

ZS Pharma

(ZSPH-NASDAQ)

Stock Rating: Outperform Industry Rating: Outperform September 24, 2014

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Good Phase III Top-Line Data; Raising Price Target to \$45

Event

ZS Pharma has reported positive top-line results from ZS004, its second Phase III clinical trial of ZS-9 for the treatment of hyperkalemia. Preliminary results showed that all three doses (5g, 10g, and 15g) of 1x/daily ZS-9 met the primary and the safety, tolerability and adverse events were in line with previous ZS-9 clinical studies. The full data will be presented at the American Heart Association Scientific meeting in November.

Impact & Analysis

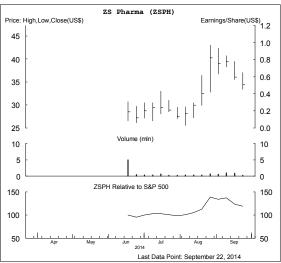
Given the positive data, we believe that ZS shares are now slightly de-risked. As a result, we are lowering our discount rate from 15% to 12%, and raising our price target to \$45 from \$38. We will be revisiting our model over the next several weeks following the presentation of the data; however, we note that our 2014 and 2015 EPS estimates have changed following the 2Q results. We believe the positive data also makes ZS Pharma a credible acquisition target, something we have not yet included in our valuation. Despite the timely completion of ZS004, we continue to take a conservative approach to our forecast by delaying the timeline by six months and risk-adjusting our sales forecast. Further, our model continues to reflect an additional financing in 2015 but recognize ZS Pharma believes it is well-positioned to fund operations into 2016.

Valuation & Recommendation

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. We maintain our Outperform rating and are raising our price target to \$45 price target.

 Price (23-Sep)
 \$38.05
 52-Week High
 \$43.00

 Target Price
 \$45.00↑
 52-Week Low
 \$25.51



| (FY-Dec.) | 2012A | 2013A | 2014E | 2015E |
|-----------------|----------|-----------|-----------|--------------|
| EPS | - \$6.74 | - \$21.84 | - \$5.05↓ | - \$3.06↑ |
| P/E | | | na | na |
| OFFIC | | | £4.00 | 60.50 |
| CFPS | na | na | - \$4.20 | - \$3.50 |
| P/CFPS | | | na | na |
| Rev. (\$mm) | \$0 | \$0 | \$0 | \$0 |
| EV | na | na | na | na |
| EBITDA (\$mm) | -\$8 | -\$32 | -\$55 | -\$73 |
| | • | - | | |
| EV/EBITDA | na | na | na | na |
| Quarterly EPS | Q1 | Q2 | Q3 | Q4 |
| 2012A | na | na | na | na |
| 2013A | na | na | na | na |
| 2014E | -\$6.60a | -\$4.72a | -\$0.77 | -\$0.76↑ |
| Dividend | \$0.00 | Yield | | 0.0% |
| Book Value | \$1.16 | Price/Bo | ok. | 32.8x |
| | | | | |
| Shares O/S (mm) | 18.7 | Mkt. Cap | | \$713 |
| Float O/S (mm) | na | Float Ca | p (mm) | na |
| Wkly Vol (000s) | 789 | Wkly \$ V | ol (mm) | \$24.8 |
| Net Debt (\$mm) | na | Next Rep | o. Date | na |

Notes: All values in US\$

Major Shareholders:

First Call Mean Estimates: ZS PHARMA INC (US\$) 2014E: -\$3.95; 2015E: -\$3.08

Annual EPS 2014E -\$3.90 to -\$5.05 2015E -\$3.10 to -\$3.06

Changes

Quarterly EPS Q4/14E -\$0.78 to -\$0.76 Target \$38.00 to \$45.00

Details & Analysis

ZS Pharma has reported positive top-line results from ZS004, its second Phase III clinical trial of ZS-9 for the treatment of hyperkalemia. Preliminary results showed that all three doses (5g, 10g, and 15g) of 1x/daily ZS-9 met the primary endpoint, which compared the mean serum potassium level of each ZS-9 treatment group to that of placebo over the interval between day 8 and day 28 of the randomized withdrawal period. Patients who completed the initial 28 day maintenance phase were able to enroll in ZS004E, an ongoing open label extension study. The safety, tolerability and adverse events were in line with previous ZS-9 clinical studies and the full data will be presented at the American Heart Association Scientific meeting in November.

Patient exposure now represents approximately 1,000 patients, many of whom have been treated with ZS-9 for over five months.

The timing of completion for ZS004 is in line with our expectations, and we believe ZS Pharma remains on track to submit the NDA and MAA filings in 1H2015 with the NDA approval in 4Q15-2Q16 and the MAA approval in 2016. ZS Pharma believes it is well-positioned to fund operations into 2016. We continue to take a 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 recognize that by doing so, we are modeling a larger cash balance that what ZS Pharma would likely need to fund operations.

Given the positive data, we believe that ZS shares are now slightly de-risked. As a result, we are lowering our discount rate from 15% to 12%, and our price target rises to \$45 from \$38. We will be revisiting our model over the next several weeks following the presentation of the data; however, we note that our 2014 and 2015 EPS estimates have changed following the 2Q results. We believe the positive data also makes ZS Pharma a credible acquisition target, something we have not yet included in our valuation.

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. We maintain our Outperform rating and have revised our price target to \$45.

Exhibit 1: ZS Pharma Income Statement (\$ millions, except per share data)

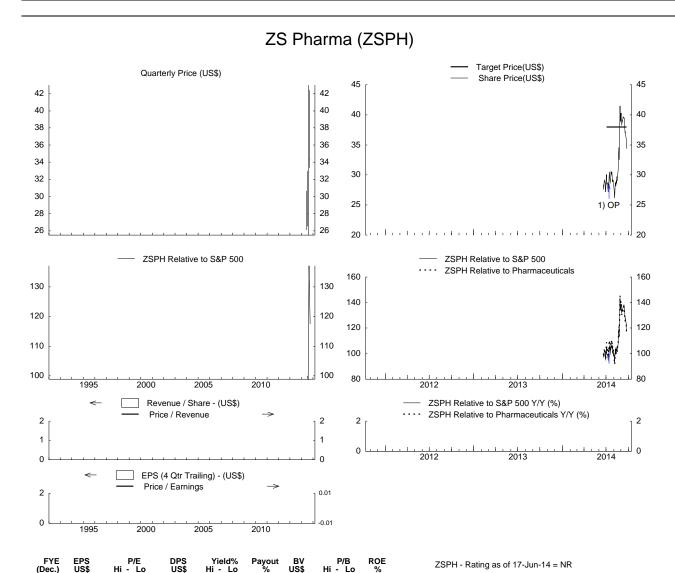
| ZS Pharma Income Statement | 2012A | 2013A | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E |
|-----------------------------------|---|-----------|----------|----------|------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| 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 % growth | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$17.4 | \$136.4 | \$269.0 97.3% | \$392.4 45.9% | \$481.9 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 Gross margin | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$13.9 80.0% | \$109.4 80.2% | \$222.9 82.9% | \$337.9 86.1% | \$416.1 86.3% |
| • | | | | | | | | | |
| R&D | \$7.0 | \$24.5 | \$40.8 | \$36.0 | \$20.0 | \$20.2 | \$25.6 | \$36.3 | \$41.7 |
| R&D as % of US sales S&M | 00.0 | 000 | 00.0 | #00 O | 114.9% | 15.0% | 10.0% | 10.0% | 9.5% |
| S&M as % of US sales | \$0.0 | \$0.0 | \$3.0 | \$29.9 | \$39.0 224.0% | \$45.9 34.1% | \$64.1 25.0% | \$80.0 22.0% | \$91.1 20.8% |
| G&A | \$1.1 | \$7.7 | \$11.8 | \$8.4 | \$1.3 | \$5.4 | \$10.3 | \$14.5 | \$17.6 |
| G&A as % of US sales | Ψι.ι | Ψ1.1 | Ψ11.0 | Ψ0.4 | 7.4% | 4.0% | 4.0% | 4.0% | 4.0% |
| Royalties | | | | | \$5.8 | \$12.2 | \$21.2 | \$31.8 | \$43.6 |
| Operating profit | (\$8.1) | (\$32.2) | (\$55.6) | (\$74.3) | (\$52.1) | \$25.7 | \$101.8 | \$175.2 | \$222.0 |
| Operating margin | | | | | | 18.9% | 37.8% | 44.7% | 46.1% |
| Interest expense (income) | \$2.1 | (\$0.0) | \$0.3 | \$0.8 | \$0.8 | \$0.8 | \$0.8 | \$0.8 | \$0.8 |
| Other expense (income) | \$0.1 | \$1.4 | \$3.1 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 |
| Pretax income | (\$10.3) | (\$33.6) | (\$59.0) | (\$75.1) | (\$52.9) | \$24.9 | \$101.0 | \$174.4 | \$221.2 |
| Pretax margin | | | | | | 18.3% | 37.5% | 44.5% | 45.9% |
| Taxes | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$3.7 | \$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) | (\$59.0) | (\$75.1) | (\$52.9) | \$21.2 | \$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) | (\$59.3) | (\$75.1) | (\$52.9) | \$21.2 | \$85.9 | \$148.3 | \$154.9 |
| Net margin | (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | (+2) | (+) | (+: -:-) | (+3=.0) | 15.5% | 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) | (\$5.05) | (\$3.06) | (\$2.11) | \$0.82 | \$3.33 | \$5.75 | \$6.00 |
| EPS % growth | | II I | II I | II I | | II I | 305.5% | 72.6% | 4.4% |

Source: Company reports and BMO Capital Markets estimates

Exhibit 2: ZS Pharma Discounted Cash Flow Statement (\$ millions)

| WACC Terminal Value EV/EBITDA Multiple | 12.0% 8.0x | | | | | | | | | |
|--|---|--|----------------------|----------------------|------------------------------------|--|--|--|------------------------------------|-----------------------------|
| Unlevered Free Cash Flows | | 2012 | <u>2013</u> | <u>2014</u> | <u>2015</u> | <u>2016</u> | <u>2017</u> | <u>2018</u> | <u>2019</u> | <u>2020</u> |
| Net Sales Growth Rate | | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$17.4 | \$136.4 683.2% | \$269.0 97.3% | \$392.4 45.9% | \$481.9 22.8% |
| EBIT Margin Pre-tax income | | (\$8.1) (\$10.3) | (\$32.2) (\$33.6) | (\$55.6) (\$59.0) | (\$74.3) (\$75.1) | (\$52.1) (\$52.9) | \$25.7 18.9% \$24.9 | \$101.8 <i>37.8%</i> \$101.0 | \$175.2 <i>44.7%</i> \$174.4 | \$222.0 46.1% \$221.2 |
| Tax | | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | (\$3.9) | (\$15.3) | (\$26.3) | (\$66.6) |
| Tax rate | | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 15.0% | 15.0% | 15.0% | 30.0% |
| EBIAT | | (\$8.1) | (\$32.2) | (\$55.6) | (\$74.3) | (\$52.1) | \$21.9 | \$86.5 | \$148.9 | \$155.4 |
| Plus: Depreciation and Amortization | | \$0.0 | \$0.7 | \$1.4 | \$1.7 | \$1.8 | \$1.9 | \$2.0 | \$2.1 | \$2.2 |
| Less: Capital Expenditures | | (\$0.7) | (\$3.8) | (\$9.7) | (\$16.0) | (\$16.0) | (\$15.0) | (\$15.0) | (\$15.0) | (\$15.0) |
| Less: Change in Net Working Capital | | \$0.6 | \$2.8 | \$5.6 | (\$0.3) | (\$1.9) | (\$9.4) | (\$4.7) | (\$4.6) | \$1.2 |
| Unlevered Free Cash Flow | _ | (\$8.2) | (\$32.5) | (\$58.4) | (\$88.8) | (\$68.2) | (\$0.6) | \$68.9 | \$131.4 | \$143.8 |
| Cumulative Unlevered FCF Terminal Value ² | \$157.09 \$1,793.7 | 0 | 0 | 0.5 | 1.5 | 2.5 | 3.5 | 4.5 | 5.5 | 6.5 |
| PV of Free Cash flow PV of Terminal Value Implied Enterprise Value | (\$6.3) \$858.7 \$852.4 | -\$8.2 | -\$32.5 | -\$58.4 | -\$88.8 | -\$68.2 | -\$0.6 | \$41.3 | \$70.4 | \$68.8 |
| Plus: Cash & Equivalents (4Q14) | \$104.0 | Implied Equity Value Sensitivity Table EBITDA Multiple Terminal Value | | | | | | | | |
| Less: Total Debt (1Q14) Implied Value of Equity Diluted Shares Outstanding Implied Value per Share | \$15.0 \$941.4 20.8 \$45.26 | | | МАСС | \$45.26 14.0% 15.0% 16.0% | 7.0x \$35.35 \$33.20 \$31.17 | 8.0x \$39.95 \$37.54 \$35.28 | 9.0x \$44.55 \$41.89 \$39.39 | | |

Source: Company Reports and BMO Capital Markets Estimates



>15 >15

34.7

1.2

na na

na

Range*:

Current*

ND

* 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.

0.00

NC

0.0

Last Price (September 22, 2014): \$34.36 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

Date

11-Jul-14

Rating Change

NR to OP

Share Price

\$29.49

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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.

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|--------------------|----------------|-----------------------|--------------------------|------------------------|-----------------------|-------------------------|----------------------|
| Buy | Outperform | 44.1% | 21.1% | 67.5% | 43.3% | 58.6% | 55.4% |
| 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% |

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(S) = speculative investment;



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