ZS Pharma, Inc. (ZSPH)

Rating	**OUTPERFORM* [V]**
Price (15 Apr 15, US$)	42.00
Target price (US$)	58.00[1]
52-week price range	51.49 - 26.17
Market cap. (US$ m)	1,046.39
Enterprise value (US$ m)	909.46

**Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.*
[1]Target price is for 12 months.
[V] = Stock considered volatile (see Disclosure Appendix).

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SMALL & MID CAP RESEARCH

New Data in NEJM Helps Highlight ZS-9's Speed of Onset

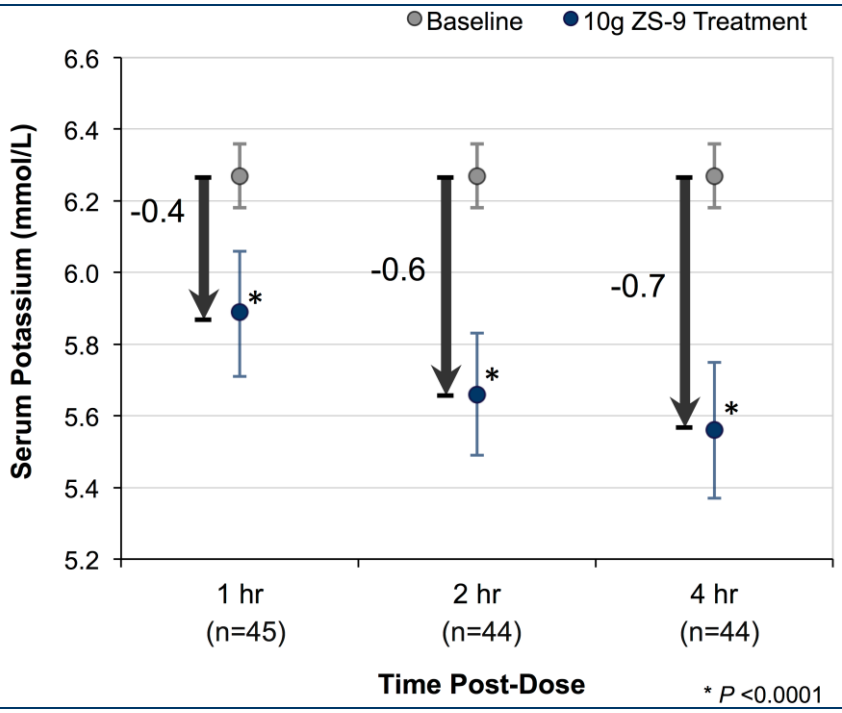
- **Bottom Line:** Results of a small (n=45) study detailed in a Letter to the Editor in the New England Journal of Medicine (NEJM) last night highlight the speed with which ZSPH's ZS-9 helps to reduce potassium levels in patients with hyperkalemia. The primary commercial opportunity for ZS-9 is in the chronic setting but strong data in the acute setting should allow for more patients to be started on ZS-9 in the acute/emergency room setting where patients are often first diagnosed and treated. We believe the upcoming FDA submission of ZS-9 along with the release of longer-term data from the ZS-004e study in the coming months should further de-risk the ZSPH story and allowed for continued appreciation in ZSPH shares.
- **ZS-9 speed of onset highlighted.** The NEJM analysis shows that for the 45 patients in the ZSPH phase 3 studies who had severe levels of hyperkalemia at baseline (minimum value of 6.0 mmol/L and mean value of 6.3 mmol/L), a single 10gm dose of ZS-9 reduced serum potassium levels by 0.4 mmol/L at one hour, 0.6 mmol/L at 2 hours and 0.7 mmol/L at 4 hours (see Exhibit 1). In addition, the median time it took after the single 10gm dose of ZS-9 for patients to get to a serum potassium level under 6.0 mmol/L was only about one hour and for them to get under 5.5 mmol/L took only four hours. The speed of onset for ZS-9, along with the overall efficacy and tolerability of the product are some of the key factors that lead us to favor ZS-9 in the emerging market for novel anti-hyperkalemia agents (see Exhibit 2).

Financial and valuation metrics

Year	12/14A	12/15E	12/16E	12/17E
EPS (CS adj.) (US$)	-5.21	-2.95	-0.41	-0.00
Prev. EPS (US$)	—	—	—	—
P/E (x)	-8.1	-14.2	-103.7	NM
P/E rel. (%)	-45.0	-80.4	-662.8	NM
Revenue (US$ m)	—	—	125.2	187.9
EBITDA (US$ m)	-59.2	-67.3	-6.2	4.3
OCFPS (US$)	-4.17	-2.71	-0.18	0.20
P/OCF (x)	-10.0	-15.5	-239.4	215.2
EV/EBITDA (current)	-17.1	-15.0	-161.6	234.7
Net debt (US$ m)	-37	-137	-123	-118
ROIC (%)	-101.30	-103.18	-12.60	0.18
Number of shares (m)	24.91	IC (current, US$ m)		59.76
BV/share (Next Qtr., US$)	12.5	EV/IC (x)		12.9
Net debt (Next Qtr., US$ m)	-194.0	Dividend (current, US$)		—
Net debt/tot eq (Next Qtr., %)	-74.6	Dividend yield (%)		2.4

Source: Company data, Credit Suisse estimates

Exhibit 1: Rapid Potassium Decrease Within 4 Hours After The First Dose of ZS-9 in Patients With Severe Hyperkalemia



Source: Kosiborod M, Peacock WF, Packham DK. Sodium zirconium cyclosilicate for urgent therapy of severe hyperkalemia. N Engl J Med 2015;372:1577-8. DOI: 10.1056/NEJMc1500353

Exhibit 2: We Believe ZS-9 Has a Stronger Overall Profile than Patiromer Based on Faster Speed of Onset, Better Overall Efficacy and a Better Tolerability Profile

	ZS-9 (ZSPH)	CS Score for ZS-9	Patiromer (RLYP)	CS Score for Patiromer	Comments
Speed of Onset	Statistically significant impact on potassium levels in **1 hour**; median time to normalized potassium **2.2 hours**	++++	Statistically significant impact on potassium levels in **7 hours**; median time to normalized potassium **>48 hours**.	+++	Commercial opportunity is much greater in the chronic setting but faster speed of onset could allow for ZS-9 to gain more traction in the acute setting (likely as an add-on to other acute measures) where many patients are first diagnosed and initiate therapy
Efficacy	**80-94%** of patients with normal potassium levels after 4 weeks of treatment (80% with 5g dose, 90% with 10g dose, 94% with 15g dose)	++++	**76%** of patients with normal potassium levels after 4 weeks of treatment	+++	Greater percentage of patients achieving normal potassium levels should give physicians more comfort in ZS-9's efficacy. Importantly, patiromer has shown the ability to maintain normal potassium levels through 52 weeks, while that data has not yet been generated for ZS-9
Tolerability	**2-4%** of patients experienced constipation during the first 4 weeks of therapy	++++	**~11%** of patients experienced constipation during the first 4 weeks of therapy	+++	For chronic use tolerability may turn out to be a key differentiating factor, with lower rates of constipation providing ZS-9 with a significant potential advantage
Electrolyte Abnormalities	**Hypokalemia** seem in 9.8% of patients on 10g dose, 10.7% of patients on 15g dose	++	**Hypomagnesemia** seen in 8-24% of patients; **hypokalemia** seen in 6% of patients	++	Selectivity for potassium helps explain lack of hypomagnesemia seen with ZS-9
Longer-Term Safety	**Higher rates of edema** seen with higher doses of ZS-9 in ZS004 (2.4% with placebo, 2.2% with 5g dose, 5.9% with 10g dose, 14.3% with 15g dose)	+++	No increase in **edema** rates seen; concerns do exist around **calcium load** with patiromer ingestion	++++	Longer-term safety data will be critical to assess potential rates of edema with ZS-9 given imbalance seen in ZS-004. Higher rates of edema have not been seen in other ZS-9 studies or in the ZS-004E extension study, per the company's public comments
Convenience/Ease of Use	**Once-daily** dosing	++++	Twice-daily dosing but company expects it to be **once-daily** at the time of launch	+++	Once-daily dosing could be an advantage for ZSPH but RLYP states they have received written communication from the FDA that a separate study looking at once-daily dosing will not be needed and, instead, current data on the product should allow for a once-daily dose to be available at the time of product approval
Clinical Trial Conduct	**Over 80%** of patients in pivotal trials were **from the US**; with remainder from South Africa and Australia	+++	**79%** of clinical trial patients **from non-EU Eastern Europe**, with remainder from EU and US	++	Geographic breakdown of patients in clinical trials may not impact approval of the products in the US and EU but greater physician experience with ZS-9 may allow for more rapid uptake in the US and EU upon approval
Regulatory Risk	Company does **not** expect an FDA Advisory Committee meeting prior to approval in 1H 2016	+++	Company does **not** expect FDA Advisory Committee meeting prior to approval Phase 3 study also conducted under a **Special Protocol Assessment (SPA)** from the FDA	++++	FDA can obviously change its mind and request an Advisory Committee meeting for either product (or both) prior to approval but it appears unlikely at this point given company comments to date. SPA for phase 3 study of patiromer given RLYP incrementally lower regulatory risk but not a guarantee for approval based on prior precedent (e.g. Amarin's Vascepa)
Time to Market	**FDA submission in 1H 2015** with approval likely in 1H 2016; EMA submission in 2H 2015	+++	FDA submission completed in Oct 2014 with **PDUFA date of Oct 22, 2015**; EMA submission expected late 2015/early 2016	++++	RLYP has clear first-to-market advantage in the US but we believe uptake will be relatively slow given this is a new class of agents and US physicians have little experience with the drug. Entry of ZS-9 in 1H 2016 should allow for market to grow more rapidly

Source: Company data, Credit Suisse estimates. "CS Score" for each agent represents our view on the profile for each drug for each metric, with ++++ being the highest/best score and + being the lowest/worst score.

Exhibit 3: **ZSPH Income Statement**

in thousands, unless otherwise stated

			FY 2015														
	FY 2013	FY 2014	Mar-15 1QE	Jun-15 2QE	Sep-15 3QE	Dec-15 4QE	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Product sales (US)	0	0	0	0	0	0	0	82,741	181,649	302,430	496,269	606,375	813,688	869,561	926,471	935,467	944,552
Milestones and royalty revenue (ex US)	0	0	0	0	0	0	0	42,500	6,206	13,624	22,682	37,220	45,478	61,027	65,217	69,485	70,160
Total revenues	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**125,241**	**187,855**	**316,054**	**518,952**	**643,595**	**859,166**	**930,588**	**991,689**	**1,004,953**	**1,014,712**
COGS	0	0	0	0	0	0	0	22,871	44,895	71,684	113,560	130,486	169,207	175,791	184,491	186,241	138,205
Gross profit	0	0	0	0	0	0	0	102,371	142,959	244,370	405,392	513,109	689,960	754,797	807,198	818,712	876,507
Research and development expenses	24,508	45,618	6,000	6,000	5,500	13,500	31,000	32,550	34,178	35,203	36,259	37,347	38,467	39,236	39,629	40,025	40,425
Selling, general and administrative expenses	7,686	14,919	6,000	7,000	12,000	14,000	39,000	79,500	108,625	124,919	138,660	152,526	167,778	171,134	172,845	174,574	176,319
Operating income (loss)	**(32,194)**	**(60,537)**	**(12,000)**	**(13,000)**	**(17,500)**	**(27,500)**	**(70,000)**	**(9,679)**	**157**	**84,248**	**230,473**	**323,236**	**483,714**	**544,427**	**594,724**	**604,113**	**659,762**
Interest (income)	(31)	(94)	(24)	(102)	(95)	(86)	(307)	(294)	(259)	(242)	(386)	(732)	(1,122)	(1,710)	(2,394)	(3,142)	(3,906)
Interest expense	9	530	223	223	223	223	891	766	517	268	0	0	0	0	0	0	0
Expense to mark w arrants to market	1,424	3,071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other expense	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Profit (Loss) before tax	(33,597)	(64,044)	(12,199)	(13,121)	(17,628)	(27,636)	(70,584)	(10,152)	(101)	84,222	230,859	323,968	484,836	546,137	597,118	607,254	663,669
Income tax expense (benefit)	0	0	0	0	0	0	0	0	0	1,684	48,625	121,488	181,814	204,801	223,919	227,720	248,876
Net profit (loss)	(33,597)	(64,044)	(12,199)	(13,121)	(17,628)	(27,636)	(70,584)	(10,152)	(101)	82,538	182,234	202,480	303,023	341,336	373,199	379,534	414,793
Preferred stock accretion	(689)	(310)					0										
Pro forma net profit (loss)	**(32,862)**	**(61,283)**	**(12,199)**	**(13,121)**	**(17,628)**	**(27,636)**	**(70,584)**	**(10,152)**	**(101)**	**82,538**	**182,234**	**202,480**	**303,023**	**341,336**	**373,199**	**379,534**	**414,793**
Weighted avg. shares used to calculate diluted EPS	10,366	11,768	20,832	24,895	24,919	24,943	23,897	25,060	25,174	25,286	25,396	25,504	25,610	25,713	25,815	25,915	26,012
EPS - Diluted	**($3.17)**	**($5.21)**	**($0.59)**	**($0.53)**	**($0.71)**	**($1.11)**	**($2.95)**	**($0.41)**	**($0.00)**	**$3.26**	**$7.18**	**$7.94**	**$11.83**	**$13.27**	**$14.46**	**$14.65**	**$15.95**
Depreciation and amortization	705	1,340	545	638	732	826	2,741	3,433	4,143	5,120	6,270	7,098	7,452	6,762	6,442	5,971	5,351
EBITDA	**(31,489)**	**(59,197)**	**(11,455)**	**(12,362)**	**(16,768)**	**(26,674)**	**(67,259)**	**(6,246)**	**4,300**	**89,369**	**236,743**	**330,334**	**491,167**	**551,189**	**601,165**	**610,084**	**665,113**
Margin Analysis																	
Gross margin (overall)								81.7%	76.1%	77.3%	78.1%	79.7%	80.3%	81.1%	81.4%	81.5%	86.4%
R&D margin (overall)								26.0%	18.2%	11.1%	7.0%	5.8%	4.5%	4.2%	4.0%	4.0%	4.0%
SG&A margin (overall)								63.5%	57.8%	39.5%	26.7%	23.7%	19.5%	18.4%	17.4%	17.4%	17.4%
EBITDA margin								-5.0%	2.3%	28.3%	45.6%	51.3%	57.2%	59.2%	60.6%	60.7%	65.5%
Operating margin								-7.7%	0.1%	26.7%	44.4%	50.2%	56.3%	58.5%	60.0%	60.1%	65.0%
Statutory tax rate	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%
Effective tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	21.1%	37.5%	37.5%	37.5%	37.5%	37.5%	37.5%
Net income margin								-8.1%	-0.1%	26.1%	35.1%	31.5%	35.3%	36.7%	37.6%	37.8%	40.9%
Year/Year Changes																	
Product revenue								NM	119.5%	66.5%	64.1%	22.2%	34.2%	6.9%	6.5%	1.0%	1.0%
Total revenue								NM	50.0%	68.2%	64.2%	24.0%	33.5%	8.3%	6.6%	1.3%	1.0%
Gross profit								NM	39.6%	70.9%	65.9%	26.6%	34.5%	9.4%	6.9%	1.4%	7.1%
R&D								5.0%	5.0%	3.0%	3.0%	3.0%	3.0%	2.0%	1.0%	1.0%	1.0%
SG&A								103.8%	36.6%	15.0%	11.0%	10.0%	10.0%	2.0%	1.0%	1.0%	1.0%
EBITDA								NM	NM	1978.4%	164.9%	39.5%	48.7%	12.2%	9.1%	1.5%	9.0%
Operating margin								NM	NM	53568.6%	173.6%	40.2%	49.6%	12.6%	9.2%	1.6%	9.2%
Net income								NM	NM	NM	120.8%	11.1%	49.7%	12.6%	9.3%	1.7%	9.3%

Source: Company data, Credit Suisse estimates

Companies Mentioned *(Price as of 15-Apr-2015)*

Relypsa (RLYP.OQ, $36.79)
ZS Pharma, Inc. (ZSPH.OQ, $42.0, OUTPERFORM[V], TP $58.0)

Disclosure Appendix

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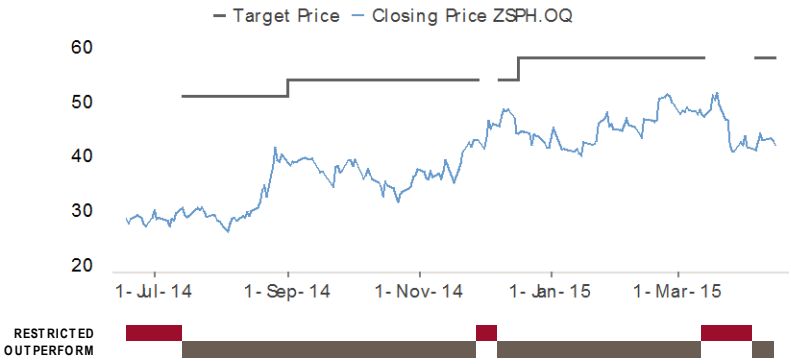
3-Year Price and Rating History for ZS Pharma, Inc. (ZSPH.OQ)

ZSPH.OQ Date	Closing Price (US$)	Target Price (US$)	Rating
18-Jun-14	28.38		R
14-Jul-14	30.49	51.00	O *
01-Sep-14	40.29	54.00	
28-Nov-14	42.96		R
08-Dec-14	45.49	54.00	O
17-Dec-14	44.18	58.00	
13-Mar-15	47.24		R
06-Apr-15	41.13	58.00	O

** Asterisk signifies initiation or assumption of coverage.*



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Price Target: (12 months) for ZS Pharma, Inc. (ZSPH.OQ)

Method: Our $58 target price is based on DCF valuation. We use a 11.5% WACC and forecast discounted cash flows through 2033, with no terminal value thereafter.

Risk: Key risks to our $58 target price include (1) pipeline setbacks; (2) poor execution; and (3) earlier-than-expected generic competition for ZS-9.

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