ZS Pharma

ZS-9 Successfully Hits on Another Phase 3 - Full Data to Be Presented at AHA - ALERT

Overweight

ZSPH, ZSPH US
Price: $38.05

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We are reiterating our OW on ZSPH following this afternoon's announcement of positive top-line results from the Phase 3 ZS004 trial of ZS-9 in hyperkalemia. While the PR is light on data (there isn't any), it indicates that all three doses of ZS-9 met the primary endpoint of the trial, preventing recurrence of hyperkalemia vs. placebo over the 28-day maintenance dosing period. Safety, tolerability and AEs were consistent with previous studies. Full data will be presented at AHA (Chicago) in a late-breaking presentation on Nov 17th. As outlined in our preview note (here), a positive outcome from the trial was largely expected in our view, but we still think shares will react positively on top of the +11% move today as the data provides further de-risking ahead of the NDA/MAA in 1H15 (and is also important on the competitive front). We also note that trading could be further impacted by the thin post-IPO float.

- **The ZS004 trial evaluated ZS-9's ability to maintain normal serum K over a 28-day maintenance dosing period.** The trial enrolled 258 patients with serum K >5 mEq/L (no upper limit in entry criteria), including CKD, HF, and diabetes patients and those on RAASi therapy. In the induction phase, pts received 10g of ZS-9 3x/day for 48 hours, and those whose serum K normalized (K levels between 3.5 and 5 mEq/L) were eligible to enter into the randomized withdrawal portion of the study in which patients received 5g, 10g or 15g of ZS-9 or placebo once daily for 28 days. The primary efficacy endpoint of the trial evaluated the mean serum K levels of each ZS-9 dosing group vs. placebo over the day 8 to day 28 interval. **Full data will be presented in a late-breaking abstract at AHA on Nov 17th.**

- **Longer-term data from ZS-9 is key given the majority of the hyperkalemia revenue potential lies in the chronic market.** Given significant safety/tolerability issues associated with kayexalate (the current acute SOC treatment), it is rarely used in maintenance/chronic setting. Thus, there are a significant number of patients who are living with elevated potassium (which is often asymptomatic until cardiac abnormalities develop), or who are on suboptimal doses of important medications (e.g. RAASi) used to manage co-morbid conditions that are known to increase serum K. It is estimated that there are 2.5-3M patients eligible for chronic hyperK treatment in the US alone. Of the ~$1B in peak revenues we model for ZS-9, ~$950M comes from use in a chronic setting.

- **NDA/MAA filings for ZS-9 are anticipated in 1H15; we model launch in 2016 with peak US sales of ~$1B in 2020.** ZS estimates there are 2.5-3M patients eligible for chronic hyperK treatment in the US alone. The use of kayexalate provides a comp for the acute setting opportunity, with ~2.2 million treatments for acute management of CKD (where ZS-9 could replace kayexalate in the treatment paradigm). To be conservative, we currently assume market shares are split 50/50 with Relypsa 4-5 years post launch. We also assume a net, compliance adjusted price of ~$400/month, and that patients are on therapy for an average of 4 months in any given year. These (we believe conservative) assumptions result in peak US sales for ZS-9 of ~$1B by 2020.

See page 2 for analyst certification and important disclosures.

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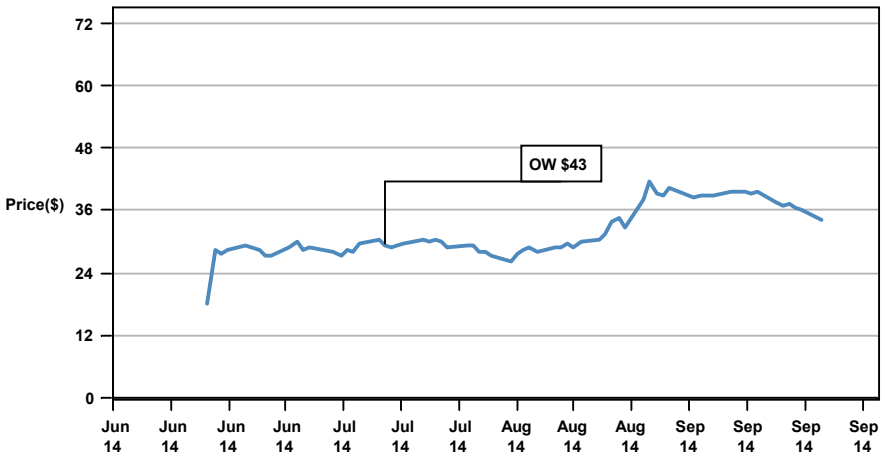
ZS Pharma (ZSPH, ZSPH US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
14-Jul-14	OW	29.49	43.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jul 14, 2014.

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