

ZS Pharma

(ZSPH-NASDAQ)

Stock Rating: Outperform**Industry Rating:** Outperform

December 8, 2014

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Market Recognizing Recent Positive Data; PT to \$54

Event

The shares of ZS Pharma have risen steadily following the company's release of Phase III data, which we believe has the market increasingly appreciating the hyperkalemia market opportunity and ZS Pharma's ZS-9.

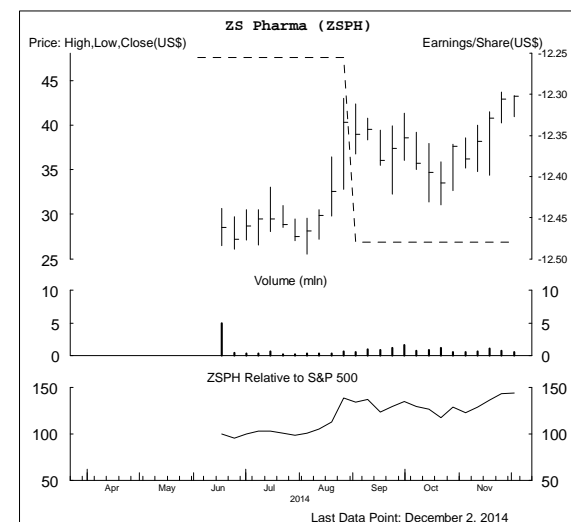
Impact & Analysis

We believe the market is appropriately upwardly adjusting its expectations for the potential of ZS Pharma's lead drug candidate, ZS-9. We believe that there are several factors behind the recent rise in the shares: 1) impressive Phase III data at the AHA and ASN medical meetings in November; 2) the response from the well-attended analyst investor day, which included several leading physicians who explained the market opportunity and ZS-9's profile; and 3) positive data from competitor Relupsa. We believe a deal for Relupsa or ZS Pharma would help validate the market expectations for investors and create further positive sentiment. ZS Pharma has a lockup expiry coming on December 15 (13.8 million shares), and thus, investors may see some greater-than-expected volatility in the near term, but we believe the company is on the right track to file 1H15 and be on the market in 2016. Although Relupsa's Patiromer may reach the market some six months or a year earlier than ZS Pharma's product, we believe that ZS-9's safety profile shown so far - rapid onset, and efficacy - puts it in an excellent competitive position.

Valuation & Recommendation

As we are rapidly approaching the close of the year, we are adjusting our DCF valuation from a 2014 base year to 2015, as well as increasing some spending assumptions, and as a result, our price target rises from \$45 to \$54.

Price (8-Dec) \$45.49 **52-Week High** \$47.98
Target Price \$54.00 **52-Week Low** \$25.51



(FY-Dec.)	2013A	2014E	2015E	2016E
EPS	-\$21.84	-\$5.33↓	-\$2.81↑	-\$2.62↓
P/E		na	na	na
CFPS	na	-\$4.52↓	-\$3.42↑	-\$3.31
P/CFPS		na	na	na
Rev. (\$mm)	\$0	\$0	\$0	\$17
EV	na	\$845	\$845	\$845
EBITDA (\$mm)	-\$32	-\$57	-\$66	-\$63
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2013A	na	na	na	na
2014E	-\$6.60a	-\$4.72a	-\$0.81a	-\$0.88↓
2015E	-\$0.71↑	-\$0.65↑	-\$0.73↑	-\$0.73↑
Dividend	\$0.00			0.0%
Book Value	\$1.16			39.6x
Shares O/S (mm)	20.8			\$956
Float O/S (mm)	20.2			\$928
Wkly Vol (000s)	840			\$28.5
Net Debt (\$mm)	-\$111			na
Yield				0.0%
Price/Book				39.6x
Mkt. Cap (mm)				\$956
Float Cap (mm)				\$928
Wkly \$ Vol (mm)				\$28.5
Next Rep. Date				na

Notes: All values in US\$

First Call Mean Estimates: ZS PHARMA INC (US\$) 2014E: -\$4.27; 2015E: -\$3.06; 2016E: -\$3.16

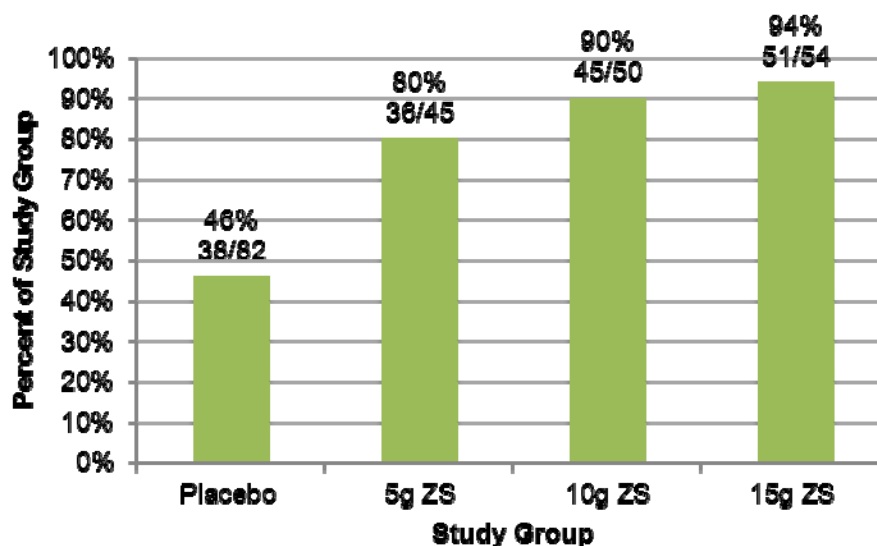
Changes	Annual EPS	Annual CFPS	Quarterly EPS	Target
	2014E -\$5.13 to -\$5.33	2014E -\$4.20 to -\$4.52	Q4/14E -\$0.76 to -\$0.88	\$45.00 to \$54.00
	2015E -\$3.06 to -\$2.81	2015E -\$3.50 to -\$3.42		
	2016E -\$2.11 to -\$2.62	2016E na to -\$3.31		
			Q1/15E -\$0.82 to -\$0.71	
			Q2/15E -\$0.75 to -\$0.65	
			Q3/15E -\$0.75 to -\$0.73	
			Q4/15E -\$0.75 to -\$0.73	

Details & Analysis

For investors that have been tied up in earnings season and may have missed some recent data from ZS Pharma, we provide a summary of some recent published data:

- **ZS004 was a success and met the primary endpoint** - by demonstrating that all three doses (5g, 10g, and 15g) of once-daily ZS-9 maintained mean potassium at lower levels than placebo over the 28-day treatment period.

Exhibit 1: Randomized Phase: Proportion of Patients With Mean Potassium Levels in Normal Range (<5.1 mEq/L) from days 8-29



Sources: Company Reports, BMO Capital Markets.

- **ZS004 showed 98% of patients achieved normokalemia within 48 hours, with the median time to normokalemia of 2.2 hours.**
- **The tolerability of ZS-9 in ZS004 was comparable to placebo**, with no treatment-related serious adverse events and numerically lower rates of GI AEs than the placebo group. ZS-9 appears to be well tolerated, also showing a low incidence of urinary tract infections (which is not one of the exclusion criteria for ZS004).
- **The company did see numerically high rates of fluid overload in the 15g ZS-9 group**, with eight patients in the group diagnosed with edema compared with two in the placebo group, one in the 5g group, and three in the 10g group. However, 7 of the 14 patients in the overall study who had edema did not require treatment, and those that did were given the standard diuretic as treatment, with all but one going on to complete the study.
- **It appears to us that the timeline remains on track.** As of this date, approximately 1,200 patients have been exposed to ZS-9, and many patients in ZS Pharma's ZS004E extension study are now out to seven months of exposure. ZS005 started in June and the

last patient last visit is expected to be in early August. The company is confident that it will have the appropriate long-term data by the time of launch to show the ability of ZS-9 to reduce the levels of serum potassium to normal levels over an extended period. ZS Pharma is expected to submit its NDA and MAA in 1H15.

Valuation

We are raising our price target from \$45 to \$54 as we move our DCF based valuation from a 2014 base year to 2015. In addition, we have made some slight adjustments to our G&A assumptions, resulting in changes to our EPS estimates as noted below.

Exhibit 2: BMO Estimates vs. Consensus

	4Q14	2014	2015	2016	2017	2018
BMO New	(\$0.88)	(\$5.33)	(\$2.81)	(\$2.62)	\$0.21	\$3.33
BMO Previous	(\$0.76)	(\$5.13)	(\$3.06)	(\$2.11)	\$0.82	\$3.33
Consensus	(\$0.76)	(\$4.27)	(\$3.06)	(\$2.54)	\$0.27	\$4.16

Source: Thomson Reuters and BMO Capital Markets Estimates

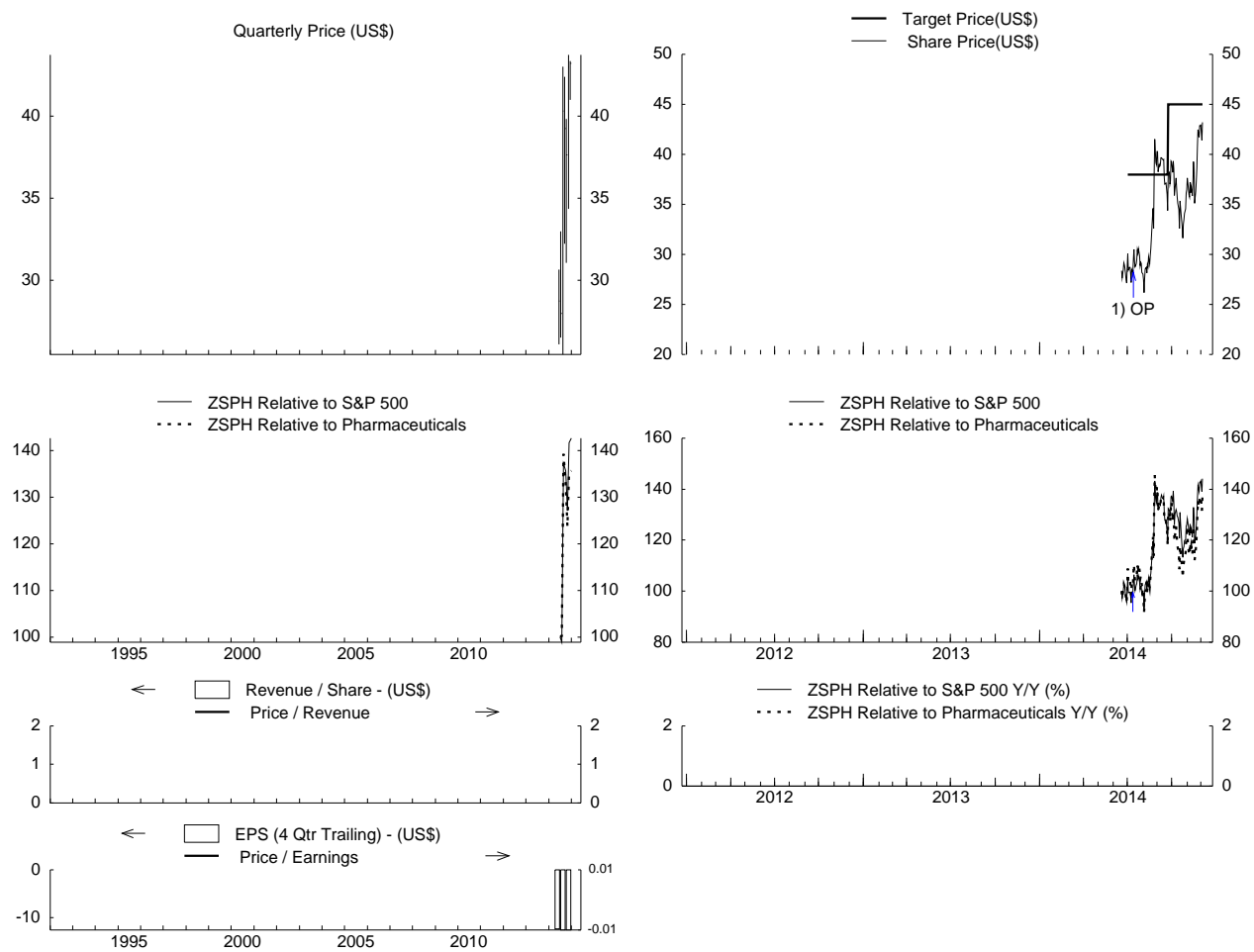
We note that our assumptions include modest market share gains and for ZS Pharma to split the market with Relypsa. We believe this may turn out to be conservative given ZS Pharma's drug profile to date. In addition, we are using an 8.0x terminal multiple for EV/EBITDA. The sector has traded at approximately 12x–14x, so this, too, may be a point of conservatism. We may choose to revisit these assumptions in the future, such as when, for example, ZSPH submits its file to the FDA (or when the file is accepted), or when and if partnerships for its product or for Relypsa's product are announced, as further risk mitigation.

Exhibit 3: ZS Pharma Income Statement (\$ millions, except per share data)

ZS Pharma Income Statement	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Net revenue for CKD patients					\$13.1	\$99.2	\$187.1	\$270.0	\$327.2
Net revenue for HF patients					\$2.9	\$27.2	\$41.3	\$60.1	\$72.9
ZS-9 episodic net revenues					\$1.4	\$8.4	\$27.8	\$33.4	\$39.0
Total ZS US net revenue					\$17.4	\$134.8	\$256.3	\$363.5	\$439.0
ZS Pharma Income Statement	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$17.4	\$136.4	\$269.0	\$392.4	\$481.9
% growth							97.3%	45.9%	22.8%
COGS	\$0.0	\$0.0	\$0.0	\$0.0	\$3.5	\$27.0	\$46.1	\$54.5	\$65.9
COGS as % of US sales					20.0%	20.0%	18.0%	15.0%	15.0%
Gross profit	\$0.0	\$0.0	\$0.0	\$0.0	\$13.9	\$109.4	\$222.9	\$337.9	\$416.1
Gross margin					80.0%	80.2%	82.9%	86.1%	86.3%
R&D	\$7.0	\$24.5	\$39.0	\$36.0	\$20.0	\$20.2	\$25.6	\$36.3	\$41.7
R&D as % of US sales					114.9%	15.0%	10.0%	10.0%	9.5%
S&M	\$0.0	\$0.0	\$0.5	\$12.0	\$33.0	\$45.9	\$64.1	\$80.0	\$91.1
S&M as % of US sales					189.5%	34.1%	25.0%	22.0%	20.8%
G&A	\$1.1	\$7.7	\$19.3	\$20.0	\$20.0	\$24.0	\$10.3	\$14.5	\$17.6
G&A as % of US sales					114.9%	17.8%	4.0%	4.0%	4.0%
Royalties					\$5.8	\$12.2	\$21.2	\$31.8	\$43.6
Operating profit	(\$8.1)	(\$32.2)	(\$58.7)	(\$68.0)	(\$64.8)	\$7.1	\$101.8	\$175.2	\$222.0
Operating margin						5.2%	37.8%	44.7%	46.1%
Interest expense (income)	\$2.1	(\$0.0)	\$0.1	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8
Other expense (income)	\$0.1	\$1.4	\$3.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pretax income	(\$10.3)	(\$33.6)	(\$62.1)	(\$68.8)	(\$65.6)	\$6.3	\$101.0	\$174.4	\$221.2
Pretax margin						4.6%	37.6%	44.5%	45.9%
Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.9	\$15.2	\$26.2	\$66.4
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	30.0%
Net income	(\$10.3)	(\$33.6)	(\$62.1)	(\$68.8)	(\$65.6)	\$5.4	\$85.9	\$148.3	\$154.9
Preferred stock accretion	(\$0.2)	(\$0.7)	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net income to common stockholders	(\$10.5)	(\$34.3)	(\$62.4)	(\$68.8)	(\$65.6)	\$5.4	\$85.9	\$148.3	\$154.9
Net margin						3.9%	31.9%	37.8%	32.1%
Shares out (diluted)	1.6	1.6	11.7	24.5	25.1	25.8	25.8	25.8	25.8
Earnings per share	(\$6.74)	(\$21.84)	(\$5.33)	(\$2.81)	(\$2.62)	\$0.21	\$3.33	\$5.75	\$6.01
EPS % growth							72.6%		4.4%

Source: Company Reports and BMO Capital Markets Estimates

ZS Pharma (ZSPH)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %	ZSPH - Rating as of 17-Jun-14 = NR		
Range*:		na na		NC			>15 >15		Date	Rating Change	Share Price
Current*	-12.48	na	0.00	0.0	0	1.2	37.0	na	1 11-Jul-14	NR to OP	\$29.49

* Current EPS is the 4 Quarter Trailing to Q3/2014.
* Valuation metrics are based on high and low for the fiscal year.
* Range indicates the valuation range for the period presented above.

Last Price (December 2, 2014): \$43.22
Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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Methodology: We arrive at our target price using a discounted cash flow analysis, a sector multiple applied to discounted earnings, and as a multiple of sales.

Risks: In addition to the normal risks inherent in pharmaceutical companies, such as regulatory, reimbursement, and competitive risks, our valuation of ZSPH carries several other risks. Among the risks to our valuation is ZSPH's dependence on approval of their lead product and anticipated sales and profitability to drive the value of ZSPH. Unseen side effects, safety issues, and competitive threats have not been taken into account in our valuation and if any of these were to emerge, it is likely ZSPH shares would be significantly and negatively impacted. ZSPH is currently running at a substantial loss, and with this fact comes several other risks, including the potential need for financing. One cannot be certain that ZSPH would be able to secure additional financing and at what cost. Our valuation does not include any value for ZSPH's additional product in the pipeline.

Distribution of Ratings (September 30, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	44.3%	18.0%	60.3%	43.9%	56.5%	56.0%
Hold	Market Perform	52.5%	9.7%	38.5%	51.6%	42.1%	39.1%
Sell	Underperform	3.2%	5.3%	1.3%	4.5%	1.4%	4.9%

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(S) = speculative investment;

NR = No rating at this time;

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