

## ZS Pharma, Inc.

### Second Phase III Trial Enrollment Complete, Potential Top-Line Readout in Late Third Quarter the Focus, Remain Outperform Rated

- After the close, ZS Pharma announced that it had completed enrollment of its second Phase III study of ZS-9 for the indication of hyperkalemia (ZS004). The study enrolled 258 patients with hyperkalemia, including patients with chronic kidney disease (CKD), congestive heart failure (CHF), diabetes, and those on renin angiotensin aldosterone (RAAS) inhibitor therapy, at 42 participating sites. The company expects top-line data from the trial to readout as early as September 2014 with full data to be presented at medical conferences. We include the trial design for ZS004 in exhibit 1.
- In addition, ZS Pharma will also be conducting a two month extension study (ZS004E) for patients enrolled in ZS004 that will generate longer-term open-label safety, tolerability, and efficacy data and is currently enrolling a 52-week open label safety and efficacy trial (ZS005) that should read out in 2015. Based on the results from their previous clinical trials, we have a high conviction in the potential for success of ZS-9 in the treatment of hyperkalemia and maintenance of normokalemia with a lower adverse effect profile than products currently on the market or in development.
- Hyperkalemia is a life-threatening condition wherein elevated levels of potassium can increase the risk of cardiac arrest and death. Given the well-documented prevalence and growing patient populations within CKD, CHF, diabetes, and individuals on RAAS inhibitors, the management of hyperkalemia has the potential to become a significant market. Additionally, there is an acute need for the management of hyperkalemia and a growing awareness for the chronic management of potassium levels in various at-risk patient populations. To date, ZS Pharma has completed a 14-day Phase III clinical trial (ZS003) of ZS-9 in 753 patients with elevated potassium levels and a 48-hour Phase II clinical trial (ZS002) of ZS-9 in 90 patients with elevated potassium levels.
- In their previous studies, ZS-9 response rates were high, with 100% of patients in the 10 gram dose arm achieving serum potassium levels below the hyperkalemic threshold (5.0 mEq/L), while roughly 88% had serum potassium levels below 4.5 mEq/L in ZS002. In ZS003, ZS-9 showed dose-dependent decreases in serum potassium levels over the first 48 hours that were highly significant ( $p < 0.0001$ ) at the 5 g and 10 g doses. In addition, the 5 g and 10 g maintenance dosing from day 2 through day 14 kept the serum potassium levels in the normokalemic range, with an average increase of 0.11 mEq/L in patients receiving 5 g of ZS-9 daily, compared with 0.25 mEq/L in placebo ( $p = 0.0075$ ), and 0.06 mEq/L in patients receiving 10 g of ZS-9 daily, compared with an increase of 0.58 Eq/L in placebo ( $p < 0.0001$ ).
- We rate shares of ZS Pharma Outperform, based on what we believe is a best-in-class profile of ZS-9 for the treatment of hyperkalemia and maintenance of normokalemia for a significant total of more than 3 million patients with few good treatment options.

ZS Pharma is a specialty pharmaceutical company located in San Mateo, California, focused on developing therapies based on highly selective ion trap chemistry.

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Stock Rating: **Outperform**  
Company Profile: **Aggressive Growth**  
Price Target: \$75.00

Symbol: ZSPH (NASDAQ)  
Price: \$30.49 (52-Wk.: \$26-\$33)  
Market Value (mil.): \$582  
Fiscal Year End: December  
Long-Term EPS Growth Rate: NA  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS FY	\$-8.52	\$-0.78	\$-1.08
CY		\$-0.78	\$-1.08
<b>Valuation</b>			
FY P/E	NM	NM	NM
CY P/E		NM	NM

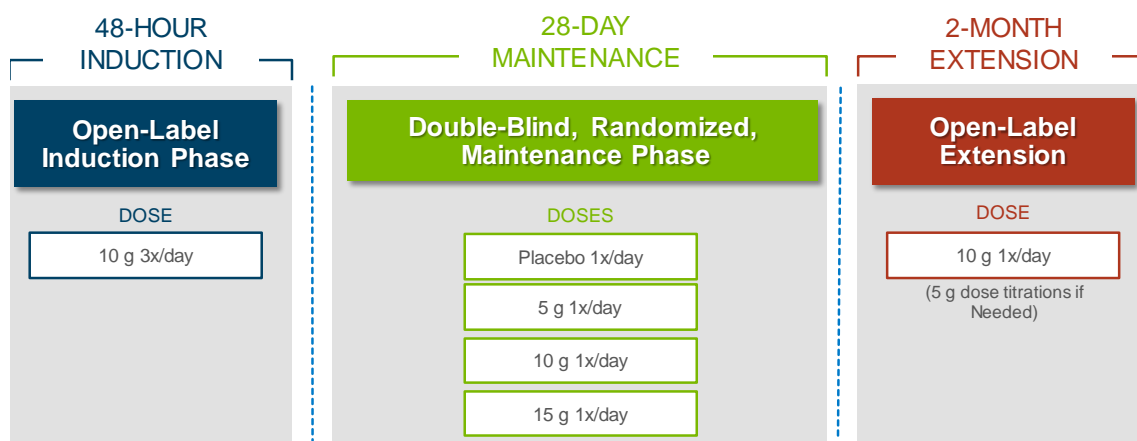
<b>Trading Data (FactSet)</b>	
Shares Outstanding (mil.)	20.6
Float (mil.)	NA
Average Daily Volume	NA

<b>Financial Data (FactSet)</b>	
Long-Term Debt/Total Capital (MRQ)	NA
Book Value Per Share (MRQ)	NA
Return on Equity (TTM)	NA

Sources: FactSet, William Blair & Company estimates

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**Exhibit 1**  
**ZS Pharma, Inc.**  
**ZS004 Study Design**



Primary Endpoint: Comparison of mean serum K<sup>+</sup> levels from day 8 to day 28

Secondary Endpoints: Proportion of patients normokalemic after induction phase

Proportion of patients normokalemic during 28-day maintenance period

Source: Company reports

## Valuation

We rate shares of ZS-9 Outperform with a \$75 price target. Our price target is derived from our net-present-value model for ZS-9 and applying a 75% probability of success (exhibit 2). Swing factors in our peak-year estimates include patient duration, which we estimate will reach six months; however, if ZS Pharma is successful in penetrating the chronic therapy market, this duration might hold upside. We anticipate peak sales for ZS-9 of \$1.17 billion by penetrating 10% to 13% of the available patient populations within select markets.

**Exhibit 2**  
**ZS Pharma, Inc.**  
**Sum of the Parts Valuation**

	Peak Sales	Discount Rate	Probability of Success	Peak Sales	Value Per Share
ZS-9	\$1,170	11%	75%	2021	\$ 72.40
Cash Per Share					\$ 4.71
NPV of Future Losses Per Share					\$ (2.41)
NPV Value					\$ 1,807,728
NPV Value Per Share					\$ 74.70

Source: William Blair & Company L.L.C. estimates

For per share numbers we use fully diluted share count of 24.2 million

## Risks

Risks to an investment in ZS Pharma include the normal clinical, regulatory, and commercial risks in development-stage therapeutics companies.

*William Blair*

**ZS Pharma  
Earnings Model**

7/14/14

(\$ in millions except EPS data)

**Rating: Outperform**  
**Company Profile: Aggressive Growth**

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	2012(A)	2013(A)	Q1(A)	Q2(E)	Q3(E)	Q4(A)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
ZS-9	-	-	-	-	-	-	-	-	-	218,357	445,814	740,445
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	36,767	-	-	-
<b>Total Revenue</b>	-	-	-	-	-	-	-	-	36,767	218,357	445,814	740,445
yr/yr growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	104.2%	66.1%
q/q growth			NA	NA	NA	NA						
incremental rev q/q												
<b>Cost of Goods Sold</b>	-	-	-	-	-	-	-	-	3,677	21,836	44,581	74,044
<b>Gross Profit</b>	-	-	-	-	-	-	-	-	33,090	196,521	401,233	666,400
<b>SG&amp;A</b>	1,148	7,686	1,053	2,498	2,998	2,998	9,992	11,990	23,980	47,961	102,537	148,089
Growth							30%	20%	100%	100%	76%	15%
<b>R&amp;D</b>	6,989	24,508	1,394	3,750	4,500	4,500	15,000	18,000	21,600	24,840	27,324	28,690
Growth		251%	-	-	-	-	-39%	20%	20%	15%	10%	5%
<b>Total Operating Expenses</b>	8,137	32,194	2,447	6,248	7,498	7,498	23,690	29,990	45,580	72,801	129,861	176,779
growth			NA	NA	NA	NA	-26%	27%	52%	60%	78%	36%
Operating Income	(8,137)	(32,194)	(2,447)	(6,248)	(7,498)	(7,498)	(23,690)	(29,990)	(12,490)	123,720	271,371	489,621
EBIT Margin							NM	NM	NM	NM	61%	66%
growth y/y (%)			NA	NA	NA	NA	NM	NM	NM	NM	NM	NM
Depreciation and Amortization	-	-	250	250	250	250	1,000	1,000	1,000	1,000	1,000	1,000
EBITDA	(8,137)	(32,194)	(2,197)	(5,998)	(7,248)	(7,248)	(22,690.0)	(28,990.2)	(11,490.0)	124,720	272,371	490,621
							NM	NM	NM	NM	61%	66%
Interest income	(17)	(31)										
Interest expense	2,099	9	(366)	750.0	750.0	750.0	3,000	2,000	1,500	1,500	1,000	1,000
Change in fair value of warrants	62	1,424										
Other	-	1										
Income Before Taxes	(10,281)	(33,597)	(2,813)	(5,498)	(6,748)	(6,748)	(21,806)	(27,990)	(10,990)	125,220	272,371	490,621
Income Tax Provision	-	-	(3,652)	275	225	225	(2,927)	1,000	1,000	45,079	92,606	166,811
Effective Tax Rate	0.0%	0.0%	NA	5.0%	NA	NA	NM	NA	NA	34%	34%	34%
Preferred stock accretion	(174)	(689)										
Net Income (loss) Attributable to Common	(10,455)	(34,286)	839	(5,773)	(6,972)	(6,973)	(18,879)	(28,990)	(11,990)	80,141	179,765	323,810
Net loss per share (diluted)	\$ (2.63)	\$ (8.52)	0.02	(0.24)	(0.29)	(0.29)	\$ (0.78)	\$ (1.08)	\$ (0.43)	\$ 2.82	\$ 6.30	\$ 11.13
Basic avg. number of shares used in computing net income	3,981	4,025	75,953	22,777	22,877	22,977	22,877	25,477	26,627	27,027	28,250	28,250
Diluted avg. number of shares used in computing net income	3,981	4,025	587,270	24,200	24,300	24,400	24,300	26,900	28,050	28,450	28,550	29,094
<b>Key Ratios (GAAP unless noted)</b>												
Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	90.0%	90.0%	90.0%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	11.4%	6.1%	3.9%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	22.0%	23.0%	20.0%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	56.7%	60.9%	66.1%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	36.7%	40.3%	43.7%
<b>Revenue Growth</b>												
Growth Yr/Yr	NM	NM	NM	NM	NM	NM	NM	NM	NM	494%	104%	66%
Growth Q/Q	NM		NM	NM	NM	NM						
<b>SG&amp;A Growth</b>												
Growth Yr/Yr	NM	570%	NM	NM	NM	NM	30%	20%	100%	100%	114%	44%
Growth Q/Q	NM		NM	NM	NM	NM						
<b>R&amp;D Growth</b>												
Growth Yr/Yr	NM	251%	NM	NM	NM	NM	-39%	20%	20%	15%	10%	5%
Growth Q/Q	NM		NM	NM	NM	NM						

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William Blair was a manager or co-manager of a public offering of equity securities for ZS Pharma, Inc. within the prior 12 months.

William Blair is a market maker in the security of ZS Pharma, Inc. and may have a long or short position.

William Blair intends to seek investment banking compensation in the next three months from ZS Pharma, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with ZS Pharma, Inc.

Additional information is available upon request.

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DOW JONES: 16,943.81

S&P 500: 1,967.57

NASDAQ: 4,415.49

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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	67	Outperform (Buy)	16
Market Perform (Hold)	30	Market Perform (Hold)	2
Underperform (Sell)	1	Underperform (Sell)	0

\*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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