William Blair

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ZS Pharma, Inc.

First-Quarter Earnings Highlight ZS-9 NDA Submission in Near Term With Long-Term Data Later in Year

- After the close on Monday, May 11, ZS Pharma reported first-quarter earnings that highlighted significant clinical progress the company has made in advancing its lead candidate, ZS-9, to regulatory submission. Some of the recent clinical milestones include publications in the *New England Journal of Medicine* on pooled analyses from two ZS-9 Phase III clinical trials and a publication in *Kidney International* on a Phase II study of ZS-9 in the treatment of hyperkalemia. In the near term, the company anticipates filing an NDA with the FDA by midyear, filing the MAA with the EMA in the second half of 2015, and presenting clinical subgroup analyses at medical meetings including those of the American Society of Hypertension (May 15-19), Heart Failure Association of the European Society of Cardiology (May 23-26), and European Renal Association–European Dialysis and Transplant Association (May 28-31). Although we do not expect the company to disclose long-term data at any of these meetings, we anticipate the data to be published after the NDA submission, potentially at one of the fall medical meetings. Given the second-quarter NDA filing, ZS-9 will be about five to six months behind Relypsa's (RLYP $36.05) patiromer, which has a PDUFA date of October 21 for its BID formulation; however, the guidance for the MAA filing suggests this may occur during the same time or be in front of Relypsa's MAA filing guidance (year-end 2015/early 2016). Lastly, we note that Relypsa's most recent 10-Q filing states that the FDA does not currently plan to convene an Advisory Committee, which is likely a positive signal regarding the review of the NDA and the need for new therapies in the hyperkalemia indication.

- In one of several symposiums on hyperkalemia at the National Kidney Foundation's spring clinical meeting, Dr. Wolfgang Winkelmayer presented an overview of clinical trials with ZS-9 and patiromer from recently published articles in the *New England Journal of Medicine* and the *Journal of the American Medical Association*. In exhibit 1, on page 3, we highlight some characteristics of the patients enrolled in each of the three studies. In the Weir et al. publication, patients were enrolled in the trial if they met the criteria of being in stage 4/5 of chronic kidney disease and if they had been on RAAS inhibitor therapy for over four weeks. In the ZS-9 trials, patients were enrolled regardless of their CKD state and RAAS inhibitor therapy (although approximately two-thirds of patients were on RAAS inhibitors). After speaking with some physicians at the meeting, we believe that during the regulatory review process, patiromer could receive a label that includes only patients on RAAS inhibitor therapy and more developed CKD, as opposed to ZS-9 which has been shown to be effective in maintaining normokalemia in a more heterogeneous population; this may serve as a differentiator with both potentially in the market by the end of 2016.

Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$75.00
Symbol:	ZSPH (NASDAQ)
Price:	$49.44 (52-Wk.: $26-$53)
Market Value (mil.):	$1,215
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

		2014A	2015E	2016E
Estimates				
EPS	Q1	$0.02	A$-1.05	NA
	Q2	$-4.72	$-0.95	NA
	Q3	$-0.81	$-0.99	NA
	Q4	$-0.98	$-1.01	NA
	FY	$-5.47	$-4.01	$-4.17
	CY		$-4.01	$-4.17
Sales (mil.)		0	0	37
Valuation				
FY P/E		NM	NM	NM
CY P/E			NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	21
Float (mil.)	24
Average Daily Volume	266,997

Financial Data (FactSet)	
Book Value Per Share (MRQ)	4.6
Return on Equity (TTM)	-124.1

Two-Year Price Performance Chart

Sources: FactSet, William Blair & Company estimates

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

- Also during the quarter, the *New England Journal of Medicine* published online material that included several letters to the editor and subsequent correspondence about previous publications in the journal on both Relypsa's patiromer and ZS Pharma's ZS-9 products for hyperkalemia entitled "New Agents for Hyperkalemia." As we have stated in a previous note, we view these concerns raised by medical professionals to be a significant positive for ZS-9, because the majority of issues raised for patiromer questioned the trial study design and population enrollment whereas questions related to ZS-9 were mainly focused on active comparators (which were also a question with patiromer). We believe ZS-9's onset-of-action continues to be a distinct differentiator that strengthens our belief that the product is a best-in-class therapy. We anticipate being able to analyze the long-term safety data from ZS-9 following the NDA submission, which should remove the uncertainty surrounding its use in the chronic setting.

- For first-quarter financials, the company reported research and development costs of $15.3 million, which was above both consensus of $11.6 million and $14 million. SG&A expenses were reported as $6.4 million, above both consensus of $5.6 million and our estimate of $5 million. Net income was reported as a loss of $21.9 million, or $1.05 per share, which was below both consensus of a loss of $17.4 million, or $0.79 per share, and our estimate of $19.5 million, or $0.93 per share. The company is well capitalized with $259.6 million in cash, cash equivalents, and short-term investments as of March 31, 2015 after a secondary offering that provided net proceeds of $173.6 million.

- We continue to believe that ZS-9 holds a best-in-class profile for the treatment of hyperkalemia and continue to rate shares of ZS Pharma Outperform with a price target of $75. In total, we believe the acute and chronic hyperkalemia market exceeds 3 million patients in the United States with few good treatment options. While we believe the market may be large enough for two winners, we ultimately view the profile of ZS-9 as the likely best-in-class product and we believe long-term safety data, which should be available later in the year at an appropriate medical meeting, will likely cement that profile. The next meaningful catalysts for ZS Pharma will likely be the filing of the ZS-9 NDA, which should occur in the near term, and the company's long-term safety data, which will likely be presented by year-end. We continue to view ZS Pharma as a top idea in 2015.

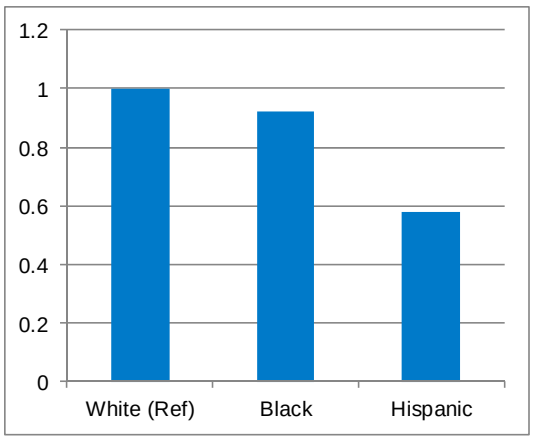
Exhibit 1
Selected Baseline Characteristics for Published Hyperkalemia Studies with ZS-9 and Patiromer

Characteristic	Weir et al. NEJM 2015	Kosiborod et al. JAMA 2014	Packham et al. NEJM 2015
N	Treatment Phase (N=243), Randomized Withdrawal Phase (Placebo N=52, Patiromer N=55)	Open-Label Phase (N=258), Randomized Phase (Placebo N=85, 5g ZS-9: N=45, 10g ZS-9 N=51, 15g ZS-9 N-56)	Placebo N=158, 1.25g ZS-9: N=154, 2.5g ZS-9 N=141, 5g ZS-9 N=157, 10g ZS-9 N=143
RAAS inhibitor use	Initial Treatment Phase: 100%; Randomized Withdrawal Phase: Placebo 100%, Patiromer 100%	Open-Label Phase: 69.8%, Randomized Phase: Placebo 71.8%, 5g ZS-9 73.3%, 10g ZS-9 70.6%, 15g ZS-9 58.9%	Placebo 63.9%, 1.25g ZS-9: 70.8%, 2.5g ZS-9 68.8%, 5g ZS-9 63.1%, 10g ZS-9 67.1%
eGFR: mean (SD)	Treatment Phase: 35.4 (16.2), Randomized Withdrawal Phase: Placebo 39 (20.4), Patiromer 38.6 (20.7)	Open-Label Phase: 46.3 (30.5), Randomized Phase: Placebo 48 (28.8), 5g ZS-9 48 (30.7), 10g ZS-9 44.7 (30.7), 15g ZS-9 44.9 (29.5)	Not reported, no specific requirements for GFR nor were patients excluded on the basiis of date of initiation of RAAS inhibitor
Caucasian ('White race')	Initial Treatment Phase 98%, Randomized Withdrawal 100%	Open-Label Phase: 83.3%, Randomized Phase: Placebo 85.9%, 5g ZS-9 80%, 10g ZS-9 86.3%, 15g ZS-9 82.1%	Placebo 86.1%, 1.25g ZS-9: 85.1%, 2.5g ZS-9 88.7%, 5g ZS-9 84.1%, 10g ZS-9 83.9%
Black/African American	Not reported	Open-Label Phase: 14.3%, Randomized Phase: Placebo 11.8%, 5g ZS-9 17.8%, 10g ZS-9 9.8%, 15g ZS-9 16.1%	Placebo 10.8%, 1.25g ZS-9: 13%, 2.5g ZS-9 7.8%, 5g ZS-9 12.7%, 10g ZS-9 13.3%
Asian	Not reported	Open-Label Phase: 1.9%, Randomized Phase: Placebo 3.5%, 5g ZS-9 0%, 10g ZS-9 2%, 15g ZS-9 1.8%	Not reported
Other	Not reported	Open-Label Phase: 1.2%, Randomized Phase: Placebo 1.2%, 5g ZS-9 2.2%, 10g ZS-9 2%, 15g ZS-9 0%	Not reported

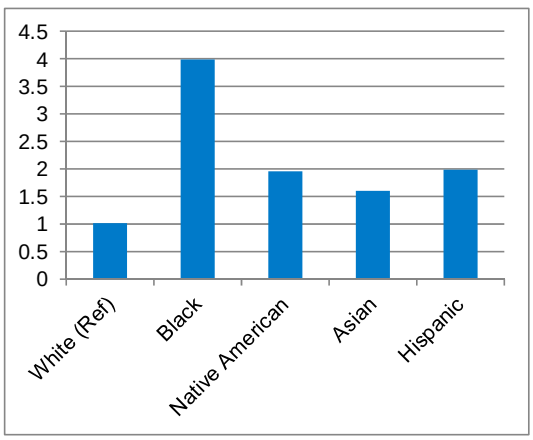
Sources: Weir et al. NEJM 2015, Kosiborod et al. JAMA 2014, Packham et al. NEJM 2015

Exhibit 2
Prevalence of CKD By Race

Relative Prevalence of Stage 1-3 CKD



Relative Prevalence of ESRD



Sources: Nicholas SB et al. Sem in Nephrol 2013

Exhibit 3
ZS Pharma
First Quarter Results and Estimates

	ZSPH Q1 15A	WB Q1 15E	Consensus Q1 15E	Q/Q Growth	Y/Y Growth
($ in thousands except EPS)					
Total Revenue	**$ -**	**$ -**	**$ -**	**NA**	**NA**
R&D	$ 15,317.0	$ 14,000.0	$ 11,600.0	5%	999%
G&A	$ 6,404.0	$ 5,000.0	$ 5,600.0	16%	508%
Operating Income (loss)	$ (21,721.0)	$ (19,000.0)	$ (17,100.0)	NM	NM
Net Income (loss)	$ (21,946.0)	$ (19,525.0)	$ (17,400.0)	NM	NM
EPS	**$ (1.05)**	**$ (0.93)**	**$ (0.79)**	**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.

William Blair

ZS Pharma
Earnings Model
5/11/15
($ in millions except EPS data)

Rating: Outperform
Company Profile: Aggressive Growth
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	2012(A)	2013(A)	2014(A)	Q1(A)	Q2(E)	Q3(E)	Q4(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
Gross Profit	-	-	-	-	-	-	-	-	33,090	196,521	401,233	666,400
SG&A	1,148	7,686	14,919	6,404	5,500	5,500	6,000	23,404	46,808	93,616	102,537	148,089
Growth			30%					20%	100%	100%	76%	15%
R&D	6,989	24,508	45,618	15,317	14,000	15,000	15,000	59,317	74,146	85,268	93,795	98,485
Growth		251%	86%	-	-	-	-	20%	25%	15%	10%	5%
Total Operating Expenses	8,137	32,194	60,537	21,721	19,500	20,500	21,000	82,721	120,954	178,884	196,332	246,574
growth			88%	788%	34%	23%	4%	37%	46%	48%	10%	26%
Operating Income	(8,137)	(32,194)	(60,537)	(21,721)	(19,500)	(20,500)	(21,000)	(82,721)	(87,864)	17,637	204,900	419,827
EBIT Margin			NM					NM	NM	NM	46%	57%
growth y/y (%)			NM	788%	34%	23%	4%	NM	NM	NM	NM	NM
Depreciation and Amortization	-		1,000	250	250	250	250	1,000	1,000	1,000	1,000	1,000
EBITDA	(8,137)	(32,194)	(59,537.0)	(21,471)	(19,250)	(20,250)	(20,750)	(81,721.0)	(86,863.9)	18,637	205,900	420,827
			NM					NM	NM	NM	46%	57%
Interest income	(17)	(31)	(94)	(50.0)	200.0	175.0	150.0	475	600	800	1,200	1,400
Interest expense	2,099	9	530	275	500.0	500.0	500.0	2,000	1,500	1,500	1,000	1,000
Change in fair value of warrants	62	1,424	3,071.0									
Other	-	1										
Income Before Taxes	(10,281)	(33,597)	(64,044)	(21,946)	(19,800)	(20,825)	(21,350)	(83,921)	(88,764)	16,937	205,100	420,227
Income Tax Provision	-	-		-	250	250	250	1,000	1,000	6,097	69,734	142,877
Effective Tax Rate	0.0%	0.0%	NM	0.0%	-1.3%	-1.2%	-1.2%	NA	NA	34%	34%	34%
Preferred stock accretion	(174)	(689)	(310)									
Net Income (loss) Attributable to Common	(10,455)	(34,286)	(64,354)	(21,946)	(20,050)	(21,075)	(21,600)	(84,671)	(89,764)	10,839	135,366	277,350
Net loss per share (diluted)	$ (2.63)	$ (8.52)	$ (5.47)	(1.05)	(0.95)	(0.99)	(1.01)	$ (4.01)	$ (4.17)	$ 0.49	$ 6.14	$ 12.28
Basic avg. number of shares used in computing net income	3,981	4,025	11,768	20,990	21,090	21,190	21,290	21,140	21,540	21,940	21,740	21,740
Diluted avg. number of shares used in computing net income	3,981	4,025	11,768	20,990	21,090	21,190	21,290	21,140	21,540	21,940	22,040	22,584

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DOW JONES: 18,191.11
S&P 500: 2,116.10
NASDAQ: 5,003.55

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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	14
Market Perform (Hold)	32	Market Perform (Hold)	2
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