

May 27, 2015

ZS Pharma, Inc.

ZS-9 NDA Submitted, Long-Term Data Likely to Be Released Later in Year; Maintain Outperform

- After the close Tuesday, May 26, ZS Pharma announced the submission of the NDA for ZS-9 for the treatment of hyperkalemia. The filing sets up the company for a mid-2016 regulatory decision following a likely standard 12-month review process. The NDA filing is based on two positive Phase III studies that have been published in two premier peer-reviewed journals, *The New England Journal of Medicine* and *The Journal of the American Medical Association*. Along with both Phase III studies, the company will also include long-term safety data in over 750 patients treated at least one year with ZS-9. We have included the ZS-9 development program in exhibit 1, on page 2.
- The filing of the ZS-9 NDA is consistent with management's prior guidance and precedes what should be an EMA filing in the second half of 2015. The NDA submission also allows for the disclosure of the company's ongoing long-term safety and efficacy data, potentially at a fall medical meeting. Given this filing, ZS-9 will be approximately six months behind Relypsa's (RLYP \$33.76) patiromer, which has a PDUFA date of October 21 for its BID formulation, and the likelihood of an early 2016 full launch of the product. The guidance for the MAA filing suggests a European filing may occur at the same time or in front of Relypsa's MAA filing guidance for year-end 2015 or early 2016. Lastly, we note that both companies currently do not believe the FDA will convene an Advisory Committee, which is likely a positive signal regarding the review of both NDAs and highlights the agency's likely desire for the approval of new therapies for hyperkalemia where the current standard of care, sodium polystyrene sulfonate (SPS), predates the modern FDA approval process.
- As shares of ZS Pharma have been strong since the company completed a financing of \$186 million in late March (up 43% in the last month alone), we have received an increase in call volume on the name. We believe the strength has likely been because of some broader sector issues, with several recent high-profile acquisitions (Auspex for \$3.2 billion and Synageva for \$8.4 billion), in addition to company-specific positives such as confidence in the regulatory review for ZS-9, with neither Relypsa nor ZS Pharma expecting an AdCom. We also believe shares are set up well for the second half of 2015 as long-term data will likely be presented at one of the fall medical meetings, and we believe data should provide the final answers to some lingering questions on the long-term safety and efficacy of ZS-9. We also believe the patiromer PDUFA may be a tailwind for ZS-9's regulatory review, as thought leaders at a recent medical meeting noted the potential for a more restrictive label than expected by the Street (only stage 4 or 5 of chronic kidney disease 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).

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

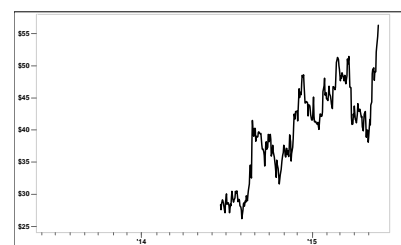
Symbol: ZSPH (NASDAQ)
Price: \$58.90 (52-Wk.: \$26-\$60)
Market Value (mil.): \$1,472
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	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.)	9
Average Daily Volume	290,974

Financial Data (FactSet)	
Book Value Per Share (MRQ)	10.1
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.

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- 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. In general, we believe ZS-9 holds a faster onset of action, is efficacious across multiple subgroups, and will likely hold a strong side effect profile. The next meaningful catalysts for ZS Pharma will likely be 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
ZS Pharma, Inc.
ZS-9 Development Program Overview

Trial	Patient Population	Duration	Objective	Summary
ZS002 (Completed)	N=90 Hyperkalemia, CKD 5-6 mEq/L	48 hours	POC for ZS-9 rapidly lowering K+ levels	Met primary endpoint
ZS003 (Completed)	N=753 Hyperkalemia, etiology. 5-6 mEq/L	14 days	Confirm rapid K+ control and POC for extended dosing	Met primary endpoint for the 2.5, 5, 10 doses and secondary endpoints for 5 and 10 dose in extended phase
ZS004/e (Completed/Ongoing)	N=258 Hyperkalemia, etiology. >5 mEq/L	1 month + 11 month	Establish an extended dose	80%, 90%, and 94% normokalemic at 5g, 10g, QD doses, respectively
ZS005 (Ongoing)	N=500 Hyperkalemia, etiology. >5 mEq/L	12 months	Establishing long-term safety and efficacy	Initiated 2Q14; Data available in 2H '15

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. 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.

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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	-	-	-	-	-	-	-	-	-	-	-	-
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	36,767	218,357	445,814	740,445
									-	-	-	-
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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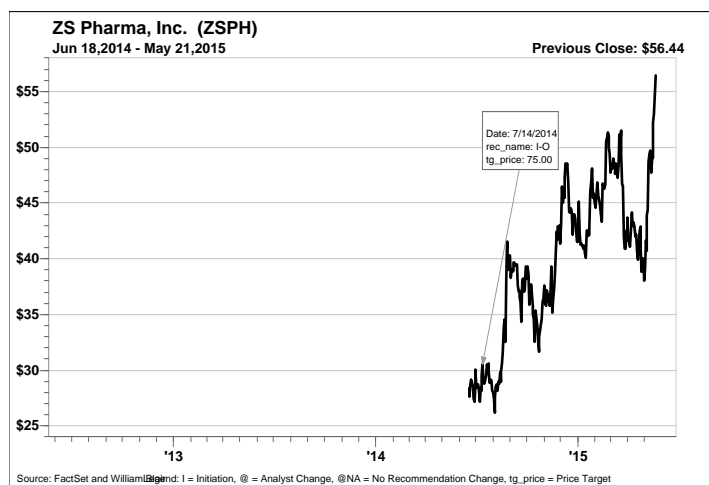
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DOW JONES: 18,041.54

S&P 500: 2,104.20

NASDAQ: 5,032.75



Current Rating Distribution (as of 04/30/15)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	14
Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

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