



ZS Pharma

(ZSPH-NASDAQ)

Stock Rating: Outperform Stock Price: US\$29.75 Target Price: US\$38.00 August 15, 2014 Specialty Pharmaceuticals

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2Q Reported; Data From Phase III (ZS004) Next Catalyst

ZS Pharma reported 2Q14 results, the first quarter reporting since its IPO, recording a net loss of \$16 million in line with our estimate of \$16 million. Since ZS Pharma is a development-stage company, our focus now is more on clinical development and milestones rather than financial results. Total operating expenses were \$14.5 million, with R&D totaling approximately \$10 million, compared with our forecast of \$15.9 million in which R&D accounted for \$12.8 million.

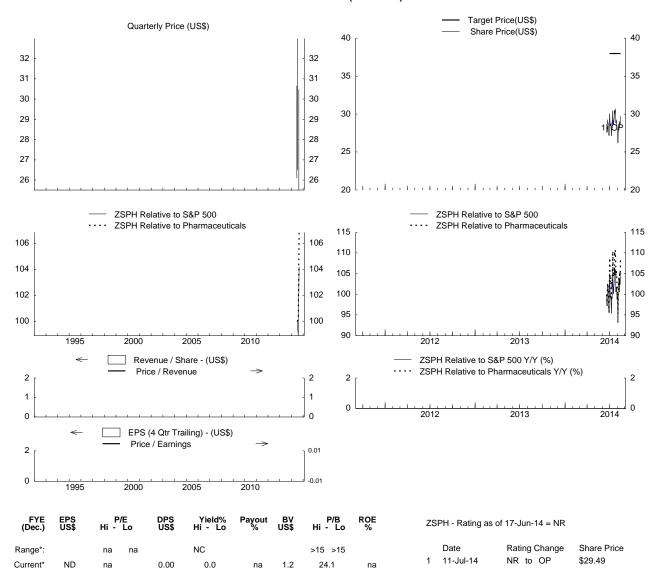
Our View:

- Operating costs increased from the prior-year period as expected. R&D in 2Q was \$9.98 million, up 57% from \$6.34 million in the prior-year period. The increase resulted from costs associated with the enrollment of ZS004, the initiation of ZS005 and manufacturing scale-up costs. G&A was \$4.55 million, up 369% from \$0.97 million in the prior-year period. The increase was largely due to increased compensation costs, professional fees, and other expenses required to support the company's expanding operations.
- Strong cash balance following the IPO. Cash and cash equivalents at June 30, 2014 were \$130 million, compared with \$23.8 million at March 30, 2014 and \$9.2 million at December 31, 2013.
- **Key events in clinical development**. There were key events including: completion of patient enrollment in ZS004 (the second Phase III trial for ZS-9) and began enrollment in ZS005 (a long-term, Phase III safety study).
- ZS Pharma remains on track to file its NDA in 1H2015. Further, ZS Pharma stated that it believes it is well-positioned to fund operations into 2016. However, we have taken a very conservative approach to our forecast by delaying the timeline by six months and risk-adjusting our sales forecast. As a result, we have modeled an additional financing in 2015 but note that by doing so we have modeled a larger cash balance than what ZS Pharma would likely need to fund operations.
- We continue to view ZS Pharma's position as a late-stage asset for an unmet medical need with a limited physician target pool as an attractive opportunity for in-licensing or acquisition by large pharma.
- Relypsa (RYLP; not rated), ZS Pharma's top competitor, recently reported 2Q results and appears to be on track to submit its NDA for Patiromer (a competing drug to ZS-9) in early 4Q. We still think it is reasonable that both companies will be able to split the market and realize significant commercial opportunities if approved.
- ZS Pharma did not host a conference call to discuss results, but we have requested a follow-up call with management. We maintain our Outperform rating and \$38 price target.

Please refer to pages 2 to 5 for Important Disclosures, including the Analyst's Certification.



ZS Pharma (ZSPH)



Last Price (August 13, 2014): \$29.75 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

^{*} Current EPS is the 4 Quarter Trailing to Q1/2014.
* Valuation metrics are based on high and low for the fiscal year.
* Range indicates the valuation range for the period presented above.





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Methodology and Risks to Price Target/Valuation

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 (June 30, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients****	Starmine Universe
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Hold	Market Perform	50.9%	8.4%	31.3%	51.2%	39.9%	39.5%
Sell	Underperform	5.0%	3.4%	1.3%	5.5%	1.5%	5.1%

- * 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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