ZS Pharma

Largely De-Risked Phase 3 Candidate Targeting Big Unmet Medical Need...Initiating at OW

Initiation
Overweight

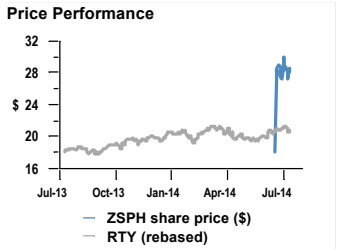
ZSPH, ZSPH US
Price: $29.49

Price Target: $43.00

We are initiating coverage of ZS Pharma with an Overweight rating based on the potential of ZS-9, its oral candidate for the treatment of hyperkalemia (elevated serum potassium), a potentially lethal condition. HyperK is relatively common (and very problematic) in people with chronic kidney disease (CKD) and heart failure (CHF). ZS-9 has effectively lowered serum K in 2 controlled trials, and an additional Phase 3 study is ongoing (data in 4Q14 offers an important potential near-term catalyst) to evaluate maintenance dosing (the largest revenue opp). We expect NDA/MAA filings in 1H15 and model peak US sales for ZS-9 at ~$1B. We conservatively assume ZS-9 captures 50% market share given a likely first-to-market competitive product from RLYP, though we (and more importantly physicians we spoke with) believe ZS-9 could have key advantages that may lead to a majority stake. At current levels we believe valuation is highly compelling on both a comp (RLYP's market cap is ~$800 vs. ZSPH's ~$600M) and absolute basis (using our rNPV and SOTP models).

- **Docs we spoke with were universally enthusiastic about ZS-9's profile.** There is only one drug approved to treat hyperK (kayexalate), but due to significant safety/tolerability concerns (diarrhea, intestinal necrosis), its use is largely relegated to the acute setting in-hospital emergency management. Docs think ZS-9 could quickly overtake kayexalate use in the hospital, and that its predictable efficacy and safety/tolerability profiles should allow for growing treatment of hyperK in a chronic setting. (see p. 7-11 for more detailed doc feedback).
- **The significant unmet need in hyperkalemia should drive robust uptake of new and improved products.** With nothing to treat hyperK long term, docs instead reduce doses of otherwise important meds that increase potassium. Thus, there is a large population of CKD/CHF pts whose primary disease is undertreated due to serum K concerns. We think the size of this market and degree of unmet need is more than enough to sustain both ZS-9 and competition (and 2 sales forces are better than 1 for market building). Though we conservatively assume a 50/50 split in market share, we do think ZS-9 could have benefits that could lead to a majority stake.
- **Initiating at OW.** Our YE15 PT of $43 per share is based on a blended average of our NPV and scenario analysis (50% each). ZS-9 in hyperK is the key driver. On a sum-of-the-parts basis, we assign ~$38/share to ZS-9 in the US (70% prob of approval) and ~$4/share in ex-US ZS-9 revenues (50% prob of approval, assuming ex-US partnership), plus ~$1/share in estimated YE15 cash.

Biotechnology
Cory Kasimov AC
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com
Bloomberg JPMA KASIMOV <GO>
Whitney G Ijem
(1-212) 622-4668
whitney.g.ijem@jpmorgan.com
Matthew J. Lowe, Ph.D.
(1-212) 622-0848
matthew.j.lowe@jpmorgan.com
Brittany Terner
(1-212) 622-8527
brittany.terner@jpmorgan.com
J.P. Morgan Securities LLC



	YTD	1m	3m	12m
Abs	56.7%	56.7%	56.7%	56.7%
Rel	56.9%	57.6%	53.7%	42.8%

ZS Pharma, Inc (ZSPH;ZSPH US)

FYE Dec	2012A	2013A	2014E	2015E	2016E
EPS Reported ($)					
Q1 (Mar)	-	(1.35)	(2.57)A	-	-
Q2 (Jun)	-	-	(1.02)	-	-
Q3 (Sep)	-	-	(0.63)	-	-
Q4 (Dec)	-	-	(0.64)	-	-
FY	(2.63)	(8.52)	(3.43)	(3.12)	(4.69)

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

Company Data	
Price ($)	29.49
Date Of Price	11-Jul-14
52-week Range ($)	30.67-26.10
Market Cap ($ mn)	123.19
Fiscal Year End	Dec
Shares O/S (mn)	4
Price Target ($)	43.00
Price Target End Date	31-Dec-15

See page 34 for analyst certification and important disclosures.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

J.P.Morgan

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Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Investment Thesis

ZS Pharma (ZSPH)

Overweight

ZS-9 is a potassium trap being developed to treat hyperkalemia, a relatively common and potentially lethal condition in CKD and CHF patients

ZS-9 (zirconium silicate) is a highly selective potassium trap being developed as an oral treatment for hyperkalemia (elevated levels of serum K). In patients with renal or cardiac disease, potassium levels within the body can rise to dangerous levels, both due to decreased renal potassium excretion and because medications used to treat the diseases promote K retention. If left untreated, hyperK leads to ventricular fibrillation/sudden cardiac death. ZS-9 was specifically designed to trap K ions (without affecting other key electrolytes) in the GI tract to increase fecal excretion to lower serum potassium and return patients to a normal range.

ZS-9 rapidly reduces serum potassium (within hours) while being safe and very well tolerated, a key advantage in an acute treatment setting

Patients found to have moderate-to-severe hyperK are admitted to the ER for immediate treatment, with the goal of rapidly normalizing serum K. The only drug approved to treat hyperK, kayexalate, is mainly used in this setting. Every doc with whom we spoke highlighted safety/tolerability issues (mainly GI) with this drug, indicating they use it only because they have no other option. In an acute treatment setting, ZS-9 has shown a dose dependent effect on serum K, with the highest dose showing stat sig efficacy one hour after the first dose and 100% of patients falling within the normal range within 48 hours. Most importantly relative to the currently approved therapy, ZS-9 was well tolerated, with transient minimal-mild GI AEs.

Chronic treatment of hyperkalemia represents a large and relatively untapped market opportunity, and early data supports ZS-9 use in this setting

Given the significant safety/tolerability issues with kayexalate, 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. Again, docs we spoke with were particularly excited about the potential of ZS-9 in this setting (see p. 7-11 for more detailed takeaways from our doc conversations). In a Phase 3 randomized controlled trial, ZS-9 was shown to maintain serum K within the normal range over a 12-day maintenance dosing period while continuing to be very safe/well tolerated. While this trial was relatively short, it provides initial evidence that ZS-9 could be used in a chronic treatment setting.

Phase 3 trials of longer-term treatment are ongoing (initial data in 4Q14), which we anticipate will be positive, further de-risking the chronic opportunity

A Phase 3 trial evaluating 28-day treatment with ZS-9 (plus 2-month open label extension) is ongoing, with the goal of confirming the effect of maintenance dosing with ZS-9. While we (and the Street) anticipate positive data, we still think longer-term Phase 3 data could be a significant catalyst for the stock, as it provides additional de-risking ahead of NDA/MAA filing in 1H15. Given that the data generated to date for ZS-9 has been relatively short term, we also think longer-term efficacy/safety data will be important for doc (and investor) perception of the ultimate market opportunity.

Though a competitive drug (patiromer) is likely to be first to market, we think the size/unmet need in hyperK is more than enough to support two products

A large proportion of CKD/CHF patients are undertreated with important meds, namely RAASi (such as ACEs and ARBs), due to serum K concerns. Given the number of these patients and the significant unmet need, we think this market will be more than sufficient for ZS-9 and competitor patiromer (RLYP, not covered). Patiromer has successfully completed a Phase 3 program under an SPA, and an NDA is anticipated in 3Q14. Patiromer demonstrated efficacy that, in our view, is similar to that of ZS-9, and both products represent significant improvements over kayexalate on safety and efficacy. Given the largest revenue opportunity is in chronic use, and because there isn't currently a SOC therapy in that setting, we think the presence of multiple players will ultimately be beneficial to all by growing the market.

We think ZS-9 could prove to have convenience/tolerability benefits over patiromer that could lead to a majority market share in the chronic setting

Like kayexalate, patiromer is an ion exchange resin 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 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 $700/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 at ~$1B by 2020E.

Balance sheet: ZSPH appears well positioned financially

ZSPH ended 1Q14 with ~$21M in cash and subsequently raised ~$112M from an initial public offering of common stock in June (J.P. Morgan acted as a joint book-runner). We estimate that ZS ends 2014 with ~$85M in cash and believe the company has sufficient capital through the expected approval of ZS-9 in early 2016.

Initiate at Overweight: ZS-9 is a differentiated treatment option in a market with significant unmet need

We are initiating coverage of ZSPH with an OW rating and YE15 PT of $43. We believe the significant unmet need in the treatment of chronic hyperkalemia will drive uptake of ZS-9 (and competitors) and that ZS-9's differentiating features could ultimately drive a majority market share. Our target is based on a blended average of our risk-adjusted NPV model (50%) and proprietary scenario analysis (50%). On a sum-of-the-parts basis, we assign ~$38/share to ZS-9 in the US (70% prob of

approval) and ~$4/share in ex-US ZS-9 revenues (50% P of approval, assuming ex-US partnership w/ avg 25% royalty), plus ~$1/share estimated milestones and cash.

Risks to Rating and Price Target

ZS Pharma is susceptible to the standard risks that apply to the entire biotech industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. Risks more specific to ZS are outlined below:

Clinical risk

Though ZS-9 has successfully completed 2 randomized, controlled clinical trials, both were relatively short in nature, with the longest time on treatment evaluated being 14 days. A longer-term Phase 3 trial is currently underway, and it is possible that this trial will not meet its primary endpoints or that new/unexpected side effects could emerge with longer durations of treatment.

Regulatory risk

ZS Pharma believes data from the two Phase 3 trials, the Phase 2 trial, and some data from the ongoing open label extension study will be sufficient to support approval. However, there remains the risk that ZS-9 will not be approved by the FDA or EMA. Regulatory agencies may want to see additional, longer-term data before approving the drug. If approved, under the current plan, it is possible that the label may not be as the company anticipates, potentially limiting the use of ZS-9 to more acute treatment settings. Further, regulatory agencies could remove ZS-9 from the market if the drug shows additional/more severe AEs in a real-world setting.

Commercial risk

The rate of uptake and/or pricing could limit sales of ZS-9. ZS-9 would be ZS Pharma's first commercial drug, and it is possible that uptake of the drug by physicians may be slower than expected. There is one therapy that is approved to treat hyperkalemia that is currently on the market that is fairly widely used. Physicians may be slower to try a new product in this relatively fragile patient population. Further, the currently approved therapy is generic, which could affect pricing power in this market and could limit ZS Pharma's ability to price favorably and/or remain competitive.

Competitive risk

Patiromer, an ion exchange resin, is being developed by Relypsa (RLYP, not covered) and is likely to be the first to reach the market. While we currently assume a 50/50 market share between the two products at peak, it is possible that patiromer will be more competitive to ZS-9 than we assume.

IP risk

We currently model patent protection through 2032 based on patents and patent applications filed by ZS Pharma that are directed towards improved zirconium silicate compositions, methods of treatment, including treatment of hyperkalemia and other conditions, and methods of manufacturing zirconium silicate compositions (US and foreign applications). It is possible that these patents may not issue, and if they

do, it is possible that they may not be strong enough or sufficient to protect ZS-9 from generic competition.

Company Description

ZS Pharma is a biopharmaceutical company focused on the development and commercialization of products for the treatment of renal, cardiovascular, liver, and metabolic disease. The company is developing ZS-9 (zirconium silicate), a highly selective ion trap for the treatment of hyperkalemia, a condition that increases the risk of muscle dysfunction, including cardiac arrhythmias and sudden cardiac death. ZS-9 was developed using ZS's proprietary technology that allows for the creation of highly selective ion traps that can be used to reduce levels of specific electrolytes without affecting others. ZS-9 has successfully completed 2 clinical trials in hyperkalemic patients, including patients with chronic kidney disease, heart failure, diabetes and patients on RAAS inhibitor therapy. A second Phase 3 trial was initiated in 1Q14, with data expected in 4Q14 and NDA/MAA filing in 1H15.

Upcoming Events

Figure 1: ZSPH News Flow Highlights

Anticipated Newsflow Highlights

Program	Event	Expected	Significance
ZS-9	Results from ZS004 Ph 3 study	4Q14	High
	Initiate ZS005 study to assess long-term safety/efficacy	2Q14	Low
	NDA and MAA filings	1H15	Medium
	US Launch	2016	High

Source: Company reports and J.P. Morgan estimates.

For ZS Pharma in 2014, the key remaining catalysts should be Phase 3 data from the ZS004 trial (28-day treatment), which is anticipated in 4Q14. While we anticipate positive data, we still think longer-term Phase 3 data could be a significant catalyst for the stock as it provides further de-risking ahead of NDA/MAA filing (1H15). Further, given that the data generated to date for ZS-9 has been relatively short term, long-term data on the efficacy/safety of maintenance dosing will be important for doc (and investor) perception of the market opportunity.

Pipeline

Figure 2: ZSPH's Pipeline

Product Pipeline Highlights

Program	P/C	Ph 1	Ph 2	Ph 3	FDA	Mkt.	Partner	Comments
ZS-9								
Hyperkalemia							--	
ZS-1								
Elevated Ammonia							--	

Source: Company reports.

ZS-9 is ZS Pharma's lone clinical drug candidate, which is in development for hyperkalemia associated with chronic kidney disease (CKD) and heart failure (HF). The company doesn't have any other clinical candidates in the pipeline, but does

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

have a preclinical candidate, ZS-1, which is currently under evaluation as a treatment for patients with high blood ammonia levels (though IND enabling studies have not yet been initiated).

Doc Rounds: Physician Thoughts on Hyperkalemia and ZS-9

We spoke with a number of physicians, both nephrologists and cardiologists, to discuss the current treatment landscape and get their impressions of ZS-9.

We had the opportunity to speak with a number of physicians who manage patients at high risk for developing hyperkalemia or those who already have the condition. We spoke with both nephrologists (for CKD patients) and cardiologists (for HF patients) about the current treatment paradigm as well as their thoughts on ZS-9 and patiromer. Key takeaways include:

Docs were enthusiastic about both the safety and efficacy profile for ZS-9, believing it is better than the only approved medication, and could also have advantages over the key competitor over the longer term.

- Regardless of their specialty, docs acknowledged the potential serious consequences of hyperkalemia and understand the importance of maintenance of serum K within the normal range;
- Docs unilaterally expressed disdain for the one currently approved product (kayexalate) given its safety/tolerability profile;
- Both ZS-9 and patiromer's efficacy and safety look far superior to kayexalate's;
- The rate of chronic hyperK treatment should go up with the availability of safe/well tolerated medications ; and
- Docs thought ZS-9's profile has some advantages over patiromer (safety, speed of effect, convenience) that could prove to be an advantage in the setting of chronic treatment.

Below we provide more detailed notes from each conversation.

Physician 1

Background: Cardiologist in Dallas, TX. Part-time practice (70% research, 30% practice). The majority of his patients have HF, and his main area of research is how CKD affects CV disease. Has worked as a consultant to ZS Pharma.

How many of your patients are hyperkalemic, and how are you managing them? 30-40% of patients have potassium levels that are concerning enough to monitor, and those patients are monitored monthly to quarterly, depending on the level of concern. Of these patients, the majority are managed by adjustment of RAASi therapy, but ~5% of his total patient population on average end up being admitted to the hospital for emergency treatment (kayexalate), which happens when pts reach serum K >5.5 mEq/L.

Thoughts on kayexalate? Though it is generic, it is still fairly expensive. It is a "nasty drug," as there are a lot of toxicities and it is difficult for people to take. Patients develop tremendous diarrhea… but it is used fairly frequently in the acute setting because there isn't anything else. Most docs are uncomfortable using it in an outpatient setting because of safety/tolerability, and because it isn't reliable enough.

Thoughts on ZS-9 safety and efficacy profile? The data so far is great…almost "flawless." The drug is zirconium based, but he's not at all worried about the buildup of metal in tissue based on the data the company has generated about absorption. Again, the lower rates of GI AEs is notable relative to kayexalate.

Views on ZS-9 vs. kayexalate? Kayexalate is expensive, and docs don't like using it. Assuming ZS-9 is priced appropriately, he thinks it could become the new hospital standard overnight.

Views on ZS-9 and patiromer? So far, based on the data released, ZS-9 seems like it will be used more in an acute setting vs. patiromer in a chronic setting. Given this expectation, he thinks there will be some pull-through use to the chronic setting, which could also be an advantage for ZS-9. Hospitals won't carry 2 products, so ZS-9 will likely win there. He sees 3 key positive differentiators for ZS-9: 1) it doesn't have the same GI issues as patiromer since it isn't a polymer; 2) ZS-9's pill formulation will be more versatile than patiromer's powder/oral suspension (and QD vs. BID)… in an adult setting, a powder almost never goes very far, and 3) patiromer isn't as specific for K.

Other thoughts: Another potential market here could be in oncology, so he would like to see ZS run some trials in cancer patients to lessen the risk of hyperkalemia in patients undergoing chemo.

Physician 2

Background: Nephrologist, large practice in Denver and in charge of research division. Time split 50/50 between research and practicing. Was involved in the Phase 3 trial (ZS003).

How many of your patients are hyperkalemic, and how are you managing them? Very little is done to treat hyperK on an ongoing basis… thus, the population of people that would benefit from ZS-9 or patiromer is underestimated by the population of patients currently being treated. Think ~10% of stage 4/5 NDD-CKD patients are currently being treated for hyperkalemia, but probably 20-25% would get treated if there were better options, and ~10-15% of the stage 3 patient population. Kayexalate isn't common in a chronic management setting; instead, patients are taken off of whatever drugs are causing hyperkalemia and switched to something else… patients are not on optimal therapy for CKD/CV disease because of hyperkalemia. 25-40% of ESRD patients come off ACE/ARB in later disease stages due to high potassium.

Thoughts on kayexalate? Is generally effective though not consistent in its PK, which can be problematic. It also has significant GI issues. Rarely used in a chronic management setting.

Thoughts on ZS-9 safety and efficacy profile? Impressed with the Phase 2 data (which is why got involved in Phase 3), and the most important aspect is that it is really well tolerated… don't see any differences between ZS-9 and placebo on AEs. Didn't have any subjects with GI side effects. Was pleased with how fast the drug worked (and how predictable it was) and that K stayed stable and well controlled, and that it didn't overshoot and cause hypokalemia. Think the overall risk of hypokalemia in the real world is fairly low if the drug is titrated appropriately for

chronic use. “0% concerned” about the risk of zirconium accumulation given the amount that is absorbed in ZS-9 vs. food and water we consume (~1000x more zirconium in food than what absorbed from ZS-9).

Views on ZS-9 vs. kayexalate? While kayexalate generally lowers K, don’t know that it works consistently. So, in the ZS-9 data, it is nice see that it works consistently and that the rate of change in the first 24-48 hours was similar among patients.... this is especially important in the acute setting.

Views on ZS-9 and patiromer? Patiromer’s efficacy data is also good, and it is clear that it works. Think the BID dosing could be more challenging for patiromer. Patiromer does have a potential advantage in that docs are familiar with polymer-based pharmacology vs. heavy metals…. though it has a slower onset of action, so that could quickly outweigh this issue. Overall, think both drugs work and that the ultimate uptake will depend on formulation, ease of use and price.

Physician 3

Background: Nephrologist in Arizona, runs the research program and maintains a full-size clinical dialysis practice. Was an investigator in the Phase 2 (ZS002) trial.

How many of your patients are hyperkalemic, and how are you managing them? Mainly treat patients in the hospital/acute setting with kayexalate, insulin, beta2 agonists. In an outpatient setting, there is no consensus on management… most people stop/reduce ACE/ARB therapy. Diuretics are used fairly frequently for want of a better agent, but are cumbersome and have to keep monitoring the patient. Roughly 1/3 of his patient population are not on ACE/ARB inhibitors or other medications that they should be taking due to potassium concerns.

Thoughts on kayexalate? People hate it; it causes significant diarrhea, and docs only use it as a desperate measure. Also there is no guarantee that it works, and it can take up to 6 hours to see it start to have an effect. But we don’t have any other options, so it is used in the ER setting more than it probably should be.

Thoughts on ZS-9 safety and efficacy profile? It is interesting that the FDA said no need for a Phase 1 trial… so first in man trial was Phase 2 RCT. Don't recall any GI issues in the trial, which is of note; people tolerated it really well. The drug was very inert, tasteless, patients tolerated it well. Saw tremendous results... saw K levels coming down very early on… had many patients request to come back into the study or be enrolled in another. The main thing in treating this disease is predictability, so encouraged to see ZS-9’s consistency of effect and that patients had no dietary restrictions and didn’t have to adjust background meds. There has been no evidence of zirconium buildup, and also radiologists use it as a labeling agent. So it is a pretty inert material, and not concerned with metal build up at all.

Views on ZS-9 vs. kayexalate? Based on the data so far, nobody would use kayexalate over ZS-9 if it were approved.

Views on ZS-9 and patiromer? Patiromer is also a polymer, so have concerns around its selectivity (vs. ZS-9, which is much more selective for K than kayexalate). ZS-9’s selectivity may allow for more predictable/consistent dose titrations in the context of dietary K intake and concomitant medications to accurately and easily

control K. While patiromer's data looks good, all else relatively equal, would prefer to use the more selective compound. Patiromer does have longer-term data though, so will be important to generate the same for ZS-9.

Physician 4

Background: Cardiologist in Missouri; spends half of the time in clinical practice and half in research. Has been a consultant to ZS Pharma and is involved in the ZS004 trial.

Thoughts on kayexalate? Use it because there is nothing else… but it is not an ideal product.

Thoughts on ZS-9 safety and efficacy profile? The Phase 3 (ZS003) data is very compelling, with a nice dose response. AEs look comparable to placebo, and if these trends continue… will be a huge benefit for physicians. On zirconium, there is little reason to believe it will be toxic, and the data to date is not generating any concerns, though long-term data from the ZS005 trial will be vital to support this.

Views on ZS-9 and patiromer? Patiromer is an ion exchange resin like kayexalate, though also appears to be much better on efficacy and safety than kayexalate. Think ZS-9's method of action could have some advantages (given it is a potassium binder and not an exchange resin that could bind other ions)… though not sure how clinically important that will be yet. In general, it is always good to have another treatment option. At this point, patiromer's safety data seems to be not quite as good as ZS's, although it's hard to compare across trials.

Physician 5

Background: Nephrologist at an academic medical center in Florida, Director of the Kidney research program. Is on ZS Pharma's Advisory Board, but has not been involved in any of the clinical trials.

How many of your patients are hyperkalemic, and how are you managing them? Majority of patients have renal disease, but also run a severe hypertension outpatient practice.... potassium disorders are a concern for ~75% of patients, with 10-20% of patients actually having a problem. Unfortunately, patients with high salt, high junk food diets don't have a problem, and patients who eat healthier (fruits, nuts and veggies) are more prone to hyperkalemia. Take a multi-factorial approach to treating patients. Generally try to adjust diet, can give diuretics to increase kidney excretion, though that then affects hydration, which can then have an effect on kidney function... so there is a balance there. Will prescribe kayexalate in an out-patient setting as a third option.

Thoughts on kayexalate? It is not well tolerated, most patients get diarrhea, it tastes terrible, "patients think it tastes the same coming in as it does going out" and it is fairly expensive for being generic.

Thoughts on ZS-9 safety and efficacy profile? The data is promising, and so far ZS-9 appears to have the better tolerability profile. Not concerned about zirconium accumulation… it isn't absorbed. Will be curious to see the long-term effects on the bowel, particularly in patients with constipation or baseline motility issues.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Views on ZS-9 vs. kayexalate? Hard to compare vs. kayexalate, as most of the data generated with the drug was single dose, and neither of the newer drugs (both ZS-9 and patiromer) were evaluated in that way. The exciting thing about this new wave of drugs is their potential in a chronic setting, where kayexalate is difficult to use.

Views on ZS-9 and patiromer? Haven't had personal experience with either drug, but based on the data presented thus far, seems like ZS-9 has the better safety/tolerability profile, specifically on GI AEs. At this point they seem similar in terms of effect on serum potassium. If ZS-9's side effect profile continues to look favorable, it will have the advantage, as it will be a better drug for longer-term therapy. The advantage that patiromer has initially is that it had longer, chronic dosing trials to start with, whereas ZS Pharma's have been fairly short term. But ultimately, if they end up having similar effects on serum potassium, long-term use will be determined by cost, side effects and the label.

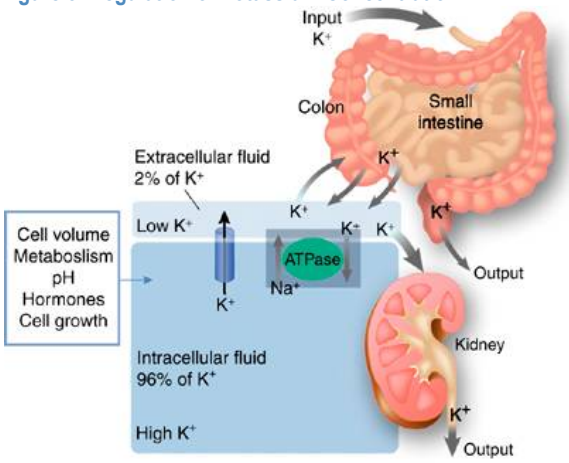
Hyperkalemia and ZS-9

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 3: 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

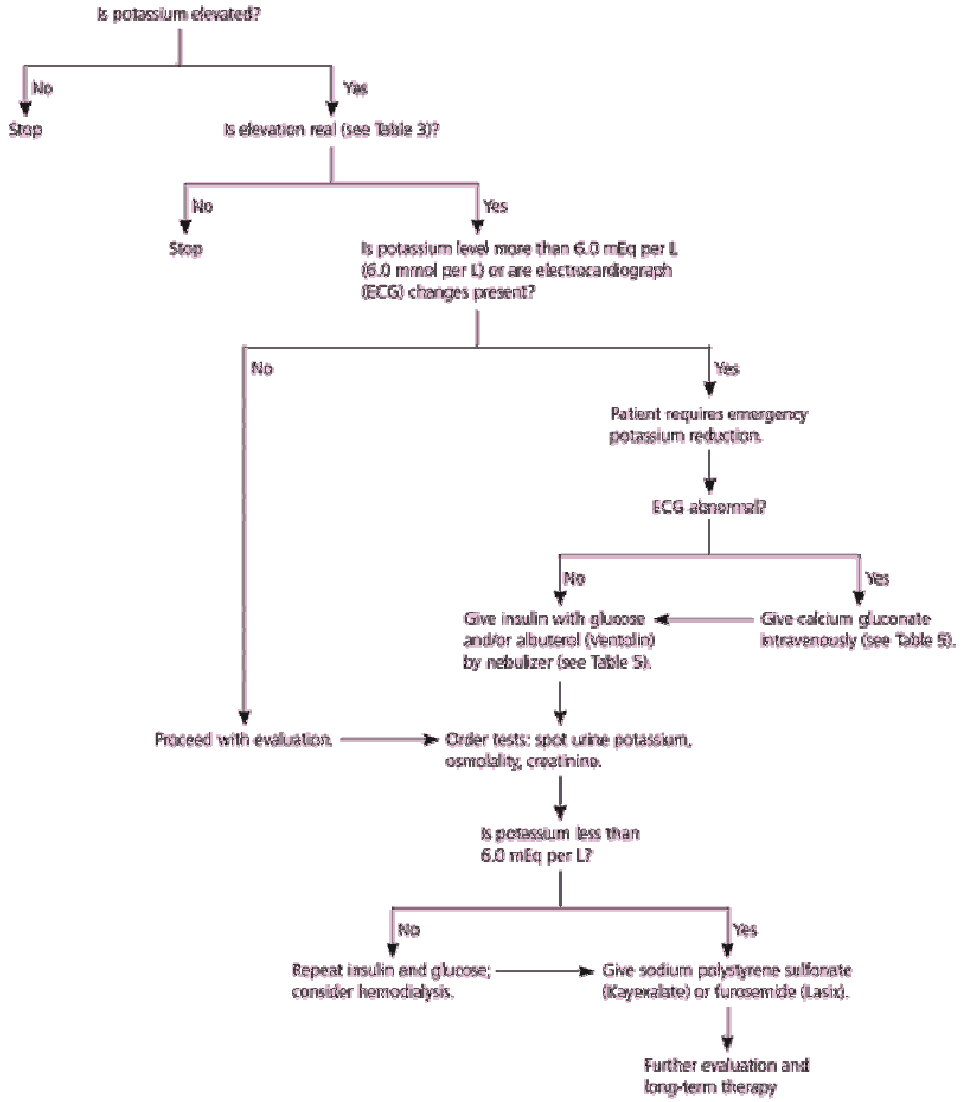
Generally treatment is thought of in two categories: acute/emergency (in the case of K >6-6.5 or with ECG changes) and longer-term chronic management (in patients with serum K< 6 mEq/L and no ECG abnormalities). In either case, docs we spoke with repeatedly noted that currently available treatment options 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.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Figure 4: 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.

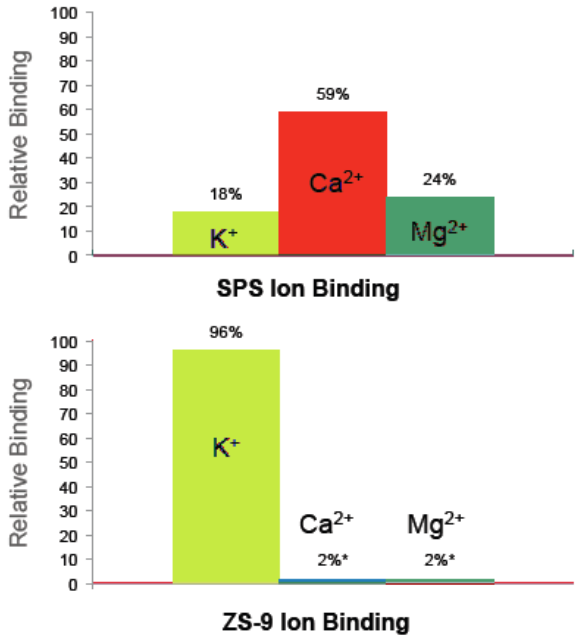
Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

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 5: 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.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Figure 6: 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.

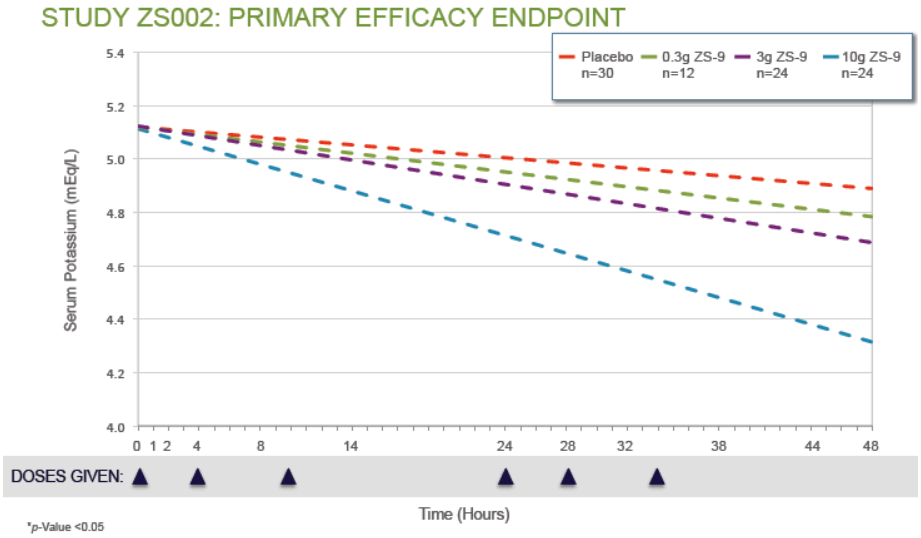
ZS002. This Phase 2 dose-escalation trial was randomized, double blind, and placebo controlled in hyperkalemic CKD patients (with and without background RAASi therapy). The trial enrolled 90 patients with stage 3 CKD (eGFR of 30-60 mL/min) and with mild to moderate hyperkalemia (5.0-6.0 mEq/L). ZS-9 (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.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Figure 7: 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.

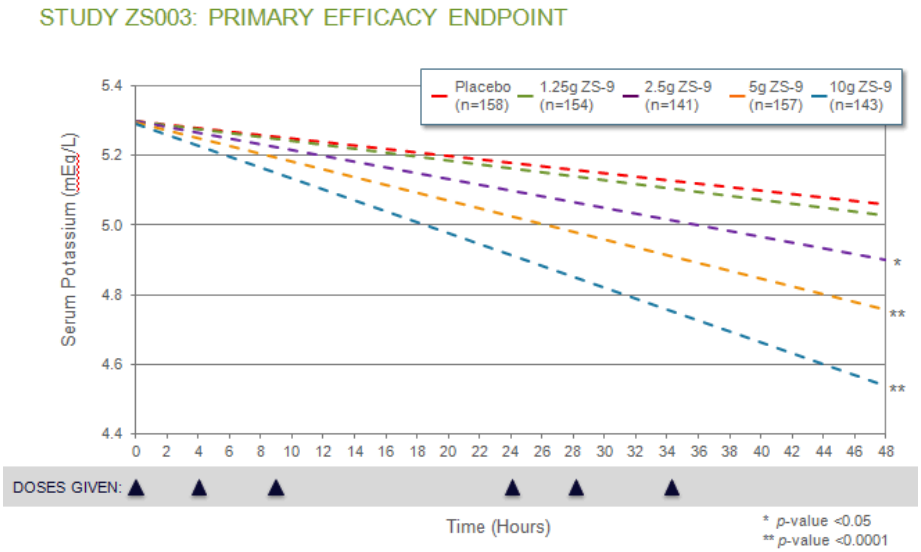
ZS003. This Phase 3 trial was conducted in 753 patients with hyperkalemia and included patients with CKD, HF, diabetes, and those on RAASi therapy. Enrolled patients had potassium levels between 5.0 and 6.5 mEq/L, and were randomized to receive ZS-9 (1.25, 2.5, 5 or 10 g doses) or placebo 3x/day for 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).

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Figure 8: ZS003 Induction Phase Primary Endpoint

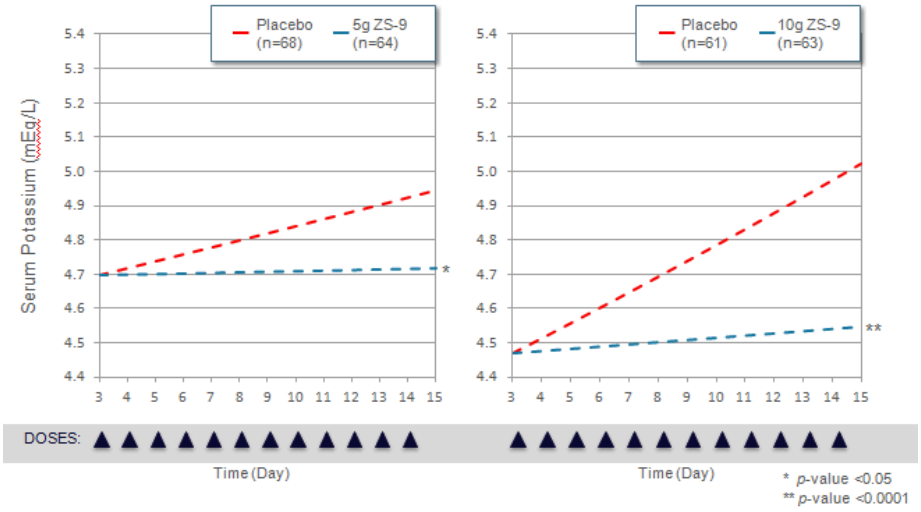


Source: Company Presentation.

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 9: 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 10: 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.

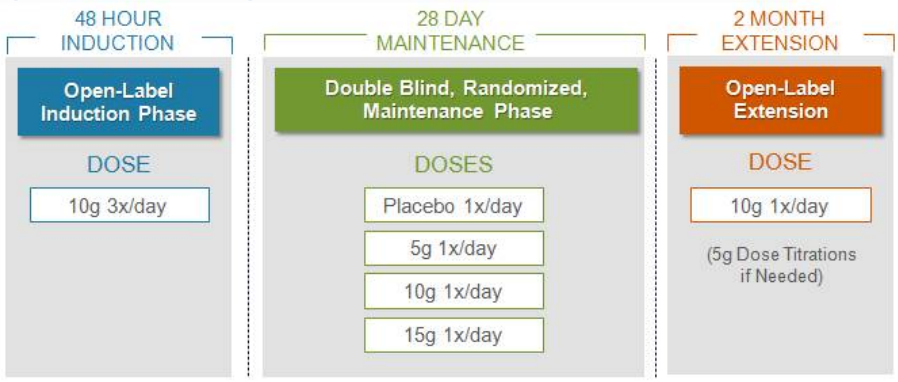
There were no clinically meaningful treatment-related changes in laboratory parameters. Hypokalemia did occur in two subjects of the 753 (0.3%), though it was mild, transient, didn't require treatment, and did not result in complications in either case. A small decrease in mean serum calcium was observed, 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, where 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.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

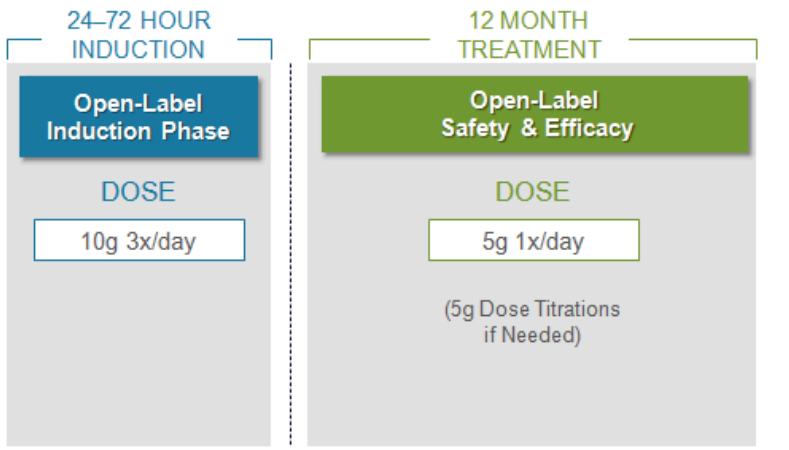
Figure 11: ZS004 Trial Design



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, where 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 12: ZS005 Trial Design



Source: Company Presentation.

Thoughts on Zirconium

Given ZS-9 is a zirconium-based product, and given the issue of metal buildup in tissue with phosphate binders, there was some initial concern that treatment with ZS-9 could lead to zirconium accumulation in tissue. However, we note that ZS-9 is non-absorbed, and essentially insoluble at physiologic conditions, so the risk of a significant amount of zirconium passing into the system is very low. Further, we note that zirconium-containing sorbent columns are used in dialysis (and have been since the 1970s) wherein a patient's blood is exposed directly to these columns, and no safety issues have developed.

Though ZS-9 is zirconium based, very little is absorbed into the human body... the daily GI exposure from a patient's diet is much higher than that from a dose of ZS-9. As such, we (and docs) aren't worried about zirconium accumulation.

Even more persuasive is the fact that zirconium is found in fairly high quantities in food, drinking water, and other products to which we are exposed on a daily basis. In other words, the amount of zirconium a patient is naturally exposed to on any given day is likely to be significantly higher than what could be absorbed from ZS-9. Perhaps most importantly, docs with whom we spoke are not at all concerned about zirconium absorption, and we do not anticipate this will be a significant concern once the broader physician population is educated on zirconium.

Figure 13: Relative Zirconium Levels in Common Products/Substances

Product	Amount	Relative to ZS-9
85g Antiperspirant Stick[1]	2295 mg	8,196,429x
Soil[2]	300 mg/L	1,071,429x
Human Body Content[3]	300 mg	1,071,429x
Daily Food Content[2]	3.65 mg	13,036x
Zr From 4Hr Sorbent Hemodialysis[3]	0.758 mg	2,707x
Daily Drinking Water Content[2]	0.65 mg	2,321x
Sea Water[2]	0.004 mg/L	14x
Soluble from 10g ZS-9[4]	0.00028 mg	1x

1. 85g Deodorant containing 19% aluminum zirconium tetrachlorohydrex
2. H. Schroeder, Abnormal Trace Metals in Man: Zirconium *J. Chron. Dis.* **1966**, Vol. 19, 573-586.
3. D. Lee, Zirconium: Biomedical and Nephrological Applications *ASAIO Journal* **2010** 550-556.
4. Amount of zirconium in solution after exposing to simulated gastric and simulated intestinal fluids for a period of 24 hours

Daily GI exposure from diet much higher than amount of zirconium released from a 10g dose of ZS-9

Source: Company Presentation.

Competitive Landscape

Relypsa's patiromer is the key competitor for ZS-9 given they have shown similar efficacy in terms of serum K reduction and will likely be first to market.

The key competitor to ZS-9 is patiromer, which is being developed by Relypsa (RLYP, not covered). Both products represent significant improvements over Kayexalate, in our view. Patiromer is a non-absorbed ion exchange polymer and has successfully completed several clinical trials, including a Phase 2b and a Phase 3. The Phase 3 trial had two parts: Part A (4-week open label treatment) showed a stat sig mean reduction in potassium of -1.01 mEq/L, with 76% of patients having normal serum K at week 4, and part B (8-week, pbo controlled, randomized withdrawal) showed that continued treatment with patiromer was able to maintain serum K in the normal range. The median increase in K in patients randomized to placebo in part B was 0.72 mEq/L vs. no increase observed in the patiromer group.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Figure 14: Patiromer Estimated Serum K+ Change from Baseline to Week 4

• 76% of subjects in the serum K+ target range of 3.8 to <5.1 mEq/L at 4 weeks.

Source: Weir et al. 2013; ASN Abstract no. SA-PO1085.

On safety, patiromer was relatively well tolerated; mild/moderate GI symptoms were the most frequently reported, and other common AES were similar to, or lower than, the placebo group.

Figure 15: AEs Reported in Parts A and B of Patiromer's Phase 3 Trial

Adverse Event	Total; N=243	
	All; n (%)	Severe; n (%)
Subjects Reporting ≥1 AE	**107 (44%)**	**1 (<1%)**
Constipation	25 (10%)	0
Diarrhea	8 (3%)	0
Hypomagnesaemia	8 (3%)	0
Nausea	8 (3%)	0
Anemia	6 (2%)	0
Left ventricular hypertrophy	6 (2%)	0
Renal failure chronic	6 (2%)	1 (<1%)
Dyslipidemia	4 (2%)	0
Flatulence	4 (2%)	0
Glomerular filtration rate decreased	4 (2%)	0
Hyperglycemia	4 (2%)	0

• Most common AEs were mild to moderate GI complaints (19%); no severe GI AEs reported.

Part B Adverse Events in ≥2% of Subjects

Adverse Event	Placebo; N=52		Patiromer; N=55	
	All n (%)	Severe n (%)	All n (%)	Severe n (%)
Subjects Reporting ≥ 1AE	24 (46%)	1 (2%)	26 (47%)	0
Headache	4 (8%)	0	2 (4%)	0
Hepatic enzyme increased	2 (4%)	0	1 (2%)	0
Hyperkalemia	2 (4%)	0	1 (2%)	0
Influenza	2 (4%)	0	1 (2%)	0
Supraventricular extrasystoles	1 (2%)	0	2 (4%)	0
Abdominal pain upper	1 (2%)	0	1 (2%)	0
Constipation	0	0	2 (4%)	0
Diarrhea	0	0	2 (4%)	0
Hypercholesterolemia	2 (4%)	0	0	0
Hypertension	2 (4%)	0	0	0
Hypomagnesaemia	1 (2%)	0	1 (2%)	0
Insomnia	1 (2%)	0	1 (2%)	0
Nausea	0	0	2 (4%)	0
Pruritus	1 (2%)	0	1 (2%)	0
Renal failure chronic	1 (2%)	0	1 (2%)	0

- Mild to moderate GI AEs were the most frequent (patiromer 13%, placebo 6%); no severe GI AEs in the patiromer group (1 severe mesenteric artery thrombosis in placebo group).

Source: Weir et al. 2013; ASN Abstract no. SA-PO1085.

Results from a Phase 2b study are supportive of the Phase 3 data, showing that 86% - 90% of patients had serum K in the normal range at 52 weeks, highlighting the potential for patiromer in long-term management of hyperkalemia. Further, a recently completed Phase 1 onset-of-action trial showed that patiromer is able to fairly rapidly reduce serum K, with a stat sig difference first observed at 7 hours after the first dose (which we note is slower than ZS-9's stat sig effects seen at 1 hour post first dose).

Ultimately, we think competitive forces will be beneficial to growing the market and that ZS-9 has some key advantages that could drive a majority market share in time.

The Phase 3 trial was conducted under an SPA, and Relypsa plans to submit an NDA in 3Q14. We anticipate patiromer will be approved and launch in 2015, ~6 months ahead of our assumptions for ZS-9. While patiromer is direct, first-to-market competition for ZS-9, we believe the presence of two players in this market will ultimately benefit both products as the companies work to increase the number of patients who are taking a chronic hyper K treatment.

Market Opportunity and Commercial Strategy

ZS-9 estimates that there are 2.5-3M patients who are eligible for chronic treatment with ZS-9 and that there are ~2.2M acute treatments that use kayexalate per year.

Hyperkalemia represents a compelling market opportunity, based on both its size and degree of unmet need. ZS estimates there are 2.5-3M patients who are eligible for chronic treatment in the US alone. We model peak US sales for ZS-9 of ~$1B in 2020. While market dynamics ex-US are less clear, we assume ZS Pharma partners the product in these territories and receives an average 25% royalty on sales. ZS-9 believes revenue opportunity in the EU is roughly ~50% that of the US, and Japan's is ~20% of the US. Below we run through the key market assumptions in our US revenue build.

- **Addressable chronic patient population – CKD:** Of the estimated 26M CKD patients in the US, ZS estimates ~19M have stage 3 or 4 disease. When accounting for only the patients who are treated by a specialist, and further

drilling down into a patient population that is on suboptimal RAAS therapy and/or has moderate to severe HK, there are 2-2.5M CKD patients who would be eligible for chronic treatment with ZS-9.

- **Addressable chronic patient population – CHF:** In CHF (excluding pts with co-morbid CKD who have already been accounted for in our model), the same RAAS/hyperkalemia criteria gives a 500-600K eligible patient count.

We believe our estimates are potentially conservative, especially with regard to the percent of pts seeking any chronic therapy (only 35% at peak) and market share for ZS-9 (takes 5 yrs to get to 50% in our model). Nevertheless, we still estimate peak US sales of ~$1B in 2020.

- **Market share:** *At peak, we conservatively assume only 35% of the eligible patients are receiving any chronic therapy (either patiromer or ZS-9)*. In this 35% of patients, we (also conservatively) assume a roughly 50/50 split between ZS-9 and patiromer after 5 years. We believe both of these assumptions potentially allow for upside to our initial estimates.
- **Price and duration:** We assume a gross price of $700/mo, a gross-to-net adjustment of 25%, compliance of 75%, and that patients are on ZS-9 for an average of 4 months in any given year.
- **Acute HK opportunity:** The use of kayexalate in the hospital setting also represents an opportunity with ~2.2 million treatments per year (as measured by kayexalate scripts in an acute setting). We think ZS-9 could fairly quickly replace kayexalate in this setting, though we conservatively assume 50% market share at peak.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

J.P.Morgan

Figure 16: ZS-9 Revenue Build

		2016E	2017E	2018E	2019E	2020E	2021E	2022E
US Chronic - CKD								
US CKD Patients	1%	26,522,600	26,787,826	27,055,704	27,326,261	27,599,524	27,875,519	28,154,274
Stage 3-4	74%	19,626,724	19,822,991	20,021,221	20,221,433	20,423,648	20,627,884	20,834,163
Treated by a neph/cardio	30%	5,888,017	5,946,897	6,006,366	6,066,430	6,127,094	6,188,365	6,250,249
pts w/ hyperkalemia	40%	2,355,207	2,378,759	2,402,547	2,426,572	2,450,838	2,475,346	2,500,100
pts reciving chornic hyperkal tx		13%	18%	25%	30%	35%	35%	35%
Chronically Treated Hyerkal Pts		294,401	416,283	600,637	727,972	857,793	866,371	875,035
ZS Share		7%	20%	30%	45%	50%	55%	55%
Relypsa Share		93%	80%	70%	55%	50%	45%	45%
ZS-9 Patients		20,608	83,257	180,191	327,587	428,897	476,504	481,269
Avg. Tx Duration per year (mo)		4	4	4	4	4	4	4
Gross Monthly Cost	2%	$700.00	$714.00	$728.28	$742.85	$757.70	$772.86	$788.31
Net Monthly Cost	25%	$525.00	$535.50	$546.21	$557.13	$568.28	$579.64	$591.24
Compliance Adjusted	75%	$393.75	$401.63	$409.66	$417.85	$426.21	$434.73	$443.43
US CKD Revenue ($m)		$32.46	$133.75	$295.27	$547.53	$731.20	$828.61	$853.63
US Chronic - CHF								
US CHF Patients	1%	5,814,570	5,872,716	5,931,443	5,990,757	6,050,665	6,111,172	6,172,283
excluding co-morbid CKD	45%	2,616,557	2,642,722	2,669,149	2,695,841	2,722,799	2,750,027	2,777,527
Treated by a neph/cardio	90%	2,354,901	2,378,450	2,402,234	2,426,257	2,450,519	2,475,024	2,499,775
pts w/ hyperkalemia	25%	588,725	594,612	600,559	606,564	612,630	618,756	624,944
pts reciving chornic hyperkal tx		13%	18%	25%	30%	35%	35%	35%
Chronically Treated Hyerkal Pts		73,591	104,057	150,140	181,969	214,420	216,565	218,730
ZS Share		7%	20%	30%	45%	50%	55%	55%
Relypsa Share		93%	80%	70%	55%	50%	45%	45%
ZS-9 Patients		5,151	20,811	45,042	81,886	107,210	119,111	120,302
Avg. Tx Duration per year (mo)		4	4	4	4	4	4	4
Gross Monthly Cost	2%	$700.00	$714.00	$728.28	$742.85	$757.70	$772.86	$788.31
Net Monthly Cost	25%	$525.00	$535.50	$546.21	$557.13	$568.28	$579.64	$591.24
Compliance Adjusted	75%	$393.75	$401.63	$409.66	$417.85	$426.21	$434.73	$443.43
US CHF Revenue ($m)		$8.11	$33.43	$73.81	$136.86	$182.78	$207.12	$213.38
US Episodic Market								
Annual grams of Kayexalate sold (m)		200	200	200	200	200	200	200
Converted to g of ZS-9	3	66.7	66.7	66.7	66.7	66.7	66.7	66.7
ZS-9 Share		10%	20%	30%	40%	50%	50%	50%
g of ZS-9 used on Acute setting (m)		6.7	13.3	20.0	26.7	33.3	33.3	33.3
net cost per gram	0%	$1.67	$1.67	$1.67	$1.67	$1.67	$1.67	$1.67
US Acute Revenue ($m)		$11.13	$22.27	$33.40	$44.53	$55.67	$55.67	$55.67

Source: J.P. Morgan and Company estimates.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Intellectual Property

ZS Pharma has rights to several patents and applications that protect ZS-9, and we assume patent protection to 2032, excluding any patent term extension. Specifically, ZS has licensed the rights patents covering composition of ZS-9 and methods of oral administration of from UOP (a division of Honeywell). Under the agreement, UOP granted ZS a worldwide, exclusive license (with the right to sublicense) to develop, make and sell products in the field of toxin removal from bodily fluids and the GI tract of humans and animals. UOP is eligible to receive a flat 5% royalty on sales of ZS-9 (minimum $100K per year). Patents licensed from UOP include two composition of matter patents that are set to expire in 2017 as well as a method of treatment patent that is set to expire in 2019 without Hatch-Waxman, and in 2024 assuming PTE is granted.

We model IP protection through 2032.

Additionally, during ZS's development of ZS-9, the company made several improvements to the ZS-9 composition and have filed several non-provisional and provisional patent applications around these improvements. Patent applications filed are directed towards improved zirconium silicate compositions, methods of treatment, including treatment of hyperkalemia and other conditions, and methods of manufacturing zirconium silicate compositions. They include US and foreign applications, and if issued, are expected to begin to expire in 2032.

In addition to patents, ZS-9 is also protected by trade secrets around the manufacturing process, as well as other barriers to entry, including specialized equipment and manufacturing conditions.

Pre-Clinical Pipeline

ZS-9 is ZS Pharma's only clinical candidate. The company has one other preclinical candidate, ZS-1, which is currently under evaluation as a treatment for high blood ammonia levels. While the company has developed a non-clinical and clinical development plan, it has not yet initiated IND enabling studies. For the time being, the company intends to devote its resources to the development of ZS-9.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Financial Outlook

ZS Pharma is a developmental-stage biotechnology company with upcoming clinical and regulatory events (Phase 3 data in 4Q14, NDA and MAA filing in 1H15), with potential for approval and launch in 2016. Currently, we do not model profitability until 2018. ZS has retained worldwide rights to ZS-9, though for modeling purposes, we assume the company out licenses ex-US rights and receives a royalty on sales (we currently assume EU only).

OpEx Expectations. Below we briefly highlight our assumptions for ZS Pharma's key operating spend line items…

- **COGS**. We anticipate COGS will be ~15% at steady state. ZS Pharma also owes a 5% royalty to UOP through the duration of those patents (~2024 assuming patent term extension).
- **R&D trends**. We assume R&D will continue to ramps as ZS Pharma executes on the ongoing Phase 3 trial and long-term safety study and builds inventory ahead of approval. In the outer years, we assume the company will continue to invest in R&D on additional products given its technology platform and eventual commercial infrastructure.
- **SG&A trends**. We anticipate ZS will begin to build commercial infrastructure in 2016, ahead of the launch of ZS-9. Our model reflects a field force of ~150 reps.

ZS-9's current cash position should be sufficient through the expected early 2016 approval of ZS-9.

ZS Pharma ended 1Q14 with ~$21 million in cash

The company's cash, cash equivalents and marketable securities totaled $21 million as of March 31, 2014. In June, ZS raised ~$112M from an Initial Public Offering of common stock (J.P. Morgan acted as a joint book runner). ZS believes its current cash position is sufficient to get through the expected early 2016 NDA approval, and we estimate that ZS will end 2014 with ~$85M in cash.

Share count

We estimate ZS Pharma currently has ~26.6 million fully diluted shares outstanding (including ~20.6 million common shares and 6 million stock options post offering).

Figure 17: ZSPH Key Financial Metrics

Key Financial Metrics	2013A	2014E	2015E	2016E	2017E	2018E
In $ M						
December financial year-end						
Cash	9.2	101.3	35.7	66.8	39.0	160.1
Debt	-	-	-	-	-	-
CFOp + CapEx (burn)	(30.3)	(52.5)	(65.7)	(119.0)	(27.9)	121.0
Expected financing	15.1	144.5	-	150.0	-	-
Revenue	-	-	-	51.7	193.1	417.3
EPS	(8.52)	(3.43)	(3.12)	(4.69)	(1.18)	3.71
Consensus EPS						
Average shares outstanding	4.0	14.5	21.6	26.2	28.2	30.8
Fully diluted shares outstanding	4.0	14.5	21.6	26.2	28.2	36.8

Source: Company reports and J.P. Morgan estimates.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Valuation

We are initiating coverage of ZSPH with an Overweight rating and a December 2015 price target of $43 per share.

Our December 2015 price target of $43 per share is based on a blended average of our proprietary probability-adjusted scenario analysis (50%) and a risk-adjusted NPV model (50%).

Figure 18: ZSPH Valuation Summary

ZSPH Valuation Summary			
Discount rate	13%		
4Q15 Fully Diluted Shares (mm)	27.6		
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	$ 45.38	50%	22.69
Risk adjusted NPV analysis	$ 40.82	50%	20.41
Total			$ 43.10
Catalyst/liquidity discount			0%
YE15 Price Target			**$ 43**

Source: J.P. Morgan estimates.

Risk-adjusted NPV analysis (50% weighting)

In our risk-adjusted NPV analysis, we estimate ZS-9 revenues and associated expenses (including taxes) over the expected patent life of the product. We complete this exercise for conservative, moderate, and aggressive sales scenarios and then assign a range of probabilities to each of these outcomes as well as to the possibility that the product is ineffective and generates zero value (which is conservatively 30% in our model). We apply a discount rate of 13%, based on ZSPH's weighted average cost of capital (WACC). We believe this is appropriate given the applied probability adjustments.

Figure 19: ZS-9 rNPV Analysis

ZS-9 - US					
	Peak Sales/Royalty	**NPV**	NPV/Share	Probability	/alue/Share
Not Approved	-	-	-	30%	-
Aggressive	2,054.6	3,569.8	129.4	3%	3.2
Base	1,369.7	2,351.6	85.2	35%	29.8
Disappointing	273.9	231.1	8.4	33%	2.7
Total				**100%**	**35.79**
ZS-9 EU/Japan					
	Peak Sales/Royalty	**NPV**	NPV/Share	Probability	/alue/Share
Not Approved	-	-	-	50%	-
Aggressive	990.0	470.0	17.0	3%	0.4
Base	660.0	313.3	11.4	25%	2.8
Disappointing	132.0	62.7	2.3	23%	0.5
Total				**100%**	**3.78**

Source: J.P. Morgan estimates.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Proprietary real options scenario analysis (50% weighting)

Using this model, we estimate the value of the company's development programs by assigning a range of probabilities to six different commercial scenarios (ranging from an ineffective product that generates zero value to a breakthrough treatment option) and analyze them over several possible peak sales years. We also evaluate a range of price-to-peak sales multiples for a small molecule asset (from 3-5x for an unpartnered small molecule drug and a 6-10x multiple on royalty revenues). Additionally, we again apply the company's WACC derived discount rate of 13%.

Multiple-based scenario analysis for ZS-9

Below, we demonstrate our analysis for ZS-9 for hyperkalemia in the US, ZSPH's key value driver. We assume a 70% probability that ZS-9 reaches the market for hyperkalemia in the US (50% in Europe), and assume that sales peak in 2020 and 2022, respectively. Below is our calculated value contribution from ZS-9 for hyperkalemia for a range of multiples if the drug generates peak sales of ~$1B in the US and ~$500 million in Europe. In our view, we utilize a series of conservative assumptions in this analysis, including only a 70% probability of approval despite positive and consistent randomized data as well as commercial scenarios that are currently negatively skewed.

Figure 20: ZS-9 Scenario Analysis

Product:	**ZS-9**		Peak year	2019			2020			2021			Average
Indication:	**Hyperkalemia**		Discount period	4.0			5.0			6.0			prob-adj
Market:	**US**												value
Ownership:	**Unpartnered**		Price/sales mult.	3	4	5	3	4	5	3	4	5	/share
	Prob.	Peak sales (millions)	Peak royalties (millions, 100%)	Value/share									
Ineffective	30%	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Disappointment	18%	276	$ 263	$ 17.51	$ 23.35	$ 29.18	$ 15.50	$ 20.66	$ 25.83	$ 13.71	$ 18.28	$ 22.85	3.74
Below average	20%	553	$ 525	$ 35.02	$ 46.69	$ 58.37	$ 30.99	$ 41.32	$ 51.65	$ 27.43	$ 36.57	$ 45.71	8.31
Average	30%	1,105	$ 1,050	$ 70.04	$ 93.38	$ 116.73	$ 61.98	$ 82.64	$ 103.30	$ 54.85	$ 73.13	$ 91.42	24.92
Above average	1.0%	1,382	$ 1,313	$ 87.55	$ 116.73	$ 145.91	$ 77.48	$ 103.30	$ 129.13	$ 68.56	$ 91.42	$ 114.27	1.04
Breakthrough	1.0%	1,658	$ 1,575	$ 105.06	$ 140.08	$ 175.10	$ 92.97	$ 123.96	$ 154.95	$ 82.28	$ 109.70	$ 137.13	1.25
Total	**100%**												**$ 39.24**

Product:	**ZS-9**		Peak year	2021			2022			2023			Average
Indication:	**Hyperkalemia**		Discount period	6.0			7.0			8.0			prob-adj
Market:	**EU /Japan**												value
Ownership:	**Partnered**		Price/sales mult.	6	8	10	6	8	10	6	8	10	/share
	Prob.	Peak sales (millions)	Peak royalties (millions, 100%)	Value/share									
Ineffective	50%	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Disappointment	8%	114	$ 23	$ 2.38	$ 3.18	$ 3.97	$ 2.11	$ 2.81	$ 3.52	$ 1.87	$ 2.49	$ 3.11	0.23
Below average	20%	285	$ 57	$ 5.96	$ 7.94	$ 9.93	$ 5.27	$ 7.03	$ 8.79	$ 4.67	$ 6.22	$ 7.78	1.41
Average	20%	570	$ 114	$ 11.92	$ 15.89	$ 19.86	$ 10.55	$ 14.06	$ 17.58	$ 9.33	$ 12.44	$ 15.55	2.83
Above average	1.0%	713	$ 143	$ 14.90	$ 19.86	$ 24.83	$ 13.18	$ 17.58	$ 21.97	$ 11.67	$ 15.55	$ 19.44	0.18
Breakthrough	1.0%	998	$ 200	$ 20.85	$ 27.81	$ 34.76	$ 18.46	$ 24.61	$ 30.76	$ 16.33	$ 21.78	$ 27.22	0.25
Total	**100%**												**$ 4.89**

Source: J.P. Morgan estimates.

Management

Below we highlight key executives at ZS Pharma.

Robert Alexander, Ph.D., CEO

Dr. Alexander became CEO of ZS in December 2013 after joining the company in March 2013 as Executive Chairman. Prior to joining ZS, Dr. Alexander was a Director at the venture capital firm Alta Partners and also acted as Executive Chairman and interim CEO of SARcode Biosciences. Before Alta, he was a Principal in MPM Capital's BioEquities fund, prior to which he worked in the business development group at Genentech.

Alvaro Guillem, Ph.D., President

ZS Pharma's President is Dr. Guillem, who co-founded the company in 2008. Before founding ZS, he held senior positions at Genzyme/Bone Care, Wyeth, and Boeringher Ingelheim, and at startup companies including Medeva Americas and Adams Respiratory Therapeutics. In his most recent role, Dr. Guillem was VP of Quality and Scientific Affairs at Ash Access Technology.

D. Jeffrey Keyser, R.Ph., J.D., M.P.A., Ph.D., COO

Dr. Keyser co-founded ZS Pharma in 2008, prior to which he served as the Chief Compliance Officer and VP of Regulatory Affairs at Encysive Pharmaceuticals. Before Encysive, he served as VP of Development and Regulatory Affairs at Adams Respiratory Therapeutics. He has also held senior management positions at Medeva Americas, Marion Merrell Dow, Marion Laboratories and Abbott Laboratories.

Todd A. Creech, M.B.A., CFO

Mr. Creech serves as ZS's CFO and joined the company in August 2013. He was previously the CFO and VP of Business Development at SARcode Biosciences. Before joining SARcode, Mr. Creech was CFO of Sirion Therapeutics, and before that worked with NovaQuest (investment group within Quintiles).

Henrik Sandvad Rasmussen, M.D., Ph.D., CMO and CSO

ZS Pharma's CMO and CSO is Dr. Rasmussen, who has been with the company since 2012. Prior to ZS, Dr. Rasmussen was the President and CEO of Rasmussen Biotech and Pharma Consulting. Before that, he held various senior management positions at Novo Nordisk, including Corporate Vice President, Head of Clinical Development and Medical and Regulatory Affairs. Previously he was Chief Medical Officer for Nabi Biopharmaceuticals and Genvec and was the SVP for Clinical Research and Regulatory Affairs at British Biotech and Global study director at Pfizer Central Research.

Cynthia Smith, M.S., M.B.A., CCO

Ms. Smith serves as ZS's Chief Commercial Officer and joined the company in June 2013. Before ZS, she was VP of Market Access and Commercial Development at Affymax, prior to which she was Executive Director of Healthcare System and Medicare Strategy at Merck. While at Merck, she held various leadership positions in managed markets, corporate strategy, public policy and external affairs. Prior to Merck, she served in the White House Office of Management and Budget (OMB) in the Clinton Administration.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Models

Figure 21: ZSPH Income Statement

ZS Pharmaceuticals Income Statement

Cory Kasimov
cory.w.kasimov@jpmorgan.com
212.622.5266

	2013A	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E
ZS-9 Revenues											
US Revenues	-	-	-	-	-	-	-	51.7	189.5	402.5	728.9
Ex-US Royalty	-	-	-	-	-	-	-	-	3.6	14.8	33.9
Total Revenues	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**51.7**	**193.1**	**417.3**	**762.8**
COGS	-	-	-	-	-	-	-	15.5	59.9	112.7	175.4
R&D	24.5	5.3	8.0	8.3	8.5	30.0	41.0	44.0	48.0	54.0	70.0
SG&A	7.7	4.0	4.5	4.5	4.6	17.7	25.5	114.3	117.8	123.1	128.6
Total Operating Expenses	**32.2**	**9.3**	**12.5**	**12.8**	**13.1**	**47.7**	**66.5**	**173.8**	**225.7**	**289.8**	**374.1**
Operating Income	**(32.2)**	**(9.3)**	**(12.5)**	**(12.8)**	**(13.1)**	**(47.7)**	**(66.5)**	**(122.1)**	**(32.6)**	**127.5**	**388.7**
Net interest & other income	(2.1)	(1.5)	(0.2)	(0.2)	(0.2)	(2.0)	(0.7)	(0.7)	(0.7)	(0.7)	(0.7)
Income Tax (benefit)	-	-	-	-	-	-	-	-	-	12.7	77.6
GAAP Net Income	**(34.3)**	**(10.7)**	**(12.7)**	**(13.0)**	**(13.3)**	**(49.7)**	**(67.2)**	**(122.8)**	**(33.3)**	**114.1**	**310.4**
Non-GAAP Net Income	**(34.3)**	**(10.5)**	**(12.5)**	**(12.8)**	**(13.1)**	**(48.9)**	**(65.7)**	**(120.0)**	**(29.3)**	**119.4**	**316.9**
GAAP Basic EPS	(8.52)	(2.57)	(1.02)	(0.63)	(0.64)	(3.43)	(3.12)	(4.69)	(1.18)	3.71	9.11
GAAP Diluted EPS	**(8.52)**	**(2.57)**	**(1.02)**	**(0.63)**	**(0.64)**	**(3.43)**	**(3.12)**	**(4.69)**	**(1.18)**	**3.10**	**7.74**
Basic Shares Outstanding	4.0	4.2	12.4	20.7	20.8	14.5	21.6	26.2	28.2	30.8	34.1
Diluted Shares Outstanding	4.0	4.2	12.4	20.7	20.8	14.5	21.6	26.2	28.2	36.8	40.1
Margin Analysis:											
Gross margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*70%*	*69%*	*73%*	*77%*
Operating margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*30.56%*	*50.96%*
Net margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*27.36%*	*40.70%*
Tax Rate	***0%***	***0%***	***0%***	***0%***	***0%***	***0%***	***0.0%***	***0.0%***	***5.0%***	***10.0%***	***20.0%***
Cost Analysis:											
COGS as % of tot. prod. sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*30%*	*31%*	*27%*	*23%*
R&D as % of tot. revenue	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*85%*	*25%*	*13%*	*9%*
SG&A as % of tot. revenue	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*221%*	*61%*	*29%*	*17%*
Year-over-year growth:											
Total revenue		*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*273.41%*	*116.13%*	*82.80%*
R&D Expense		*19.28%*	*NM*	*NM*	*NM*	*22.45%*	*36.63%*	*7.32%*	*9.09%*	*12.50%*	*29.63%*
SG&A Expense		*461.82%*	*NM*	*NM*	*NM*	*129.67%*	*44.46%*	*348.04%*	*3.11%*	*4.49%*	*4.50%*
Total operating expenses		*81.03%*	*NM*	*NM*	*NM*	*48.04%*	*39.53%*	*161.30%*	*29.86%*	*28.41%*	*29.10%*
Operating income		*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*83.54%*	*-73.31%*	*-491.43%*	*204.80%*
Net income		*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*#REF!*	*#REF!*
EPS		*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*50.41%*	*-74.81%*	*-362.42%*	*149.89%*
Basic Shares		*4.58%*	*NM*	*NM*	*NM*	*260.18%*	*48.71%*	*21.45%*	*7.64%*	*9.31%*	*10.55%*
Diluted Shares		*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*7.21%*	*17.37%*	*7.64%*	*9.31%*

Source: Company reports and J.P. Morgan estimates.

Figure 22: ZSPH Balance Sheet

ZS Phamaceuticals BalanceSheet ($ millions)

Cory W. Kasimov
cory.w.kasimov@jpmchase.com
212.622.5216

	2013A	2014E	2015E	2016E	2017E	2018E	2019E
Assets							
Cash and cash equivalents	9.2	101.3	35.7	66.8	39.0	160.1	478.8
Restricted Cash	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Prepaid Expenses	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Other Current Assets	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Current Assets	**9.4**	**101.5**	**35.9**	**67.0**	**39.3**	**160.4**	**479.1**
PPE, Net	4.6	9.9	11.6	12.3	12.6	12.7	12.8
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Assets	**14.0**	**111.5**	**47.6**	**79.4**	**51.9**	**173.1**	**491.9**
Liabilities & Equity							
Accounts Payable	1.5	1.6	1.6	1.7	1.8	1.9	2.0
Accrued liabilities	3.1	3.3	3.4	3.6	3.8	4.0	4.2
Current portion of capital lease obligation	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Current Liabilities	**4.7**	**4.9**	**5.1**	**5.4**	**5.7**	**5.9**	**6.2**
Deferred Rent	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Lease Incentive	0.2	0.2	0.2	0.2	0.3	0.3	0.3
Capital lease obligation	-	-	-	-	-	-	-
Series B redeemable preferred stock warrant liability	2.7	2.7	2.7	2.7	2.7	2.7	2.7
Others							
Total Liabilities	**7.59**	**7.85**	**8.12**	**8.40**	**8.70**	**9.02**	**9.35**
Series B convertible, pref. stock	8.4						
Series C convertible, pref. stock	43.2						
Series A convertible pref. stock	1.2						
Common stock, par value	0.0		-	-	-	-	-
Additional paid-in capital	3.9						
Accumulated Deficit	(50.2)	103.6	39.4	71.0	43.2	164.1	482.5
Total Shareholders' Equity	**6.5**	**103.6**	**39.4**	**71.0**	**43.2**	**164.1**	**482.5**
Total Liabilities & Equity	**14.0**	**111.5**	**47.6**	**79.4**	**51.9**	**173.1**	**491.9**

Source: Company reports and J.P. Morgan estimates.

Figure 23: ZSPH Cash Flow Statement

ZS Pharmaceuticals Cash Flow Statement ($ millions)

Cory W. Kasimov
cory.w.kasimov@jpmchase.com
212.622.5216

	2013A	2014E	2015E	2016E	2017E	2018E	2019E
Cash Flow from Operations							
Net Income	$ (33.6)	$ (49.7)	$ (67.2)	$ (122.8)	$ (33.3)	$ 114.1	$ 310.4
Adjustments to reconcile net loss to net operating cash							
Depreciation & Amortization	0.7	2.7	5.8	6.8	7.2	7.4	7.5
Amortization of lease incentive	(0.0)	-	-	-	-	-	-
Share-based compensation expense	2.1	0.8	1.5	2.8	4.0	5.3	6.5
Warrant expense	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Amortization of deferred debt	-	-	-	-	-	-	-
Interest expense repaidin Series B pref. stock	-	-	-	-	-	-	-
Others	(0.0)	-	-	-	-	-	-
Changes in operating assets and liabilities							
Prepaid expenses and other assets	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Accounts payable	0.5	0.1	0.1	0.1	0.1	0.1	0.1
Accrued expenses	2.3	0.2	0.2	0.2	0.2	0.2	0.2
Deferred rent	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Cash Flow from Operations	**$ (26.5)**	**$ (44.5)**	**$ (58.2)**	**$ (111.5)**	**$ (20.4)**	**$ 128.5**	**$ 326.1**
Purchase of PPE	(3.8)	(8.0)	(7.5)	(7.5)	(7.5)	(7.5)	(7.5)
Other							
Cash Flow from Investing	**$ (3.8)**	**$ (8.0)**	**$ (7.5)**	**$ (7.5)**	**$ (7.5)**	**$ (7.5)**	**$ (7.5)**
Proceeds from issuance of note payable	-	-	-	-	-	-	-
Proceeds from exercise of stock options and warrants	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Proceeds from exercise of pref. stock	15.1	25.0	-	-	-	-	-
Principal payments on capital lease	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Restricted cash	(0.2)	-	-	-	-	-	-
Proceeds from issuance of common stock		119.5		150.0	-	-	-
Cash Flow from Financing	**$ 15.1**	**$ 144.6**	**$ 0.1**	**$ 150.1**	**$ 0.1**	**$ 0.1**	**$ 0.1**
Total Change in Cash	(15.2)	92.1	(65.6)	31.1	(27.8)	121.1	318.7
Beginning Cash Balance	24.4	9.2	101.3	35.7	66.8	39.0	160.1
Ending Balance: Cash and Investments	**$ 9.2**	**$ 101.3**	**$ 35.7**	**$ 66.8**	**$ 39.0**	**$ 160.1**	**$ 478.8**

Source: Company reports and J.P. Morgan estimates.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

J.P.Morgan

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)	(30)	(41)	(44)
Operating income	(32)	(48)	(67)	(122)
EBITDA	(32)	(48)	(67)	(122)
Net interest (income) / expense	(2)	(2)	(1)	(1)
Other income / (expense)	-	-	-	-
Income taxes	0	0	0	0
Net income - GAAP	(34)	(50)	(67)	(123)
Net income - recurring	(34)	(50)	(67)	(123)
Diluted shares outstanding	4	14	22	26
EPS - excluding non-recurring	(8.52)	(3.43)	(3.12)	(4.69)
EPS - recurring	(8.52)	(3.43)	(3.12)	(4.69)

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	9	101	36	67
Accounts receivable	-	-	-	-
Inventories	-	-	-	-
Other current assets	0	0	0	0
Current assets	9	102	36	67
PP&E	5	10	12	12
Total assets	14	111	48	79
Total debt	-	-	-	-
Total liabilities	8	8	8	8
Shareholders' equity	6	104	39	71
Net income (including charges)	(34)	(50)	(67)	(123)
D&A	1	3	6	7
Change in working capital	3	0	0	0
Other	4	2	3	4
Cash flow from operations	(27)	(44)	(58)	(112)
Capex	(4)	(8)	(8)	(8)
Free cash flow	(28)	(50)	(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	2Q14E	3Q14E	4Q14E
Revenues	0A	0	0	0
Cost of products sold	0A	0	0	0
Gross profit	-	-	-	-
SG&A	(4)A	(5)	(5)	(5)
R&D	(5)A	(8)	(8)	(9)
Operating income	(9)A	(13)	(13)	(13)
EBITDA	(9)A	(13)	(13)	(13)
Net interest (income) / expense	(1)A	(0)	(0)	(0)
Other income / (expense)	-	-	-	-
Income taxes	0A	0	0	0
Net income - GAAP	(11)A	(13)	(13)	(13)
Net income - recurring	(11)A	(13)	(13)	(13)
Diluted shares outstanding	4A	12	21	21
EPS - excluding non-recurring	(2.57)A	(1.02)	(0.63)	(0.64)
EPS - recurring	(2.57)A	(1.02)	(0.63)	(0.64)

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	-	-	-	-
EBIT growth	295.6%	48.0%	39.5%	83.5%
EPS growth - recurring	224.3%	(59.8%)	(9.0%)	50.4%
Gross margin	-	-	-	-
EBIT margin	-	-	-	(236.1%)
EBITDA margin	-	-	-	(236.1%)
Tax rate	0.0%	0.0%	0.0%	0.0%
Net margin	-	-	-	(237.4%)
Net Debt / EBITDA	-	-	-	-
Net Debt / Capital (book)	-	-	-	-
Return on assets (ROA)	(172.9%)	(79.1%)	(84.5%)	(193.4%)
Return on equity (ROE)	(235.2%)	(90.2%)	(93.9%)	(222.4%)
Enterprise value / sales	-	-	-	1.0
Enterprise value / EBITDA	NM	NM	NM	NM
Free cash flow yield	(23.8%)	(11.8%)	(10.2%)	(15.3%)

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

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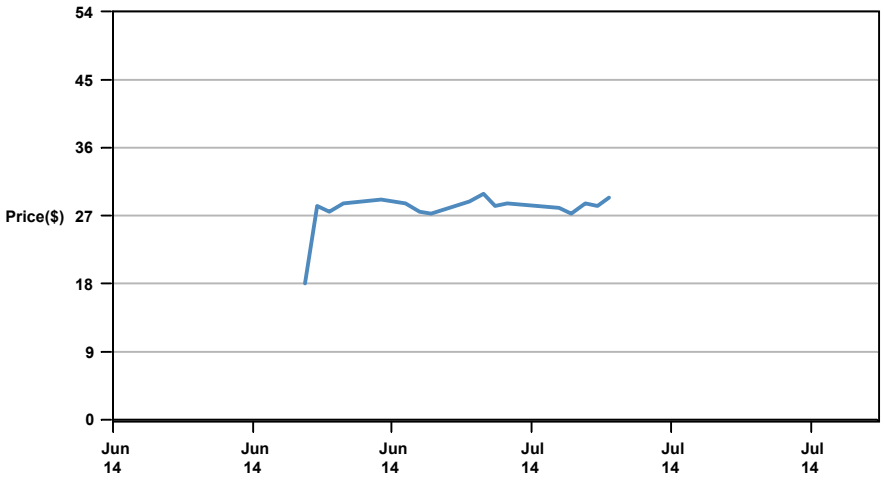
ZS Pharma (ZSPH, ZSPH US) Price Chart



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