

ZS Pharma

(ZSPH-NASDAQ)

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

March 13, 2015

David Maris

BMO Capital Markets Corp.

david.maris@bmo.com

212-885-4091

Katie Brennan

BMO Capital Markets Corp.

212-885-4123

katie.brennan@bmo.com

Earnings in Line; U.S. Submission Timeline on Track

Event

ZS Pharma reported a net loss of \$20.3mm for 4Q14, or approximately \$2mm more than our estimate of a net loss of \$18.4mm, mainly due to higher-than-expected R&D spend.

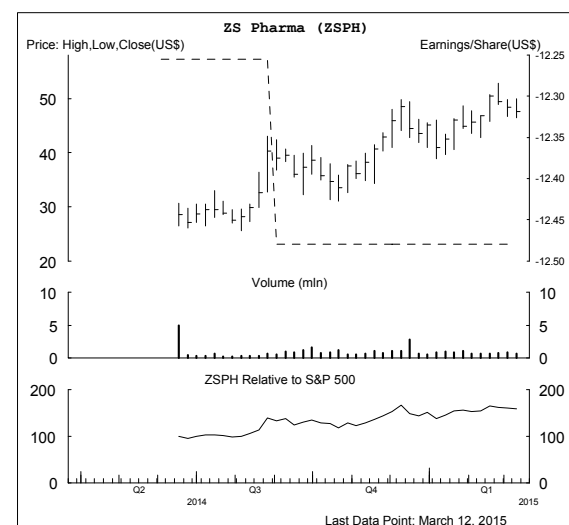
Impact & Analysis

As ZS Pharma is a Phase III development company, we believe investors are less focused on the financial results just reported than the upcoming clinical and regulatory milestones, such as ZS-9's anticipated 2Q15 NDA submission. ZS is on track to file its ZS-9 NDA in 2Q15. As we have previously mentioned, its main competitor, Relypsa, filed for approval in October 2014 and ZS Pharma was expected to file in 1H15. Based on the release this morning, ZS Pharma's timeline to file its MAA in Europe is slightly pushed back to 2H15 vs. its previous estimate of 1H15. We are assuming a 4Q17 launch in EU, so this slight delay does not change our expectations, and competitively means little since Relypsa does not intend to file in the EU until late 2015 or early 2016. We note our previous conversations with ZS, the company may choose to seek a partnership deal on the EU rights to ZS-9. Overall, the key driver, a U.S. filing, remains on track. We recently met with the company, and it remains focused on building the foundation for the commercial launch. While Relypsa is slightly ahead having already filed, we think ZS's drug, if approved, has the characteristics that matter most to physicians – fast onset of action, high efficacy, and solid safety.

Valuation & Recommendation

We updated our model for 4Q14 earnings and maintain our Outperform rating and \$54 price target.

Price (12-Mar) \$47.62 **52-Week High** \$52.80
Target Price \$54.00 **52-Week Low** \$25.51



(FY-Dec.)	2013A	2014A	2015E	2016E
EPS	-\$21.84	-\$5.50	-\$2.85↓	-\$2.66↓
P/E			na	na
CFPS	na	-\$4.65	-\$3.46↓	-\$3.36↓
P/CFPS			na	na
Rev. (\$mm)	\$0	\$0	\$0	\$17
EV	na	\$1,017	\$1,017	\$1,017
EBITDA (\$mm)	-\$32	-\$59	-\$66	-\$63
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2013A	na	na	na	na
2014A	-\$6.60	-\$4.72	-\$0.81	-\$0.98
2015E	-\$0.72↓	-\$0.66↓	-\$0.74↓	-\$0.74↓
Dividend	\$0.00			
Book Value	\$1.16			
Shares O/S (mm)	20.8			
Float O/S (mm)	20.2			
Wkly Vol (000s)	890			
Net Debt (\$mm)	-\$92			
Yield				0.0%
Price/Book				41.1x
Mkt. Cap (mm)				\$991
Float Cap (mm)				\$962
Wkly \$ Vol (mm)				\$34.3
Next Rep. Date				na

Notes: All values in US\$

First Call Mean Estimates: ZS PHARMA INC (US\$) 2014E: -\$4.27; 2015E: -\$3.00; 2016E: -\$3.33

Changes

Annual EPS

2015E -\$2.81 to -\$2.85
 2016E -\$2.62 to -\$2.66

Annual CFPS

2015E -\$3.42 to -\$3.46
 2016E -\$3.31 to -\$3.36

Quarterly EPS

Q1/15E -\$0.71 to -\$0.72
 Q2/15E -\$0.65 to -\$0.66

Q3/15E -\$0.73 to -\$0.74
 Q4/15E -\$0.73 to -\$0.74

Details & Analysis

4Q earnings are a non-event. ZS Pharma reported 4Q14 results, including a net loss of \$20.3 million, nearly \$2 million more than our estimate of a net loss of \$18.4 million. This was mainly due to higher-than-expected R&D spend. The company's EPS of a loss of \$0.98 fell short of our 4Q14 estimate of a loss of \$0.88.

As ZS Pharma is a Phase III development company, we believe investors are less focused on the financial results just reported than the upcoming clinical and regulatory milestones, such as ZS-9's anticipated 2Q15 NDA submission.

The R&D expense for the quarter of \$14.6 million was roughly \$1.8 million higher than our estimate of \$12.8 million, and G&A was \$5.5 million compared with our estimate of \$5.0 million. The company did a reclassification of spending on medical affairs from G&A to R&D in the fourth quarter. The reclassification should be detailed in the company's 10-K filing in the next couple of days, and we will revisit our model following the filing. We had also estimated \$0.5 million in S&M spend in the quarter.

ZS Pharma had \$102.3 million in cash and cash equivalents and marketable securities as of December 31, 2014, compared with \$121.5 million as of September 30, 2014.

NDA submission on track. ZS is on track to file its ZS-9 NDA in 2Q15. As we have previously mentioned, ZS Pharma's main competitor, Relypsa, filed for approval in October 2014 and ZS Pharma expected to file in 1H15.

The profile to beat. We continue to believe there is substantial data supporting that ZS-9 is a safe and efficacious treatment for hyperkalemia, and should it be approved, it will succeed in the market, despite potential competition. Being calcium-free is not just a tag-line of differentiation, but may point to a characteristic that matters to physicians.

MAA submission slightly delayed. ZS Pharma's timeline to file its MAA in Europe has been slightly delayed from the company's previous estimate of 1H15 to 2H15. We note our previous conversations with the company indicated it may choose to seek a partnership deal on the EU rights to ZS-9. The level of interest in partnering by outside partners at the time was described as "strong and real." Our timeline assumes a 4Q17 launch, which is in keeping with the 2H15 submission. We also note that Relypsa has not filed an MAA yet, and expects to file in late 2015 or early 2016.

Model update. We have updated our model for 4Q earnings and our new EPS estimates are detailed below.

Exhibit 1: ZSPH Adjusted EPS BMO and Consensus

	2015	2016	2017	2018
BMO New	(\$2.85)	(\$2.66)	\$0.18	\$3.30
BMO Previous	(\$2.81)	(\$2.62)	\$0.21	\$3.33
Consensus	(\$3.00)	(\$3.33)	\$0.00	\$4.16

Sources: Company Reports, Thomson Reuters, BMO Capital Markets

We maintain our Outperform rating and \$54 price target.

Exhibit 2: ZSPH Income Statement (\$ in millions, except per share data)

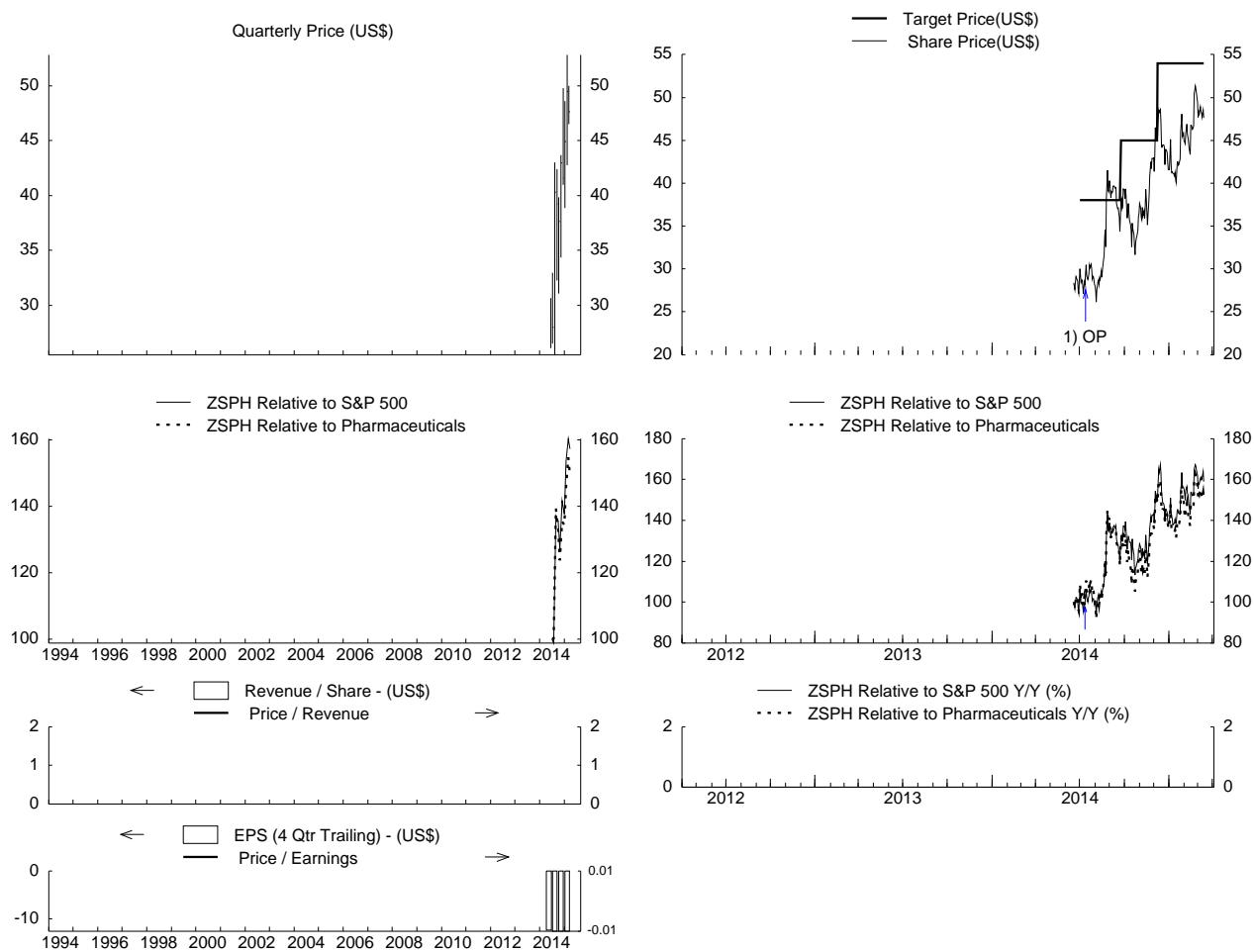
ZS Pharma Income Statement	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total revenues	\$0.0	\$0.0	\$17.4	\$136.4	\$269.0	\$392.4	\$481.9
<i>% growth</i>					97.3%	45.9%	22.8%
COGS	\$0.0	\$0.0	\$3.5	\$27.0	\$46.1	\$54.5	\$65.9
<i>COGS as % of US sales</i>			20.0%	20.0%	18.0%	15.0%	15.0%
Gross profit	\$0.0	\$0.0	\$13.9	\$109.4	\$222.9	\$337.9	\$416.1
<i>Gross margin</i>			80.0%	80.2%	82.9%	86.1%	86.3%
R&D	\$45.6	\$36.0	\$20.0	\$20.2	\$25.6	\$36.3	\$41.7
<i>R&D as % of US sales</i>			114.9%	15.0%	10.0%	10.0%	9.5%
S&M	\$0.0	\$12.0	\$33.0	\$45.9	\$64.1	\$80.0	\$91.1
<i>S&M as % of US sales</i>			189.5%	34.1%	25.0%	22.0%	20.8%
G&A	\$14.9	\$20.0	\$20.0	\$24.0	\$10.3	\$14.5	\$17.6
<i>G&A as % of US sales</i>			114.9%	17.8%	4.0%	4.0%	4.0%
Royalties			\$5.8	\$12.2	\$21.2	\$31.8	\$43.6
Operating profit	(\$60.5)	(\$68.0)	(\$64.8)	\$7.1	\$101.8	\$175.2	\$222.0
<i>Operating margin</i>				5.2%	37.8%	44.7%	46.1%
Interest expense (income)	(\$0.1)	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8
Other expense (income)	\$3.6	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0
Pretax income	(\$64.0)	(\$69.8)	(\$66.6)	\$5.3	\$100.0	\$173.4	\$220.3
<i>Pretax margin</i>				3.9%	37.2%	44.2%	45.7%
Taxes	\$0.0	\$0.0	\$0.0	\$0.8	\$15.0	\$26.0	\$66.1
<i>Tax rate</i>	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	30.0%
Net income	(\$64.0)	(\$69.8)	(\$66.6)	\$4.5	\$85.0	\$147.4	\$154.2
Preferred stock accretion	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net income to common stockholders	(\$64.4)	(\$69.8)	(\$66.6)	\$4.5	\$85.0	\$147.4	\$154.2
<i>Net margin</i>				3.3%	31.6%	37.6%	32.0%
Shares out (diluted)	11.7	24.5	25.1	25.8	25.8	25.8	25.8
Earnings per share	(\$5.50)	(\$2.85)	(\$2.66)	\$0.18	\$3.30	\$5.72	\$5.98

Sources: Company Reports, BMO Capital Markets estimates.

Companies mentioned (priced as of the close on March 12, 2015):

Relypsa (RLYP, \$40.05, Not Rated)

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	42.6	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 (March 12, 2015): \$47.62
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 (December 31, 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	43.4%	16.2%	60.6%	42.6%	51.7%	55.6%
Hold	Market Perform	52.6%	8.1%	36.6%	53.0%	45.8%	39.5%
Sell	Underperform	3.9%	8.3%	2.8%	4.5%	2.5%	4.9%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

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(S) = speculative investment;

NR = No rating at this time;

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