

ZS Pharma, Inc.

Third-Quarter Earnings; All Eyes on HARMONIZE Full Data Presentation at AHA Annual Meeting on November 17

- After the close on Monday, November 10, ZS Pharma announced third-quarter earnings and an update on business development. The most important development in the quarter was the announcement of top-line results of the company's second Phase III trial (HARMONIZE) that showed all three doses of ZS-9 tested (5 g, 10 g, and 15 g, once-daily) significantly reduced mean serum potassium below placebo over a 28-day treatment period. In addition, it was reported that the safety, tolerability, and adverse event profile was consistent with previous ZS-9 studies. We believe the company was limited in the amount of disclosure possible ahead of the complete data set for HARMONIZE to be presented and discussed at the 2014 Annual Meeting of the American Heart Association in a late-breaking platform session on November 17 in Chicago, making this event a focus ahead of the potential NDA/MAA submission in the first half of 2015.
- In the HARMONIZE trial design, 258 patients with hyperkalemia, including patients with congestive heart failure (CHF), chronic kidney disease (CKD), and diabetes, went through a 48-hour induction phase of 10 g ZS-9 three times per day. Patients were also on a variety of renin angiotensin aldosterone (RAAS) inhibitor therapies. Following the induction phase, patients were randomized into a maintenance phase of placebo, 5 g ZS-9, 10 g ZS-9, and 15 g ZS-9 once/day for 28 days. The primary endpoint of the study was the comparison of mean serum potassium levels from day 8 through day 28 with secondary endpoints being the proportion of normokalemic patients after the induction phase and during the 28-day maintenance period. In addition, patients can be continued into an open-label extension period (ZS004E) at the 10 g dose once/day, with 5 g dose titrations if necessary to maintain normokalemia.
- Relypsa (RLYP \$19.90) recently filed its NDA for patiromer in the fourth quarter with approximately 700 treated patients' worth of data including a Phase I onset of action study in 25 patients, a Phase III Part A and Part B study in 301 patients (conducted under a special protocol assessment from the FDA), and a 52-week Phase IIb study in 306 patients (a key differentiator from the ZS-9 data set). While the ZS-9 program is tracking one to two quarters behind Relypsa in its NDA filing, the ZS Pharma program is of higher quality, in our view. The clinical trial program for ZS-9 has now completed three studies, a Phase II in 90 patients, its first pivotal Phase III trial in 753 patients, and its second pivotal Phase III trial (HARMONIZE) in 258 patients. The total anticipated size of the safety and efficacy database at regulatory filing will be large, with over 1000 patients treated to date. While we believe ZS-9 has the best profile to date, one which we believe will be strengthened when the company reports longer-term safety data in 2015, after recent discussions with a leading hyperkalemia key opinion leader, Dr. Bertram Pitt, we note that the market for hyperkalemia therapies is large in the chronic setting, which may leave room for more than one successful therapy in the market.

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: \$36.79 (52-Wk: \$26-\$43)
Market Value (mil.): \$766
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

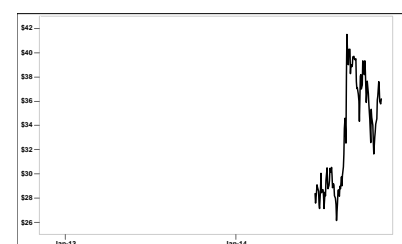
	2013A	2014E	2015E
Estimates			
EPS FY	\$-8.52	\$-3.28	\$-2.96
CY		\$-3.28	\$-2.96

Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	3
Float (mil.)	9
Average Daily Volume	134,067

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	6.2
Return on Equity (TTM)	-235.2

Two-Year Price Performance Chart

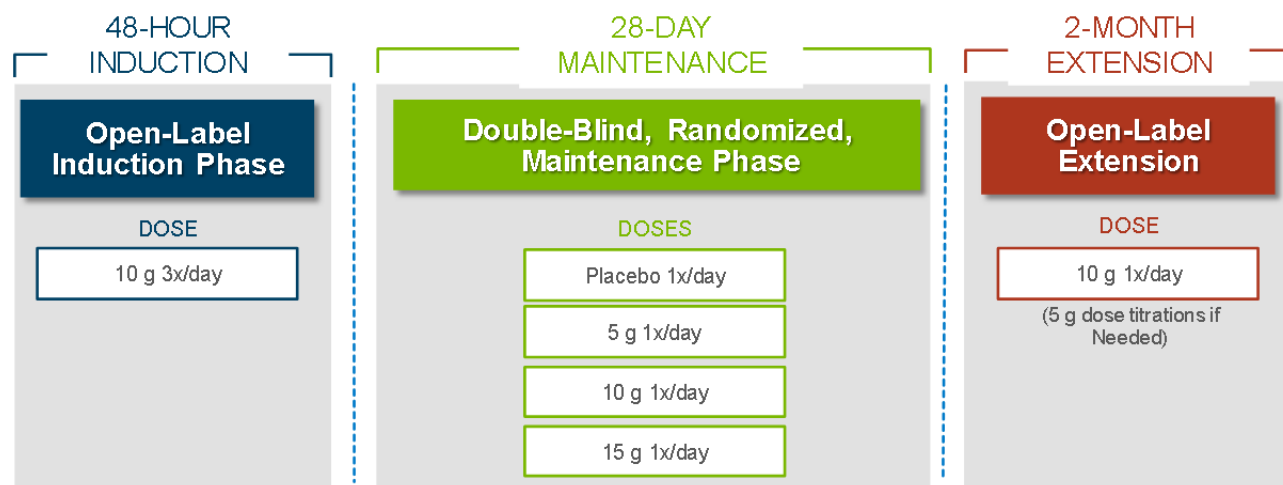


Sources: FactSet, William Blair & Company estimates

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- While we largely view earnings as a nonevent for shares of ZS Pharma, third-quarter financials were largely in line with expectations. The company reported R&D and SG&A expenses of \$10.92 million and \$5.7 million, respectively, which was relatively in line with our estimates of \$ 10 million and \$5 million as well as consensus of \$10.5 million and \$5 million. Net income was reported as a loss of \$16.9 million, or \$0.81 per share, slightly lower than both our estimate of \$15.5 million or \$0.74 per share and consensus of a loss of \$16.3 million or \$0.74 per share. As of the end of the third quarter, the company had cash and cash equivalents of \$121.5 million.
- The positive top-line readout of HARMONIZE shows that ZS-9 is effective, safe, and tolerable up to 28 days, double the length of the previous pivotal Phase III trial (14 days). However, we believe the presentation of long-term safety data will be important to the success and utilization of ZS-9 in the chronic setting. Given discussions with management we believe the approximately 500-person open-label safety and efficacy study is progressing well; however, full data from the study will not be available until 2015. We believe data from the 52-week open label long-term study (ZS005) and the extension portion of HARMONIZE (ZS004E) are highly anticipated, and should solidify the ability of ZS-9 use to maintain normokalemia in the long term. To date, the safety profile of ZS-9 has been shown to be a major clinically differentiating factor from patiromer as well as having what we believe is a faster onset of action, and we expect full data presentations at AHA as well as the company's analyst event on November 19. Our recent discussions with thought leaders also suggest the primary site of action between the two products—with patiromer active in the colon whereas ZS-9's site of binding is in the intestine—could favor ZS-9 in the acute setting, the setting where most hyperkalemic patients are now diagnosed. We believe this is a major differentiator; if ZS-9 were to show rapid lowering of potassium levels, it may prove to be the best therapy in the acute setting, and following long-term data that should be available in 2015, the product may be ideal for rolling patients onto a maintenance therapy following an acute attack.
- We continue to rate shares of ZS Pharma Outperform with a price target of \$75 given our belief that ZS-9 holds a best-in-class profile for the treatment of the large hyperkalemia and maintenance of normokalemia market. We believe that the company is well capitalized to bring ZS-9 through the regulatory process, barring any significant setbacks.

Exhibit 1
ZS Pharma, Inc.
HARMONIZE Study Design



Primary Endpoint: Comparison of mean serum K⁺ 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

Exhibit 2
ZS Pharma
Third Quarter Results and Estimates

	ZSPH Q3 14A	WB Q3 14E	Consensus Q3 14E	Q/Q Growth	Y/Y Growth
(\$ in thousands except EPS)					
Total Revenue	\$ -	\$ -	\$ -	NA	NA
R&D	\$ 10,923.0	\$ 10,000.0	\$ 10,500.0	9%	53%
G&A	\$ 5,699.0	\$ 5,000.0	\$ 5,000.0	25%	156%
Operating Income (loss)	\$ (16,622.0)	\$ (15,000.0)	\$ (15,000.0)	NM	NM
Net Income (loss)	\$ (16,863.0)	\$ (15,525.0)	\$ (16,300.0)	NM	NM
EPS	\$ (0.81)	\$ (0.74)	\$ (0.74)	NM	NM

Source: Company reports, William Blair & Company L.L.C. estimates
Consensus estimates reported by FactSet

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. 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. Currently, we anticipate peak sales for ZS-9 of \$1.17 billion by penetrating 10% to 13% of the available patient populations within select markets.

Risks

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



ZS Pharma
Earnings Model
 11/10/14
 (\$ in millions except EPS data)

Rating: Outperform
Company Profile: Aggressive Growth
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	2012(A)	2013(A)	Q1(A)	Q2(A)	Q3(A)	Q4(E)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
ZS-9	-	-	-	-	-	-	-	-	36,767	218,357	445,814	740,445
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	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												
Cost of Goods Sold	-	-	-	-	-	-	-	-	3,677	21,836	44,581	74,044
<i>Gross Profit</i>	-	-	-	-	-	-	-	-	33,090	196,521	401,233	666,400
SG&A	1,148	7,686	1,053	4,554	5,699	5,500	16,806	22,000	44,000	88,000	102,537	148,089
<i>Growth</i>							30%	20%	100%	100%	76%	15%
R&D	6,989	24,508	1,394	9,976	10,923	11,000	33,293	45,000	54,000	62,100	68,310	71,726
<i>Growth</i>		251%	-	-	-	-	36%	20%	20%	15%	10%	5%
Total Operating Expenses	8,137	32,194	2,447	14,530	16,622	16,500	50,099	67,000	98,000	150,100	170,847	219,814
<i>growth</i>			NA	NA	NA	NA	56%	34%	46%	53%	14%	29%
Operating Income	(8,137)	(32,194)	(2,447)	(14,530)	(16,622)	(16,500)	(50,099)	(67,000)	(64,910)	46,421	230,385	446,586
EBIT Margin							NM	NM	NM	NM	52%	60%
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)	(14,280)	(16,372)	(16,250)	(49,099.0)	(66,000.0)	(63,909.7)	47,421	231,385	447,586
Interest income	(17)	(31)		5	-31	225	199	750	600	800	1,200	1,400
Interest expense	2,099	9	(366)	(1,774)	272	750	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)	(16,299)	(16,863)	(17,025)	(53,000)	(68,250)	(65,810)	45,721	230,585	446,986
Income Tax Provision	-	-	(3,652)	-	-	-	(3,652)	1,000	1,000	16,460	78,399	151,975
Effective Tax Rate	0.0%	0.0%	NA	0.0%	NA	NA	NM	NA	NA	34%	34%	34%
Preferred stock accretion	(174)	(689)		(129)								
Net Income (loss) Attributable to Common	(10,455)	(34,286)	839	(16,428)	(16,863)	(17,025)	(49,348)	(69,250)	(66,810)	29,261	152,186	295,011
Net loss per share (diluted)	\$ (2.63)	\$ (8.52)	0.02	(4.72)	(0.81)	(0.81)	\$ (3.28)	\$ (2.96)	\$ (2.72)	\$ 1.17	\$ 6.07	\$ 11.52
Basic avg. number of shares used in computing net income	3,981	4,025	75,953	3,482	20,818	20,918	15,073	23,418	24,568	24,968	24,768	24,768
Diluted avg. number of shares used in computing net income	3,981	4,025	587,270	3,482	20,818	20,918	15,073	23,418	24,568	24,968	25,068	25,612
Key Ratios (GAAP unless noted)												
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	28.4%	15.3%	9.7%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	40.3%	23.0%	20.0%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	21.3%	51.7%	60.3%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	13.4%	34.1%	39.8%
Revenue Growth												
Growth Yr/Yr	NM	NM	NM	NM	NM	NM	NM	NM	NM	494%	104%	66%
Growth Q/Q	NM		NM	NM	NM	NM						
SG&A Growth												
Growth Yr/Yr	NM	570%	NM	NM	NM	NM	119%	31%	100%	100%	17%	44%
Growth Q/Q	NM		NM	NM	NM	NM						
R&D Growth												
Growth Yr/Yr	NM	251%	NM	NM	NM	NM	36%	35%	20%	15%	10%	5%
Growth Q/Q	NM		NM	NM	NM	NM						

IMPORTANT DISCLOSURES

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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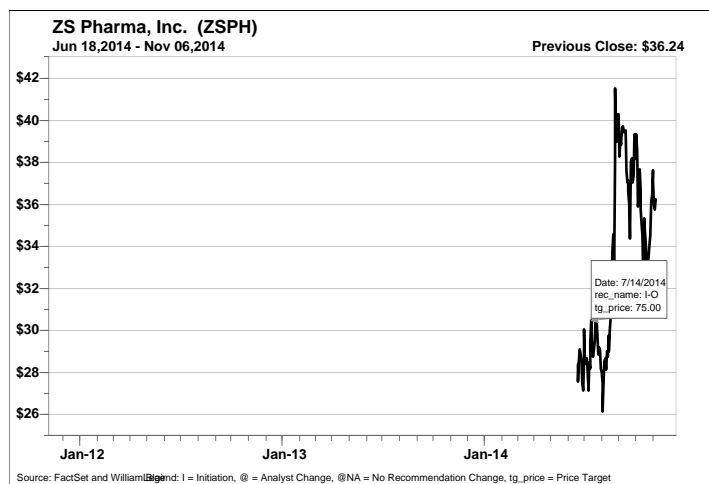
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DOW JONES: 17,613.74

S&P 500: 2,038.26

NASDAQ: 4,651.62



Current Rating Distribution (as of 10/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
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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