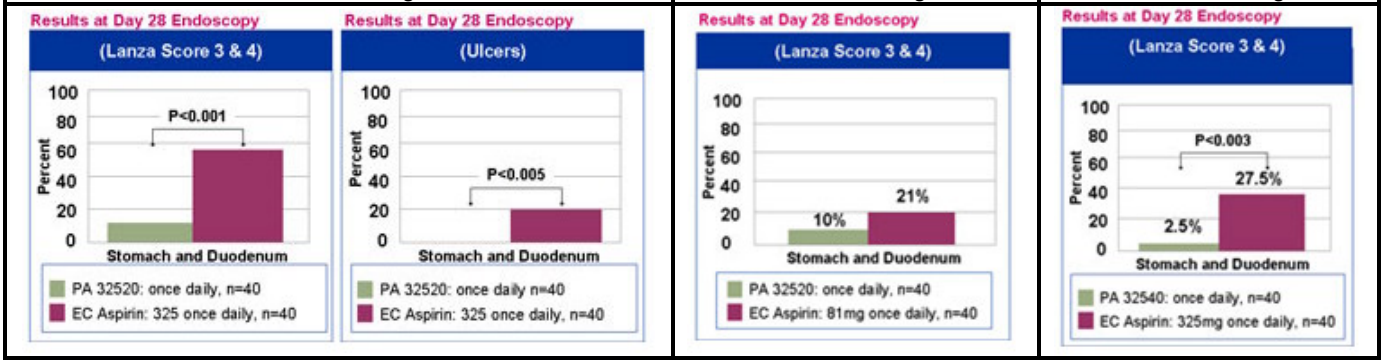
Following the release of the top-line data from the phase 3 program, Pozen met with the U.S. FDA to discuss the planned NDA filing. At that meeting, the FDA suggested that Pozen also seek approval for a lower dose formulation of the product containing 81 mg of enteric-coated aspirin as part of its NDA for PA-325/40. The FDA further notified Pozen that absent the availability of such a lower dose formulation in the market, if PA-325/40 is approved, the label indication may be limited to use in post coronary artery bypass graft surgery (CABG) with treatment duration not to exceed one year.

...What's All The Fuss...

Pozen believes that the FDA is concerned that, without a formulation containing a lower dose of aspirin, physicians will not have a full range of dosing options available to prescribe in accordance with current cardiovascular treatment guidelines, which recommend doses of 81 mg or 162 mg of aspirin for most indications. Of the 50+ million Americans that take daily aspirin therapy, about 65% are on 81 mg. We suspect the majority of these patients are taking this low dose “baby” aspirin due to the potential GI risk. Still, despite the AHA warnings on GI adverse events, approximately 21% of all patients taking daily 81 mg aspirin still develop gastric and duodenal Lanza 3 / 4 scores in as little as two weeks.

The company has generated clinical pharmacology data and chemical, manufacturing and controls (CMC) data for a product which contains 81 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet (PA-81/40). We note that safety data also exists with PA-81/20 mg from a phase 2 program (see below).

PA325/20 vs. 325mg ECA	PA325/20 vs. 81mg ECA	PA325/40 vs. 325mg ECA



Management intends to file this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81 mg of aspirin as part of its NDA for PA-325/40. We note that Pozen does not intend to conduct a phase 3 clinical trials for PA-81/40. Management made this quite clear to us and to the FDA. It seems as though the FDA is on board with this plan, although we caution investors that this does present risk to the filing.

Instead, the company anticipates that the data package submitted for PA-81/40 will be similar to that which was used to gain approval for a lower dosage formulation of Vimovo, a fixed-dose formulation of naproxen and esomeprazole, containing 375 mg of naproxen instead of the 500 mg naproxen studies in the company’s two pivotal registration trials.

…Bioequivalence A Separate Issue…

In June 2012, Pozen announced that the U.S. FDA had provided the company with an Advice / Information Request letter indicating that the FDA has made a preliminary review of the study results and Pozen's summary analyses of a phase 1 study (115 Study) to assess the bioequivalence of PA-325/40 to enteric-coated (EC) aspirin 325 mg using acetylsalicylic acid (ASA) as the analyte.

According to the letter, the FDA did not agree that bioequivalence of PA-325/40 to EC aspirin 325 mg was demonstrated. It seems as though the phase 1 data Pozen submitted had substantial variability with respect to the blood levels tested in the ASA group. The trial was not adequately powered for such variation in the data, and as a result the phase 1 study came up short of demonstrating statistically significant bioequivalence. The FDA does not seem to have any issues with the approach Pozen took to collect or analyze the data, known as a reference-scaled bioequivalence approach. The data simply was not sufficient as submitted.

We remind investors that Pozen had previously demonstrated bioequivalence of PA-325/40 to EC aspirin 325 mg using salicylic acid (SA) as the analyte. Salicylic acid is the main metabolite of acetylsalicylic acid. Generic aspirin manufacturers must show bioequivalence to SA prior to OTC approval. It seems as though for ethical use the FDA is taking the approval hurdle one-step higher, requesting bioequivalence to ASA.

After a follow-up teleconference with the FDA in July 2012, Pozen requested and was granted a Type A meeting to take place in late August 2012. Pozen has submitted additional information and analyses from the bioequivalence study, as well as other relevant pharmacokinetic, clinical pharmacology, and in vitro dissolution data as a Briefing Document to the FDA for this upcoming meeting. After the Type A meeting, Pozen expects the FDA to review and provide a written response as to whether the company has sufficient data in totality to establish a clinical and pharmacological bridge between PA-325/40 and EC ASA 325 mg. If the outcome of this meeting is favorable, an NDA filing could be made in Q4 2012. We expect Pozen will provide an update on the outcome in September.

If the meeting does not go as planned, then Pozen will need to conduct another phase 1 bioequivalence trial. If necessary, the trial will seek to enrolling more patients and collecting more blood samples than the 115 study. The new trial should have higher statistical powering, allowing Pozen to account for the blood variability levels typically seen with ASA. We believe this trial will start sometime in September 2012 and cost around $1 million. However, management made it clear on their second quarter conference call, this event is unlikely following what they called a very favorable teleconference with the agency in July.

…What's Next For Pozen…

Plans with respect to the PA-81/40 product have yet to be determined. Ideally, Pozen would like to file for a biowaiver (clinical exemption) based on the strength of the PA-325/40 data they generate. Collecting bioequivalence data on EC 325 mg ASA has proved difficult enough. We see challenges to demonstrating bioequivalence to EC 81 mg ASA. In theory, the biowaiver should be approved if the data is sufficient with PA-325/40. We expect many of these questions will be answered at the upcoming Type A meeting with the FDA. However, if Pozen needs to conduct a phase 1 (in vivo) bioequivalence study to EC 81 mg ASA, it would delay the planned NDA filing beyond the fourth 2012 into the first quarter of 2013.

With respect to the application in the Europe Union, Pozen recently gained clarity from the Medicines Evaluation Board (MEB) in the Netherlands 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). Importantly, the MEB agreed that no phase 3 clinical trials for PA-100/40 to demonstrate the reduction of gastric ulcers vs. EC aspirin will be necessary. This is a huge win for Pozen, as it removes two to three years and over $20 million in costs from the filing goal.

Instead, the agency would like to see a phase 1 pharmacodynamic (pd) study demonstrating appropriate gastric pH control with PA-100/40. In addition, a study to demonstrate bioequivalence of PA-100/40 to a currently marketed EC ASA product using aspirin pharmacokinetics is required. Pozen plans to discuss further the bioequivalence study design with the MEB, although we note these conversations will probably be similar to the same conversations with the U.S. FDA so Pozen will most likely wait until after the Type A meeting in late August to go back to the MEB. On a side note, MEB 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 58 countries around the world.

We currently model the PA-325/40 NDA in the fourth quarter 2012. Therefore, we suspect that FDA approval late 2013, with a launch in the first quarter 2014 with peak sales $400 million in 2020 (includes entire PA-franchise of 325 mg, 100 mg and 81 mg). We still believe that Pozen will be able to secure a U.S. commercialization partner for PA around the NDA filing. As noted above, we believe an upfront payment on PA could be in the area of $15 to $20 million, along with over $150 million in back-end milestones and royalties on sales. A deal that includes countries outside the U.S. presents upside (perhaps a doubling) to these figures. We remind investors that in October 2011, Pozen retained Keelin Reeds LLC to assist in the strategic partner search for PA. Keelin Reeds is a global expert in helping life science companies value assets, develop business development strategies and execute partnership transactions. We are not expecting a deal until visibility improves after the Type A meeting minutes come out.

We previously believed that the deal would be superior to the Vimovo transaction with AstraZeneca that provided $40 million upfront, $45 million in approval milestones, and potentially $290 million in sales milestones plus roughly 10% royalties on sales. Now, we are unsure. It is possible that Pozen can still close a deal for PA later this year, but an asset that we previously viewed as very low risk - considering that both phase 3 programs were run under an SPA and the U.S. FDA has already approved Pozen's similar product in Vimovo - just got a little riskier. Hence, we think it is wise to ratcheted down our expectations.

Assuming Pozen cleans up the bioequivalence to ASA issue following the Type-A meeting later this month, there are essentially three outcomes after Pozen files the NDA:

1. The FDA approves PA-325/40 and PA-81/40 with a full label for secondary prevention of cardiovascular disease in patients at risk for gastric ulcers.

2. The FDA approves PA-325/40, only with a limited patient population of post coronary artery bypass graft surgery (CABG) with treatment duration not to exceed one year.

3. The FDA rejects PA-325/40 with a complete response letter asking Pozen to conduct a separate phase 3 trial with PA-81/40 before any dose is approved.

Considering the FDA approved a lower dose Vimovo (375mg naproxen vs. 500mg naproxen) without a phase 3 program, there is clear precedent for Outcome #1 above. As a reminder, to gain approval for Vimovo, then called PN-500/20, Pozen ran 2 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. It could all happen again with PA.

…A Simple Concept…

PA is such a simple product concept. Over 50 million American's use daily aspirin therapy, with 50% of those patients at risk of developing 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. Roughly 65% of the market is taking 81 mg "baby" aspirin, and we estimate that half of these patients are being under-dosed because of the potential GI toxicity. We believe that PA-325/40, at $1/day, is about a $250 million product in the U.S., and that's with only 5% penetration. We think that PA-81/40, also at $1/day, essentially doubles the market opportunity to the company. We think this is easily achievable.

We think a similar opportunity exists in Europe. Aspirin is used pretty commonly all around the world. We peg the E.U. opportunity at around $150 million, bringing peak global sales of PA to around $400 million.

To the right is a cartoon that first appeared in the New Yorker magazine (Artist: Aaron Bacall) we believe sums up the PA story nicely.



" I am going to prescribe something that works like aspirin, but costs much, much more."

Source: The New Yorker

Vimovo Sales On Track

Vimovo sales of $16.6 million were shy of our forecast at $17.5 million. To date, Vimovo has been approved in 58 countries and launched in 30. AstraZeneca received eight country approvals on Vimovo and launched in two of those in the last three months alone. Our sales number may have been a tad too high, as we expected launches to be north of 35 by the end of the second quarter. Sales in the U.S. have been disrupted by sales force streamlining at AstraZeneca. Despite the longer-than-expected lag between approvals and launches and some disruption in the U.S., we believe Vimovo remains on track for peak sales in $200 million range worldwide. Applications have been filed in a total of 78 countries to date. For 2012, we see Vimovo sales totaling $70 million, which should provide a net royalty to Pozen of nearly $6 million.

MT-400 Offers Upside Potential

May 2012, Pozen announced that it has entered into a license agreement with Desitin Arzneimittel GmbH, for the development and commercialization of MT-400 for the 27 countries of the European Union, as well as Switzerland and Norway. MT-400 is Pozen's internal code name for Treximet (85 mg sumatriptan / 500 mg naproxen), sold in the U.S by GlaxoSmithKline. We remind investors that in November 2011, Pozen entered into an agreement with CPPIB Credit Investments (CIT) whereby the company sold the U.S. royalty rights to Treximet for $75 million.

Desitin made an initial upfront payment to Pozen of $0.5 million (booked in the second quarter 2012). Pozen is eligible for milestone payments related to the development and launch of MT-400 in certain specified countries totaling $2.5 million. Following approval, Desitin will pay Pozen a double digit royalty on net sales of MT-400 that increases based on annual sales volume.

This was not the first Ex-U.S. deal Pozen struck on MT-400. 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 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. We are expecting that J&J will be in position to file with NHSAB in 2012.

Valuation

We believe Pozen can still close a deal on PA in 2012, but management will most likely have to give up some of the upfront payment in lieu of backend milestones contingent on sales levels and label expansion. Still however, we see the sales opportunity with PA-81/40 as doubling the market opportunity to Pozen's partner. Therefore, giving up some modest upfront payment in lieu of more sales related payments may be the smart thing to do.

We are maintaining our 'Outperform' rating on the shares and adjusting our target to $8 per share. We are starting to get more comfortable with the filing strategy on PA-325/40 in the U.S. We suspect that the application will include all the necessary data to gain approval for PA-81/40 as well. We expect clarity on the bioequivalence requirements following the Type A meeting expected to take place in late August 2012. As of now, we are expecting the U.S. NDA to be filed late 2012.

We are pleased with the company's progress with PA outside the U.S. Guidance from the MED in the Netherlands suggest that no phase 3 trial is necessary for approval in Europe. This saves Pozen probably 2-3 years and $20+ million in costs.

We have conducted a discounted cash flow (DCF) analysis on Pozen and arrived at a fair value of $10 per share. We have adjusted this down to $8 per share to account for the current overhang prior to the outcome of the Type A meeting schedule for late August 2012. A positive outcome from this meeting has the potential to send the shares above $8 and close to our $10 fair-value model.

PROJECTED INCOME STATEMENT

Income statement:

	2010 A	2011 A	Q1 A	Q2 A	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Treximet / MT400 (royalty)	**$15.7**	**$12.2**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*265.0%*	*-22.6%*	-	-	-	-	*-100.0%*	-	-	-
Vimovo (sales)	$4.6	$33.8	$16.0	$16.6	$18.0	$20.0	$70.6	$92.0	$112.0	$145.0
Vimovo (royalty)	**$0.5**	**$2.9**	**$1.3**	**$1.3**	**$1.4**	**$1.6**	**$5.6**	**$8.3**	**$11.2**	**$14.5**
YOY Growth	-	*533.0%*	-	-	-	-	*94.0%*	*46.6%*	*35.3%*	*29.5%*
PA-Franchise (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$18.8**	**$31.3**
YOY Growth	-	-	-	-	-	-	-	-	-	*66.7%*
Licensing / Development	**$52.3**	**$71.9**	**$0**	**$0.5**	**$0**	**$15.0**	**$15.0**	**$20.0**	**$0**	**$0**
YOY Growth	*87.6%*	-	-	-	-	-	-	-	-	-
Total Revenues	$68.5	$87.0	$1.3	$1.8	$1.4	$16.6	$20.6	$28.3	$30.0	$45.8
YOY Growth	*113.0%*	*26.8%*	*-70.3%*	*-93.9%*	*-97.9%*	*272.1%*	*-76.3%*	*37.0%*	*5.9%*	*52.8%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$23.8	$21.8	$5.6	$4.1	$4.8	$5.0	$19.5	$21.0	$22.0	$22.5
% SG&A	*34.7%*	*25.0%*	*438.2%*	*230.2%*	*333.3%*	*30.1%*	*94.5%*	*74.3%*	*73.5%*	*49.2%*
R&D	$22.6	$23.0	$4.1	$2.9	$3.2	$5.0	$15.2	$15.0	$15.0	$15.0
% R&D	*6+.%*	*26.5%*	*318.4%*	*162.6%*	*222.2%*	*30.1%*	*73.5%*	*53.0%*	*50.1%*	*32.8%*
Operating Income	$22.1	$42.2	($8.5)	($5.2)	($6.6)	$6.6	($14.0)	($7.7)	($7.1)	$8.3
Operating Margin	*32.3%*	*48.5%*	*-656.6%*	*-292.8%*	*-455.6%*	*39.8%*	*-68.0%*	*-27.3%*	*-23.5%*	*18.0%*
Interest Income / Net	$0.9	$0.2	$0.1	$0.1	$0.1	$0.1	$0.3	$0.5	$0.5	$0.5
Pre-Tax Income	$23.1	$42.3	($8.4)	($5.1)	($6.5)	$6.7	($13.7)	($7.2)	$6.6	$8.8
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$23.1	$42.3	($8.4)	($5.1)	($6.5)	$6.7	($13.7)	($7.2)	($6.6)	$8.8
YOY Growth	-	*83.5%*	-	-	-	-	*-132.4%*	*-47.3%*	*-9.3%*	*-233.6%*
Net Margin	*33.7%*	*48.7%*	*-651.3%*	*-288.7%*	*-448.6%*	*40.4%*	*-66.4%*	*-25.5%*	*-21.9%*	*19.1%*
Reported EPS	$0.76	$1.40	($0.28)	($0.17)	($0.21)	$0.22	($0.46)	($0.24)	($0.21)	$0.27
Fully Diluted Shares	30.2	30.3	30.0	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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