Zacks Small-Cap Research

October 23, 2012
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

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

POZEN, Inc. (POZN-NASDAQ)

POZN: Impressive Data At ACG Presented On PA-325/40…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	03/07/2007
Current Price (10/23/12)	$6.30
Target Price	**$10.00**

NOTE

On October 22, 2012, Pozen presented a full analysis of the integrated results of the two phase 3 studies comparing 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. Below we highlight the data and how we believe it could drive meaningful uptake for Pozen's drug once approved.

Our rating is 'Outperform' and our target is $10.

SUMMARY DATA

52-Week High	**$7.91**
52-Week Low	**$2.35**
One-Year Return (%)	**134.20**
Beta	**1.36**
Average Daily Volume (sh)	**124,212**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$189**
Short Interest Ratio (days)	**17.32**
Institutional Ownership (%)	**64**
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	1.6 E	6.1 E
2013					28.3 E
2014					50.0 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	-$0.27 E	-$0.94 E
2013					-$0.24 E
2014					$0.43 E

© Copyright 2012, Zacks Investment Research. All Rights Reserved.

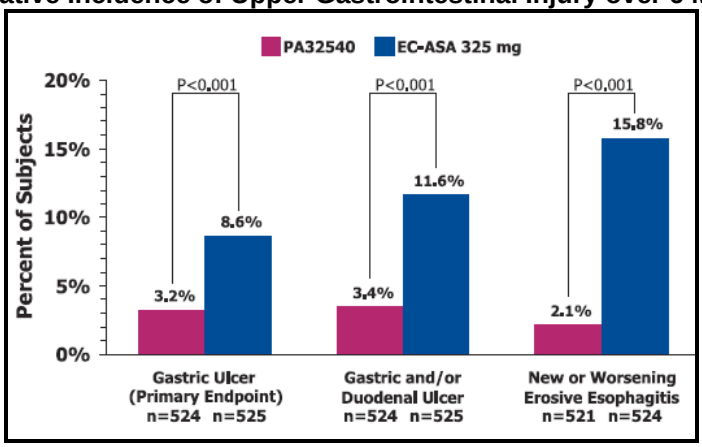
WHAT'S NEW

Phase 3 Data Impresses At ACG

On October 22, 2012, Pozen presented a full analysis of the integrated results of the two phase 3 studies comparing 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, 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 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:

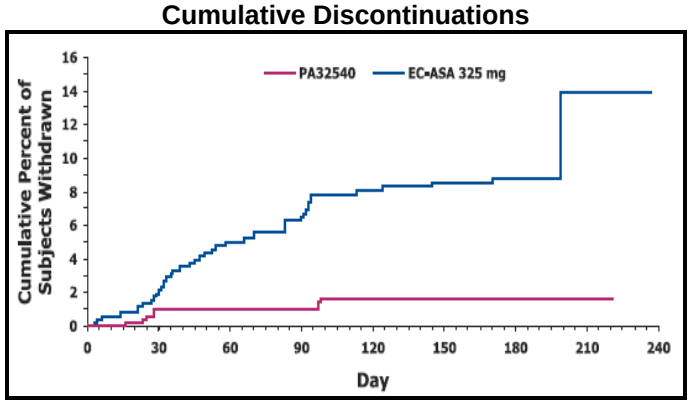
Cumulative Incidence of Upper Gastrointestinal Injury over 6 Months



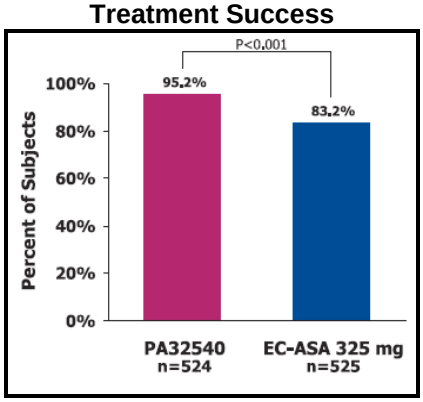
The data equate to an impressive 63% reduction in gastric ulcer. In a previous report we noted that we expected the ASA cohort to offer a gastric ulcer rate around 10% and PA-325/40 to be low-single digits. These results are consistent with our expectations and show the powerful efficacy of Pozen's drug. 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.

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. 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).

Cumulative Discontinuations

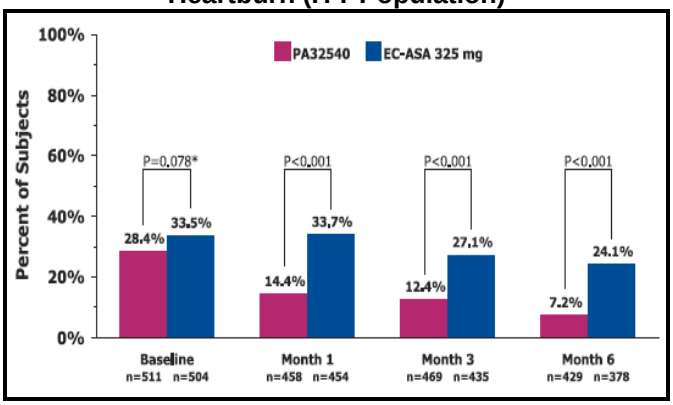


Treatment Success



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). 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).

Heartburn (ITT Population)



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)

The data above was presented in poster form (Poster 608: "*PA32540 (Enteric-coated Aspirin 325 mg + Immediate-release Omeprazole 40 mg) Is Associated with Significantly Fewer Gastric Ulcers and Significantly Less Endoscopic Erosive Esophagitis than Enteric-coated Aspirin (EC-ASA) Alone: Results of Two Phase 3 Studies.*") at the American College of Gastroenterology (ACG) meeting on October 22, 2012 in Las Vegas, NV. Pozen received two awards for its poster. The first award was the ACG Auxiliary Award for $1,000 to the primary authors of the two best papers presented at ACG2012. The $1,000 is hardly anything to get excited about, but over 1,600 posters were presented at ACG this year. The fact that Pozen's poster was considered among the best two certainly says something about the quality of the data and the excitement it generated from the attendees.

The second award was the prestigious Presidential Poster Award. According to the ACG's website, ACG Educational Affairs Committee will identify the most highly ranked abstracts selected for the poster sessions in each category and acknowledge their achievement with the ACG Presidential Poster Award. These recipients will receive a special commendation on their poster in the Poster Hall, a certificate of achievement, and recognition in the meeting program book. All posters are eligible for this award. Similar to the Auxiliary Award, the fact that Pozen's poster of the phase 3 data was selected to win the Presidential Poster Award certainly validates the quality of the data and the efficacy of the drug. We think this type of data and recognition by the ACG could help drive meaningful market share for PA-325/40 post approval.

NDA Expected 1H-2013

On August 23, 2012, Pozen provided an update on its Type-A meeting with the FDA. The key topic for discussion at the meeting was to define a path forward for both PA-325/40, Pozen's high dose "safer aspirin", and PA-81/40, the company's low dose version. We assume that talks at the meeting centered on the recently completed phase 1 study (Study 115) to assess the bioequivalence / bioavailability of PA-325/40 to enteric-coated aspirin (Ecotrin) 325 mg using acetylsalicylic acid (ASA) as the analyte.

We remind investors that in June 2012, the FDA provided Pozen with an Advice / Information Request letter indicating that the FDA has made a preliminary review of the results from Study 115 and concluded that bioequivalence of PA-325/40 to Ecotrin 325 mg, the Reference Listed Drug ("RLD") for the 505(b)(2) application, was not demonstrated. Pozen noted that data from Study 115 had substantial variability with respect to the blood levels tested in the ASA group, and that the trial was not adequately powered for such variation in the data.

At the meeting, the FDA confirmed that, although it still believes the data from Study 115 did not strictly establish bioequivalence, a bridge to Ecotrin 325 mg can be established by the submission of additional data in the new drug applications ("NDA"). Pozen plans to compile this data over the next several months and file the NDA in the first half of 2013. On the company's update conference call, held on August 24, 2012, management would not get specific on what additional data it plans to include in the NDA, only that no additional bioequivalence studies will be

conducted with the PA-325/40 dose formulation. We assume the additional data will be pharmacokinetic, clinical pharmacology, and in vitro dissolution data.

We remind investors that Pozen had previously demonstrated bioequivalence of PA-325/40 to enteric-coated 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.

…Good News On PA-81/40…

During the Type-A meeting, Pozen and the FDA also came to an agreement on a path forward for the company's low dose formulation, PA-81/40. The FDA confirmed that no phase 3 trial for PA-81/40 is necessary – a big win for Pozen and a decision that saves two years and $40 million in expense. Instead, the FDA would like to see Pozen demonstrate bioequivalence / bioavailability to Ecotrin 81 mg. We expect that Pozen will conduct a similar study to the Study 115 conducted with PA-325/40, only making small changes to improve the outcome. We expect these changed to include enrolling more patients and collecting more blood samples during the study. This should result in higher statistical powering, allowing Pozen to account for the blood variability levels typically seen with ASA. We believe this trial is current underway and cost around $1 million.

We believe Pozen will have this data in hand by the end of the year. We previously modeled the NDA in late 2012. The delay in filing the NDA to the first half of 2013 (our best guess is May 2012) stems from a lack of stability data required for the NDA on the PA-81/40 formulation. Pozen originally planned to file for approval of only the 325 mg dose. When the FDA asked Pozen to include both the 325 mg and 81 mg dose in the PA NDA back in April 2012, Pozen immediately began Chemistry, Manufacturing and Controls ("CMC") work on the new formulation. The FDA requires 12 months of "real time" product stability to be included in the NDA. This data is in hand for PA-325/40. Pozen still needs to generate the data for PA-81/40. We expect the CMC data on PA-81/40 will be in hand in April 2012, allowing Pozen to file the NDA in May 2012. The six-month delay, although clearly disappointing, is inconsequential from a valuation standpoint.

…European Application In 2013…

Pozen is also in the process of preparing to file for PA in Europe. 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). Similar to the FDA, MED confirmed that no phase 3 trial was necessary. We expect that the bioequivalence / bioavailability data necessary for the EU approval of PA-325/40 and PA-100/40 can mirror the work being done for the U.S. NDA application. We expect the MAA filing during the second half of 2013.

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.

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.

…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. Gaining approval of a low dose PA opens the door to allow millions access to the drug. We think our sales forecasts are 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. Again, we believe these forecasts are conservative.

…Partnership Could Drive Shares Higher…

We still believe that Pozen will be able to secure a U.S. commercialization partner for PA in the near future. Management has previously stated they would like to have a deal signed by the end of the year. However, that was when the NDA was also planned at the end of the year. Pozen would not give specifics on a timeline for a deal, but we are not expecting a deal until the first half of 2013.

That being said, 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.

As a point of reference, the Vimovo transaction with AstraZeneca provided $40 million upfront, $45 million in approval milestones, and $290 million in sales milestones plus roughly 10% royalties on sales. Pulling in a deal of this magnitude has the potential to double the stock.

Valuation

We are maintaining our 'Outperform' rating and $10 per share target on the stock. We are comfortable with the filing strategy on PA-325/40 and PA-81/40 in the U.S. We suspect that the application will include all the necessary data to gain approval during the first half of 2014. Additionally, 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. We have conducted a discounted cash flow (DCF) analysis on Pozen and arrived at a fair value of $10 per share.

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 (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**	**$0**	**$0.5**	**$20.0**	**$20.0**	**$0**
YOY Growth	*87.6%*	-	-	-	-	-	-	-	-	-
Total Revenues	$68.5	$87.0	$1.3	$1.8	$1.4	$1.6	$6.1	$28.3	$50.0	$45.8
YOY Growth	*113.0%*	*26.8%*	*-70.3%*	*-93.9%*	*-97.9%*	*-64.1%*	*-92.9%*	*360.0%*	*76.6%*	*-8.4%*
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%*	*312.5%*	*317.5%*	*74.3%*	*44.0%*	*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%*	*312.5%*	*246.9%*	*53.0%*	*30.0%*	*32.8%*
Operating Income	$22.1	$42.2	($8.5)	($5.2)	($6.6)	($8.4)	($28.5)	($7.7)	$13.0	$8.3
Operating Margin	*32.3%*	*48.5%*	*-656.6%*	*-292.8%*	*-455.6%*	*-525.0%*	*-464.4%*	*-27.3%*	*25.9%*	*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)	($8.3)	($28.2)	($7.2)	$13.5	$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)	($8.3)	($28.2)	($7.2)	$13.5	$8.8
YOY Growth	-	*83.5%*	-	-	-	-	*-166.6%*	*-74.4%*	*-286.3%*	*-34.9%*
Net Margin	*33.7%*	*48.7%*	*-651.3%*	*-288.7%*	*-448.6%*	*-518.8%*	*-458.8%*	*-25.5%*	*26.9%*	*19.1%*
Reported EPS	$0.76	$1.40	($0.28)	($0.17)	($0.21)	($0.27)	($0.94)	($0.24)	$0.43	$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*

© Copyright 2012, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1004 companies covered: Buy/Outperform- 15.1%, Hold/Neutral- 75.8%, Sell/Underperform – 8.7%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2012, Zacks Investment Research. All Rights Reserved.