

ZS Pharma

Takeaways from Analyst Event

This evening ZSPH hosted an analyst event to go over Phase 3 data presented at AHA on Monday (see our note [here](#), presentations slides [here](#)), as well as review the clinical program for ZS-9. The AHA presenter, Dr. Mikhail Kosiborod (University of Missouri) very effectively addressed concerns around edema in our view, essentially concluding this was a chance result while also noting all cases were mild, half didn't require treatment, and the one severe case was in a patient with eGFR<30 who had recently been taken off diuretics. Dr. Frank Peacock (Baylor) highlighted the medical need in the emergency room setting, and Dr. Bruce Spinowitz (Weill) discussed the data from a nephrology point of view noting ZS-9's effect on bicarbonate and aldosterone could have a disease modifying effect on kidney disease. Bottom line, we continue to see ZS-9 as a differentiated treatment option in a large market with significant unmet need, which we think could lead to a majority market share in time vs. RLYP's patiomer. Even assuming equal share, we believe ZSPH's valuation is compelling given the potential size of the hyperkalemia market. Maintain Overweight.

- ZS004 reinforces ZS-9's promising clinical profile, with Dr. Kasiborod very effectively addressing edema concerns, in our view.** Post AHA, edema was in focus (6% and 14% at 10 and 15g vs. 2% each on placebo and 5g). Dr. Kasiborod noted there were imbalances in baseline characteristics (% pts with heart failure and BNP levels) weighted towards higher doses, which are likely playing a factor in edema rates. Seven of 8 cases at 15g were peripheral (mostly foot/ankle), and the one case of generalized edema was in a 74 yr old pt with an eGFR<30, BP of 193/71, and who had been taken off diuretics prior to entering the study. Edema rates in all ZS-9 trials (edema cases per days of patient exposure) is <0.0001 in all trials to date, and importantly, there have been no cases reported in pts on the 15g dose in the ZS004e study. On hypokalemia, it was noted there hasn't been a single severe case across trials to date.
- The first DMC review in the 11mo ZS004e found no issues, and progress with the ZS005 trial continues.** In addition to the ZS004e trial passing its first independent DMC review, the company also noted that ~200 pts are enrolled in the ZS005 trial thus far. Of note, no patients have required up titrations to the 15g dose (all on 5 or 10g), highlighting that real world use of the highest dose is likely to be minimal. On preclinical tox progress, the co also noted that the 6 mo rat and 9 mo dog studies are now complete, with no measurable levels of zirconium detected with long term dosing.

ZS Pharma, Inc (ZSPH;ZSPH US)

FYE Dec	2013A	2014E	2015E	2016E
EPS Reported (\$)				
Q1 (Mar)	(1.35)	(2.57)A	-	-
Q2 (Jun)	-	(4.72)A	-	-
Q3 (Sep)	-	(0.81)A	-	-
Q4 (Dec)	-	(0.84)	-	-
FY	(8.52)	(4.99)	(3.09)	(4.65)

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

Overweight

ZSPH, ZSPH US

Price: \$37.33

Price Target: \$43.00

Biotechnology

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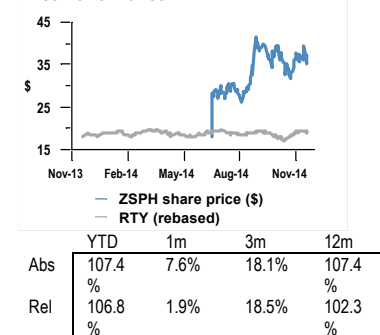
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Price Performance



Company Data

Price (\$)	37.33
Date Of Price	19 Nov 14
52-week Range (\$)	43.00-25.51
Market Cap (\$ mn)	777.17
Fiscal Year End	Dec
Shares O/S (mn)	21
Price Target (\$)	43.00
Price Target End Date	31-Dec-15

See page 5 for analyst certification and important disclosures.

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- **Prespecified endpoints in ZS004 show ZS-9 has dose dependent effects on bicarbonate and aldosterone.** On the cardiology front, aldosterone has been shown to be a key determinant in the development of heart failure (and high levels of aldosterone have been shown to be toxic to the myocardium). Dr. Spinowitz was also enthusiastic about ZS-9's effect on these parameters, noting that improvements in both could have a renal-protective effect, potentially modifying the progression of kidney disease. He also noted the potential cost implications (in the cost sensitive ESRD setting) of that potential for disease modification.
- **Acute management of hyperkalemia in the ER is lacking, with emergency dialysis being the only safe and effective option to eliminate K from the body.** Dr. Peacock highlighted the unmet need in this setting, noting the current protocols (e.g. calcium, glucose, beta2 agonists) are effective 1) for short periods of time and 2) don't actually eliminate K from the body. The only treatments that do remove K are kayexalate (which he noted he hasn't used in 2 years due to tolerability) and emergency dialysis, which is both expensive and logistically challenging for these pts given the time sensitivity of hyperkalemia. The doc also highlighted ZS-9's rapid onset of action (stat sig reductions observed in 1 hr) as key when time is of the essence (to prevent cardiac mortality). While the acute setting represents a relatively small portion of the potential revenue, the doc/ZSPH noted that ~50% of pts are first diagnosed in the hospital.

Investment Thesis, Valuation and Risks

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

Investment Thesis

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

Valuation

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

ZSPH Valuation Summary

ZSPH Valuation Summary			
Discount rate	13%		
4Q15 Fully Diluted Shares (mm)	27.8		
Main value drivers	Prob of approval	Peak WW sales est (avg. scenario)	Avg peak yr
ZS-9 US	70%	\$ 1,105	2020
ZS-9 EU/Japan	50%	\$ 570	2022
Valuation methodology	Value / share	Weighting	Adj. value/ share
DCF			
P/E 2016			
Real options scenario analysis	\$ 45.21	50%	22.61
Risk adjusted NPV analysis	\$ 40.69	50%	20.34
Total			\$ 42.95
Catalyst/liquidity discount			0%
YE15 Price Target			\$ 43

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

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

ZS Pharma: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14A	3Q14A	4Q14E
Revenues	0	0	0	52	Revenues	0A	0A	0A	0
Cost of products sold	0	0	0	(16)	Cost of products sold	0A	0A	0A	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(8)	(20)	(26)	(114)	SG&A	(4)A	(5)A	(6)A	(6)
R&D	(25)	(38)	(41)	(44)	R&D	(5)A	(10)A	(11)A	(12)
Operating income	(32)	(58)	(67)	(122)	Operating income	(9)A	(15)A	(17)A	(17)
EBITDA	(32)	(58)	(67)	(122)	EBITDA	(9)A	(15)A	(17)A	(17)
Net interest (income) / expense	(2)	(4)	(1)	(1)	Net interest (income) / expense	(1)A	(2)A	(0)A	(0)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Income taxes	0	0	0	0	Income taxes	0A	0A	0A	0
Net income - GAAP	(34)	(62)	(67)	(123)	Net income - GAAP	(11)A	(16)A	(17)A	(18)
Net income - recurring	(34)	(62)	(67)	(123)	Net income - recurring	(11)A	(16)A	(17)A	(18)
Diluted shares outstanding	4	12	22	26	Diluted shares outstanding	4A	3A	21A	21
EPS - excluding non-recurring	(8.52)	(4.99)	(3.09)	(4.65)	EPS - excluding non-recurring	(2.57)A	(4.72)A	(0.81)A	(0.84)
EPS - recurring	(8.52)	(4.99)	(3.09)	(4.65)	EPS - recurring	(2.57)A	(4.72)A	(0.81)A	(0.84)
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	9	89	24	55	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	295.6%	79.5%	15.1%	83.5%
Inventories	-	-	-	-	EPS growth - recurring	224.3%	(41.5%)	(38.0%)	50.6%
Other current assets	0	0	0	0	Gross margin	-	-	-	-
Current assets	9	90	24	55	EBIT margin	-	-	-	(236.1%)
PP&E	5	10	12	12	EBITDA margin	-	-	-	(236.1%)
Total assets	14	99	35	67	Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	-	-	-	-	Net margin	-	-	-	(237.6%)
Total liabilities	8	8	8	8	Net Debt / EBITDA	-	-	-	-
Shareholders' equity	6	92	27	59	Net Debt / Capital (book)	-	-	-	-
Net income (including charges)	(34)	(62)	(67)	(123)	Return on assets (ROA)	(172.9%)	(108.6%)	(99.7%)	(239.2%)
D&A	1	3	6	7	Return on equity (ROE)	(235.2%)	(125.7%)	(113.1%)	(285.1%)
Change in working capital	3	0	0	0	Enterprise value / sales	-	-	-	13.8
Other	4	2	3	4	Enterprise value / EBITDA	NM	NM	NM	NM
Cash flow from operations	(27)	(56)	(58)	(112)	Free cash flow yield	(18.8%)	(13.1%)	(8.0%)	(12.0%)
Capex	(4)	(8)	(8)	(8)					
Free cash flow	(28)	(61)	(65)	(118)					
Cash flow from investing activities	(4)	(8)	(8)	(8)					
Cash flow from financing activities	15	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

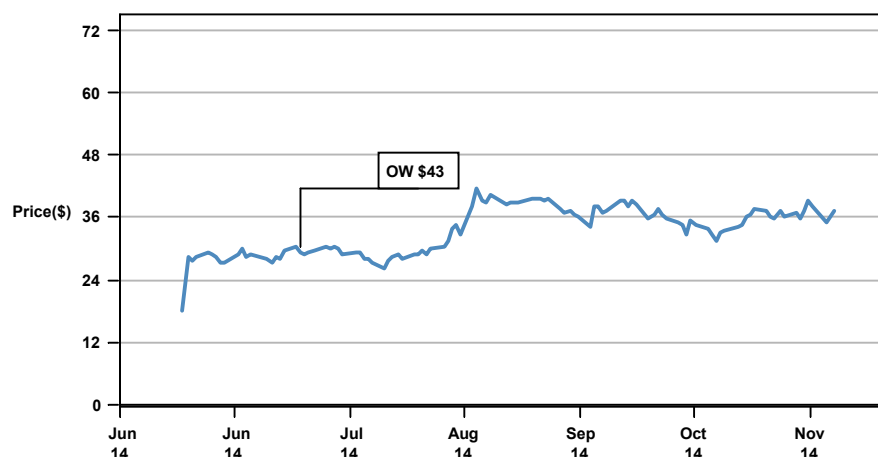
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ZS Pharma (ZSPH, ZSPH US) Price Chart



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

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

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