

## ZS Pharma

### No Longer in Stealth Mode...Latest Thoughts and Feedback on ZSPH; PT to \$75

With shares of ZSPH up 45% this month alone, it looks like our favorite “off the radar” name has finally been detected. Given the increased investor dialogue, imminent NDA filing, and recent publications, we thought this would be a good time to address the questions we get on the relative competitive positioning of ZS-9 for the treatment of hyperkalemia (high blood potassium). *First and foremost, we believe HK – with roughly 4M potential patients – represents a multi-billion-dollar opportunity in the US alone, and thus could easily support more than one successful product.* That said, ZS-9 has potentially important advantages over RLYP’s patiomer that may eventually set it apart in the commercial marketplace (see full note for comp table), incl onset of action, tolerability, and dosing among other things. On the flip side, we believe ZS has been hurt by relatively low (but improving) market liquidity and a perception of a lack of catalysts (though regulatory progress and a potential LT safety update this yr are important). The bottom line is that we view ZS-9 as a differentiated treatment option in a large market with significant unmet need and continue to think ZSPH’s current valuation is highly compelling. Key assumptions/scenarios in our model still remain quite conservative, but we are increasing our target to \$75 based on slightly higher average peak sales. Reiterate OW.

- **ZS-9’s faster onset of action and more convenient dosing could potentially lead to a commercial advantage.** ZS-9 demonstrated a stat sig reduction in serum potassium after 1 hour, with an average time to K<sup>+</sup> normalization of 2.2 hrs. This compares favorably to patiomer’s 7 hrs post first dose to reach a stat sig reduction in serum K<sup>+</sup> and could prove to be a key advantage in both the acute and chronic settings. Additionally, ZS-9 is administered once daily vs. twice daily for patiomer, which may be particularly important in the chronic setting where compliance is critical.
- **Both ZS-9 and patiomer are clearly efficacious agents in treating hyperkalemia.** In ZS-9’s Phase 3 trial (ZS004), the proportion of patients with mean K <5.1 mEq/L during days 8-29 was 46% with placebo, 80% with ZS-9 5g, 90% with ZS-9 10g, and 94% with ZS-9 15g. In comparison, 76% of patients on patiomer had normal serum K at week 4, with pts able to maintain serum K in the normal range with continued treatment during the 8 week withdrawal phase.
- **ZS-9 looks to have better GI tolerability vs. patiomer.** With ZS-9, the rates of GI AEs were 7%, 2%, 9% with ZS-9 5g, 10g, 15g, respectively, vs. 14% with placebo. This compares favorably to the Ph3 patiomer trial wherein mild to moderate GI AEs were the most frequent with a rate of 13% on patiomer vs. 6% on placebo.

#### ZS Pharma, Inc (ZSPH;ZSPH US)

FYE Dec	2013A	2014A	2015E	2016E
EPS Reported (\$)				
Q1 (Mar)	(1.35)	(2.57)	(1.05)A	-
Q2 (Jun)	-	(4.72)	(0.85)	-
Q3 (Sep)	-	(0.81)	(0.87)	-
Q4 (Dec)	-	(0.98)	(0.90)	-
FY	(8.52)	(5.47)	(3.64)	(5.10)

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

## Overweight

### ZSPH, ZSPH US

Price: \$56.50

▲ **Price Target: \$75.00**  
Previous: \$57.00

### Biotechnology

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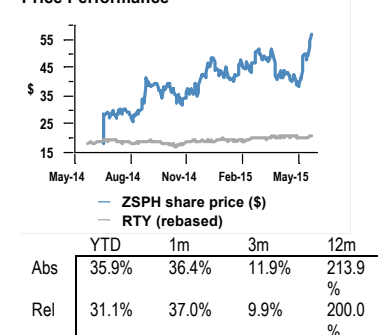
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#### Price Performance



#### Company Data

Price (\$)	56.50
Date Of Price	21 May 15
52-week Range (\$)	56.74-25.51
Market Cap (\$ mn)	1,412.10
Fiscal Year End	Dec
Shares O/S (mn)	25
Price Target (\$)	75.00
Price Target End Date	31-Dec-15

#### See page 7 for analyst certification and important disclosures.

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- **We're not overly concerned about edema or zirconium.** We note that although edema was a point of focus for ZS-9 (edema rate in ZS004 of 14% with ZS-9 15g and 6% with ZS-9 10g vs. 2% with placebo and ZS-9 5g), the rate of edema in the ZS004e & ZS005 trials is reportedly lower than the pbo rate in the ZS004 trial. Lastly, while some may still question the zirconium in ZS-9, we believe this issue has already been thoroughly addressed, and more importantly, the FDA's initial view that an AdCom isn't necessary appears to further diminish this risk.
- **Model update; PT to \$75 with a lot of potential dry powder to go.** We still think our assumptions are conservative, including overall percentage of HK pts being treated with either ZS-9 or patiomer, price, compliance, duration of use, and ultimate market share. The key changes we made to our model are 1) accelerating the time it takes for ZS-9 to catch patiomer in total share by 1 year, to 2018 from 2019 (still conservative in our view), 2) increasing peak market split for ZS-9 to 60/40 from 55/45 starting in 2021, and 3) increasing average duration per patient to 5 mos from 4 mos starting in 2020 (still net out a 75% compliance adjustment from that number). The net effect is our peak US sales estimate goes to almost \$1.5B from just over \$1B. Despite this, our two valuation models (multiple based SOTP scenario analysis and rNPV) still assume just a 75% probability of success in the US and only 50% in EU, sales scenarios that are skewed to more disappointing assumptions, and a 12% discount rate despite probability adjustments.

Table 1: ZS-9 vs. Patiromer

	ZS-9	Patiromer
<b>Description</b>	ZS-9 (zirconium silicate) is an insoluble, non-absorbed compound with a three-dimensional crystalline lattice structure that was specifically designed to trap potassium ions	Patiromer is a non-absorbed ion exchange polymer
<b>Dosing</b>	Oral, once daily	Oral, twice daily
<b>Phase 3 Description</b>	ZS004: Randomized, double-blind, placebo-controlled withdrawal study  Induction phase: pts received 10g of ZS-9 3x/day for 48 hrs, and pts whose serum K normalized were eligible to enter the randomized withdrawal portion, where pts received 5g, 10g, or 15g of ZS-9 or placebo once daily for 28 days	Two part, single-blind, randomized, placebo-controlled Phase 3 study  Part A: 4-week single-group, single-blind initial treatment phase where pts received patiromer 4.2g or 8.4g 2x daily and Part B: 8-week, placebo-controlled, single-blind, randomized withdrawal study (eligible pts had a baseline potassium level of 5.5 to <6.5 mmol per liter in whom the level decreased to 3.8 to <5.1 mmol per liter)
<b>Patient population</b>	N=230; Hyperkalemia regardless of etiology, serum K >5 mEq/L	N=243; Pts with stage 3 or 4 CKD on RAAS inhibitors, serum potassium levels of 5.1 to <6.5 mmol per liter
<b>Duration</b>	4 weeks	12 weeks
<b>Primary endpoint</b>	Compare the mean serum K levels between placebo and each of the dosing groups during days 8-29 of the randomized phase	Initial phase: mean change in the serum potassium level from baseline to week 4  Withdrawal phase: between-group difference in the median change in the serum potassium level over the first 4 weeks of that phase
<b>Secondary endpoints</b>	Open label phase: change from baseline in serum K levels at all time intervals, proportion of pts achieving normokalemia by 24 and 48 hrs, time to K normalization  Randomized phase: proportion of pts with mean K <5.1 mEq/L during days 8-29	Initial phase: proportion of patients who had a serum potassium level of 3.8 to less than 5.1 mmol per liter at week 4  Withdrawal phase: proportion of patients with a recurrence of hyperkalemia according to two definitions: a serum potassium level of 5.1 mmol per liter or higher and a serum potassium level of 5.5 mmol per liter or higher
<b>Efficacy data</b>	Open label phase: 0.2, 0.4, and 0.5 mEq/L K decline at 1, 2, and 4 hrs, respectively (p<0.001); mean time to K+ normalization was 2.2 hrs; 84% of pts normalized by 24 hrs, 98% of pts normalized by 48 hrs; stat sig achieved for primary endpoint of mean K+ maintenance on days 8-29 for all doses (p<0.001) – mean K of 5.06 mEq/L, 4.75 mEq/L, 4.51 mEq/L, and 4.37 mEq/L for placebo, ZS-9 5g, 10g, and 15g, respectively  Randomized phase: proportion of pts with mean K <5.1 mEq/L during days 8-29 was 46% with placebo, 80% with ZS-9 5g, 90% with ZS-9 10g, and 94% with ZS-9 15g	Initial phase: showed a stat sig mean reduction in potassium of -1.01 mmol/L (P<0.001), with 76% of patients having normal serum K at week 4.  Withdrawal phase: 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 mmol/L vs. no increase observed in the patiromer group (p<0.001)  Recurrence of hyperkalemia (potassium level, ≥5.5 mmol/L) occurred in 60% of the pts on placebo vs. 15% in the patiromer group through week 8 (P<0.001)
<b>Time to onset</b>	1 hour post first dose	7 hours post first dose



## ZSPH Valuation Summary

ZSPH Valuation Summary			
Discount rate	12%		
4Q15 Fully Diluted Shares (mm)	28.8		
<b>Main value drivers</b>	Prob of approval	Peak WW sales est (avg. scenario)	Avg peak yr
ZS-9 US	75%	\$ 1,489	2020
ZS-9 EU/Japan	50%	\$ 768	2022
<b>Valuation methodology</b>	Value / share	Weighting	Adj. value/ share
DCF			
P/E 2016			
Real options scenario analysis	\$ 76.37	50%	38.19
Risk adjusted NPV analysis	\$ 73.92	50%	36.96
Total			\$ 75.15
Catalyst/liquidity discount			0%
<b>YE15 Price Target</b>			<b>\$ 75</b>

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.

## ZS Pharma: Summary of Financials

Income Statement - Annual	FY14A	FY15E	FY16E	FY17E	Income Statement - Quarterly	1Q15A	2Q15E	3Q15E	4Q15E
Revenues	0	0	52	-	Revenues	0A	0	0	0
Cost of products sold	0	0	(16)	-	Cost of products sold	0A	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(20)	(26)	(114)	-	SG&A	(6)A	(6)	(7)	(7)
R&D	(41)	(60)	(64)	-	R&D	(15)A	(15)	(15)	(15)
Operating income	(61)	(87)	(142)	-	Operating income	(22)A	(21)	(22)	(22)
EBITDA	(61)	(87)	(142)	-	EBITDA	(22)A	(21)	(22)	(22)
Net interest (income) / expense	(4)	(1)	(1)	-	Net interest (income) / expense	(0)A	(0)	(0)	(0)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Income taxes	0	0	0	-	Income taxes	0A	0	0	0
Net income - GAAP	(64)	(87)	(143)	-	Net income - GAAP	(22)A	(21)	(22)	(23)
Net income - recurring	(64)	(87)	(143)	-	Net income - recurring	(22)A	(21)	(22)	(23)
Diluted shares outstanding	12	24	28	-	Diluted shares outstanding	21A	25	25	25
EPS - excluding non-recurring	(5.47)	(3.64)	(5.10)	-	EPS - excluding non-recurring	(1.05)A	(0.85)	(0.87)	(0.90)
EPS - recurring	(5.47)	(3.64)	(5.10)	-	EPS - recurring	(1.05)A	(0.85)	(0.87)	(0.90)
Balance Sheet and Cash Flow Data	FY14A	FY15E	FY16E	FY17E	Ratio Analysis	FY14A	FY15E	FY16E	FY17E
Cash and cash equivalents	87	1	12	-	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	88.0%	43.2%	63.9%	-
Inventories	-	-	-	-	EPS growth - recurring	(35.8%)	(33.4%)	40.2%	-
Other current assets	0	0	0	-	Gross margin	-	-	-	-
Current assets	87	1	12	-	EBIT margin	-	-	(274.7%)	-
PP&E	10	12	12	-	EBITDA margin	-	-	(274.7%)	-
Total assets	97	13	24	-	Tax rate	0.0%	0.0%	0.0%	-
Total debt	-	-	-	-	Net margin	-	-	(276.3%)	-
Total liabilities	8	8	8	-	Net Debt / EBITDA	-	-	-	-
Shareholders' equity	89	4	16	-	Net Debt / Capital (book)	-	-	-	-
Net income (including charges)	(64)	(87)	(143)	-	Return on assets (ROA)	(116.1%)	(160.0%)	(775.4%)	-
D&A	3	6	7	-	Return on equity (ROE)	(134.9%)	(187.4%)	(1405.6%)	-
Change in working capital	0	0	0	-	Enterprise value / sales	-	-	27.1	-
Other	2	3	4	-	Enterprise value / EBITDA	NM	NM	NM	-
Cash flow from operations	(59)	(79)	(132)	-	Free cash flow yield	(9.5%)	(6.3%)	(8.7%)	-
Capex	(8)	(8)	(8)	-					
Free cash flow	(63)	(85)	(138)	-					
Cash flow from investing activities	(8)	(8)	(8)	-					
Cash flow from financing activities	145	0	150	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

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



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



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