

ZS Pharma

(ZSPH-NASDAQ)

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

May 1, 2015

David MarisBMO Capital Markets Corp.
david.maris@bmo.com**212-885-4091****Katie Brennan**BMO Capital Markets Corp.
katie.brennan@bmo.com**212-885-4123**

Top 10 Takeaways From BMO Doctor Panel on Novel Treatments in Hyperkalemia

Event

In this note we highlight the top 10 takeaways from a conference call we hosted this week on new treatments in hyperkalemia (high potassium), including ZS Pharma's ZS-9 and Relypsa's Patiromer. On the call, we had a panel of doctors: Dr. Mikhail Kosiborod (Cardiologist, Saint Luke's Mid America Heart Institute), Dr. Stuart Linas (Chief of Nephrology, Denver Health Medical Center), and Dr. Peter McCullough (Cardiologist, Baylor Heart and Vascular Institute).

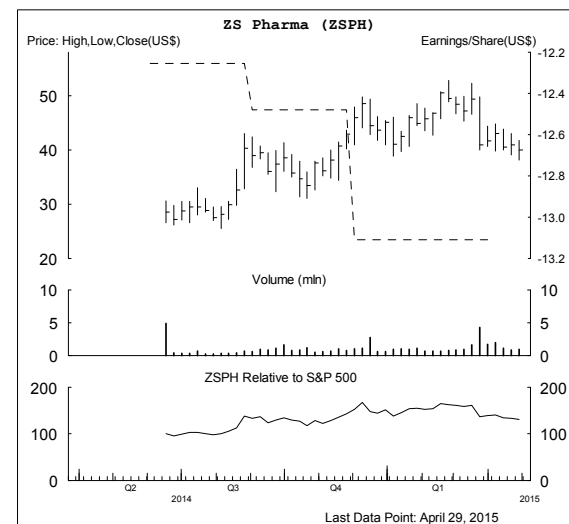
Impact & Analysis

Our expert physician panel's comments were mostly balanced and measured, except when asked to predict the market share ZS-9 and Patiromer would have a few years after launch: the doctors predicted ZSPH's ZS-9 would have 75%-80% share. They noted the importance of quick onset of action in acute treatment, and highlighted ZS-9's speed. We do not want to overestimate their enthusiasm, but note that, if it is correct, it would represent significant upside to our current assumptions. The panel did not see any major approvability risk for either drug.

Valuation & Recommendation

We believe that ZSPH is a compelling investment at the current valuation. While their approval may be a year or so away (the NDA filing is imminent), we believe their data is robust and that over time, ZS Pharma's market cap (currently \$996 million) will match or exceed Relypsa (\$1.3 billion). We have updated our model following the company's recent secondary offering and updated our DCF, moving to a 2015 base year. Our DCF-derived price target remains \$54.00.

Price (30-Apr) \$38.07 **52-Week High** \$52.80
Target Price \$54.00 **52-Week Low** \$25.51



(FY-Dec.)	2013A	2014A	2015E	2016E
EPS	-\$21.84	-\$5.47	-\$2.78↑	-\$2.63↑
P/E			na	na
CFPS	na	-\$4.85	-\$3.64	-\$0.30
P/CFPS			na	na
Rev. (\$mm)	\$0	\$0	\$0	\$17
EV	na	\$1,021	\$1,168	\$1,168
EBITDA (\$mm)	-\$32	-\$59	-\$66	-\$63
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2013A	na	na	na	na
2014A	-\$6.60	-\$4.72	-\$0.81	-\$0.98
2015E	-\$0.66↑	-\$0.66	-\$0.73↑	-\$0.73↑
Dividend	\$0.00			
Book Value	\$1.16			
Shares O/S (mm)	20.8			
Float O/S (mm)	20.2			
Wkly Vol (000s)	1,026			
Net Debt (\$mm)	-\$92			
Yield				0.0%
Price/Book				32.8x
Mkt. Cap (mm)				\$793
Float Cap (mm)				\$769
Wkly \$ Vol (mm)				\$41.0
Next Rep. Date				na

Notes: All values in US\$

First Call Mean Estimates: ZS PHARMA INC (US\$) 2015E: -\$3.61; 2016E: -\$4.89

Changes

Annual EPS

2015E -\$2.85 to -\$2.78
 2016E -\$2.66 to -\$2.63

Quarterly EPS

Q1/15E -\$0.72 to -\$0.66
 Q3/15E -\$0.74 to -\$0.73
 Q4/15E -\$0.74 to -\$0.73

Top 10 Takeaways: Hyperkalemia Doctor Panel

We hosted a panel of key opinion leaders, and the following are what we consider to be the top 10 key takeaways from the call:

1. **There are two main ways hyperkalemia presents:** in the emergency room or hospital setting, where it is usually severe and in need of immediate acute treatment, and in a less severe setting, where patients with chronic kidney disease or with heart failure need chronic treatment to maintain normal potassium levels.
2. **The doctors on our panel believe the use of ZS-9 and Patiromer would likely increase the use of these life-saving treatments.** Doctors are currently limiting their use of important medications (such as RAAS-inhibitors and mineralocorticoid-receptor blockers) because these medications can lead to hyperkalemia. ZS-9 and Patiromer have both shown they can effectively reduce potassium levels as well as maintain normal potassium levels over time.
3. **The physicians on our panel highlighted the likelihood that kayexalate will exit the market once ZS-9 and Patiromer enter.** The current standard of care, kayexalate, is not only limited in its efficacy and leads to significant GI side effects, but it has not been tested in clinical trials. Furthermore, the FDA has actually advised against prescribing kayexalate in the form most physicians prescribe it for hyperkalemia, alongside sorbitol, because of the potential for the concomitant use to cause intestinal necrosis, which could be fatal. No physician wants to take the unnecessary risk of fatal complications from an untested and advised-against treatment.
4. **Doctor comments that ZS Pharma has the more robust data set.** Based on number of patients exposed to treatment, our panel noted ZS Pharma has conducted a much more extensive clinical development program when compared with Relypsa's. According to the panel, ZS Pharma will have more than 1,400 patients exposed to ZS-9 when its NDA is filed with the FDA, which is due to happen any day now, while Relypsa has approximately 300 patient exposures in its FDA briefing document according to the panel.
5. **The panel agreed the majority, if not all, acute treatment for hyperkalemia will eventually transition to ZS-9 based on fast onset of action.** Our panel of physicians called attention several times to the data that shows ZS-9 reliably and effectively begins working within one hour, and brings 80% of patients into normal potassium levels within four hours. They noted the dire importance of a quick onset in situations where patients' potassium levels are severely high and could lead to cardiac arrest and death if not treated immediately. Patiromer is not as highly selective for potassium as ZS-9 and therefore does not begin to absorb high levels of potassium until it reaches the high concentration in the colon, which can take hours.
6. **A hidden upside – ZS-9 prevents acidosis?** Although the clinical significance has not yet been tested, our physician panel noted the data so far shows ZS-9 raised the bicarbonate levels in patients' blood, which lowers the acidity of the blood. Acidosis is known to increase the progression of kidney disease, so protecting against it by

increasing bicarbonate levels with ZS-9 could potentially delay the progression of chronic kidney disease and delay heart failure.

7. **Side effect profile is favorable for ZS Pharma's ZS-9.** The panel noted the data shows higher instances of GI side effects in patients treated with Patiromer than those treated with ZS-9. The panel noted the presentation of these side effects may lead to some physicians switching their chronic patients to ZS-9 from Patiromer, although they noted that, if they were well controlled, switching may not happen dramatically, although it may drive new starts to ZS-9. However, in the acute setting, the doctors seemed to favor ZS-9's side effect profile.
8. **ZS-9 will claim the majority of the hyperkalemia market.** Our panel suggested that if price, coverage, and ease of prescription are similar between ZS-9 and Patiromer, the market will likely go mostly to ZS-9. While acute treatment will nearly all go to ZS-9, the panel noted overall chronic and acute use will be approximately 75%-80% ZS-9 and the rest will be left to Patiromer. The panel noted that, while there will be a portion of doctors who do not adopt novel treatments quickly, the likelihood is that eventually kayexalate will be abandoned by physicians and exit the market.
9. **ZS-9 will benefit from the current healthcare trend of reducing invasive treatments and preventing avoidable hospitalization.** The current standard of care for patients with severely high potassium levels is expensive and is invasive dialysis to remove the potassium from the blood or hospitalization to treat with kayexalate. ZS-9 presents an alternative to a significant cost burden in the CNS space in that it prevents hospitalization and reduces the need for emergent dialysis. **Our panel noted there is high potential the majority of acute treatment of severe hyperkalemia will move to an outpatient setting due to ZS-9.**
10. **Our conviction that ZS-9 is the drug to beat in hyperkalemia is stronger than ever.** Our discussion with our expert physician panel further strengthened our confidence in ZS-9 as the drug to beat in the hyperkalemia market. If approved, Relypsa's Patiromer could have nearly a year head start, and the advantage of being the first mover. That said, we believe the profile of ZS-9, especially the fast onset and strong efficacy, will tip the balance in ZS Pharma's favor over time.

Model Changes

We have updated our model following the filing of the company's 10-K, as well as the completion of the secondary offering in which the company sold approximately 4 million shares at \$46.25 a share, resulting in aggregate proceeds to the company of approximately \$185.7 million. We have also changed our DCF to a 2015 base year and lowered our discount rate to 10% from 12% to account for what we now consider to be a lowered risk profile given the recent secondary that should provide enough cash through the launch, and the recent data, which provides confidence in the drug's profile. We note to investors that we are not yet attributing any value in our valuation for ex-US rights, which could be sizable, and our terminal multiple remains 8x, even though sector averages are substantially higher. Our DCF-derived price remains \$54. Our new EPS estimates are listed in Exhibit 1.

Exhibit 1: ZSPH EPS Estimates

	2015	2016	2017	2018
BMO New	(\$2.78)	(\$2.63)	\$0.17	\$3.23
BMO Previous	(\$2.85)	(\$2.66)	\$0.18	\$3.30
Consensus	(\$4.89)	(\$0.65)	\$4.83	\$11.25

Source: Company Reports, BMO Capital Markets

Companies mentioned (priced as of the close on April 30, 2015):

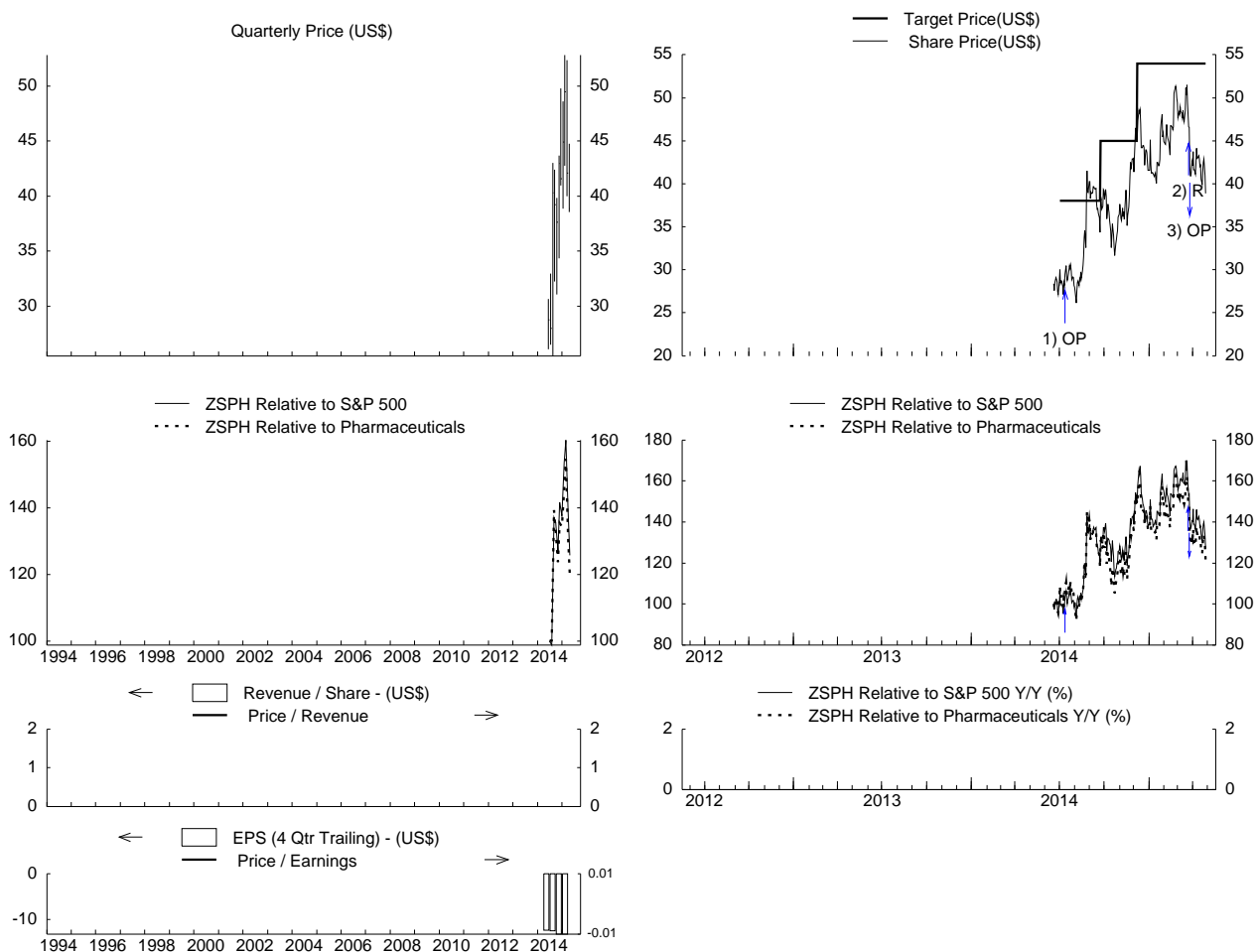
Relypsa (RLYP \$28.93, Not Rated)

Exhibit 2: ZSPH Income Statement (\$ in millions, except per share data)

ZS Pharma Income Statement	2014A	2015E	2016E	2017E	2018E	2019E	2020E
Total revenues	\$0.0	\$0.0	\$17.4	\$136.4	\$269.0	\$392.4	\$481.9
<i>% growth</i>					97.3%	45.9%	22.8%
COGS	\$0.0	\$0.0	\$3.5	\$27.0	\$46.1	\$54.5	\$65.9
<i>COGS as % of US sales</i>			20.0%	20.0%	18.0%	15.0%	15.0%
Gross profit	\$0.0	\$0.0	\$13.9	\$109.4	\$222.9	\$337.9	\$416.1
<i>Gross margin</i>			80.0%	80.2%	82.9%	86.1%	86.3%
R&D	\$45.6	\$36.0	\$20.0	\$20.2	\$25.6	\$36.3	\$41.7
<i>R&D as % of US sales</i>			114.9%	15.0%	10.0%	10.0%	9.5%
S&M	\$0.0	\$12.0	\$33.0	\$45.9	\$64.1	\$80.0	\$91.1
<i>S&M as % of US sales</i>			189.5%	34.1%	25.0%	22.0%	20.8%
G&A	\$14.9	\$20.0	\$20.0	\$24.0	\$10.3	\$14.5	\$17.6
<i>G&A as % of US sales</i>			114.9%	17.8%	4.0%	4.0%	4.0%
Royalties			\$5.8	\$12.2	\$21.2	\$31.8	\$43.6
Operating profit	(\$60.5)	(\$68.0)	(\$64.8)	\$7.1	\$101.8	\$175.2	\$222.0
<i>Operating margin</i>				5.2%	37.8%	44.7%	46.1%
Interest expense (income)	(\$0.1)	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8	\$0.8
Other expense (income)	\$3.6	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0
Pretax income	(\$64.0)	(\$69.8)	(\$66.6)	\$5.3	\$100.0	\$173.4	\$220.3
<i>Pretax margin</i>				3.9%	37.2%	44.2%	45.7%
Taxes	\$0.0	\$0.0	\$0.0	\$0.8	\$15.0	\$26.0	\$66.1
<i>Tax rate</i>	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	30.0%
Net income	(\$64.0)	(\$69.8)	(\$66.6)	\$4.5	\$85.0	\$147.4	\$154.2
Preferred stock accretion	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net income to common stockholders	(\$64.4)	(\$69.8)	(\$66.6)	\$4.5	\$85.0	\$147.4	\$154.2
<i>Net margin</i>				3.3%	31.6%	37.6%	32.0%
Shares out (diluted)	11.8	25.1	25.4	26.3	26.3	26.3	26.4
Earnings per share	(\$5.47)	(\$2.78)	(\$2.63)	\$0.17	\$3.23	\$5.60	\$5.85

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 %
2014	-5.50	na na	0.00	0.0 0.0	0	ND	>15 >15	
Range*		na na		0.0 0.0			>15 >15	
Current*	-13.11	na	0.00	0.0	0	1.2	36.3	na

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

Date	Rating Change	Share Price
1 11-Jul-14	NR to OP	\$29.49
2 23-Mar-15	OP to R	\$46.65
3 25-Mar-15	R to OP	\$42.00

* Current EPS is the 4 Quarter Trailing to Q4/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (April 27, 2015): \$38.87
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

IMPORTANT DISCLOSURES**Analyst's Certification**

I, David Maris, hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities or issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Analysts who prepared this report are compensated based upon (among other factors) the overall profitability of BMO Capital Markets and their affiliates, which includes the overall profitability of investment banking services. Compensation for research is based on effectiveness in generating new ideas and in communication of ideas to clients, performance of recommendations, accuracy of earnings estimates, and service to clients.

Analysts employed by BMO Nesbitt Burns Inc. and/or BMO Capital Markets Limited are not registered as research analysts with FINRA (exceptions: Alex Arfaei and Brodie Woods). These analysts may not be associated persons of BMO Capital Markets Corp. and therefore may not be subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

Company Specific Disclosure

Disclosure 1: BMO Capital Markets has undertaken an underwriting liability with respect to this issuer within the past 12 months.

Disclosure 2: BMO Capital Markets has provided investment banking services with respect to this issuer within the past 12 months.

Disclosure 3: BMO Capital Markets has managed or co-managed a public offering of securities with respect to this issuer within the past 12 months.

Disclosure 4: BMO Capital Markets or an affiliate has received compensation for investment banking services from this issuer within the past 12 months.

Disclosure 6: This issuer is a client (or was a client) of BMO NB, BMO Capital Markets Corp., BMO CM Ltd. or an affiliate within the past 12 months: Investment Banking Services.

Disclosure 9: BMO Capital Markets makes a market in this security.

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 (March 31, 2015)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	43.7%	18.6%	58.2%	42.7%	55.5%	54.1%
Hold	Market Perform	51.4%	10.4%	38.5%	52.1%	41.9%	40.5%
Sell	Underperform	4.9%	9.4%	3.3%	5.2%	2.6%	5.5%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

** Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage within ratings category.

*** Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage of Investment Banking clients.

**** Reflects rating distribution of all companies covered by BMO Capital Markets equity research analysts.

***** Reflects rating distribution of all companies from which BMO Capital Markets has received compensation for Investment Banking services as percentage of Investment Banking clients.

Rating and Sector Key (as of April 5, 2013):

We use the following ratings system definitions:

OP = Outperform - Forecast to outperform the analyst's coverage universe on a total return basis

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).

Prior BMO Capital Markets Ratings System (January 4, 2010–April 4, 2013):

http://researchglobal.bmocapitalmarkets.com/documents/2013/prior_rating_system.pdf

Other Important Disclosures

For Other Important Disclosures on the stocks discussed in this report, please go to http://researchglobal.bmocapitalmarkets.com/Public/Company_Disclosure_Public.aspx or write to Editorial Department, BMO Capital Markets, 3 Times Square, New York, NY 10036 or Editorial Department, BMO Capital Markets, 1 First Canadian Place, Toronto, Ontario, M5X 1H3.

Dissemination of Research

BMO Capital Markets Equity Research is available via our website <https://research-ca.bmocapitalmarkets.com/Public/Secure/Login.aspx?ReturnUrl=/Member/Home/ResearchHome.aspx>. Institutional clients may also receive our research via Thomson Reuters, Bloomberg, FactSet, and Capital IQ. Research reports and other commentary are required to be simultaneously disseminated internally and externally to our clients.

General Disclaimer

BMO Capital Markets” is a trade name used by the BMO Investment Banking Group, which includes the wholesale arm of Bank of Montreal and its subsidiaries BMO Nesbitt Burns Inc., BMO Capital Markets Limited in the U.K. and BMO Capital Markets Corp. in the U.S. BMO Nesbitt Burns Inc., BMO Capital Markets Limited and BMO Capital Markets Corp are affiliates. Bank of Montreal or its subsidiaries (“BMO Financial Group”) has lending arrangements with, or provide other remunerated services to, many issuers covered by BMO Capital Markets. The opinions, estimates and projections contained in this report are those of BMO Capital Markets as of the date of this report and are subject to change without notice. BMO Capital Markets endeavours to ensure that the contents have been compiled or derived from sources that we believe are reliable and contain information and opinions that are accurate and complete. However, BMO Capital Markets makes no representation or warranty, express or implied, in respect thereof, takes no responsibility for any errors and omissions contained herein and accepts no liability whatsoever for any loss arising from any use of, or reliance on, this report or its contents. Information may be available to BMO Capital Markets or its affiliates that is not reflected in this report. The information in this report is not intended to be used as the primary basis of investment decisions, and because of individual client objectives, should not be construed as advice designed to meet the particular investment needs of any investor. This material is for information purposes only and is not an offer to sell or the solicitation of an offer to buy any security. BMO Capital Markets or its affiliates will buy from or sell to customers the securities of issuers mentioned in this report on a principal basis. BMO Capital Markets or its affiliates, officers, directors or employees have a long or short position in many of the securities discussed herein, related securities or in options, futures or other derivative instruments based thereon. The reader should assume that BMO Capital Markets or its affiliates may have a conflict of interest and should not rely solely on this report in evaluating whether or not to buy or sell securities of issuers discussed herein.

Additional Matters

To Canadian Residents: BMO Nesbitt Burns Inc. furnishes this report to Canadian residents and accepts responsibility for the contents herein subject to the terms set out above. Any Canadian person wishing to effect transactions in any of the securities included in this report should do so through BMO Nesbitt Burns Inc.

The following applies if this research was prepared in whole or in part by David Round, Edward Sterck or Brendan Warn: This research is not prepared subject to Canadian disclosure requirements. This research is prepared by BMO Capital Markets Limited and subject to the regulations of the Financial Conduct Authority (FCA) in the United Kingdom. FCA regulations require that a firm providing research disclose its ownership interest in the issuer that is the subject of the research if it and its affiliates own 5% or more of the equity of the issuer. Canadian regulations require that a firm providing research disclose its ownership interest in the issuer that is the subject of the research if it and its affiliates own 1% or more of the equity of the issuer that is the subject of the research. Therefore BMO Capital Markets Limited will disclose its and its affiliates’ ownership interest in the subject issuer only if such ownership exceeds 5% of the equity of the issuer.

To U.S. Residents: BMO Capital Markets Corp. furnishes this report to U.S. residents and accepts responsibility for the contents herein, except to the extent that it refers to securities of Bank of Montreal. Any U.S. person wishing to effect transactions in any security discussed herein should do so through BMO Capital Markets Corp.

To U.K. Residents: In the UK this document is published by BMO Capital Markets Limited which is authorised and regulated by the Financial Conduct Authority. The contents hereof are intended solely for the use of, and may only be issued or passed on to, (I) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (II) high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together referred to as “relevant persons”). The contents hereof are not intended for the use of and may not be issued or passed on to retail clients.

Unauthorized reproduction, distribution, transmission or publication without the prior written consent of BMO Capital Markets is strictly prohibited.

[Click here](#) for data vendor disclosures when referenced within a BMO Capital Markets research document.

ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

BMO Financial Group (NYSE, TSX: BMO) is an integrated financial services provider offering a range of retail banking, wealth management, and investment and corporate banking products. BMO serves Canadian retail clients through BMO Bank of Montreal and BMO Nesbitt Burns. In the United States, personal and commercial banking clients are served by BMO Harris Bank N.A. (Member FDIC). Investment and corporate banking services are provided in Canada and the US through BMO Capital Markets.

BMO Capital Markets is a trade name used by BMO Financial Group for the wholesale banking businesses of Bank of Montreal, BMO Harris Bank N.A. (Member FDIC), BMO Ireland Plc, and Bank of Montreal (China) Co. Limited and the institutional broker dealer businesses of BMO Capital Markets Corp. (Member SIPC) and BMO Capital Markets GKST Inc. (Member SIPC) in the U.S., BMO Nesbitt Burns Inc. (Member Canadian Investor Protection Fund) in Canada, Europe and Asia, BMO Capital Markets Limited in Europe and Australia, and BMO Advisors Private Limited in India.

Nesbitt Burns® is a registered trademark of BMO Nesbitt Burns Corporation Limited, used under license. "BMO Capital Markets" is a trademark of Bank of Montreal, used under license. "BMO (M-Bar roundel symbol)" is a registered trademark of Bank of Montreal, used under license.

® Registered trademark of Bank of Montreal in the United States, Canada and elsewhere.

TM Trademark Bank of Montreal

©COPYRIGHT 2015 BMO CAPITAL MARKETS CORP

A member of BMO  Financial Group
