

ZS Pharma, Inc.

Second Quarter Reflects Fast Enrollment of ZS004 Study, Data Likely in September With NDA Submission in First Quarter 2015

- After the close Thursday, August 14, ZS Pharma announced second-quarter results. The company reported a net loss of \$16.428 million, significantly ahead of our estimate of a loss of \$5.773 million and consensus of a loss of \$9.98 million based primarily on higher-than-expected R&D expenses due to the enrollment of ZS004, the initiation of ZS005, and manufacturing scale-up costs. G&A expense of \$4.554 million was also higher than our estimate of \$2.498 million and consensus of \$3.2 million. Cash and cash equivalents at the end of the quarter were \$130 million. Given proceeds from the company's initial public offering and an additional \$20 million in debt available (with \$10 million already drawn down), the company is well-positioned to fund operations into 2016. We outline reported second-quarter earnings, our estimates, and consensus in exhibit 1, on page 2.
- Earlier in the quarter, ZS Pharma announced that it had completed enrollment of ZS004, the company's second Phase III study of ZS-9 for the indication of hyperkalemia. The study enrolled 258 patients with hyperkalemia, including patients with chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes and those on renin angiotensin aldosterone (RAAS) inhibitor therapy, at 42 participating sites. The company expects top-line data from the trial to read out as early as September 2014, with full data to be presented at medical conferences. In addition, ZS Pharma is rolling ZS004 patients into an extension study, which is expected to eventually provide one year of open-label safety, tolerability, and efficacy data. During the quarter, the company also began enrolling ZS005, a 52-week open label safety and efficacy trial that should read out in 2015 and also supplement the company's regulatory filing. The company remains on track to file a NDA in the first half of 2015 and we continue to have a high conviction in the potential for success of ZS-9 in the long-term treatment of hyperkalemia and maintenance of normokalemia with a lower adverse effect profile than products currently on the market or under development given the data to date.
- Regarding competitive programs, hyperkalemia development competitor Relypsa (RLYP \$27.21) announced in its second-quarter results a slight pushback in timelines. The company is now guiding to an NDA submission for patiromer early in the fourth quarter, a slight delay versus its previous guidance for a third-quarter submission previously mentioned in its first-quarter press release and S-1 filing. We view this as a minor positive for ZS Pharma, as Relypsa is now only one quarter ahead of the application of ZS-9. However, in totality we note that the patiromer pivotal program continues to take longer than previously anticipated, given that top-line Phase III data from the program was announced in October 2013. Regardless of the patiromer timelines, as we detail below, we continue to view ZS-9 as a more favorable product.

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: \$29.02 (52-Wk.: \$26-\$33)
Market Value (mil.): \$587
Fiscal Year End: December

Long-Term EPS Growth Rate:

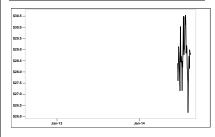
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A\$0.02	NA
Q2	NA	A\$-4.72	NA
Q3	NA	\$-0.74	NA
Q4	NA	\$-0.81	NA
FY	\$-8.52	\$-3.18	\$-2.94
CY		\$-3.18	\$-2.94
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM
Trading Da	ta (FactCot)	,	

Trauling Data (ractiset)	
Shares Outstanding (mil.)	10
Float (mil.)	8
Average Daily Volume	188,966

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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- As shown in exhibit 2, on page 3, the relative adverse event profile for patiromer seems to show a greater percentage of adverse events, and particularly GI events, in comparison to ZS-9. We believe these data show that ZS-9 has a best-in-class safety profile, which is in line with our view that the product is highly selective to binding potassium. In addition to a potentially cleaner side effect profile, ZS Pharma enrolled a broader patient population, with the clinical trials recruiting patients with hyperkalemia regardless of etiology. We also believe ZS-9 as a once-a-day maintenance therapy likely has an improved profile over patiromer in the large chronic dosing market.
- Although head-to-head studies of development compounds are rarely available and cross-trial comparison is always difficult because of different patient populations, we attempted to directionally compare the efficacy profiles of ZS-9 and patiromer in exhibit 3 using baseline and post-treatment mean serum potassium levels for patiromer studies using company reports. In the early-stage study comparison, at the 48-hour period, ZS-9 patients (especially at doses above 2.5 grams three times per day or TID) are in the normokalemic range after treatment, whereas patiromer patients are still above the range (though significantly reduced from baseline) for normal potassium concentration. In addition, in the comparison of data after two weeks of treatment, ZS-9 in the maintenance phase showed lower mean serum potassium concentration (4.71 mEq/L for 5g QD, and 4.55 mEq/L for 10g QD), while our best estimate for 14-day data for patiromer suggests end-values of 4.8 mEq/L for both the mild and moderate-to-severe hyperkalemia patients. We continue to believe that ZS-9 has a faster onset of action and a sustained benefit in comparison to patiromer.
- 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. In
 addition, 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. In total, we believe the hyperkalemia market
 exceeds 3 million patients in the United States alone with few good treatment options.
- We continue to rate shares of ZS Pharma Outperform with a price target of \$75 given our belief that ZS-9 holds a best-inclass profile for the treatment of the large hyperkalemia and maintenance of normokalemia market. We view shares as our
 best near-term idea ahead of a possible readout of the ZS004 trial in September.

Exhibit 1
ZS Pharma
Second Quarter Results and Estimates

		ZSPH Q2 14A	WB Q2 14E	onsensus Q2 14E	Y/Y Growth
(\$ in thousands except EPS)					
Total Revenue	\$	-	\$ -	\$ -	NA
R&D	\$	9,976.0	\$ 3,750.0	\$ 4,400.0	57%
G&A	\$	4,554.0	\$ 2,498.0	\$ 3,200.0	369%
Operating Income (loss)	\$ (14,530.0)	\$ (6,248.0)	\$ (9,200.0)	-99%
Net Income (loss)	\$ (16,428.0)	\$ (5,773.0)	\$ (9,300.0)	-125%
EPS	\$	(4.72)	\$ (0.24)	\$ (0.65)	NM

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

Consensus estimates reported by FactSet

Exhibit 2 ZS Pharma, Inc.

Safety Measures From ZS-9 and Patiromer (RLY5016)

	Induction F	Phase (48 h)	Maintenance P	hase (2 weeks)
Safety Measurement	Placebo	ZS-9	Placebo	ZS-9
All Adverse Events	10.8%	12.9%	24.5%	25.1%
GI Events	5.2%	3.5%	3.7%	5.5%
Safety Measurement	Placebo	RLY5016		
All Adverse Events	31%	54%		
GI Events	6%	21%		

Sources: Pitt et al. Eur Heart J 2011, Company Reports, William Blair & Company, L.L.C.

Exhibit 3 ZS Pharma, Inc.

Change in Serum Potassium After Treatment With ZS-9 and Patiromer

Time Point	Patiromer	Dose	RLYP Study	ZS-9	Dose	ZSPH Study
48 hours	5.83 mEq/L -> 5.1 mEq/L	8.4g b.i.d.	Phase I Onset-of-	5.3 mEq/L -> 5 mEq/L	1.25g t.i.d.	ZS-003
			Action	$5.3 \text{ mEq/L} \rightarrow 4.84 \text{ mEq/L}$	2.5g t.i.d.	Induction Phase
				$5.3 \text{ mEq/L} \rightarrow 4.76 \text{ mEq/L}$	5g t.i.d.	induction i hase
				$5.3 \text{ mEq/L} \rightarrow 4.57 \text{ mEq/L}$	10g t.i.d.	
2 weeks	Mild HK: \sim 5.2 mEq/L -> \sim 4.8 mEq/L	10g t.i.d	RLY5016-205	5.3 mEq/L ->4.71 mEq/L	5g q.d.	ZS-003
	Moderate/Severe HK ~5.6 mEq/L -> 4.8 mEq/L		(AMETHYST-DN)	5.3 mEq/L -> 4.55 mEq/L	10g q.i.d.	Maint. Phase
4 weeks	Mild HK: ~5.1 mEq/L -> ~4.65 mEq/L Moderate/Severe HK: ~5.8 mEq/L -> 4.5 mEq/L	Mild: 8.4 q.d. Mod/Sev HK: 8.4g b.i.d.	Phase III	Study Results in Q4	2014	ZS-004
52 weeks	Mild HK: ~5.2 mEq/L -> ~4.6 mEq/L Moderate/Severe HK: ~5.65 mEq/L -> ~4.6 mEq/L	10-40g q.d.	RLY5016-205 (AMETHYST-DN)	Study Initiated in Q2	2 2014	ZS-005

Sources: ZS Pharma and Relypsa 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 4). 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.

Exhibit 4 ZS Pharma, Inc. Sum of the Parts Valuation

	Peak Sales	Discount Rate	Probability of Success	Peak Sales	٧	alue 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
8/14/14
(\$ in millions except EPS data)

Rating: Outperform Company Profile: Aggressive Growth Tim Lugo 415.248.2870 tlugo@williamblair.com

	2012(A)	2013(A)	Q1(A)	Q2(A)	Q3(E)	Q4(E)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
								-	-			
ZS-9 Royalty/Milestone Revenue	-	-	-	-	-	-		-	36,767	218,357	445,814	740,445
Total Revenue	- 1	-	-	-	-	-	-	-	36,767	218,357	445,814	740,445
yr/yr growth g/g growth	NA	NA	NA NA	NA NA	NA NA	NA NA	NA	NA	NA	NA	104.2%	66.1%
incremental rev q/q			101	101	141	101						
Cost of Goods Sold	-	-	-	-	-	-	-	-	3,677	21,836	44,581	74,044
Gross Profit	-	-	-	-	-	-	-	-	33,090	196,521	401,233	666,400
SG&A Growth	1,148	7,686	1,053	4,554	5,000	5,500	16,107 30%	22,000 20%	44,000 100%	88,000 100%	102,537 76%	148,089 15%
R&D	6,989	24,508	1,394	9,976	10,000	11,000	32,370	45,000	54,000	62,100	68,310	71,726
Growth Total Operating Expenses	8,137	251% 32,194	2,447	14,530	15,000	16,500	32% 48,477	20% 67,000	20% 98,000	15% 150,100	10% 170,847	5% 219,814
growth			NA	NA	NA	NA	51%	38%	46%	53%	14%	29%
Operating Income	(8,137)	(32,194)	(2,447)	(14,530)	(15,000)	(16,500)	(48,477)	(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)	(14,750)	(16,250)	(47,477.0) NM	(66,000.0) NM	(63,909.7) NM	47,421 NM	231,385 52%	447,586 60%
Interest income	(17)	(31)		5	225	225	455	750	600	800	1,200	1,400
Interest expense Change in fair value of warrants	2,099 62	9 1,424	(366)	(1,774)	750	750	3,000	2,000	1,500	1,500	1,000	1,000
Other	-	1,424										
Income Before Taxes	(10,281)	(33,597)	(2,813)	(16,299)	(15,525)	(17,025)	(51,662)	(68,250)	(65,810)	45,721	230,585	446,986
Income Tax Provision	(10,00)	(==,===)	(3,652)	-	(10,000)	(,==,	(3,652)	1,000	1,000	16,460	78,399	151,975
Effective Tax Rate	0.0%	0.0%	NA 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)	(15,525)	(17,025)	(48,010)	(69,250)	(66,810)	29,261	152,186	295,011
Net loss per share (diluted)	\$ (2.63)	\$ (8.52)	0.02	(4.72)	(0.74)	(0.81)	\$ (3.18)	\$ (2.94)	\$ (2.71)	\$ 1.17	\$ 6.05	\$ 11.47
Basic avg. number of shares used in computing net income	3,981	4,025	75,953	3,482	20,918	21,018	15,139	23,518	24,668	25,068	24,868	24,868
Diluted avg. number of shares used in computing net income	3,981	4,025	587,270	3,482	20,918	21,018	15,139	23,518	24,668	25,068	25,168	25,712
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.) Operating Margin	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	40.3% 21.3%	23.0% 51.7%	20.0% 60.3%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	13.4%	34.1%	39.8%
Revenue Growth											40.404	
Growth Yr/Yr Growth Q/Q	NM NM	NM	NM NM	NM NM	NM NM	NM NM	NM	NM	NM	494%	104%	66%
SG&A Growth	14141		14141	14141	1 4141	1 4141						
Growth Yr/Yr	NM	570%	NM	NM	NM	NM	110%	37%	100%	100%	17%	44%
Growth Q/Q	NM		NM	NM	NM	NM						
R&D Growth Growth Yr/Yr	NM	251%	NM	NM	NM	NM	32%	39%	20%	15%	10%	5%
Growth Q/Q	NM	20170	NM	NM	NM	NM	0E/0	5575	20,0	1070	.0,0	0,0

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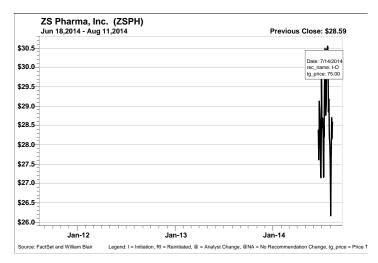
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DOW JONES: 16,651.80 S&P 500: 1,946.72 NASDAQ: 4,434.13



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