ZS Pharma

(ZSPH-NASDAQ)

Stock Rating: **Outperform**
Industry Rating: **Outperform**

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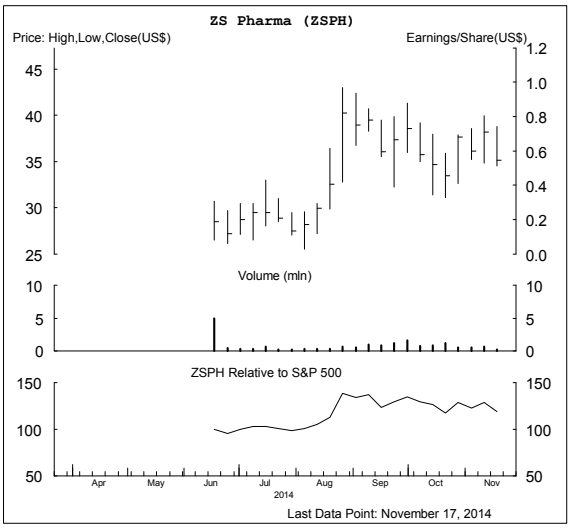
David Maris **212-885-4091**
BMO Capital Markets Corp.
david.maris@bmo.com

Positive Data and Feedback From Two Medical Meetings—Docs Ready for New Options

Price (18-Nov)	$36.31	**52-Week High**	$43.00
Target Price	$45.00	**52-Week Low**	$25.51



Event

We attended the American Society of Nephrology and the American Heart Association medical meetings in the past week where both ZS Pharma and competitor Relypsa presented data. We had a chance to meet with management of both companies, as well as Relypsa's CEO, and to meet with physicians at the meetings to discuss the respective products. Additionally, Relypsa hosted a well-attended reception with a discussion led by two key opinion leaders. ZS Pharma presented positive data from its second Phase III trial (Harmonize/ZS004) of ZS-9 in patients with hyperkalemia at the AHA session on Monday.

Impact & Analysis

Overall, we continue to have a positive view of the hyperkalemia market opportunity and believe that the ZS004 data again showed ZS-9's impressive efficacy and tolerability, with 98% of patients achieving normokalemia within 48 hours. ZS-9 maintained mean potassium at lower levels than placebo over the 28-day treatment period in all three doses studied (5g, 10g, 15g). It appears to us that ZS Pharma's timeline remains on track, with an expected NDA and MAA filing in 1H2015. Our physician interviews at the meetings further convinced us that nephrologists and cardiologists are eager for a drug that safely and effectively treats both acute and chronic hyperkalemia and that ZS-9, as well as its likely competitor, Relypsa's Patriomer, will see rapid adoption if approved. We look forward to hearing more about the ZS004 data and ZS Pharma's timeline at the company's analyst day later today.

Valuation & Recommendation

We updated our model for 3Q earnings. We are maintaining our $45 price target, in line with our DCF valuation of $46. We maintain our Outperform rating.

(FY-Dec.)	2012A	2013A	2014E	2015E
EPS	- $6.74	- $21.84	- $5.13↓	- $3.06
P/E			na	na
CFPS	na	na	- $4.20	- $3.50
P/CFPS			na	na
Rev. ($mm)	$0	$0	$0	$0
EV	na	na	na	na
EBITDA ($mm)	-$8	-$32	-$55	-$73
EV/EBITDA	na	na	na	na
Quarterly EPS	**Q1**	**Q2**	**Q3**	**Q4**
2012A	na	na	na	na
2013A	na	na	na	na
2014E	-$6.60a	-$4.72a	-$0.81a	-$0.76

Dividend	$0.00	**Yield**	0.0%
Book Value	$1.16	**Price/Book**	31.3x
Shares O/S (mm)	18.7	**Mkt. Cap (mm)**	$681
Float O/S (mm)	na	**Float Cap (mm)**	na
Wkly Vol (000s)	859	**Wkly $ Vol (mm)**	$28.5
Net Debt ($mm)	na	**Next Rep. Date**	na

Notes: All values in US$
First Call Mean Estimates: ZS PHARMA INC (US$) 2014E: -$4.25; 2015E: -$3.06

Changes	Annual EPS
	2014E -$5.05 to -$5.13

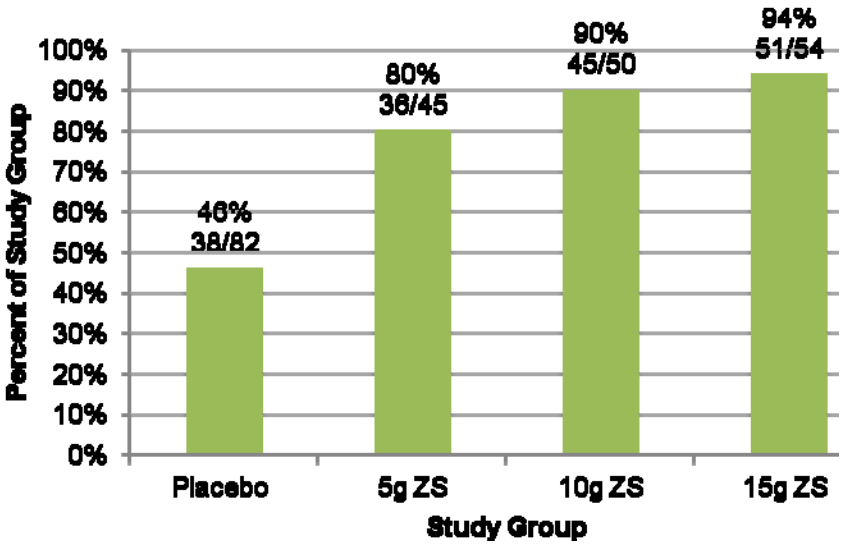
Please refer to pages 8 to 11 for Important Disclosures, including the Analyst's Certification.

ZS004 Shows ZS-9's Efficacy and Tolerability

At the American Society of Nephrology last week, we met with ZS Pharma's management, including CEO Robert Alexander, SVP of Business Development Adam Tomasi, and CFO Todd Creech, to get an update on the business. We again spoke with management at the AHA following its data release. Overall, all appears on track and the data was as expected. The stock sold off a little, as we believe investors were anticipating positive news and simply "sold on the news." Our key takeaways include the following:

ZS004 was a success, and again proved ZS-9's impressive efficacy. The randomized, double-blind, placebo-controlled and dose-ranging trial met the primary efficacy endpoint by demonstrating that all three doses (5g, 10g, and 15g) of once daily ZS-9 maintained mean potassium at lower levels than placebo over the 28-day treatment period.

Exhibit 1: Randomized Phase: Proportion of Patients With Mean Potassium Levels in Normal Range (<5.1 mEq/L) from days 8-29



Source: Company Reports, BMO Capital Markets.

ZS004 delivers impressive onset of action data. In the open-label acute phase of the trial, the data show 98% of patients achieved normokalemia within 48 hours, with the median time to normokalemia of 2.2 hours, an encouraging result demonstrating ZS-9's rapid onset of action.

Results demonstrate ZS-9's safety and tolerability. The tolerability of ZS-9 in ZS004 was comparable to placebo, with no treatment-related serious adverse events and numerically lower rates of GI AEs in the ZS-9 treated study groups than in the placebo group. ZS-9 appears to be well tolerated, also showing low incidence of urinary tract infections (which is not one of the exclusion criteria for ZS004).

Edema rates are most likely not drug related. The company did see numerically high rates of fluid-overload in the 15g ZS-9 group, with eight patients in the group diagnosed with edema compared with two in the placebo group, one in the 5g group, and three in the 10g group. However, 7 of the 14 patients in the overall study who had edema did not require treatment, and

those that did were given the standard diuretic as treatment, with all but one going on to complete the study.

ZS-9 secretes hydrogen and sodium as it moves through the body and binds to potassium, which led us to some initial concern that increased sodium may lead to edema. However, ZS points to extensive tests showing patients do not experience edema any more than in the placebo group, and also tested weight gain and blood pressure, which would typically rise when edema develops. The company also saw no notable difference in weight gain or blood pressure in the ZS004 patients, which suggests the edema did not develop during the study, but may have been more noticeable as physicians in the trial paid closer attention to the patients. ZS Pharma attributes the higher edema rates in the 15g group to the fact that there was a higher percentage of patients with heart failure in the group, considering edema is very common in heart failure patients. ZS believes that the detailed and comprehensive testing ZS Pharma has done demonstrates the higher edema rates are likely not drug related.

Timelines and long-term data: It appears to us that the timeline remains on track. According to ZS Pharma, approximately 1,200 patients have been exposed to ZS-9, and many patients in ZS Pharma's ZS004E extension study are now out to seven months of exposure. ZS005 started in June and last patient last visit (LPLV) is expected to be in early August. The company is confident that it will have the appropriate long-term data by the time of launch to show the ability of ZS-9 to reduce the levels of serum potassium to normal levels over an extended period. ZS Pharma is expected to submit its NDA and MAA in 1H2015. Some have raised concerns that ZS Pharma will not have sufficient long-term safety data by the time of filing or approval, something that ZS flatly denies and counters with the above data.

The manufacturing process continues to go well. The company has successfully scaled up to a 2,000-liter from a 500-liter reactor and the 2,000-liter reactor has produced 8-10 batches so far. ZS Pharma continues to evaluate the eventual use of a 5,000 liter reactor. ZS stated that the conversions to the larger reactors have gone practically flawlessly. The company explained that scaling up from 20L to 200L was the most difficult; 200L to 500L pretty flawless; 500L to 2,000L also pretty flawless. The company noted that it has already ordered a 5,000L reactor and since there is a 9- to 12-mont lead time, it will likely be installed in 3Q-4Q15.

Doctor Interviews Reaffirm Our Belief That the Market Is Large

At the ASN meeting, we had an opportunity to interview a nephrologist who treats on average approximately 40-45 hyperkalemic patients per month. On par with our previously published KOL calls and doctor surveys, he indicated that the current standard of care treatment, Kayexalate, has a poor profile with many side effects. In addition, he reiterated the view that a long-term treatment is needed to treat chronic hyperkalemia and was aware of both ZS Pharma's ZS-9 and Relypsa's Patiromer. When asked how quickly he would likely adopt ZS-9 for the treatment of hyperkalemia he answered, "for acute six weeks to two months to see how it performs in the market, but might use it earlier, and 6-8 weeks for chronic." In a physician survey we conducted back in June, approximately 95% responded that they would prescribe ZS-9 within six months of it being on the market. We believe this indicates a strong interest in ZS-9 and the need for a better treatment that Kayexalate.

We also spoke with a cardiologist following the ZS004 presentation at AHA, who treats more than 25 patients a month with hyperkalemia. He told us he believes a drug like ZS-9 or Relypsa's Patiromer would significantly increase cardiologists' ability to treat patients with chronic heart failure. The doctor indicated approximately only 20-30% of patients who should be on RAAS inhibitors are on them now, since the risk of hyperkalemia is so high, but that a drug that treats hyperkalemia as effectively as the ZS004 study shows ZS-9 might increase that percentage to 100%, as physicians would be much more inclined to prescribe the very beneficial heart therapy treatment alongside ZS-9 or Patiromer.

Overall, we believe that nephrologists and cardiologists are eager for a drug that safely and effectively treats both acute and chronic hyperkalemia and that ZS-9 will see significant profits in the future if both ZS-9 and Patiromer are approved given the large addressable market. These discussions mirror our previous work and mirror similar, more informal discussions we had at these meetings.

Doctor Dinner and Meeting With Relypsa

At the ASN last week, ZS Pharma's key competitor Relypsa (which has what Relypsa hopes is a six-month-plus lead on ZS Pharma) hosted a dinner inviting doctors George Bakris and David Bushinsky, who discussed their thoughts on the challenges of hyperkalemia and their experience with Relypsa's Patiromer.

Background:

- **George Bakris, MD**, Professor of Medicine, University of Chicago Medicine and Director of the Comprehensive Hypertension Center
- **David Bushinsky, MD**, John J. Kuiper Distinguished Professor of Medicine, University of Rochester School of Medicine, Chief of Nephrology Unit at Strong Memorial Hospital and Associate Chair for Academic Affairs in the Department of Medicine

In addition, we sat down with John Orwin (President and CEO) and Sylvia Wheeler (VP, Investor Relations and Corporate Affairs) who shed light on the company's views on upcoming catalysts and data, the recent NDA submission, market dynamics, and the competitive landscape.

Some key takeaways from the dinner and meeting:

- The aforementioned doctors presented data at the dinner and felt that doctors would prefer Patiromer as there have been incidents in the past in which metal-based treatments have been shown to be unsafe; therefore, doctors may be hesitant to try a metal-based drug again.
- Interestingly, Relypsa had completed 1x daily dose in its Phase I with healthy patients. The company plans to start a study for 1x daily dosing in an upcoming trial.
- Patiromer causes a change in magnesium levels; however, the doctors stated they do not believe the changes in magnesium are a significant event and thus not a major risk.
- Both management and the experts presenting at the meeting believe that doctors will begin prescribing Patiromer early on as the existing standard of care treatment—kayexalate—is not very effective.

Model Update

Unrelated to the medical meetings, we are publishing our post-3Q14 model and our new EPS estimates are below. We maintain our $45 price target and our Outperform rating.

Exhibit 2: ZSPH EPS Estimates

	4Q14	2014	2015	2016	2017	2018
BMO New	($0.76)	($5.13)	($3.06)	($2.11)	$0.82	$5.75
BMO Previous	($0.76)	($5.05)	($3.06)	($2.11)	$0.82	$3.33
Consensus	($0.76)	($4.25)	($3.06)	($3.16)	$0.27	$4.16

Source: Company Reports, BMO Capital Markets.

Summary

ZS Pharma has a unique position as a late-stage asset for an unmet medical need with a limited physician target pool, and as such remains an attractive opportunity for in-licensing or acquisition by large pharma.

We look forward to hearing more about the ZS004 data and ZS Pharma's timeline at the company's analyst day later today.

Exhibit 3: ZSPH Income Statement ($ in millions, except per share data)

ZS Pharma Income Statement	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Net revenue for CKD patients					**$13.1**	**$99.2**	**$187.1**	**$270.0**	**$327.2**
Net revenue for HF patients					**$2.9**	**$27.2**	**$41.3**	**$60.1**	**$72.9**
ZS-9 episodic net revenues					**$1.4**	**$8.4**	**$27.8**	**$33.4**	**$39.0**
Total ZS US net revenue					**$17.4**	**$134.8**	**$256.3**	**$363.5**	**$439.0**

ZS Pharma Income Statement	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$17.4**	**$136.4**	**$269.0**	**$392.4**	**$481.9**
% growth							*97.3%*	*45.9%*	*22.8%*
COGS	$0.0	$0.0	$0.0	$0.0	$3.5	$27.0	$46.1	$54.5	$65.9
COGS as % of US sales					*20.0%*	*20.0%*	*18.0%*	*15.0%*	*15.0%*
Gross profit	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$13.9**	**$109.4**	**$222.9**	**$337.9**	**$416.1**
Gross margin					*80.0%*	*80.2%*	*82.9%*	*86.1%*	*86.3%*
R&D	$7.0	$24.5	$39.0	$36.0	$20.0	$20.2	$25.6	$36.3	$41.7
R&D as % of US sales					*114.9%*	*15.0%*	*10.0%*	*10.0%*	*9.5%*
S&M	$0.0	$0.0	$1.5	$29.9	$39.0	$45.9	$64.1	$80.0	$91.1
S&M as % of US sales					*224.0%*	*34.1%*	*25.0%*	*22.0%*	*20.8%*
G&A	$1.1	$7.7	$15.9	$8.4	$1.3	$5.4	$10.3	$14.5	$17.6
G&A as % of US sales					*7.4%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Royalties					$5.8	$12.2	$21.2	$31.8	$43.6
Operating profit	**($8.1)**	**($32.2)**	**($56.3)**	**($74.3)**	**($52.1)**	**$25.7**	**$101.8**	**$175.2**	**$222.0**
Operating margin						*18.9%*	*37.8%*	*44.7%*	*46.1%*
Interest expense (income)	$2.1	($0.0)	$0.1	$0.8	$0.8	$0.8	$0.8	$0.8	$0.8
Other expense (income)	$0.1	$1.4	$3.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pretax income	**($10.3)**	**($33.6)**	**($59.7)**	**($75.0)**	**($52.9)**	**$24.9**	**$101.0**	**$174.4**	**$221.2**
Pretax margin						*18.3%*	*37.6%*	*44.5%*	*45.9%*
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$3.7	$15.2	$26.2	$66.4
Tax rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*	*15.0%*	*15.0%*	*30.0%*
Net income	**($10.3)**	**($33.6)**	**($59.7)**	**($75.0)**	**($52.9)**	**$21.2**	**$85.9**	**$148.3**	**$154.9**
Preferred stock accretion	($0.2)	($0.7)	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net income to common stockholders	**($10.5)**	**($34.3)**	**($60.0)**	**($75.0)**	**($52.9)**	**$21.2**	**$85.9**	**$148.3**	**$154.9**
Net margin						*15.5%*	*31.9%*	*37.8%*	*32.1%*
Shares out (diluted)	1.6	1.6	11.7	24.5	25.1	25.8	25.8	25.8	25.8
Earnings per share	**($6.74)**	**($21.84)**	**($5.13)**	**($3.06)**	**($2.11)**	**$0.82**	**$3.33**	**$5.75**	**$6.01**
EPS % growth							*305.2%*	*72.6%*	*4.4%*

Source: Company reports, BMO Capital Markets.

Exhibit 3: ZSPH DCF ($ in millions, except per share data)

ZS Pharma ZSPH
Discounted Cash Flow Analysis
$ Millions, except per share

WACC	**12.0%**									
Terminal Value EV/EBITDA Multiple	**8.0x**									
Unlevered Free Cash Flows										
		2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Net Sales		$0.0	$0.0	$0.0	$0.0	$17.4	$136.4	$269.0	$392.4	$481.9
Growth Rate							*683.2%*	*97.3%*	*45.9%*	*22.8%*
EBIT		($8.1)	($32.2)	($56.3)	($74.3)	($52.1)	$25.7	$101.8	$175.2	$222.0
Margin							*18.9%*	*37.8%*	*44.7%*	*46.1%*
Pre-tax income		($10.3)	($33.6)	($59.7)	($75.0)	($52.9)	$24.9	$101.0	$174.4	$221.2
Tax		$0.0	$0.0	$0.0	$0.0	$0.0	($3.9)	($15.3)	($26.3)	($66.6)
Tax rate		0.0%	0.0%	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	30.0%
EBIAT		($8.1)	($32.2)	($56.3)	($74.3)	($52.1)	$21.9	$86.5	$148.9	$155.4
Plus: Depreciation and Amortization		$0.0	$0.7	$1.3	$1.7	$1.8	$1.9	$2.0	$2.1	$2.2
Less: Capital Expenditures		($0.7)	($3.8)	($8.8)	($16.0)	($16.0)	($15.0)	($15.0)	($15.0)	($15.0)
Less: Change in Net Working Capital		$0.6	$2.8	$5.4	($0.7)	($3.2)	($7.4)	($4.7)	($4.6)	$1.2
Unlevered Free Cash Flow		**($8.2)**	**($32.5)**	**($58.3)**	**($89.2)**	**($69.5)**	**$1.3**	**$68.9**	**$131.4**	**$143.8**
Cumulative Unlevered FCF	$157.39	0	0	0.5	1.5	2.5	3.5	4.5	5.5	6.5
Terminal Value[2]	$1,793.7									
PV of Free Cash flow	($6.4)	-$8.2	-$32.5	-$58.3	-$89.2	-$69.5	$0.9	$41.3	$70.4	$68.8
PV of Terminal Value	$858.7									
Implied Enterprise Value	$852.3									
Plus: Cash & Equivalents **(4Q14)**	$108.7									
Less: Total Debt **(3Q14)**	$10.0									
Implied Value of Equity	$951.0									
Diluted Shares Outstanding	20.8									
Implied Value per Share	**$45.72**									

Implied Equity Value Sensitivity Table

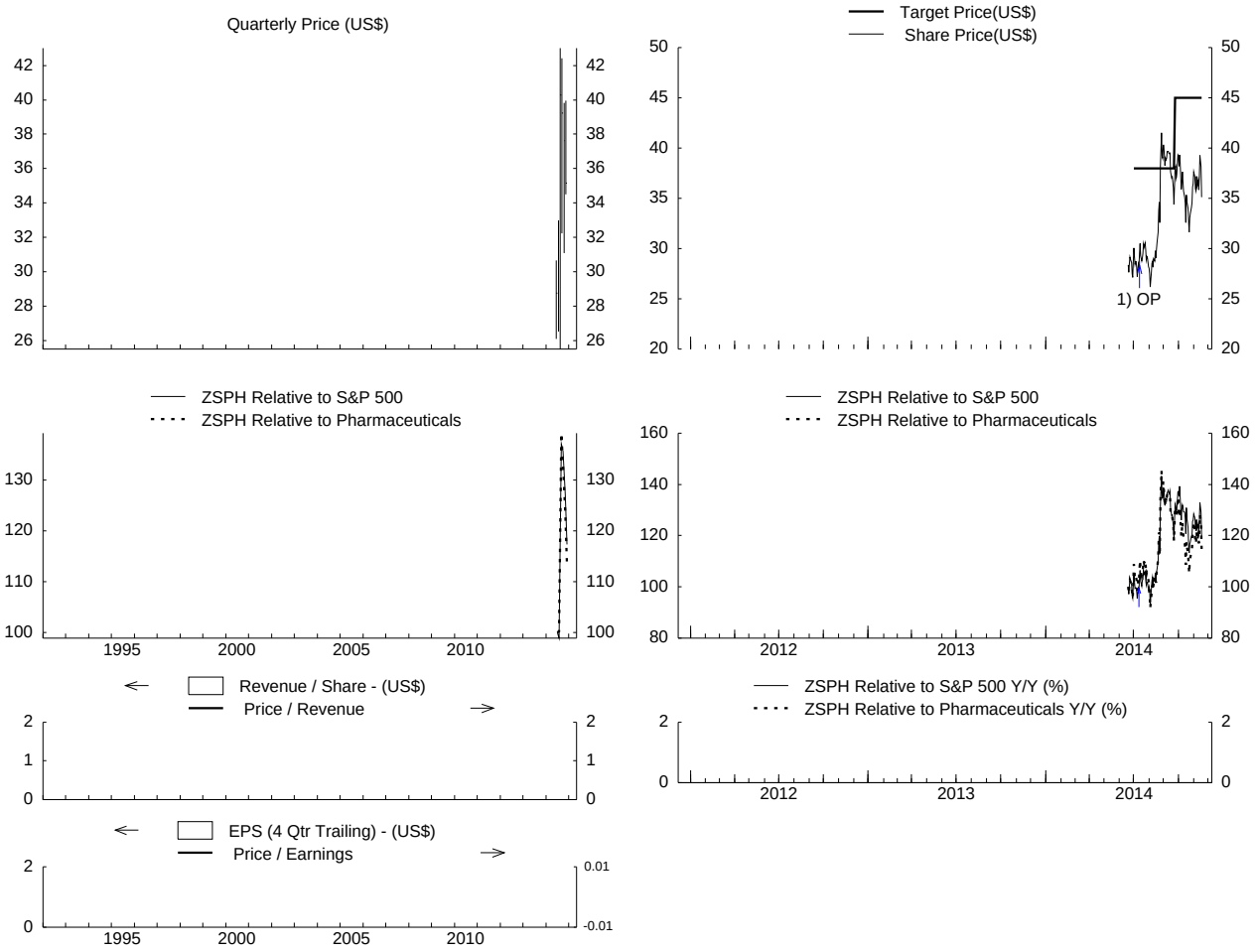
EBITDA Multiple Terminal Value

WACC	**$45.72**	**7.0x**	**8.0x**	**9.0x**
	14.0%	$35.81	$40.41	$45.01
	15.0%	$33.65	**$38.00**	$42.34
	16.0%	$31.63	$35.74	$39.85

Current share price	$36.31
Price target % from current share price	25.9%
Price target	**$45.72**

Source: Company reports, BMO Capital Markets.

ZS Pharma (ZSPH)



FYE (Dec.)	EPS US$	P/E Hi - Lo	DPS US$	Yield% Hi - Lo	Payout %	BV US$	P/B Hi - Lo	ROE %
Range*:		na na		NC			>15 >15	
Current*	ND	na	0.00	0.0	na	1.2	32.4	na

ZSPH - Rating as of 17-Jun-14 = NR

	Date	Rating Change	Share Price
1	11-Jul-14	NR to OP	$29.49

* Current EPS is the 4 Quarter Trailing to Q2/2014.
* Valuation metrics are based on high and low for the fiscal year.
* Range indicates the valuation range for the period presented above.

Last Price (November 17, 2014): $35.14
Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

IMPORTANT DISCLOSURES

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Methodology and Risks to Price Target/Valuation
Methodology: We arrive at our target price using a discounted cash flow analysis, a sector multiple applied to discounted earnings, and as a multiple of sales.
Risks: In addition to the normal risks inherent in pharmaceutical companies, such as regulatory, reimbursement, and competitive risks, our valuation of ZSPH carries several other risks. Among the risks to our valuation is ZSPH's dependence on approval of their lead product and anticipated sales and profitability to drive the value of ZSPH. Unseen side effects, safety issues, and competitive threats have not been taken into account in our valuation and if any of these were to emerge, it is likely ZSPH shares would be significantly and negatively impacted. ZSPH is currently running at a substantial loss, and with this fact comes several other risks, including the potential need for financing. One cannot be certain that ZSPH would be able to secure additional financing and at what cost. Our valuation does not include any value for ZSPH's additional product in the pipeline.

Distribution of Ratings (September 30, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	44.3%	18.0%	60.3%	43.9%	56.5%	56.0%
Hold	Market Perform	52.5%	9.7%	38.5%	51.6%	42.1%	39.1%
Sell	Underperform	3.2%	5.3%	1.3%	4.5%	1.4%	4.9%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.
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Mkt = Market Perform - Forecast to perform roughly in line with the analyst's coverage universe on a total return basis
Und = Underperform - Forecast to underperform the analyst's coverage universe on a total return basis
(S) = speculative investment;

NR = No rating at this time;
R = Restricted – Dissemination of research is currently restricted.

BMO Capital Markets' seven Top 15 lists guide investors to our best ideas according to different objectives (CDN Large Cap, CDN Small Cap, US Large Cap, US Small cap, Income, CDN Quant, and US Quant have replaced the Top Pick rating).

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