ZS Pharma

Notes from the Road

Overweight

ZSPH, ZSPH US
Price: $37.02

Price Target: $43.00

We're reiterating our OW rating on ZSPH after hosting CEO Robert Alexander, CFO Todd Creech, and SVP, Corporate Development Adam Tomasi for investor meetings this week. After the company recently announced that the Phase 3 ZS004 trial was successful (see our note here) but didn't (couldn't) release any data due to the AHA embargo, many of the questions focused on general progress towards NDA filing (on track for 1H15) and the commercial opportunity. Given ZS just went public in June, not much new came out of the meetings though there are 3 incremental updates worth noting, incl 1) the patents that provide protection to 2032 have issued; 2) 6 month rat and 9 month dog toxicology studies are complete to facilitate extended dosing in the ZS004e and ZS005 studies; and 3) the company is now manufacturing ZS-9 at commercial scale. More detailed takeaways are outlined below.

- **Data in the ZS004 press release was light due to an AHA embargo; full results will be presented at the conference (Chicago) on November 17th.** A common question throughout meetings was around the lack of data in the recent press release announcing that the ZS004 trial was successful (see our note here). Mgmt indicated that AHA is very strict around their embargo, and noted that they had to negotiate for even what little information was included in the PR. Thus commentary was limited, but mgmt reiterated that ZS004 data are directionally very similar to the ZS003 trial. Mgmt also indicated that they expect data from ZS002, ZS003 and ZS004 trials will be published within the next 6 mo.

- **The NDA is on track for 1H15, with an MAA to follow.** With ZS004 now complete, the company noted that it has everything it needs on the clinical front to file the NDA. The remaining rate limiting steps are CMC and the process of actually compiling the NDA. In the EU, the company thinks the EMA will stick to the ICH guidelines, and thus will require a total of 1,500 pts exposed – including 300 at 6 months and 100 at 1 year – for approval. The company intends to have the appropriate patient numbers next year (the exact timing of which is dependent on the enrollment rates on the ongoing ZS004 extension study, and the ZS005 trial). Upon approval, the company plans to have approximately 150 sales reps hired and ready to go; reps will target high prescribing cardiologists, nephrologists, as well as targeted hospital systems to get ZS-9 on formulary for use in the acute setting.

Biotechnology

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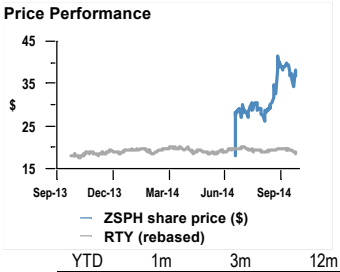

	YTD	1m	3m	12m
Abs	105.7 %	-3.1%	29.5%	105.7 %
Rel	110.3 %	1.6%	35.6%	102.3 %

ZS Pharma, Inc (ZSPH;ZSPH US)

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

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

Company Data	
Price ($)	37.02
Date Of Price	25 Sep 14
52-week Range ($)	43.00-25.51
Market Cap ($ mn)	128.92
Fiscal Year End	Dec
Shares O/S (mn)	3
Price Target ($)	43.00
Price Target End Date	31-Dec-15

See page 6 for analyst certification and important disclosures.

- **In addition to the powder formulation, ZSPH is working on a tablet formulation, which could be a key differentiator vs. competition.** Both ZS-9 and patiromer are powder formulations that are dosed as suspensions. ZSPH is working on a tablet (tablets have been produced but not yet optimized), though the co noted that it is still working on market research to determine if there is a demand for a pill. As such, and as the tablet has not yet been optimized, the co will launch with the powder formulation, and a tablet (if they decide to move forward with it) could come to market ~1yr post launch. Given the large amount of API per dose (~5g in a maintenance setting) ZSPH noted the pills are large and a patient would need to take several at a time, so a tablet/capsule formulation may not be ideal On the other hand, using Renagel/Renvela (phosphate binder with a similarly high dose) as a comp points in the opposite direction: ~75% of usage is in the pill form vs. the powder despite the significant pill burden.

- **ZS-9's specificity for K is differentiating, leading to a highly predictable and rapid onset of action.** The co reiterated the importance of the speed of the onset of action (ZS-9 shows a stat sig effect 1hr post 1st dose) in the acute treatment setting given that the goal of acute treatment is to prevent a potentially deadly arrhythmia. Currently most pts are admitted to the ER when hyperkalemia is discovered, where docs immediately administer insulin and albuterol (which gets K out of the blood by moving it into cells), and then load patients with kayexalate to facilitate fecal excretion of the K (as it effluxes from the cells). ZS-9's ability to rapidly and predictably remove K from the body is a key benefit (especially vs. kayexalate which has no randomized data showing efficacy or speed of effect).

- **Recently issued composition of matter and utility patents extend IP to 2032.** ZSPH highlighted the recently issued COM (patent no. 8,802,152) and utility (patent no. 8,808,750) patents, which expire in 2032 and 2030, respectively. The COM patent covers an API slightly different than the one described in the UOP composition of matter patents (which are set to expire in 2017) - ZSPH improved upon the original by making tweaks to the composition in order to "avoid increase in pH of urine in patients and/or avoid potential entry of particles into the bloodstream of the patient." The newly issued utility patent has claims around the use of the new patent composition in the treatment of hyperkalemia. The co noted that it doesn't intend to seek IP around the manufacturing process given 1) trade secrets involved in the process and 2) it manufactures the API in house (and is the only API manufacturer in the world).

- **The risk of hypokalemia with Z-9 (or competitor patiromer) is low given the body's ability to regulate K.** ZSPH noted that rates of hypokalemia are very low in their trials to date. They haven't seen any significant cases as defined by serum K ≤3mmol/L, and mgmt noted that docs don't tend to get worried until serum K drops to around 2.5 mmol/L. While the company believes that the risk is likely to be mentioned in the label for both drugs, based on data to date it doesn't believe it will be an issue in real world use given the body tends to begin to "fight back" around serum K levels of ~4.5mmol/L. Further, the co noted that hypokalemia can be quickly reversed by taking a potassium supplement or drinking a Gatorade.

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- **The co is now up to commercial manufacturing scale using 2000L reactors, with potential to move up to 5000L reactors.** CMC work is progressing on schedule, and the co noted it is up to commercial scale. At peak, ZSPH is planning for production of ~600,000kg of API per year (one 2000L reactor can produce ~30,000kg/year). Post scale up, the co believes that further scale up to 5000L reactors would be possible. On a CapEx basis, the all in cost of a 2000L reactor suite (which contains two 2000L reactors) is ~$10M, while a 5000L suite (also 2 reactors) is ~$15M.

- **The co ended 2Q14 with $130M in cash; should be sufficient through the expected 1H16 approval of ZS-9.** The company raised ~$112M in its June IPO (J.P. Morgan acted as a joint book-runner) and believes the current cash position should be sufficient into early 2016. The cash guidance includes CapEx related to manufacturing scale up/build out as well as launch prep (including having the ~150 person sales force ready to go at the time of launch).

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Investment Thesis, Valuation and Risks

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

Investment Thesis

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

Valuation

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

ZSPH Valuation Summary

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

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

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

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ZS Pharma: Summary of Financials

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

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

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

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	-	-	-	-
EBIT growth	295.6%	70.3%	21.3%	83.5%
EPS growth - recurring	224.3%	(41.2%)	(36.9%)	49.1%
Gross margin	-	-	-	-
EBIT margin	-	-	-	(236.1%)
EBITDA margin	-	-	-	(236.1%)
Tax rate	0.0%	0.0%	0.0%	0.0%
Net margin	-	-	-	(240.6%)
Net Debt / EBITDA	-	-	-	-
Net Debt / Capital (book)	-	-	-	-
Return on assets (ROA)	(172.9%)	(109.6%)	(103.7%)	(255.4%)
Return on equity (ROE)	(235.2%)	(126.9%)	(117.9%)	(307.6%)
Enterprise value / sales	-	-	-	1.0
Enterprise value / EBITDA	NM	NM	NM	NM
Free cash flow yield	(18.9%)	(12.6%)	(8.1%)	(12.1%)

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

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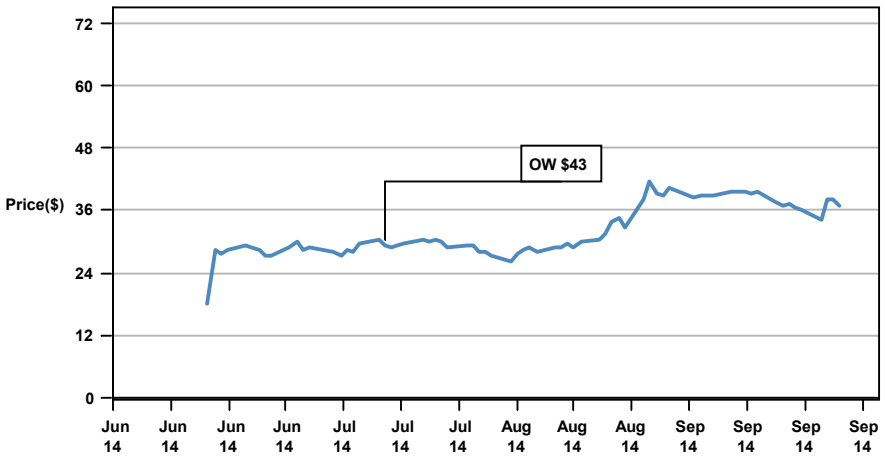
ZS Pharma (ZSPH, ZSPH US) Price Chart



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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IB clients*	75%	66%	54%

*Percentage of investment banking clients in each rating category.
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