William Blair

ZS Pharma, Inc.

November 24, 2014

NEJM Publications Increase Our Conviction That ZS-9 Is a Best-in-Class Product, Maintain Outperform

- To cap off an event-filled week for the company, on Friday, November 21, ZS Pharma announced the publication of data from its first pivotal Phase III study (ZS003) in the *New England Journal of Medicine* (NEJM). In addition to the company's publication, a simultaneous publication of competitor Relypsa's (RLYP $23.71) Phase III data was also in the journal, as well as an editorial by Dr. Julie Ingelfinger summarizing both studies entitled, "A New Era for the Treatment of Hyperkalemia?" The ZS003 publication followed a presentation of ZS004 (or HARMONIZE) at the American Heart Association meeting earlier in the week, publication of HARMOZINE in *The Journal of the American Medical Association* (JAMA), and an analyst event.

- We believe the NEJM publications continue to show a significantly differentiated onset-of-action profile for ZS-9 with a median time to normalization reported by the company at 2.2 hours. Although questions about longer-term efficacy and safety remain (over four weeks), we believe the company is adequately addressing the issue with its open-label extension study (ZS004E) and one-year safety study (ZS005) set to read out in 2015. During the maintenance phase, both the 5 gram and 10 gram daily doses of ZS-9 were superior to placebo in maintaining normokalemia (P=0.008 and P<0.001, respectively), while patients during the randomized withdrawal period showed serum potassium increases between day 15 and day 21. We outline trial results for all published trials from both ZS-9 and patiromer in exhibit 5, on page 6.

- For the competitive product patiromer, while the product also appears effective, we note the differences in results from the NEJM study when stratified by region. We also note that the definition of hypomagnesemia between the PEARL and OPAL-HK studies has likely reduced the instance of this side effect (24% in PEARL-HF and 3%-4% in OPAL-HK) while patiromer continued to hold a higher rate of GI adverse events when compared with ZS-9. While we continue to view ZS-9 as holding an improved product profile over patiromer based on what we also view as a higher quality clinical program, we note that both products appear safe and effective and we view the hyperkalemia market as large enough to support two successful products.

- We continue to rate shares of ZS Pharma Outperform with a price target of $75 given our belief that ZS-9 holds a best-in-class profile for the treatment of hyperkalemia. *In total, we believe the acute and chronic hyperkalemia market exceeds 3 million patients in the United States and has been reported in up to 10% of all hospitalized patients with few good treatment options. The next meaningful catalysts for ZS Pharma will likely be the filing of the ZS-9 NDA and data from the company's long-term safety and efficacy programs in mid-2015.*

ZS Pharma is a specialty pharmaceutical company located in San Mateo, California, focused on developing therapies based on highly selective ion trap chemistry.

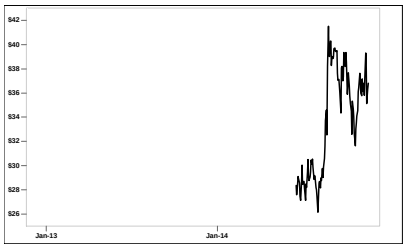
Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$75.00
Symbol:	ZSPH (NASDAQ)
Price:	$40.75 (52-Wk.: $26-$43)
Market Value (mil.):	$848
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

		2013A	2014E	2015E
Estimates				
EPS	Q1	NA	A$0.02	NA
	Q2	NA	A$-4.72	NA
	Q3	NA	A$-0.81	NA
	Q4	NA	$-0.81	NA
	FY	$-8.52	$-3.28	$-2.96
	CY		$-3.28	$-2.96
Valuation				
FY P/E		NM	NM	NM
CY P/E			NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	3
Float (mil.)	9
Average Daily Volume	142,592

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	6.2
Return on Equity (TTM)	-235.2

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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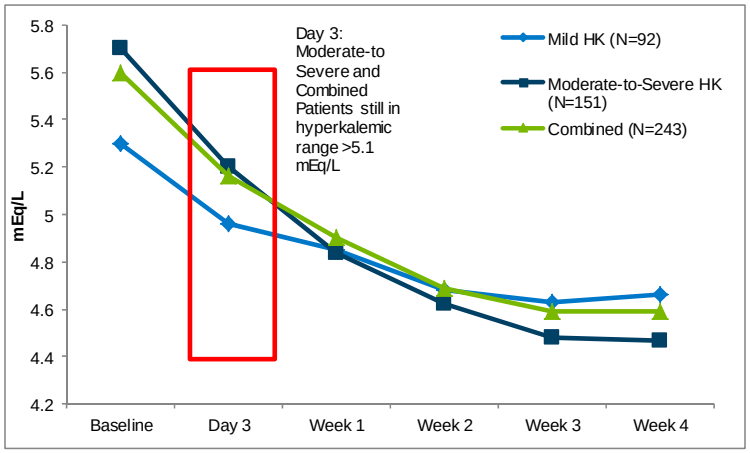
Additional Detail on *New England Journal of Medicine* Publications of ZS003 and OPAL-HK

On Friday, November 21, ZS Pharma announced the publication of data from its first pivotal Phase III study (ZS003) in the *New England Journal of Medicine* (NEJM). In addition to the company's publication, a simultaneous publication of competitor Relypsa's Phase III data was also in the journal as well as an editorial by Dr. Julie Ingelfinger summarizing both studies entitled, "A New Era for the Treatment of Hyperkalemia?" In our view, the ZS-9 study continues to show a significantly differentiated onset-of-action profile, and although questions on longer-term efficacy and safety remain (over four weeks), we believe the company is adequately addressing the issue with its open-label extension study (ZS004E) and one-year safety study (ZS005) set to read out in 2015. For competitive product patiromer, while the product also appears effective, we note the differences in results from the NEJM study when stratified by region, which may further narrow an already smaller number of patient exposures; we also note the evolving definition of hypomagnesemia between PEARL and OPAL-HK, and what appears to be a higher rate of GI adverse events. Overall, we continue to believe that ZS Pharma has a best-in-class therapy for the treatment of hyperkalemia.

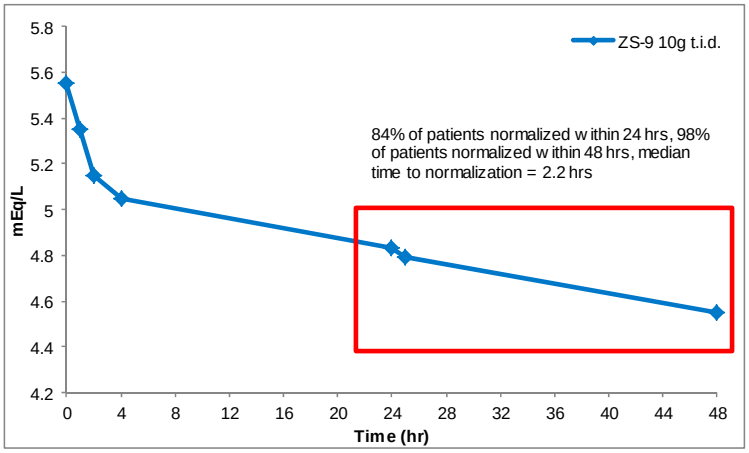
Regarding onset of action between the two products, in exhibit 1, on the following page, we examine the efficacy of the four-week phase of patiromer's OPAL-HK study and ZS-9's HARMONIZE study in reducing and maintaining serum potassium levels in the normokalemic range. Both studies met their primary endpoint at the four-week time point of maintaining normokalemic range in a significantly greater number of patients. However, the onset-of-action for ZS-9 seems to be much faster, with a median time to normalization reported by the company at 2.2 hours. Using the sensitivity analysis in the supplemental portion of Relypsa's NEJM article, we estimate that at day 3, the mean serum potassium level are approximately 5.2 mEq/L in the moderate-to-severe hyperkalemia subset and approximately 5.16 mEq/L in the combined population. Both values are above the range of normokalemia, which is defined as above 5.0 mEq/L. We also note that the lack of a placebo control in OPAL-HK makes this initial 48-hour period difficult to interpret, as there was a placebo response of 0.25 mEq/L during the corresponding period in the ZS-9 study results. We believe the rapid onset of action for ZS-9 may be a significant differentiating factor between the two compounds, since most hyperkalemia patients are initially identified within the acute care setting.

Exhibit 1
Patiromer Efficacy Results in OPAL-HK Treatment Phase

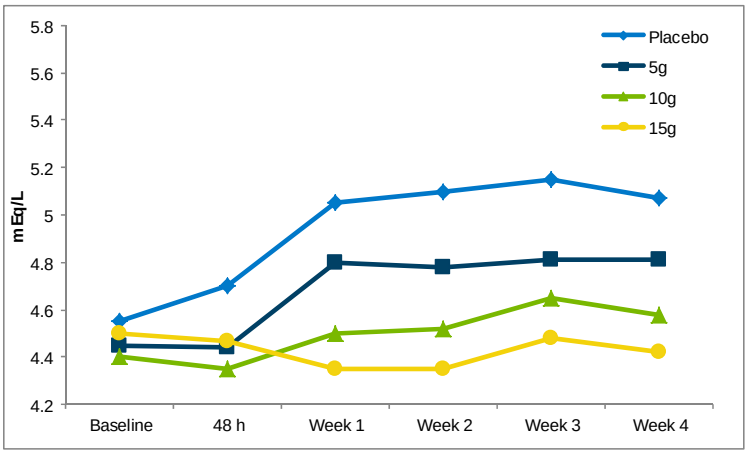


Source: Weir et al. NEJM 2014

ZS-9 Efficacy Results in HARMONIZE Initiation Phase



ZS-9 Efficacy Results in HARMONIZE Maintenance Phase



Sources: Kosiborod et al. JAMA 2014 and American Heart Assocation 2014 Annual Meeting

After ZS Pharma's presentation at the annual meeting of the American Heart Association, there were some concerns over edema in the 15 gram dose group. We believe that the company adequately addressed the concerns over edema in the 15 gram dose at its analyst event last week, with Dr. Kosiborod providing an in-depth analysis of results from ZS002 and ZS003 in addition to up-to-date results from the ZS004 extension study and ZS005 studies. As shown in exhibit 2, edema rates (defined as cases of edema divided by the number of patient days' exposure) were lower in the retrospective

analysis of ZS003 with a placebo rate of 0.00011 and the ZS003 treatment groups (both 5 gram and 10 gram doses) of 0.00016. In the ZS004 extension study, the placebo rate was 0.00066 and the 15 gram dose exposure edema rate in the ZS004 extension study (1013 patient days) was 0.00000, also lower than placebo arm. The ZS005 open-label edema rate results to date (6230 patient days) was 0.00016 with no patients currently titrated to the 15 gram dose. In addition, 7 out of 14 patients did not require any treatment adjustment, and of the patients with edema, 7 out of 8 had relatively mild peripheral edema (the majority being foot/ankle edema). We continue to believe that the edema rate seen in the HARMONIZE results was likely because of an artifact seen as a result of randomization in the study where patients in the 15 gram dose included patients with more advanced chronic kidney disease (lower glomerular filtration rate) and increased brain natriuretic peptide (a marker for increased chronic cardiovascular disease).

Exhibit 2
Edema Rates Over ZS-9 Clinical Program

Study	Edema Rate (# of cases/# of patient days)
ZS003 Placebo group	0.00011
ZS003 Treatment Group (5g, 10g)	0.00016
ZS004 Placebo Group	0.00089
ZS004E Open-Label Study (5g, 10g, 15g) - Ongoing (exposure: 15,050 patient days)	0.00066
ZS004 15g dose (exposure: 1,013 patient days)	0.000000
ZS005 Open-Label Study (5, 10, 15g*) - Ongoing (exposure: 6,230 patient days)	0.00016

Source: ZS Pharma Analyst Event
*No one titrated to 15g

Decreasing rates of hypomagnesemia observed with patiromer between the PEARL-HF and OPAL-HK studies looks to be aided by changes in definitions. When examining the publication for patiromer, there was a change in the definition of hypomagnesemia from the PEARL-HF study to the OPAL-HK study. As shown in exhibit 3, in the PEARL-HF study, patients were considered to have reduced serum Mg2+ concentrations at values less than 1.8 mg/dL. This yielded 24% of patients treated with patiromer in the study with hypomagnesemia compared with 2.1% in placebo, a statistically significant difference. However, in the OPAL-HK study, hypomagnesemia is defined as serum Mg2+ of less than 1.4 mg/dL, and only 3% of patiromer-treated patients were included in this definition. In addition, 4% of patients in the patiromer group received magnesium-replacement therapy during the initial treatment phase. We believe that the change in definition from study to study as well as the replacement therapy introduced in the initial treatment phase may have also contributed to the reported decreases in hypomagnesimia rate. A paper examining nine studies on hypomagnesemia showed that most of the studies defined hypomagnesemia as ≤ 1.7 mg/dL or <1.7 mg/dL, with one study defining it slightly higher at <1.8 mg/dL and one study defining it slightly lower at <1.6 mg/dL (Park et al. *PLoS One* 2014).

Exhibit 3
Definition of Hypomagnesemia in PEARL-HF and OPAL-HK and Reported Events

	PEARL-HF	OPAL-HK
Hypomagnesemia Definition	serum Mg2+ <1.8 mg/dL	serum Mg2+ <1.4 mg/dL
Rate of Hypomagnesemia reported	24% of patients treated with patiromer vs. 2.1% in placebo, statistically significant decrease from baseline was observed (-0.22 vs. 0.01 mg/dL for the patiromer and placebo groups respectively, P<0.001)	A serum magnesium level of less than 1.4 mg per deciliter (0.58 mmol per liter) occurred in eight patients (3%) during the initial treatment phase and through its follow-up period. Magnesium-replacement therapy was initiated in nine patients (4%) in the patiromer group during the initial treatment phase.

Sources: Pitt et al. Eur Heart J 2011, Weir et al. NEJM 2014

In exhibit 4, we compare the adverse event profiles of each study. Overall, none of the studies showed significant differences between treatment and placebo in total adverse events; however, as we noted above for hypomagnesemia, differing definitions and patient populations make cross-study comparisons difficult. It should also be noted that in all studies, no serious adverse events were deemed treatment related and in general safety results suggest both therapies can be considered safe for the population tested. The gastrointestinal events in the patiromer-treated patients are higher than placebo in both studies, whereas the ZS-9 study showed placebo-like rates. This may be due to the backbone composition of each product; patiromer is thought to swell within the GI tract, whereas ZS-9 with less drug dosed and a more stable structure does not.

Exhibit 4
ZS-9 and Patiromer Adverse Event Profile in Published Clinical Trials

	ZS-9		Patiromer FOS	
	ZS003	HARMONIZE	PEARL-HF	OPAL-HK
Total Adverse Events	Initial Phase: 12.9% in ZS-9, 10.8% in placebo; Maintenance Phase: 25.1% in ZS-9, 24.5% in placebo	Initial Phase: 7.8%, Withdrawal Phase: 31.8% (Placebo), 53.3% (5g), 29.4% (10g), 44.6% (15g)	31% Placebo, 53% Patiromer	Initial Phase: 47%, Randomized Phase: 50% (Placebo), 47% (Patiromer)
Serious Adverse Events	Initial Phase: 1 (placebo), Maintenance Phase: 5 (placebo), 4 (1.25g), 3 (2.5g), 7 (5g), 1 (10g)	Initial Phase: 0%, Withdrawal Phase: 0% (Placebo), 11.1% (5g), 3.9% (10g), 5.4% (15g)	4% Placebo, 4% Patiromer	Initial Phase 1%, Randomized Phase: 2% (Placebo), 0% Patiromer
GI Adverse Events	Initial Phase: Placebo: 5.1%, 1.25g: 4.5%, 2.5g: 2.1%, 5g: 3.8%, 10g: 3.5%; Maintenance Phase: 10 (Placebo), 6 (1.25g), 8 (2.5g), 8 (5g), 4 (10g)	Initiation Phase: 0.8%, Withdrawal Phase: 7.1% (Placebo), 0% (5g), 2% (10g), 1.8% (15g)	6% (Placebo), 21% (Patiromer)	Initiation Phase: 14%, Randomized Phase: 0% (Placebo), 8% (Patiromer)

Sources: Packham et al. NEJM 2014, Kosiborod et al. JAMA 2014, Pitt et al. Eur Heart J 2011, Weir et al. NEJM 2014

When comparing the two studies, another difference between the ZS-9 and patiromer publications is the geographic breakdown for each study. In the OPAL-HK study in particular, patients showed a significant difference (P=0.003) in the primary endpoint when stratified by region in the randomized withdrawal phase. Non-EU Eastern Europe enrolled 85 patients (79% of the total tested) and showed a difference in median change of 0.51 mEq/L (with a 95% confidence interval from 0.25-0.77), whereas the European Union and the United States enrolled 22 patients (22% of the total tested) and showed a difference in median change of 1.39 mEq/L (with a 95% confidence interval of 0.91 to 1.88). According to the supplemental information included with the study, the authors suggest that the difference by region resulted from a lower baseline eGFR rate in the E.U./U.S. region; however, the authors also note that, "with only 12 placebo subjects in the E.U. and U.S. region combined, the data were to sparse to permit further exploration." We believe the limited number of Western EU and U.S. patients tested in the study and the differences in the baseline characteristics between the regions may raise questions during the review process; however, patiromer in general looks to be an effective (although with a slower onset of action) and safe therapy. ZS Pharma's HARMONIZE study enrolled approximately 80% of patients in the United States; however, as the company is pursuing a worldwide regulatory strategy, we believe the company is hoping to increase the European enrollment in the ongoing ZS005 study.

In the editorial piece on the published papers by Dr. Ingelfinger, she notes that both of the studies published in the *New England Journal of Medicine* are relatively short-term studies that excluded patients with serum potassium greater than 6.5 mmol/L, electrocardiographic changes, hospitalized patients, and patients undergoing dialysis. We note that in the HARMONIZE study results published earlier this week in JAMA, patients were enrolled and treated in the second pivotal Phase III trial with ZS-9 with serum potassium levels greater than 6.5 mmol/L, with one patient (according to the analyst event) having a baseline level of 7.6 that was decreased to normokalemic levels in the study. The HARMONIZE 48-hour initiation phase also enrolled ambulatory patients, which addresses two of Dr. Ingelfinger's concerns. The remaining underlying question for ZS-9 is whether these significant effects will continue over the long term. We believe that the

company is adequately addressing this question with the ZS004 extension study as well as the ZS005 long-term safety study, with patients treated up to eight months as of the analyst event, and top-line data expected in mid-2015.

We believe that the last several events (the presentation of HARMONIZE at AHA, JAMA/NEJM publications, and ZS Pharma's analyst event) have further solidified our hypothesis that ZS-9 represents a best-in-class therapy of the treatment of hyperkalemia. We believe that the ZS Pharma's robust data set at the time of its potential NDA submission in the first half of 2015 (with approximately 1500 tested patients expected, with patient results out to one year) may be a differentiating factor in a potential advisory committee meeting with the FDA. In exhibit 5, we provide a summary of the clinical trials published to date for ZS-9 and patiromer.

Exhibit 5
ZS-9 and Patiromer FOS Clinical Trial Publication Summary

	ZS-9		Patiromer FOS	
	ZS003	HARMONIZE	PEARL-HF	OPAL-HK
Citation	Packham et al. *NEJM* 2014	Kosiborod et al. *JAMA* 2014	Pitt et al. *Eur Heart J* 2011	Weir et al. *NEJM* 2014
Number of Patients Enrolled	Initiation phase: 753 patients (158 placebo, 154 1.25g, 141 2.5g, 158 5g, 143 10g), Maintenance Phase: 543 patients (216 placebo, 94 1.25g, 104 2.5g, 65 5g, 63 10g)	Initiation phase: 258, Randomized Phase: 237 (45 - 5g, 51 - 10g, 56 - 15g, 85 - placebo)	105 (56 patiromer, 49 placebo)	243 patients: single-arm initiation (92 with mild hyperkalemia, 151 with moderate/severe); 107 patients: randomized withdrawal phase, 55 patiromer, 52 placebo
Underlying Etiologies	Hyperkalemia, regardless of underlying etiology	Hyperkalemia, regardless of underlying etiology	CHF, CKD, RAASi	CKD, RAASi, Diabetes, CHF (no Class IV)
Baseline Mean Serum K+	Initation Phase: 5.3 mEq/L, Maintenance Phase: 4.7 mEq/L (placebo/5g), 4.45 mEq/L (placebo/10g)	Initiation phase: 5.6 mEq/L, Maintenance phase: 5.55 mEq/L (placebo), 5.53 mEq/L (5g), 5.58 mEq/L (10g), 5.55 mEq/L (15g)	4.69 mEq/L for patiromer group, 4.65 mEq/L in placebo	Initiation phase: Mild Hyperkalemia: 5.3 mEq/L, Moderate-to-Severe Hyperkalemia: 5.7 mEq/L; Withdrawal phase: 4.45 mmol/L in placebo, 4.49 mmol/L in patiromer
Treatment Duration	48 h initiation phase, 12 day maintenance phase (2 weeks total)	48 h initiation phase, 26 day maintenance phase (4 weeks total)	28 days (4 weeks)	4 week single-group, single-blind initial treatment phase and 8 week placebo-controlled, single-blind, randomized withdrawal phase (12 weeks total)
Dosing Regimen	Initiation phase: 10g t.i.d. for 48 hr, Maintenance Phase: placebo, 1.25g, 2.5g, 5g, 10g, q.d for days 3-15	Initiation Phase: 10g t.i.d. for 48 hr, Withdrawal Phase: 5g, 10g, 15g, or placebo q.d. for days 8-29	15g in AM and PM (b.i.d.), 30g total	Initation phase: mean daily dose of 12.8g in mild HK, 21.4g in mod-to-sev HK
Primary Endpoint	Initiation Phase: mean serum potassium, Maintenance Phase: mean serum potassium	Initiation phase: mean serum potassium, Maintenance Phase: Percent of normokalemic patients	Mean change of serum K+ from baseline to day 28	Mean change of serum K+ from baseline to day 28, Mean change in serum K+ in withdrawal phase (week 8)
Mean Serum K+ at Primary Endpoint	Initiation Phase: 5.05 mEq/L (placebo), 4.84 mEq/L (2.5g), 4.76 mEq/L (5g), 4.57 mEq/L (10g), Maintenance Phase: 4.78 mEq/L (5g) vs. 4.95 mEq/L (placebo); 4.59 mEq/L (10g) vs. 5.01 mEq/L (placebo)	Initation phase: 4.5 mEq/L, Withdrawal Phase: 5.1 mEq/l in placebo, 4.8 mEq/L in 5g, 4.5 mEq/L in 10g, 4.4 mEq/L in 15g	4.47 mEq/L for patiromer, 4.88 mEq/L in placebo	Initiation phase: Mild Hyperkalemia: 4.65 mEq/L, Moderate-to-Severe Hyperkalemia: 4.47 mEq/L; Withdrawal phase: 4.49 mEq/L in patiromer group, 5.17 mEq/L in placebo
% of Normokalemic Patients	Initiation Phase: 75% 2.5g, 90% 5g, 99% 10g	Initiation phase 98% at 48 h, Withdrawal phase: 80% 5g dose, 90% 10g dose, 94% 15g dose, 46% placebo	93% (patiromer) vs 75% (placebo)	Initiation Phase: 74% (mild HK) and 77% (mod-to-sev HK); Withdrawal Phase: 85% (patiromer) vs. 40% (placebo)

Sources: Packham et al. NEJM 2014, Kosiborod et al. JAMA 2014, Pitt et al. Eur Heart J 2011, Weir et al. NEJM 2014, William Blair & Company, L.L.C.

Valuation

We rate shares of ZS-9 Outperform with a $75 price target. Our price target is derived from our net-present-value model for ZS-9 and applying a 75% probability of success. Swing factors in our peak-year estimates include patient duration, which we estimate will reach six months; however, if ZS Pharma is successful in penetrating the chronic therapy market, this duration

might hold upside. Currently, we anticipate peak sales for ZS-9 of $1.17 billion by penetrating 10% to 13% of the available patient populations within select markets.

Risks

Risks to an investment in ZS Pharma include the normal clinical, regulatory, and commercial risks in development-stage therapeutics companies.

IMPORTANT DISCLOSURES

William Blair was a manager or co-manager of a public offering of equity securities for ZS Pharma, Inc. within the prior 12 months.

William Blair is a market maker in the security of ZS Pharma, Inc. and may have a long or short position.

William Blair intends to seek investment banking compensation in the next three months from ZS Pharma, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with ZS Pharma, Inc.

Additional information is available upon request.

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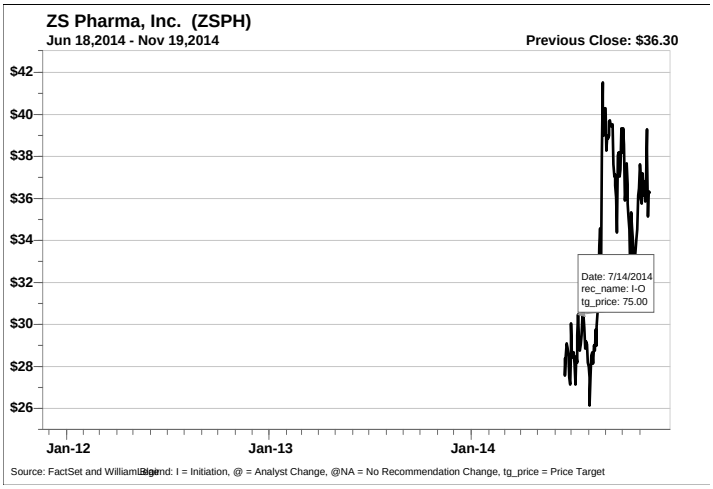
DOW JONES: 17,810.06
S&P 500: 2,063.50
NASDAQ: 4,712.97



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

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