

ZS Pharma

(ZSPH-NASDAQ)

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

May 27, 2015

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NDA Filed: Updated Thoughts on Potential

Event

ZS Pharma submitted its New Drug Application (NDA) to the FDA for ZS-9, its novel treatment for hyperkalemia (high potassium). This filing is on track with the company's guidance of 2Q15. We are updating our model following discussions with the company regarding spending and we outline one potential upside scenario.

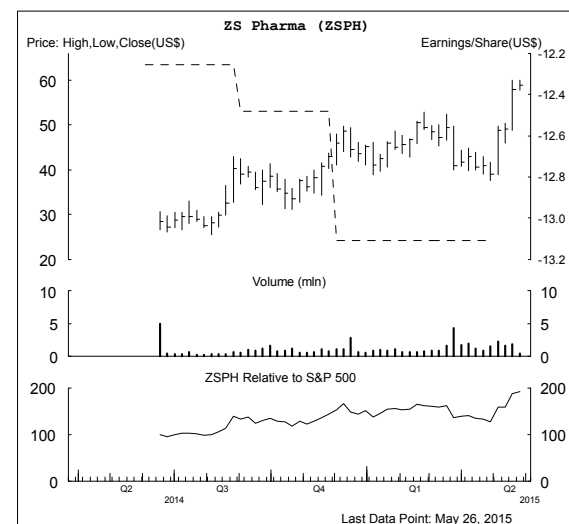
Impact & Analysis

We believe this filing slightly de-risks ZS-9's pathway to approval. While we don't see any reason why the FDA would not accept ZS Pharma's application, we will look out for the acceptance, which would further de-risk the program. We have updated our model to indicate slightly higher penetration rates post-approval, but have also added higher spending in the near term following conversations with management. We have made no changes to our two-month duration of treatment assumption; however, we note that, based on our discussions with management and physicians, this may be overly conservative and a duration of four months or more may be more appropriate. If we assume a duration of four months within chronic kidney disease patients and a 15% penetration rate, total U.S. revenues in 2020 would be approximately \$1 billion vs. our current forecast of \$583 million.

Valuation & Recommendation

We continue to believe ZS Pharma is a compelling investment at the current valuation. Approval is approximately a year away, but we believe the robust, high-quality data ZS Pharma has accumulated will differentiate it from competitor Relypsa's Patiromer. We have updated our model following the filing of the ZS-9 NDA, as well as increased our near-term spending assumptions while raising our post-approval penetration rates. Our resulting DCF-derived price target is now \$70. We maintain our Outperform rating.

Price (27-May) \$60.86 **52-Week High** \$59.92
Target Price \$70.00 **52-Week Low** \$25.51



(FY-Dec.)	2013A	2014A	2015E	2016E
EPS	-\$21.84	-\$5.47	-\$4.54	-\$5.44
P/E			na	na
CFPS	na	-\$4.85	-\$4.88	-\$6.02
P/CFPS			na	na
Rev. (\$mm)	\$0	\$0	\$0	\$17
EV	na	\$1,021	\$1,760	\$1,760
EBITDA (\$mm)	-\$32	-\$59	-\$108	-\$147
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	-\$1.05a	-\$1.06	-\$1.19	-\$1.22
Dividend	\$0.00			0.0%
Book Value	\$1.16			52.5x
Shares O/S (mm)	20.8			Mkt. Cap (mm)
Float O/S (mm)	20.2			\$1,267
Wkly Vol (000s)	1,092			Float Cap (mm)
Net Debt (\$mm)	-\$92			\$1,229
				Wkly \$ Vol (mm)
				\$44.7
				Next Rep. Date
				na

Notes: All values in US\$

First Call Mean Estimates: ZS PHARMA INC (US\$) 2015E: -\$3.35; 2016E: -\$3.08

Changes

Annual EPS

2015E -\$2.78 to -\$4.54
 2016E -\$2.63 to -\$5.44

Annual CFPS

2015E -\$3.64 to -\$4.88
 2016E -\$0.30 to -\$6.02

Quarterly EPS

Q2/15E -\$0.66 to -\$1.06
 Q3/15E -\$0.73 to -\$1.19
 Q4/15E -\$0.73 to -\$1.22

Target

\$54.00 to \$70.00

Details & Analysis

ZS Pharma submitted its New Drug Application (NDA) to the FDA for ZS-9, its novel treatment for hyperkalemia (high potassium). This filing is on track with the company's guidance of 2Q15.

We have updated our model following the filing of the company's 10-Q and ZS-9 NDA, as well as increased our near term spending assumptions while raising our post-approval penetration rates. Our new EPS estimates are shown in Exhibit 1.

Exhibit 1: ZS Pharma EPS

	2015	2016	2017	2018	2019	2020
BMO New	(\$4.54)	(\$5.44)	(\$1.93)	\$1.36	\$4.66	\$7.38
BMO Previous	(\$2.78)	(\$2.63)	\$0.17	\$3.23	\$5.60	\$5.85
Consensus	(\$3.35)	(\$3.02)	(\$0.36)	\$4.23	\$9.29	N/A

Source: Company reports, Thomson Reuters, BMO Capital Markets.

On April 27, 2015, we hosted a conference call on new treatments in hyperkalemia, including ZS-9 and Relypsa's Patiromer, with a panel of expert physicians. Our panel's comments were mostly balanced and measured, except when asked to predict the market share ZS-9 and Patiromer would have a few years after launch: the doctors predicted ZSPH's ZS-9 would have 75-80% share. They noted the importance of quick onset of action in acute treatment, and highlighted ZS-9's speed. We do not want to overestimate their enthusiasm, but note that, if it is correct, it would represent significant upside to our current assumptions. The panel did not see any major approvability risk for either drug.

During the past several weeks we have had an opportunity to conduct further doctor calls, as well as follow up extensively with management about the potential market and our current assumptions. While the most immediate result of these discussions with management was a better appreciation of the near-term spending for marketing costs, we also came away from the discussion with a better appreciation for potential duration of therapy. We are currently modeling two-month average duration of therapy and management believes that there is a good basis for expecting average duration of four months or more if one looks at average duration of drug therapy in CKD or one just makes simple assumptions of how long a patient who should be using a product chronically might use the drug (perhaps six months-plus).

If we change our two-month assumed duration of therapy to four months or six months, our sales and earnings estimates rise dramatically:

Exhibit 2: Duration of Therapy (\$ in millions, except per share data)

	Current (2 mo.)	4 month duration	6 month duration
2020 U.S. Sales	\$584	\$1,084	\$1,584
2020 EPS	\$7.38	\$17.73	\$28.08

Sources: Company reports, BMO Capital Markets.

We are maintaining our two-month duration assumption and leaving this as further potential upside that we may reassess as we get closer to approval. We have raised modestly our

penetration rates to 15% in 2020 from 12%, based on our recent feedback from physicians and what we believe is ZS-9's better clinical profile.

Based on our discussions with physicians and the company, we estimate that there are approximately 1 million CKD patients who would be candidates for an oral hyperkalemia treatment, and assuming pricing at \$550/month, six months of therapy would translate into a >\$3 billion potential market. Assuming that ZS garners only 25% of this market, sales would be \$825 million in CKD alone. Given ZS's profile, we would not be surprised if the market share were greater than 50%.

We note that it is easy to get to sizable potential sales numbers when one is making general assumptions with large patient populations. We are providing this not as an accurate prediction of what ZS will do, but rather to point out how our current \$409 million forecast in CKD in 2020 is only a fraction of what could turn out to be a much larger market.

In addition to raising our penetration rate, we have also changed our DCF base year from 2015 to 2016 and also assume an additional equity raise in 2016 in our forecasts. Non-dilutive financing via partnerships would be additive to our forecasts. Rather than use a higher discount rate, we have chosen to risk-adjust our sales forecasts. Underlying our assumption is that ZS's drug gets approved, and while we see no significant risk at this point for non-approval, investors need to be aware that drug approvals are never a certainty and without approval, the shares, we expect, would drop significantly. We cite ZS-9's very clean safety profile, the robust data set, and the issues with the current standard of care as some of the reasons we believe ZS-9 will be approved.

Our resulting DCF-derived price target is now \$70, up from our previous target of \$54. We maintain our Outperform rating.

Companies mentioned (priced as of the close on May 27, 2015):

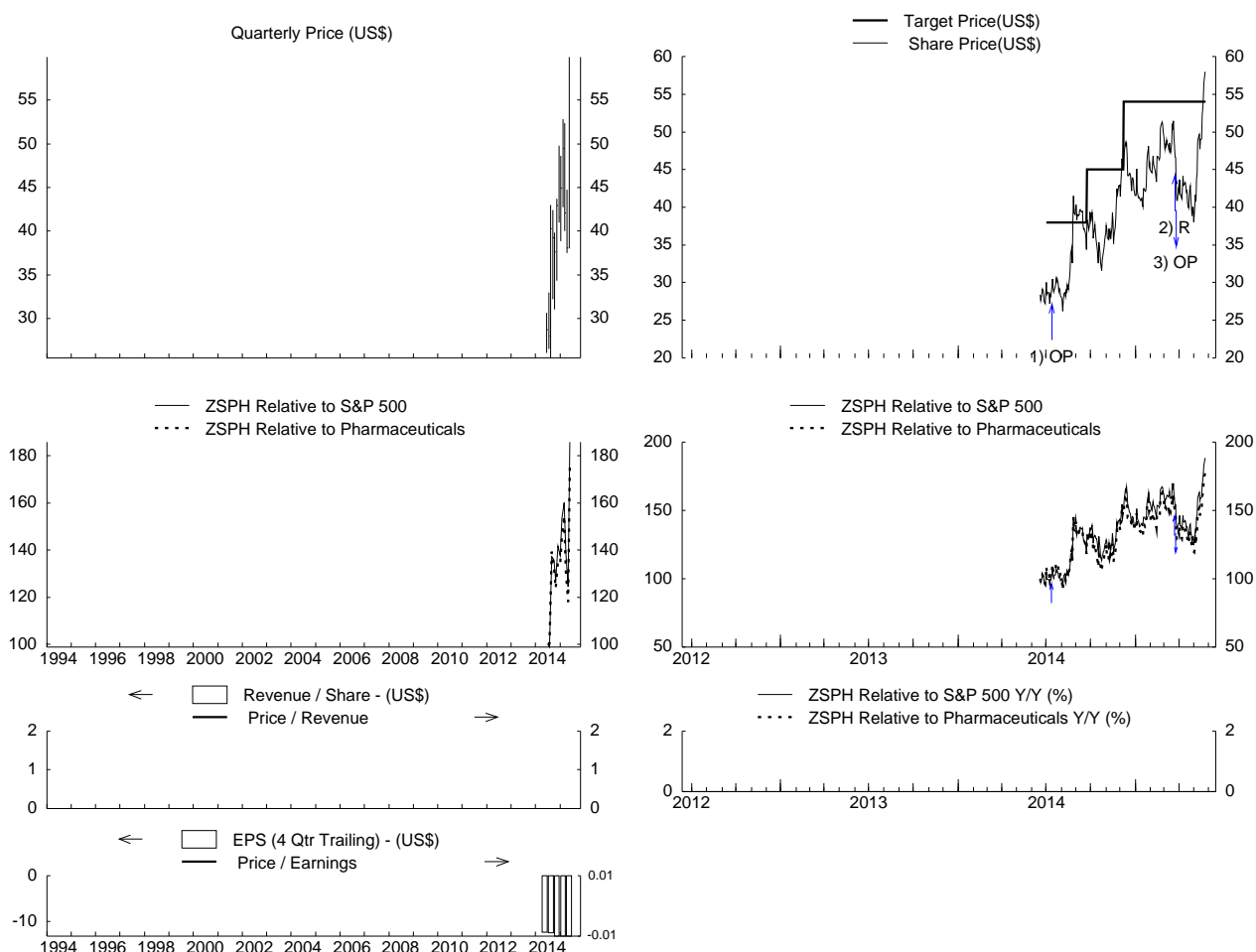
Relypsa (RLYP, \$35.42, Not Rated)

Exhibit 3: ZSPH Income Statement (\$ in millions, except per share data)

ZS Pharma Income Statement	2014A	2015E	2016E	2017E	2018E	2019E	2020E
Total revenues	\$0.0	\$0.0	\$17.4	\$136.4	\$275.7	\$429.0	\$628.1
<i>% growth</i>					102.2%	55.6%	46.4%
COGS	\$0.0	\$0.0	\$6.1	\$27.0	\$47.3	\$59.9	\$78.8
<i>COGS as % of US sales</i>			35.0%	20.0%	18.0%	15.0%	13.5%
Gross profit	\$0.0	\$0.0	\$11.3	\$109.4	\$228.4	\$369.1	\$549.3
<i>Gross margin</i>			65.0%	80.2%	82.8%	86.0%	87.5%
R&D	\$45.6	\$64.8	\$50.0	\$40.4	\$39.4	\$47.9	\$61.3
<i>R&D as % of US sales</i>			287.2%	30.0%	15.0%	12.0%	10.5%
SG&A	\$14.9	\$44.9	\$105.0	\$120.0	\$120.0	\$130.0	\$140.0
<i>SG&A as % of US sales</i>			603.1%	89.0%	45.6%	32.6%	24.0%
Royalties			\$5.8	\$12.2	\$21.2	\$31.8	\$43.6
Operating profit	(\$60.5)	(\$109.7)	(\$149.4)	(\$63.2)	\$47.8	\$159.4	\$304.4
<i>Operating margin</i>				-46.4%	17.3%	37.2%	48.5%
Interest expense (income)	(\$0.1)	\$0.6	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8
Other expense (income)	\$3.6	\$1.1	\$1.1	\$1.1	\$1.1	\$1.1	\$1.1
Pretax income	(\$64.0)	(\$111.4)	(\$151.3)	(\$65.1)	\$45.9	\$157.5	\$302.5
<i>Pretax margin</i>				-47.8%	16.6%	36.7%	48.2%
Taxes	\$0.0	\$0.0	\$0.0	(\$9.8)	\$6.9	\$23.6	\$90.8
<i>Tax rate</i>	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	30.0%
Net income	(\$64.0)	(\$111.4)	(\$151.3)	(\$55.4)	\$39.0	\$133.9	\$211.8
Preferred stock accretion	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net income to common stockholders	(\$64.4)	(\$111.4)	(\$151.3)	(\$55.4)	\$39.0	\$133.9	\$211.8
<i>Net margin</i>				-40.6%	14.1%	31.2%	33.7%
Shares out (diluted)	11.8	24.5	27.9	28.7	28.7	28.7	28.7
Earnings per share	(\$5.47)	(\$4.54)	(\$5.44)	(\$1.93)	\$1.36	\$4.66	\$7.38

Sources: Company reports, Thomson Reuters, BMO Capital Markets.

ZS Pharma (ZSPH)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %
2014	-5.50	na na	0.00	0.0 0.0	0	ND	>15 >15	
Range*		na na		0.0 0.0			>15 >15	
Current*	-13.11	na	0.00	0.0	0	1.2	32.8	na

ZSPH - Rating as of 17-Jun-14 = NR

Date	Rating Change	Share Price
1 11-Jul-14	NR to OP	\$29.49
2 23-Mar-15	OP to R	\$46.65
3 25-Mar-15	R to OP	\$42.00

* Current EPS is the 4 Quarter Trailing to Q4/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (May 25, 2015): \$57.94
 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 (March 31, 2015)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	43.7%	18.6%	58.2%	42.7%	55.5%	54.1%
Hold	Market Perform	51.4%	10.4%	38.5%	52.1%	41.9%	40.5%
Sell	Underperform	4.9%	9.4%	3.3%	5.2%	2.6%	5.5%

* 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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