

## ZS Pharma

### 4Q Snapshot & Model Update

We are updating our model and reiterating our OW rating on ZSPH following the release of 4Q results. Most importantly, the NDA for hyperkalemia agent ZS-9 is on track to be submitted in 2Q15 after the company had a positive pre-NDA meeting with the FDA, during which the agency indicated that it does not plan to conduct an AdCom for ZS-9 at this time (similar message for competitor RLYP). ZSPH also highlighted the recent publication of Phase 3 ZS003 results in NEJM ([here](#)) as well as Phase 3 ZS004 data that was presented at AHA in Nov (see our note [here](#)). 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 over time vs. competitor RLYP's patiromer. Even assuming equal share, we believe ZSPH's valuation is compelling given the potential size of the hyperkalemia market.

- **Upcoming events: NDA on track for 2Q15 submission, MAA anticipated in 2H15.** The key event for ZSPH in 2015 will be regulatory filings for ZS-9. The company also plans to present clinical trial results (previously reported) at the upcoming ACC meeting (March 14-16, San Diego) and the NKF spring clinical meeting (March 25-29, Dallas).
- **4Q results.** 4Q EPS was \$(0.98) vs. JPMe of \$(0.84). 4Q OpEx of \$20.1M was slightly higher than JPMe of \$17.4M. That said, ZSPH is not yet an earnings story.
- **Estimate changes.** We have updated our model for 4Q results; changes were minimal. We are maintaining our YE15 probability-adjusted price target of \$57.
- **Balance sheet update.** ZSPH ended 4Q with \$102.3M in cash (and no debt), after having raised \$112M in its June IPO (J.P. Morgan acted as a joint book-runner). The current cash position should be sufficient through the expected approval of ZS-9 in 1H16.

## Overweight

ZSPH, ZSPH US

Price: \$47.62

Price Target: \$57.00

### Biotechnology

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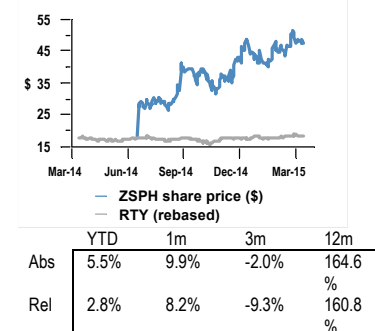
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### Price Performance



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

FYE Dec	2013A	2014A	2015E (Prev)	2015E (Curr)	2016E (Prev)	2016E (Curr)
EPS Reported (\$)						
Q1 (Mar)	(1.35)	(2.57)	-	(0.99)	-	-
Q2 (Jun)	-	(4.72)	-	(1.01)	-	-
Q3 (Sep)	-	(0.81)	-	(1.03)	-	-
Q4 (Dec)	-	(0.98)	-	(1.06)	-	-
FY	(8.52)	(5.47)	(3.09)	(4.09)	(4.65)	(5.93)

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

### Company Data

Price (\$)	47.62
Date Of Price	12 Mar 15
52-week Range (\$)	52.80-25.51
Market Cap (\$ mn)	991.40
Fiscal Year End	Dec
Shares O/S (mn)	21
Price Target (\$)	57.00
Price Target End Date	31-Dec-15

### See page 6 for analyst certification and important disclosures.

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## Pipeline

Figure 1: ZSPH Pipeline

### Product Pipeline Highlights

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

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

## Upcoming Events

Figure 2: ZSPH Upcoming Events

Program	Event	Expected Timing	Significance
<b>ZS-9</b>	NDA Filing	2Q15	Medium
	NDA and MAA filings	2H15	Medium
	US Launch	2016	High

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

Figure 3: ZSPH Income Statement

ZS Pharmaceuticals Income Statement

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	2013A	1Q14A	2Q14A	3Q14A	4Q14A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	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
<b>Total Revenues</b>	-	-	-	-	-	-	-	-	-	-	-	<b>51.7</b>	<b>193.1</b>	<b>417.3</b>	<b>762.8</b>
COGS % of revenue						0%	0%	0%	0%	0%	0%	30%	31%	27%	23%
COGS	-	-	-	-	-	-	-	-	-	-	-	15.5	59.9	112.7	175.4
R&D	24.5	5.3	10.0	10.9	14.6	40.7	14.8	14.9	15.0	15.2	59.9	64.0	66.0	67.0	70.0
SG&A	7.7	4.0	4.6	5.7	5.5	19.8	5.7	6.1	6.6	7.1	25.5	114.3	117.8	123.1	128.6
<b>Total Operating Expenses</b>	<b>32.2</b>	<b>9.3</b>	<b>14.5</b>	<b>16.6</b>	<b>20.1</b>	<b>60.5</b>	<b>20.4</b>	<b>21.0</b>	<b>21.6</b>	<b>22.3</b>	<b>85.4</b>	<b>193.8</b>	<b>243.7</b>	<b>302.8</b>	<b>374.1</b>
<b>Operating Income</b>	<b>(32.2)</b>	<b>(9.3)</b>	<b>(14.5)</b>	<b>(16.6)</b>	<b>(20.1)</b>	<b>(60.5)</b>	<b>(20.4)</b>	<b>(21.0)</b>	<b>(21.6)</b>	<b>(22.3)</b>	<b>(85.4)</b>	<b>(142.1)</b>	<b>(50.6)</b>	<b>114.5</b>	<b>388.7</b>
Net interest & other income	(2.1)	(1.5)	(1.9)	(0.2)	(0.2)	(3.8)	(0.2)	(0.2)	(0.2)	(0.2)	(0.8)	(0.8)	(0.8)	(0.8)	(0.8)
Income Tax (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	11.4	77.6
<b>GAAP Net Income</b>	<b>(34.3)</b>	<b>(10.7)</b>	<b>(16.4)</b>	<b>(16.9)</b>	<b>(20.3)</b>	<b>(64.4)</b>	<b>(20.6)</b>	<b>(21.2)</b>	<b>(21.8)</b>	<b>(22.5)</b>	<b>(86.2)</b>	<b>(142.8)</b>	<b>(51.4)</b>	<b>102.4</b>	<b>310.4</b>
Non-GAAP Adjustments :															
R&D SBC	-	0.1	0.1	0.1	0.1	0.4	0.3	0.3	0.3	0.3	1.0	2.0	3.0	4.0	5.0
G&A SBC	-	0.1	0.1	0.1	0.1	0.4	0.1	0.1	0.1	0.1	0.5	0.8	1.0	1.3	1.5
<b>Non-GAAP Net Income</b>	<b>(34.3)</b>	<b>(10.5)</b>	<b>(16.2)</b>	<b>(16.7)</b>	<b>(20.1)</b>	<b>(63.6)</b>	<b>(20.2)</b>	<b>(20.8)</b>	<b>(21.4)</b>	<b>(22.2)</b>	<b>(84.7)</b>	<b>(140.1)</b>	<b>(47.4)</b>	<b>107.6</b>	<b>316.9</b>
<b>GAAP Basic EPS</b>	<b>(8.52)</b>	<b>(2.57)</b>	<b>(4.72)</b>	<b>(0.81)</b>	<b>(0.98)</b>	<b>(5.47)</b>	<b>(0.99)</b>	<b>(1.01)</b>	<b>(1.03)</b>	<b>(1.06)</b>	<b>(4.09)</b>	<b>(5.93)</b>	<b>(2.11)</b>	<b>4.15</b>	<b>12.41</b>
<b>GAAP Diluted EPS</b>	<b>(8.52)</b>	<b>(2.57)</b>	<b>(4.72)</b>	<b>(0.81)</b>	<b>(0.98)</b>	<b>(5.47)</b>	<b>(0.99)</b>	<b>(1.01)</b>	<b>(1.03)</b>	<b>(1.06)</b>	<b>(4.09)</b>	<b>(5.93)</b>	<b>(2.11)</b>	<b>3.33</b>	<b>10.00</b>
Basic Shares Outstanding	4.0	4.2	3.5	20.8	20.8	11.8	20.9	21.0	21.1	21.2	21.1	24.1	24.4	24.7	25.0
Diluted Shares Outstanding	4.0	4.2	3.5	20.8	20.8	11.8	20.9	21.0	21.1	21.2	21.1	24.1	24.4	30.7	31.0
<b>Margin Analysis:</b>															
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	70%	69%	73%	77%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	27.45%	50.96%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	24.53%	40.69%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.0%	0.0%	5.0%	10.0%	20.0%
<b>Cost Analysis:</b>															
COGS as % of tot. prod. sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	30%	31%	27%	23%
R&D as % of tot. revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	124%	34%	16%	9%
SG&A as % of tot. revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	221%	61%	29%	17%
<b>Year-over-year growth:</b>															
Total revenue		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	273.41%	116.13%	82.80%
R&D Expense		19.28%	NM	NM	NM	66.20%	180.47%	49.31%	37.70%	4.22%	47.00%	6.89%	3.13%	1.52%	4.48%
SG&A Expense		461.82%	NM	NM	NM	157.68%	41.27%	34.06%	15.42%	29.03%	28.76%	348.04%	3.11%	4.49%	4.50%
Total operating expenses		81.03%	NM	NM	NM	88.04%	120.19%	44.53%	30.07%	11.05%	41.03%	126.95%	25.75%	24.26%	23.55%
Operating income		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	66.39%	-64.39%	-326.43%	239.40%
Net income		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	582.09%
EPS		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	45.12%	-64.49%	-258.18%	200.04%
Basic Shares		4.58%	NM	NM	NM	192.38%	400.78%	503.60%	1.44%	1.86%	79.03%	14.24%	1.27%	1.28%	1.29%
Diluted Shares		NM	NM	NM	NM	NM	NM	401.98%	1.20%	1.68%	NM	1.92%	13.16%	1.27%	1.28%

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

## Investment Thesis, Valuation and Risks

### ZS Pharma (Overweight; Price Target: \$57.00)

#### 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 \$57 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	12%			
4Q15 Fully Diluted Shares (mm)	25.8			
<b>Main value drivers</b>	<b>Prob of approval</b>	<b>Peak WW sales est (avg. scenario)</b>	<b>Avg peak yr</b>	
ZS-9 US	75%	\$ 1,105	2020	
ZS-9 EU/Japan	50%	\$ 570	2022	
<b>Valuation methodology</b>	<b>Value / share</b>	<b>Weighting</b>	<b>Adj. value/ share</b>	
DCF				
P/E 2016				
Real options scenario analysis	\$ 58.51	50%		29.26
Risk adjusted NPV analysis	\$ 54.85	50%		27.43
Total				\$ 56.68
Catalyst/liquidity discount				0%
<b>YE15 Price Target</b>				<b>\$ 57</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	1Q15E	2Q15E	3Q15E	4Q15E
Revenues	0	0	52	-	Revenues	0	0	0	0
Cost of products sold	0	0	(16)	-	Cost of products sold	0	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(20)	(26)	(114)	-	SG&A	(6)	(6)	(7)	(7)
R&D	(41)	(60)	(64)	-	R&D	(15)	(15)	(15)	(15)
Operating income	(61)	(85)	(142)	-	Operating income	(20)	(21)	(22)	(22)
EBITDA	(61)	(85)	(142)	-	EBITDA	(20)	(21)	(22)	(22)
Net interest (income) / expense	(4)	(1)	(1)	-	Net interest (income) / expense	(0)	(0)	(0)	(0)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Income taxes	0	0	0	-	Income taxes	0	0	0	0
Net income - GAAP	(64)	(86)	(143)	-	Net income - GAAP	(21)	(21)	(22)	(23)
Net income - recurring	(64)	(86)	(143)	-	Net income - recurring	(21)	(21)	(22)	(23)
Diluted shares outstanding	12	21	24	-	Diluted shares outstanding	21	21	21	21
EPS - excluding non-recurring	(5.47)	(4.09)	(5.93)	-	EPS - excluding non-recurring	(0.99)	(1.01)	(1.03)	(1.06)
EPS - recurring	(5.47)	(4.09)	(5.93)	-	EPS - recurring	(0.99)	(1.01)	(1.03)	(1.06)
Balance Sheet and Cash Flow Data	FY14A	FY15E	FY16E	FY17E	Ratio Analysis	FY14A	FY15E	FY16E	FY17E
Cash and cash equivalents	87	2	13	-	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	88.0%	41.0%	66.4%	-
Inventories	-	-	-	-	EPS growth - recurring	(35.8%)	(25.2%)	45.1%	-
Other current assets	0	0	0	-	Gross margin	-	-	-	-
Current assets	87	2	13	-	EBIT margin	-	-	(274.7%)	-
PP&E	10	12	12	-	EBITDA margin	-	-	(274.7%)	-
Total assets	97	14	26	-	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	6	17	-	Net Debt / Capital (book)	-	-	-	-
Net income (including charges)	(64)	(86)	(143)	-	Return on assets (ROA)	(116.1%)	(155.7%)	(722.7%)	-
D&A	3	6	7	-	Return on equity (ROE)	(134.9%)	(181.9%)	(1241.5%)	-
Change in working capital	0	0	0	-	Enterprise value / sales	-	-	18.9	-
Other	2	3	4	-	Enterprise value / EBITDA	NM	NM	NM	-
Cash flow from operations	(59)	(77)	(132)	-	Free cash flow yield	(11.3%)	(8.4%)	(12.1%)	-
Capex	(8)	(8)	(8)	-					
Free cash flow	(63)	(84)	(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



Date	Rating	Share Price (\$)	Price Target (\$)
14-Jul-14	OW	30.49	43.00
16-Dec-14	OW	47.02	57.00

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%	67%	52%

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