ZS Pharma

ZS-9 Phase 3 Data Preview

Overweight

ZSPH, ZSPH US
Price: $36.61

Price Target: $43.00

At some point in the next several weeks, we anticipate top-line results from ZS004, a pivotal Phase 3 trial evaluating ZS-9's ability to treat hyperkalemia (high potassium) over a 28-day period (full results will be presented during an oral session at AHA in Nov). ZS-9 has already successfully completed two randomized trials, one of which was a shorter 14-day Phase 3 (ZS003); thus, we think positive results from ZS004 are largely expected. Regardless, given that data generated to date have been relatively short term, new information on the efficacy/safety of longer-term dosing will be important for doc (and investor) perception of the market opportunity. The bottom line is that we see this as a critical fundamental (and competitive) event for ZSPH that should be a meaningful catalyst for shares and further de-risk the asset ahead of NDA/MAA regulatory filings in 1H15. We see the potential for a 15%+ share price move, but note the extent of this is likely to be impacted by ZSPH's relatively thin float post the company's recent IPO. Reiterate Overweight.

- **The ZS004 trial is evaluating once-daily ZS-9 over 28 days; we anticipate data readout in late 3Q/early 4Q.** ZS004 is a randomized, double-blind withdrawal study that aims to confirm the dosing regimen for chronic administration. The trial enrolled patients with serum K >5 mEq/L. There's an open-label induction phase followed by a randomized, double-blind placebo controlled withdrawal phase. In the induction phase, pts will receive 10g of ZS-9 3x/day for 48 hours, and those whose serum K normalizes will be eligible to enter into the randomized withdrawal portion of the study in which patients will receive 5g, 10g or 15g of ZS-9 or placebo once daily for 28 days. The primary endpoint of the trial is to compare the mean serum K levels between the dosing groups. The clinicaltrials.gov listing indicates a primary completion date of August, and management has confirmed that top-line results should be available in late Sept or early Oct.
- **Based on data to date, we anticipate ZS004 will be positive, showing maintenance of normal K levels while being safe/well tolerated.** ZS-9 has been evaluated in two double-blind RCTs that enrolled a total of 843 pts: ZS002 (Ph 2) and ZS003 (Ph 3). The primary endpoints of both trials were met, with the former demonstrating that ZS-9 can rapidly lower K in a predictable manner, and the latter confirming those results and also establishing proof-of-concept for maintenance of effect with continued dosing. In ZS003, QD doses of 5g and 10g ZS-9 showed a stat sig difference vs. placebo, with 82% of ZS-9 patients having normal serum K at the end of 14 days. ZS004's design is similar to ZS003 (induction phase + maintenance dosing), and we believe the positive 14-day data bode well for the ZS004 readout. A more detailed data review starts on p. 4 (also in our initiation).

Biotechnology

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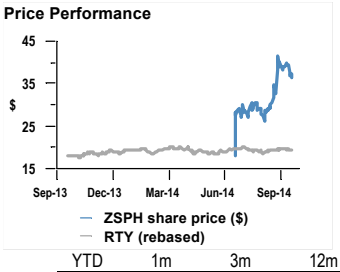

	YTD	1m	3m	12m
Abs	103.4 %	19.8%	29.0%	103.4 %
Rel	103.1 %	18.7%	30.9%	96.3%

ZS Pharma, Inc (ZSPH;ZSPH US)

FYE Dec	2013A	2014E	2015E	2016E
EPS Reported ($)				
Q1 (Mar)	(1.35)	(2.57)A	-	-
Q2 (Jun)	-	(4.72)A	-	-
Q3 (Sep)	-	(0.82)	-	-
Q4 (Dec)	-	(0.85)	-	-
FY	(8.52)	(5.01)	(3.16)	(4.71)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	36.61
Date Of Price	18 Sep 14
52-week Range ($)	43.00-25.51
Market Cap ($ mn)	127.49
Fiscal Year End	Dec
Shares O/S (mn)	3
Price Target ($)	43.00
Price Target End Date	31-Dec-15

See page 15 for analyst certification and important disclosures.

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- **We suspect shares could be up 15%+ on the positive headline; absolute downside on a failed trial is significantly greater but unlikely in our view.** As noted, we anticipate a positive outcome in this trial (and think the Street does as well), though we still expect an upward move on a favorable headline. Assuming efficacy and safety are as expected, we suspect shares could be up 15%+. On the flip side, if efficacy and/or safety fail to meet expectations (which we think is unlikely), we would expect a significant downward move. While the weight of the issue will dictate the magnitude of the move, we note that ZS-9 is ZS Pharma's only clinical stage product. We would note the company has ~$4/sh in cash. Lastly, we'd also point out that the thin post-IPO float has the potential to exacerbate the move up or down.

- **Longer-term data from ZS-9 is key given the majority of the hyperkalemia revenue potential lies in the chronic market.** Given significant safety/tolerability issues associated with kayexalate (the acute SOC treatment), it is rarely used in maintenance/chronic setting. Thus, there are a significant number of patients who are living with elevated potassium (which is often asymptomatic until cardiac abnormalities develop), or who are on suboptimal doses of important medications used to manage co-morbid conditions that are known to increase serum K. Docs we spoke with were particularly excited about the potential of ZS-9 in this setting. ZS estimates there are 2.5-3M patients eligible for chronic hyperK treatment in the US alone. Of the ~$1B in peak revenues we model for ZS-9, ~$950 comes from use in a chronic setting.

- **An additional trial is ongoing, ZS005, that will evaluate ZS-9 chronically over 12 months.** ZS005 is an open-label safety/exposure study, designed to show the safety/tolerability of ZS-9 when administered chronically (over 12 months). Once again, the trial consists of an open-label induction phase (48-72h), but this one also has a 12-month-long open-label treatment phase. Patients will receive 10g in the induction phase (3x/day), and will then roll into the treatment phase, during which they will initially receive 5g of QD ZS-9 that will be subsequently titrated (in 5g increments) to maintain serum K in a normal range. The primary endpoint of this trial is to demonstrate the safety and tolerability of ZS-9, though efficacy data coming from this trial will also be important. Data from this trial are anticipated in 2H15.

- **We continue to believe that ZS-9 has benefits over competition that could lead to a majority market share.** In our opinion, the size of this market and degree of unmet need is more than enough to sustain both ZS-9 and competitor patiromer (RLYP, not covered). Moreover, we assume that two sales forces are better than one in a what is essentially a new market. Though we conservatively assume a 50/50 split in market share, we do think ZS-9 has advantages that could lead to a majority stake. Specifically, patiromer is an ion exchange resin (like kayexalate) that binds potassium in the GI tract to facilitate fecal excretion. While patiromer appears to be much better tolerated than kayexalate, docs we spoke with pointed to constipation and diarrhea rates of 5-10% in the Phase 3 data (52 weeks) that could be a nuisance in longer-term treatment (while the GI event rate in ZS003 was 3.5% vs. a 5% rate on placebo at the highest dose in its shorter trials). Further, patiromer is dosed BID (as an oral suspension) vs. ZS-9's QD (as oral suspension or tablet), which again could be a competitive advantage as patients consider taking a potassium binder chronically

- **NDA/MAA filings for ZS-9 are anticipated in 1H15; we model launch in 2016 with peak US sales of ~$1B in 2020.** ZS estimates there are 2.5-3M patients eligible for chronic hyperK treatment in the US alone. The use of kayexalate provides a comp for the acute setting opportunity, with ~2.2 million treatments requiring acute management of their CKD (where ZS-9 could replace kayexalate in the treatment paradigm). To be

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conservative, we currently assume market shares are split 50/50 with Relypsa 4-5 years post launch. We also assume a net, compliance adjusted price of ~$400/month, and that patients are on therapy for an average of 4 months in any given year. These (we believe conservative) assumptions result in peak US sales for ZS-9 of ~$1B by 2020.

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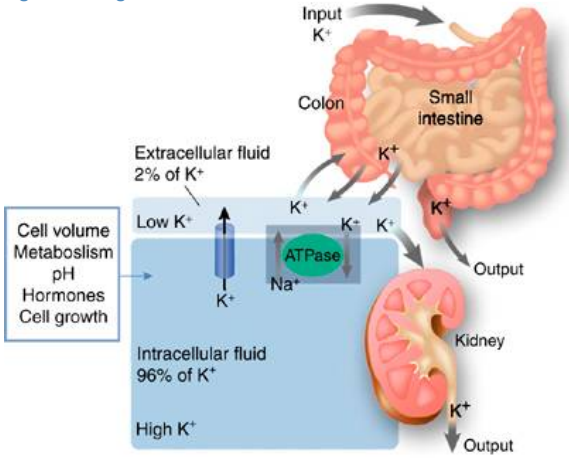
Hyperkalemia and ZS-9

Background on Hyperkalemia

An abnormally high concentration of potassium in the blood (a.k.a. hyperkalemia) is a common problem in CKD and HF patients given decreased renal excretion of K and medication-induced K retention.

Potassium is a key electrolyte in the human body, as it regulates several important functions, including membrane activation (in order to propagate electrochemical signals in both neurons and cardiac cells). Given its important role, the amount of potassium in the body is tightly regulated, and potassium stores are determined by dietary intake and renal excretion. More specifically, potassium is absorbed from food passively in the GI tract and rapidly enters circulation. This stimulates the production of insulin, and elevated insulin levels cause rapid transport of potassium from the extracellular to the intracellular space. On the other hand, excretion of potassium is regulated by the Renin–Angiotensin–Aldosterone System (RAAS). Higher levels of potassium in circulation cause certain renal cells to release rennin which then stimulates hepatic activation of angiotensin I, which is then converted into angiotensin II, which subsequently stimulates the secretion of aldosterone. Elevated aldosterone stimulates the kidney to excrete potassium.

Figure 1: Regulation of Potassium Concentration



Source: Giebisch et al. Kidney International (2007) 72, 397–410.

Serum potassium levels are typically maintained in a range from 3.5 - 5 mEq/L. Hyperkalemia, or serum potassium >5.5 mEq/L, is a potentially life-threatening problem that, if left untreated, can lead to sudden cardiac death (the electrolyte imbalance leads to ventricular fibrillation). As the condition is relatively asymptomatic until cardiac toxicity develops (though sometimes weakness is reported), it is often found during routine serum electrolyte monitoring. The condition can develop via one or more of three mechanisms: increased potassium intake, impaired movement of K+ from the extracellular to intracellular space, and most frequently, impaired renal excretion.

If left untreated, hyperkalemia can eventually lead to dangerous ventricular fibrillation and sudden cardiac death.

Patients with renal disease, congestive heart failure, severe hypertension, and diabetes often have renal insufficiency, putting them at increased risk for hyperkalemia. Certain drugs can also lead to potassium retention, including angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), aldosterone receptor antagonists, and direct renin inhibitors (collectively

termed RAAS inhibitors, or RAASi). As RAAS inhibitor therapy is a cornerstone in the treatment of high blood pressure, cardiovascular and renal diseases, patients with chronic kidney disease (CKD) and chronic heart failure (CHF) often have elevated serum potassium.

Current Treatment Landscape for Hyperkalemia

Generally treatment is thought of in two categories: acute/emergency (in the case of K >6-6.5 or with ECG changes) and longer-term chronic management (in patients with serum K< 6 mEq/L and no ECG abnormalities). In either case, docs we spoke with repeatedly noted that currently available treatment options are generally ineffective, poorly tolerated, or limit the cardio-renal benefits patients could otherwise derive from other medications.

Patients with moderate to severe hyperkalemia are admitted to the ER for emergency treatment. A series of treatments are administered to rapidly lower serum K, including kayexalate, the only drug approved to treat hyperkalemia.

Acute management for moderate/severe hyperkalemia (K > 6-6.5 mEq/L). If moderate or severe hyperkalemia is detected during routine screening, patients are instructed to go straight to the emergency room for immediate treatment. Acute/emergency treatment of hyperkalemia aims to rapidly shift potassium from the intracellular to the extracellular space, and to stabilize the myocardium to prevent arrhythmias. Any K-retaining drugs are stopped, and IV calcium is administered to lower the threshold potential within cardiac cells to counteract the effect of high potassium. Shifting potassium out of the cells is accomplished using insulin or a beta2 agonist. Subsequently the effluxed potassium needs to be removed from the body, which in patients with normal kidney function, can be accomplished by administering IV saline in combination with a diuretic. Patients with decreased kidney function, however, may be resistant to this strategy; thus, GI excretion can be increased via the use of a cation exchange resin – sodium polystyrene sulfonate (kayexalate). Kayexalate is the only drug approved to treat hyperkalemia, and it binds potassium in the gut (exchanging a K+ ion for an Na+) and facilitates fecal elimination. While kayexalate is relatively widely used in the hospital setting, docs with whom we spoke all noted that they don't like using it given the SAEs (e.g., significant diarrhea, potential for intestinal necrosis) and poor tolerability and adherence.

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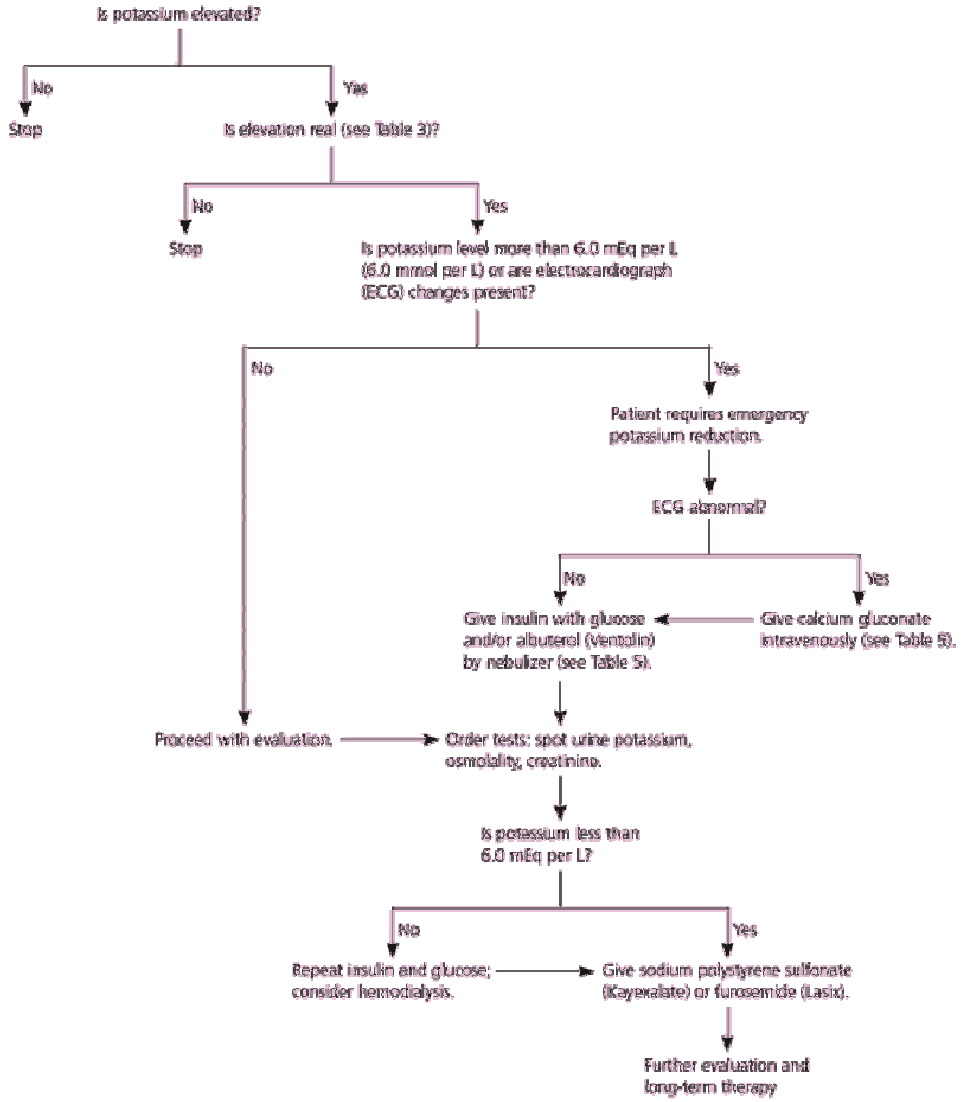
Figure 2: Treatment Algorithm for Hyperkalemia



Source: Hollander-Rodriguez and Calvert; Am Fam Physician. 2006 Jan 15;73(2):283-290.

Due to significant safety/tolerability concerns, kayexalate is rarely used in the long-term management of hyperkalemia. Instead, chronic treatment focuses on dietary restrictions and adjustment of medications that promote K retention.

Longer-term management of mild hyperkalemia (K < 6 mEq/L). While oral kayexalate could theoretically be used in a chronic management setting to maintain serum K, docs rarely or never prescribe it given its worrisome SAEs (especially in an outpatient setting) and it is not well tolerated (low outpatient compliance). Thus, the first step in managing mild hyperK is often a low-potassium diet, with patients avoiding potassium-rich foods such as avocado, bananas, broccoli, spinach, and milk. While this can be somewhat effective, longer term it is relatively ineffective due to poor compliance. Patients may also be prescribed potassium sparing diuretics to increase potassium excretion, though these can have undesirable effects and are often not appropriate for use in later state CKD patients. For patients taking RAASi therapy, doses of those medications are often decreased to limit their effect on serum K, resulting in sub-optimal dosing of medications that would otherwise provide cardio-renal benefits.

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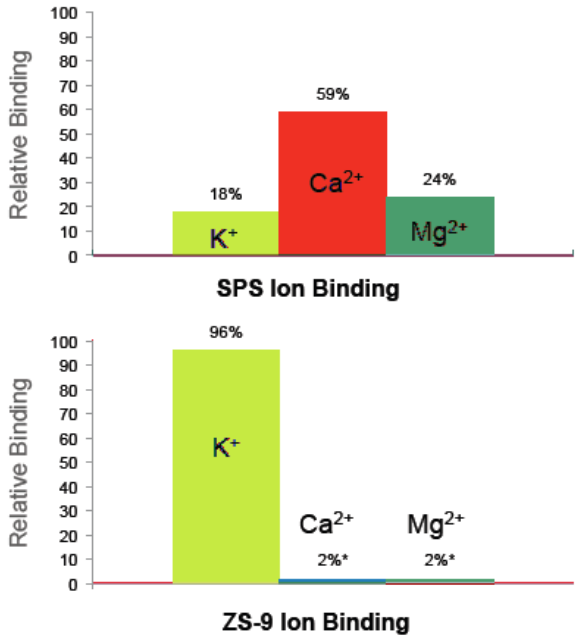
ZS-9 Overview

ZS-9 is a highly specific potassium ion trap that binds K in the GI tract to facilitate fecal excretion.

ZS-9 (zirconium silicate) is a highly selective potassium trap that is being developed as an oral treatment for hyperkalemia. It is an insoluble, non-absorbed compound with a three-dimensional crystalline lattice structure that was specifically designed to trap potassium ions. Oral administration of the compound results in K binding to ZS-9, which is then excreted fecally. The potassium selectivity of ZS-9 gives it a high in vitro capacity for K+, and in head-to-head in vitro studies, ZS-9 was shown to have ~10x the potassium binding capacity of kayexalate (SPS).

Figure 3: In Vitro Characterization of Binding Capacity and Specificity for ZS-9 and Kayexalate (SPS)



Source: Company Presentation.

ZS-9 has successfully completed Phase 2 and Phase 3 trials, with data from an additional Phase 3 trial expected in 4Q14 ahead of 1H15 NDA/MAA filings.

In clinical trials, the drug has been shown to be safe, well tolerated, and efficacious in the maintenance of normal serum K in the treatment of hyperK regardless of the underlying cause. Importantly, the drug has shown no effect on other electrolytes that are important in physiological functioning. The drug has successfully completed a Phase 2 and Phase 3 trial. An additional Phase 3 trial is ongoing, with data expected in 4Q14, for NDA/MAA filings in 1H15.

Figure 4: ZS-9's Completed and Ongoing Trials

Trial	Trial Type	Patient Population	Duration	Objective	Summary
ZS002 (Completed)	Double-blind RCT Phase II	N=90 Hyperkalemia, CKD 5.0–6.0 mEq/L	48 hours	POC for ZS-9 rapidly lowering K^+ levels	Met primary endpoint
ZS003 (Completed)	Double-blind RCT Phase III	N=753 Hyperkalemia regardless of etiology 5.0–6.5 mEq/L	14 days	Confirm rapid K+ control and POC for maintenance dosing	Met primary endpoint for the 2.5g, 5g and 10g doses, and met secondary endpoint for 5g and 10g doses in maintenance phase
ZS004/e (Ongoing)	Double-blind RCT Phase III	N=230 Hyperkalemia regardless of etiology >5.0 mEq/L	1 Month + Extension	Establish a maintenance dose	Ongoing; results expected in Q4 '14
ZS005 (Ongoing)	Open label safety study	N=500 Hyperkalemia regardless of etiology >5.0 mEq/L	Up to 12 months	Establish long-term safety and efficacy	Expect to initiate Q2 '14
Approximately 1,500+ Patients Will Be Exposed to Drug					

Source: Company Presentation.

Clinical Trial Data Review

ZS-9 has been evaluated in two double-blind, randomized, controlled trials that enrolled a total of 843 patients: ZS002 (Phase 2) completed in May 2012 and ZS003 (Phase 3) completed in November 2013. The primary endpoints of both trials were met, with the former demonstrating that ZS-9 can rapidly lower K levels in a predictable manner, and the latter confirming that effect and also establishing proof-of-concept for maintenance of effect with continued dosing. Two additional trials are ongoing: ZS004 (Phase 3) will establish a maintenance dose and ZS005 (open-label safety study) will establish long-term efficacy and safety of the compound.

ZS002 was a randomized Phase 2 trial that evaluated the effect of ZS-9 over 48 hours in an acute treatment setting.

ZS002. This Phase 2 dose-escalation trial was randomized, double blind, and placebo controlled in hyperkalemic CKD patients (with and without background RAASi therapy). The trial enrolled 90 patients with stage 3 CKD (eGFR of 30-60 mL/min) and with mild to moderate hyperkalemia (5.0-6.0 mEq/L). ZS-9 (at doses of 0.3, 3, or 10 grams) or placebo was dosed 3x/day with food during the 48-hour treatment phase. Serum K was measured at multiple time points during the 48-hour treatment phase, as well as once-daily during a 5-day follow-up period. The primary endpoint of the trial was the rate of change in serum potassium over 48 hours.

The trial met its primary endpoint, showing stat sig reductions in serum K 1 hour post dose, with 100% of patients reaching a normal K range within 48 hours at the highest dose.

The trial met its primary endpoint at the 3mg and 10mg doses ($p=0.048$ and $p<0.0001$, respectively), and treatment with ZS-9 resulted in a dose dependent effect on serum K levels. Importantly, the onset of action was rapid, with the 10g dose showing stat sig efficacy one hour after the first dose, and reducing serum potassium by a mean of 0.92 mEq/L in 38 hours. At 38 hours, 100% of patients on the 10g dose had serum K < 5 mEq/L, and 88% had levels <4.5mEq/L. Of note, the effect was observed regardless of whether a patient was on RAASi therapy. After ZS-9 treatment was stopped, serum potassium levels reverted to near-baseline levels.

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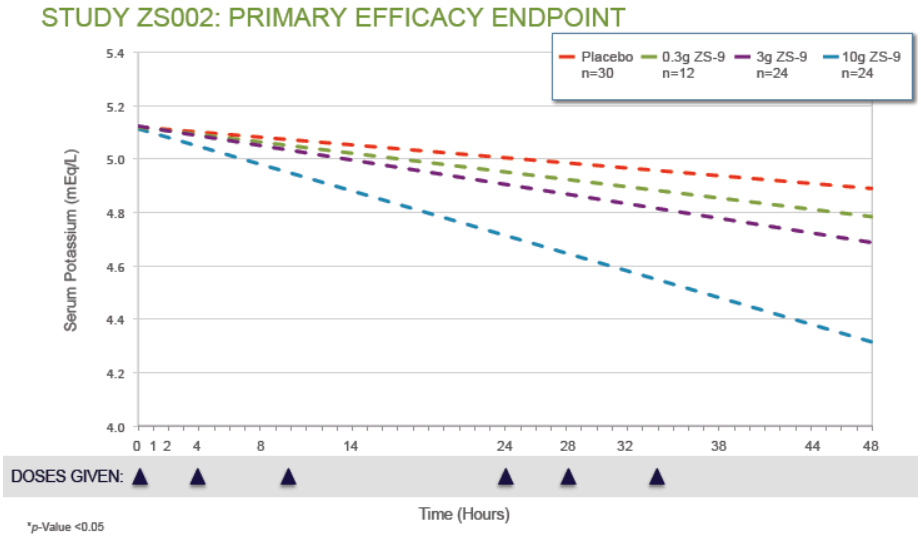
Figure 5: ZS-9's Achieves Primary Endpoint in ZS002 Phase 2 Trial



Source: Company Presentation.

ZS-9 was very well tolerated, with only transient and mild GI AEs observed, and no patients discontinued the trial.

ZS-9 was well tolerated, with transient minimal-mild GI AEs, the most frequent of which were nausea, vomiting, constipation, and diarrhea. The favorable safety/tolerability profile was further evidenced by the fact that no patients discontinued the trial, there were no treatment-related SAEs, no clinically significant changes in non-potassium electrolytes, and no cases of significant hypokalemia.

ZS003 is a Phase 3 trial that evaluated the effect of ZS-9 over a 14-day period.

ZS003. This Phase 3 trial was conducted in 753 patients with hyperkalemia and included patients with CKD, HF, diabetes, and those on RAASi therapy. Enrolled patients had potassium levels between 5.0 and 6.5 mEq/L, and were randomized to receive ZS-9 (1.25, 2.5, 5 or 10 g doses) or placebo 3x/day for the first 48 hours – the induction phase. Patients whose potassium levels normalized in the induction phase (3.5-5 mEq/L) were then randomized to receive either placebo or ZS-9 (at the same dose as induction phase) once daily for 12 days – the maintenance phase. The primary endpoint in the induction phase was rate of change in serum potassium (the same as ZS002), and for the maintenance phase it was the rate of change from placebo over 12 days.

In a 48-hour induction phase, ZS-9 was once again successful in rapidly bringing serum K within the normal range.

In the induction phase, the trial met the primary endpoint at the 2.5g, 5g and 10g doses vs. placebo, with ZS-9 again demonstrating the ability to produce rapid, dose dependent reductions in serum K within hours of the first dose. The mean K reduction at the 10g dose was -0.73 mEq/L, with ***99% of patients reaching normal serum K within 48 hours***. As in ZS002, stat sig reductions in serum K were observed one hour after the first dose of ZS-9. The drug was equally effective across patient subsets, with all groups (CKD, CHF, diabetes, and those on RAASi therapy) showing the same magnitude reduction in serum K. Interestingly, patients with higher starting potassium levels had a higher response to treatment with ZS-9. This is significant, as it supports a hypothesis for why treatment with ZS-9 has rarely resulted in hypokalemia. Briefly, ZS Pharma believes that when serum K is greater than 5 mEq/L the drug works in combination with the body to remove potassium. As serum K drops below 5, however, ZS believes the body responds accordingly, lowering physiologic excretion to avoid hypokalemia (serum K below 3.5 mEq/L).

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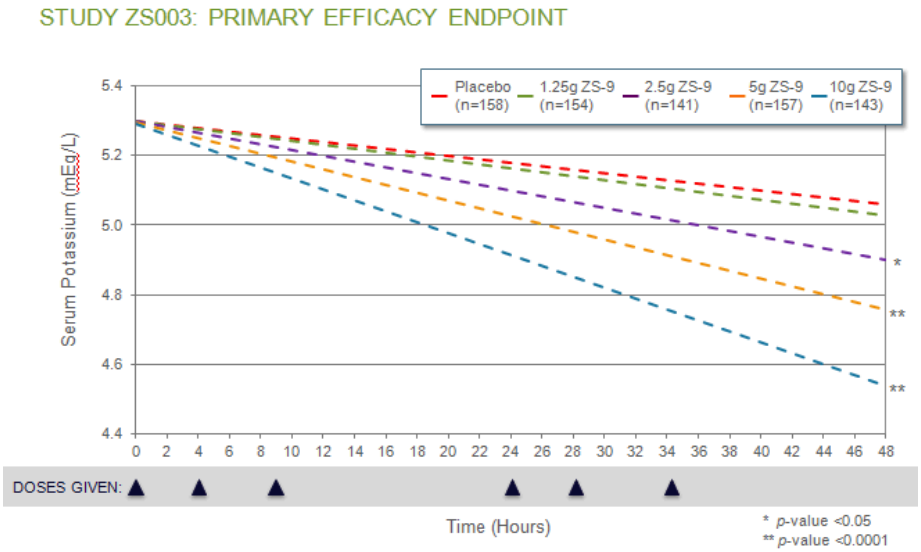
Figure 6: ZS003 Induction Phase Primary Endpoint

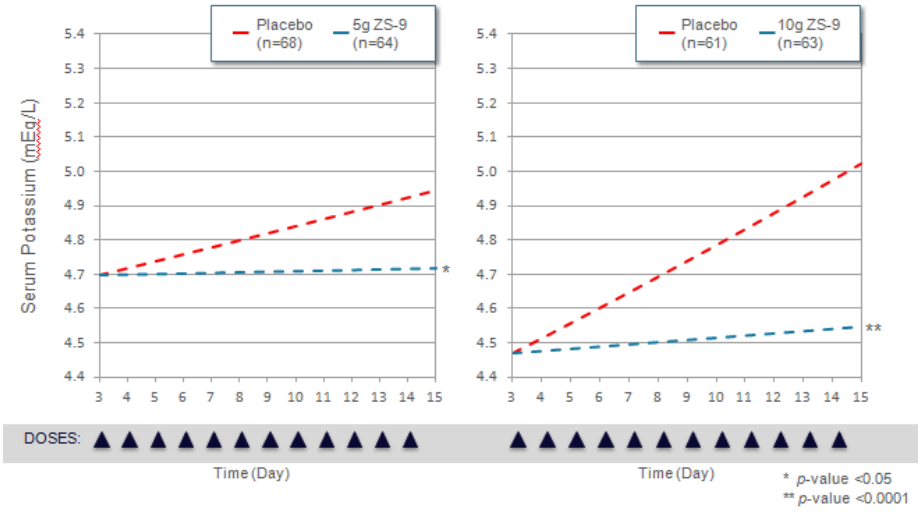


Source: Company Presentation.

In the 12-day maintenance dosing phase, continued treatment with ZS-9 was shown to maintain K within normal ranges with a safety/tolerability profile that was relatively in line with placebo.

In the maintenance phase, the primary endpoint was met at doses of 5g and 10g of ZS-9 once daily vs. placebo (p=0.075 and p<0.0001, respectively). Patients at the 5g dose experienced a mean increase of .11 mEg/L vs. an increase on placebo of 0.25. At the 10g dose, the average increase observed was 0.06 mEq/L vs. an average of 0.58 in the placebo group. At the end of 12 days, 82% of patients in the 10g dose group had serum potassium in the normal range. After treatment with ZS-9 ceased, potassium once again rebounded to near baseline levels.

Figure 7: ZS003Maintenance Phase Primary Endpoint



Source: Company Presentation.

ZS-9 once again proved to be safe and well tolerated in this trial, with the incidence of AEs being similar to those seen with placebo. At the 10g dose, the GI event rate was 3.5% vs. a 5% rate on placebo. UTIs were observed more frequently in patients taking ZS-9, though they did not seem to be dose related and the rate was within

expectations given the patient population had significant co-morbidities (CKD, diabetes, HF).

Figure 8: ZS003Treatment Emergent AEs

	Induction Phase		Maintenance Phase	
	Placebo (n=158)	ZS-9 (n=595)	Placebo (n=216)	ZS-9 (n=327)
All Adverse Events	10.8% (17)	12.9% (77)	24.5% (53)	25.1% (82)
Gastrointestinal Events	5.2% (8)	3.5% (21)	3.7% (8)	5.5% (18)

Source: Company Presentation.

There were no clinically meaningful treatment-related changes in laboratory parameters. Hypokalemia did occur in two subjects of the 753 (0.3%), though it was mild, transient, didn't require treatment, and did not result in complications in either case. A small decrease in mean serum calcium was observed, though all patients remained within the normal range, and it was deemed to be not clinically relevant. There were no stat sig changes in serum sodium or magnesium. Overall, AEs were generally mild/moderate and transient. Of the 16 SAEs in the study, 15 were assessed to be not be drug related, and the other SAE (gastroenteritis) was in the placebo group.

ZS004, a longer-term Phase 3 trial (28-day dosing period) is ongoing, with data expected in 4Q14. ZS005, also ongoing, is an open-label extension study that will evaluate ZS-9 dosing over 12 months.

Ongoing trials. ZS Pharma is conducting an additional, longer-term Phase 3 trial (ZS004) as well as an open-label, long term extension study (ZS005). **ZS004** is a randomized, double-blind withdrawal study that aims to confirm the dosing regimen for chronic administration. The trial will enroll patients with serum K >5 mEq/L. Similar to ZS003, there will be an induction phase (though open label here) followed by a randomized, double-blind placebo controlled withdrawal phase. In the induction phase, patients will receive 10g of ZS-9 3x/day for 48 hours, and patients whose serum K normalizes will be eligible to enter into the randomized withdrawal portion of the study, in which patients will receive 5g, 10g, or 15g of ZS-9 or placebo once daily for 28 days. The primary endpoint of the trial is to compare the mean serum K levels between the dosing groups. Subsequent to the 4-week treatment phase, patients will be eligible to continue to receive ZS-9 for two additional months in an open-label extension.

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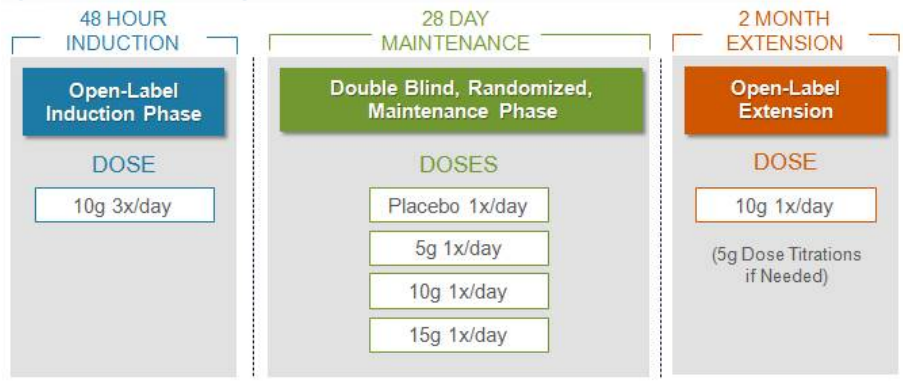
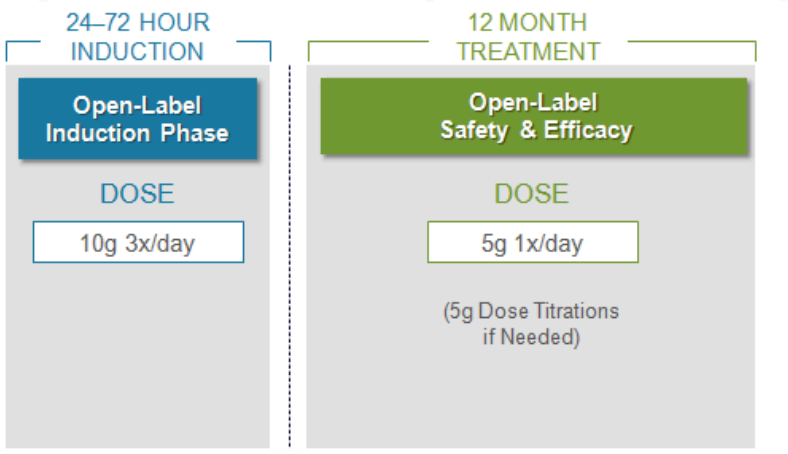
Figure 9: ZS004 Trial Design



Source: Company Presentation.

ZS005 is an open-label safety/exposure study, designed to show the safety/ tolerability of ZS-9 when administered chronically (over 12 months). Once again, the trial consists of an open label induction phase (48-72h), but this one also has a 12-month open-label treatment phase. Patients will receive 10g in the induction phase (3x/day) and will then roll into the treatment phase, during which they will initially receive 5g of QD ZS-9 which will be subsequently titrated (in 5g increments) to maintain serum K in a normal range. The primary endpoint of this trial is to demonstrate the safety and tolerability of ZS-9, though efficacy data coming from this trial will also be important.

Figure 10: ZS005 Trial Design



Source: Company Presentation.

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Investment Thesis, Valuation and Risks

ZS Pharma *(Overweight; Price Target: $43.00)*

Investment Thesis

We have an OW rating on ZSPH based on the potential of ZS-9for the treatment of hyperkalemia – a relatively common and potentially lethal condition in CKD and CHF patients. We see ZS-9 as a differentiated treatment option in a large market with significant unmet need, which we think could lead to a majority market share over time vs. competitor RLYP's patiromer. Even assuming equal share, we believe ZSPH's valuation is highly compelling on both a comp and absolute basis. Maintain Overweight.

Valuation

Our probability-weighted Dec-15 PT of $43 is based on a blended average of our proprietary probability-adjusted sum-of-the-parts scenario analysis (50% weighting) and risk-adjusted NPV model (50% weighting).

ZSPH Valuation Summary

ZSPH Valuation Summary			
Discount rate	13%		
4Q15 Fully Diluted Shares (mm)	27.8		
Main value drivers	Prob of approval	Peak WW sales est (avg. scenario)	Avg peak yr
ZS-9 US	70%	$ 1,105	2020
ZS-9 EU/Japan	50%	$ 570	2022
Valuation methodology	Value / share	Weighting	Adj. value/ share
DCF			
P/E 2016			
Real options scenario analysis	$ 45.04	50%	22.52
Risk adjusted NPV analysis	$ 40.51	50%	20.25
Total			$ 42.77
Catalyst/liquidity discount			0%
YE15 Price Target			**$ 43**

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

ZSPH is susceptible to the standard risks that apply to the entire biotech industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. More specific risks to the downside include clinical setbacks for ZS-9, regulatory hurdles, commercial setbacks, and personnel risk.

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ZS Pharma: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E
Revenues	0	0	0	52
Cost of products sold	0	0	0	(16)
Gross profit	-	-	-	-
SG&A	(8)	(18)	(26)	(114)
R&D	(25)	(37)	(41)	(44)
Operating income	(32)	(55)	(67)	(122)
EBITDA	(32)	(55)	(67)	(122)
Net interest (income) / expense	(2)	(7)	(2)	(2)
Other income / (expense)	-	-	-	-
Income taxes	0	0	0	0
Net income - GAAP	(34)	(62)	(69)	(124)
Net income - recurring	(34)	(62)	(69)	(124)
Diluted shares outstanding	4	12	22	26
EPS - excluding non-recurring	(8.52)	(5.01)	(3.16)	(4.71)
EPS - recurring	(8.52)	(5.01)	(3.16)	(4.71)

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	9	89	22	51
Accounts receivable	-	-	-	-
Inventories	-	-	-	-
Other current assets	0	0	0	0
Current assets	9	89	22	51
PP&E	5	10	12	12
Total assets	14	99	34	64
Total debt	-	-	-	-
Total liabilities	8	8	8	8
Shareholders' equity	6	91	25	55
Net income (including charges)	(34)	(62)	(69)	(124)
D&A	1	3	6	7
Change in working capital	3	0	0	0
Other	4	2	3	4
Cash flow from operations	(27)	(57)	(60)	(113)
Capex	(4)	(8)	(8)	(8)
Free cash flow	(28)	(58)	(65)	(118)
Cash flow from investing activities	(4)	(8)	(8)	(8)
Cash flow from financing activities	15	145	0	150
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Income Statement - Quarterly	1Q14A	2Q14A	3Q14E	4Q14E
Revenues	0A	0A	0	0
Cost of products sold	0A	0A	0	0
Gross profit	-	-	-	-
SG&A	(4)A	(5)A	(5)	(5)
R&D	(5)A	(10)A	(11)	(11)
Operating income	(9)A	(15)A	(15)	(16)
EBITDA	(9)A	(15)A	(15)	(16)
Net interest (income) / expense	(1)A	(2)A	(2)	(2)
Other income / (expense)	-	-	-	-
Income taxes	0A	0A	0	0
Net income - GAAP	(11)A	(16)A	(17)	(18)
Net income - recurring	(11)A	(16)A	(17)	(18)
Diluted shares outstanding	4A	3A	21	21
EPS - excluding non-recurring	(2.57)A	(4.72)A	(0.82)	(0.85)
EPS - recurring	(2.57)A	(4.72)A	(0.82)	(0.85)

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	-	-	-	-
EBIT growth	295.6%	70.3%	21.3%	83.5%
EPS growth - recurring	224.3%	(41.2%)	(36.9%)	49.1%
Gross margin	-	-	-	-
EBIT margin	-	-	-	(236.1%)
EBITDA margin	-	-	-	(236.1%)
Tax rate	0.0%	0.0%	0.0%	0.0%
Net margin	-	-	-	(240.6%)
Net Debt / EBITDA	-	-	-	-
Net Debt / Capital (book)	-	-	-	-
Return on assets (ROA)	(172.9%)	(109.6%)	(103.7%)	(255.4%)
Return on equity (ROE)	(235.2%)	(126.9%)	(117.9%)	(307.6%)
Enterprise value / sales	-	-	-	1.0
Enterprise value / EBITDA	NM	NM	NM	NM
Free cash flow yield	(19.1%)	(12.7%)	(8.2%)	(12.2%)

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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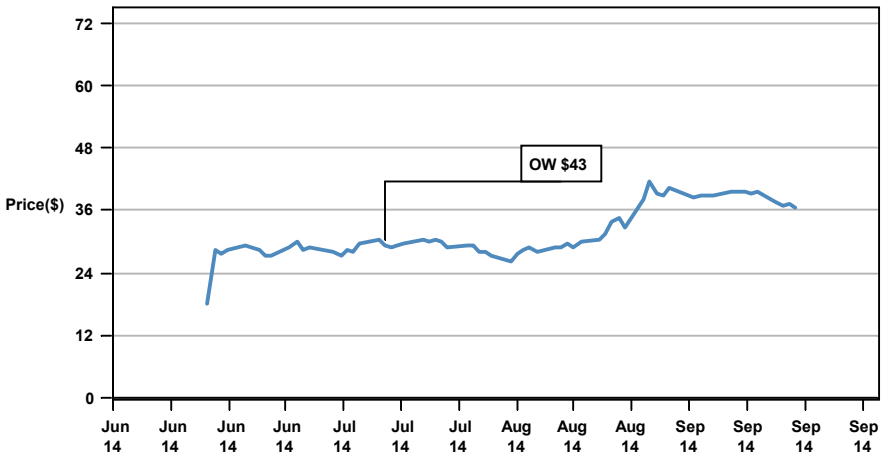
ZS Pharma (ZSPH, ZSPH US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
14-Jul-14	OW	30.49	43.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jul 14, 2014.

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