Zacks Small-Cap Research

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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: KOLs Highlight Necessity For Effective Hip Fracture Treatment; Positive Results From Long-Term In Vivo *Study of VK0214 in X-ALD Model…*

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $7/share. This model is highly dependent upon continued clinical success of those compounds and will be adjusted accordingly based upon future clinical results.

Current Price (10/11/17)	$2.28
Valuation	**$7.00**

OUTLOOK

On October 9, 2017, Viking Therapeutics, Inc. (VKTX) hosted a Key Opinion Leader (KOL) event to discuss how VK5211 may fit into the treatment paradigm for those suffering from hip fracture. Included in the event was an overview of VK5211's discovery and early clinical data, an overview of the hip fracture market, the lack of effective treatments for osteoporosis, and what endpoints the FDA finds acceptable for interventional studies in sarcopenia and hip fracture. Viking held this event in preparation for data from a Phase 2 study of VK5211, which is expected later in the fourth quarter of 2017.

Viking also recently announced positive data from a long term *in vivo* study of VK0214 in a mouse model of X-linked adrenoleukodystrophy (X-ALD), with statistically significant reductions in levels of very long chain fatty acids (VLCFAs) in plasma and key tissues.

SUMMARY DATA

52-Week High	**$2.28**
52-Week Low	**$0.93**
One-Year Return (%)	**78.13**
Beta	**1.50**
Average Daily Volume (sh)	**615,470**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$65**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**20**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**-0.9**
P/E using 2017 Estimate	**-1.1**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 E	0 E	0 E
2018					0 E
2019					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.40 A	- $0.22 A	-$0.20 A	-$0.18 A	-$0.90 A
2017	-$0.23 A	-$0.21 A	-$0.19 E	-$0.19 E	-$0.81 E
2018					-$0.72 E
2019					-$0.70 E

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WHAT'S NEW

Business Update

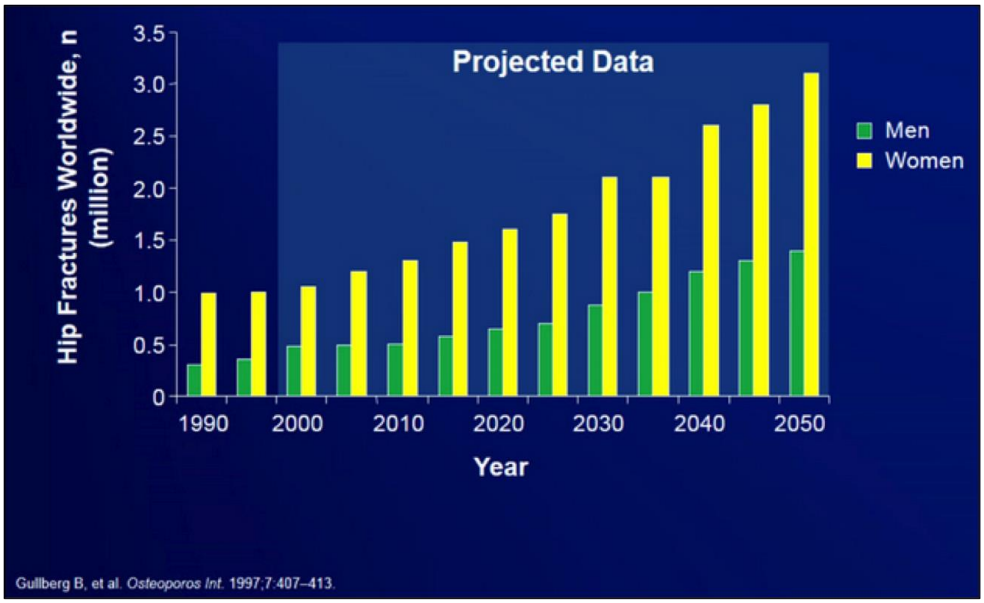
KOLs Highlight Necessity For Effective Post-Hip Fracture Treatment

On October 9, 2017, Viking Therapeutics, Inc. (VKTX) hosted a key opinion leader (KOL) event that featured presentations on VK5211 as well as the hip fracture market, the lack of effective osteoporosis treatments, and regulatory outcomes for therapies targeting sarcopenia and hip fracture.

VK5211 is a third-generation non-steroidal Selective Androgen Receptor Modulator (SARM) that is being developed for maintenance or improvement of lean body mass (LBM), bone mineral density (BMD), and function in patients recovering from non-elective hip fracture surgery. For a detailed overview of VK5211, please see our previous report.

Hip Fracture Overview

Dr. Jay Magaziner, Professor and Chair of Epidemiology and Biostatistics at the University of Maryland School of Medicine, gave an overview of the hip fracture market. According to Dr. Magaziner, there are approximately 1.6 million hip fractures each year worldwide. In the U.S., 285,000 individuals are hospitalized each year for hip fracture, with three-quarters of those patients being women. The number of hip fractures is expected to grow considerably due to the aging population. As the following figure shows, by 2050 it is estimated that 3.9 million hip fractures will occur worldwide, with 700,000 of those occurring in the U.S.

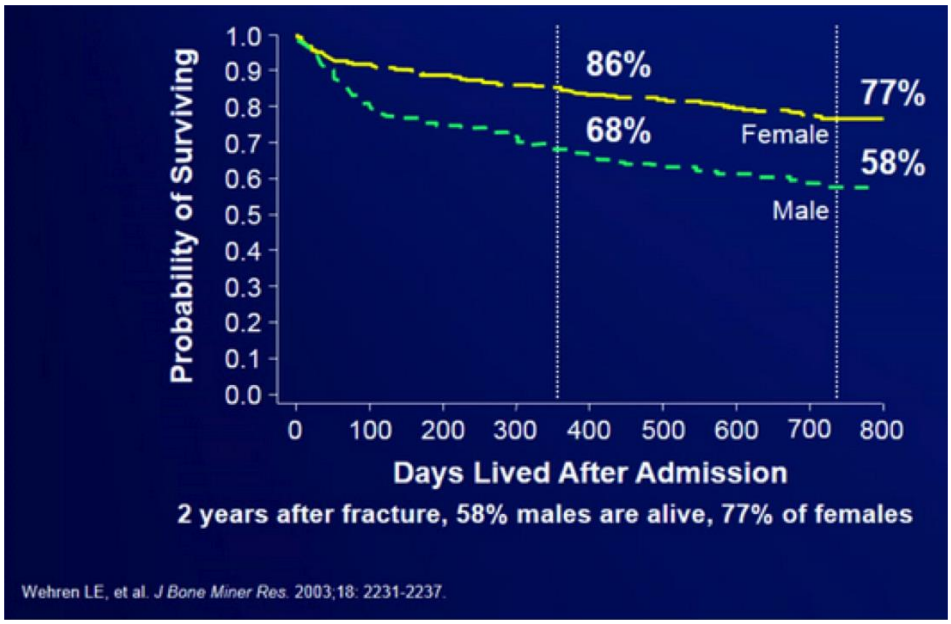


Source: Magaziner, 2017

Dr. Magaziner discussed a number of serious consequences of hip fracture, including:

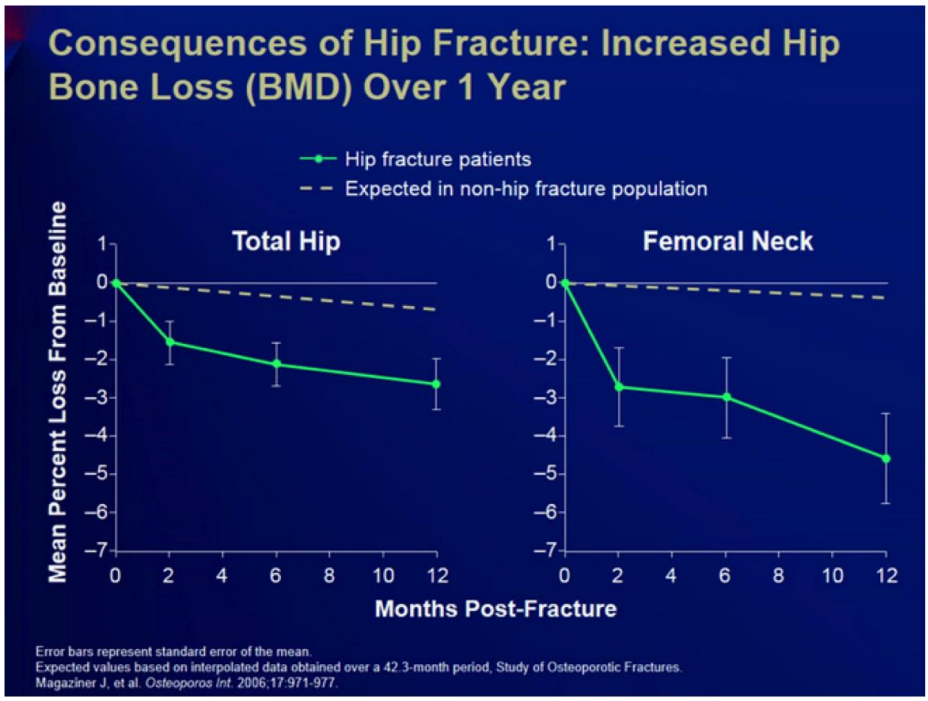
- 18-33% mortality rate within 1 year
- 15-25% end up in an institution for one or more years
- 25-75% do not regain pre-fracture function
- Unspecified burden placed on patients, their families, and health care systems

The increase in mortality is the most alarming consequence of hip fracture. As the following graph shows, two years after a hip fracture only 58% of men and 77% of women are alive, representing a substantially increased risk of death.



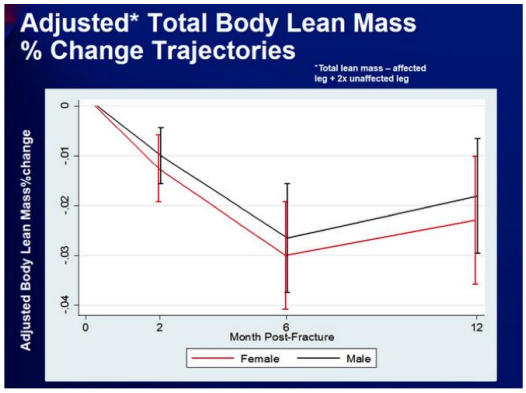
Source: Magaziner, 2017

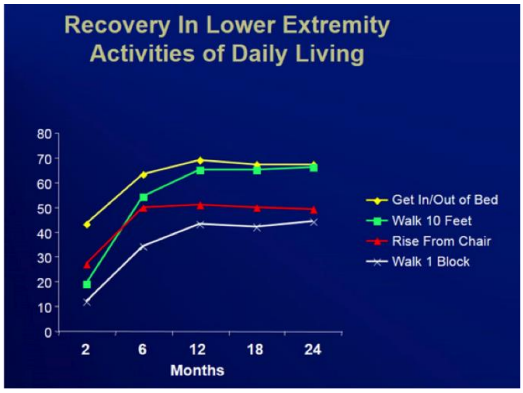
Dr. Magaziner also discussed the Baltimore Hip Studies, which over the past 30 years have followed more than 4,000 hip fracture patients in 25 Baltimore-area hospitals. The studies have included both outcome studies, which followed patients to examine such things as mortality, function, and bone and muscle strength, as well as interventional studies that tested various treatment options. The following charts show that following a hip fracture, there is increased bone loss (BMD) in those patients compared to what would be expected for patients of a similar age.



Source: Magaziner, 2017

This loss in BMD is accompanied by a loss of lean body mass, with the end result being that most patients do not regain full recovery to enable them to perform basic tasks, as shown in the following two figures.





Source: Magaziner, 2017

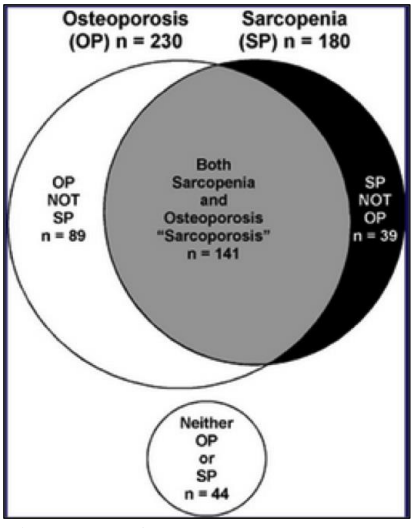
In summary, the number of hip fractures occurring each year is expected to continue rising and the burden that is placed on these patients, their families, and the health care system is significant. Hip fracture patients have an increased risk of mortality and many patients are not able to resume similar activities they could perform before the accident.

Osteoporosis Treatment in Crisis

Dr. Neil Binkley, a Professor in the Department of Medicine and Co-Director of the Osteoporosis Clinical Center and Research Program at the University of Wisconsin School of Medicine and Public Health, gave a presentation on the state of current treatment options for osteoporosis and those who suffer an osteoporotic fracture (e.g., hip fracture). He began his talk by stating that fewer than 10% of patients with hip fracture receive an osteoporotic treatment for it. This is in stark contrast to patients who suffer from other ailments, for example patients who have a myocardial infarction are prescribed a wide range of medications (e.g., statins, anti-hypertensives, anti-clotting agents, etc.). Dr. Binkley believes that the failure to treat patients following hip fracture has to do with patient and provider fears of osteoporosis drug side effects, and that new treatment options are needed.

As opposed to considering a fracture part of the normal aging process or simply indicative of an accident, Dr. Binkley believes that fracture may be indicative of underlying osteoporosis that needs to be treated. In addition, considering only bone likely will lead to missing a number of patients that should be treated as fewer than half of women (and only 21% of men) who sustain non-vertebral fractures have “osteoporosis” as determined by bone mineral density.

Dr. Binkley also discussed risk factors for hip fracture, with over 90% of hip fractures due to falls. Risk factors for falls include indicators of impaired activity, including self reported physical activity and slower walking speed. Thus, sarcopenia (loss of muscle) and impaired function with resultant falls is what most accurately predicts risk for hip fracture. The following graph shows that there is a significant association between those with both sarcopenia and osteoporosis and those that suffer a hip fracture.



Source: Adapted from Di Monaco *et al.*, 2011

In conclusion, Dr. Binkley believes that to focus solely on bone health in the prevention and treatment of fracture is improper, but instead the treatment of hip fractures (and osteoporosis) should focus on both muscle and bone health. This supports the idea of using VK5211 to treat hip fracture (and potentially even patients with osteoporosis) as it both increases muscle mass and bone mineral density.

Positive Results From In Vivo Study of VK0214

On October 4, 2017, Viking announced positive results from a 25-week proof-of-concept study of VK0214 in an in vivo model of X-linked adrenoleukodystrophy (X-ALD). For a detailed review of the scientific rationale for using VK0214 in X-ALD, please see our previous report.

The results of this study showed that treatment with VK0214 resulted in statistically significant reductions in the levels of very long chain fatty acids (VLCFAs) in both plasma and key tissues, including liver, brain, and spinal cord. There were effects on multiple VLCFAs, including C26, C24, C22, and C20 that included decreases of 45% to 82% relative to controls. The reductions were maintained or even increased over the course of the 25-week treatment period. Since elevated levels of VLCFAs likely contribute to the pathophysiology of X-ALD, the decrease in VLCFAs seen in brain in spinal cord is particularly relevant and may suggest a potential therapeutic benefit. The results will be presented at the 87th Annual Meeting of the American Thyroid Association, which is taking place from October 18-22 in Victoria, British Colombia.

Financial Update

On September 29, 2017, Viking announced a $15 million common stock purchase agreement with Lincoln Park Capital Fund. Under the agreement, Viking will have the right to sell to Lincoln Park up to $15 million worth of common stock over a 30-month period. Under a separate purchase agreement, Lincoln Park purchased $1.25 million of Viking stock for $1.78 per share, which was a 14% premium to the closing price on Sep. 27, 2017. This agreement gives the company added financial flexibility with potential future access to capital at favorable terms.

Conclusion

The KOL event hosted by Viking offered a comprehensive overview of VK5211 and the hip fracture market and we encourage Viking investors to view the entire event, which can be accessed here. VK5211 has a number of positive attributes that could lead it to be a blockbuster treatment for those suffering a hip fracture and we are looking forward to reviewing the results of the Phase 2 trial later in the fourth quarter of 2017. Assuming a positive outcome, Viking would then meet with the FDA in 2018 to determine a plan for pivotal Phase 3 trials, including the number of patients and outcomes.

Viking's stock price has risen over 100% over the past month, however we continue to believe the company is undervalued and that there is considerable upside left for investors heading into the release of Phase 2 data for VK5211 in the fourth quarter of 2017 and VK2809 in the first half of 2018. Our current valuation is $7.00 per share.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 E
VK5211 (Hip Fracture)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK2809 (Hypercholesterolemia)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK0214 (ALD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$9.0	$3.5	$3.7	$3.7	$3.8	$14.7	$16.0	$18.0
General & Administrative	$4.8	$1.4	$1.3	$1.3	$1.3	$5.3	$5.7	$6.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.8)	($5.0)	($5.0)	($5.0)	($5.1)	($20.1)	($21.7)	($24.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	($0.3)	($0.2)	($0.1)	($0.1)	($0.6)	($0.5)	($0.6)
Pre-Tax Income	($14.7)	($5.22)	($5.17)	($5.1)	($5.2)	($20.7)	($22.2)	($24.6)
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.7)**	**($5.2)**	**($5.2)**	**($5.1)**	**($5.2)**	**($20.7)**	**($22.2)**	**($24.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.90)**	**($0.23)**	**($0.21)**	**($0.19)**	**($0.19)**	**($0.81)**	**($0.72)**	**($0.70)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.278	22.353	24.119	27.500	28.000	25.493	31.000	35.000

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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HISTORICAL STOCK PRICE



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