Zacks Small-Cap Research

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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Poster Presentations on VK2809 and VK0214 Highlight Positive Preclinical Data for Both Compounds…

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 (10/26/17)	$2.76
Valuation	**$7.00**

OUTLOOK

Viking Therapeutics, Inc. (VKTX) recently presented preclinical data on VK2809 and VK0214 at scientific conferences.

VK2809 was assessed in a mouse model of biopsy-confirmed diet-induced non-alcoholic steatohepatitis (NASH). Results showed statistically significant improvements in several key measures relevant to the development and progression of NASH. We anticipate topline data from the Phase 2 study of VK2809 in patients with NAFLD and hypercholesterolemia in 1H18. If positive, we would expect future studies to target NASH.

VK0214 was assessed in a long-term *in vivo* study in a mouse model of X-linked adrenoleukodystrophy (X-ALD). Results showed a statistically significant reduction in levels of very long chain fatty acids (VLCFAs) in plasma and key tissues, including the liver, brain, and spinal cord. The reduction of VLCFAs is thought to be a promising therapeutic target, thus the results presented by Viking are very encouraging and fully support the initiation of a human proof-of-concept study of VK0214.

SUMMARY DATA

52-Week High	**$3.00**
52-Week Low	**$0.93**
One-Year Return (%)	**162.86**
Beta	**1.50**
Average Daily Volume (sh)	**1,272,120**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$79**
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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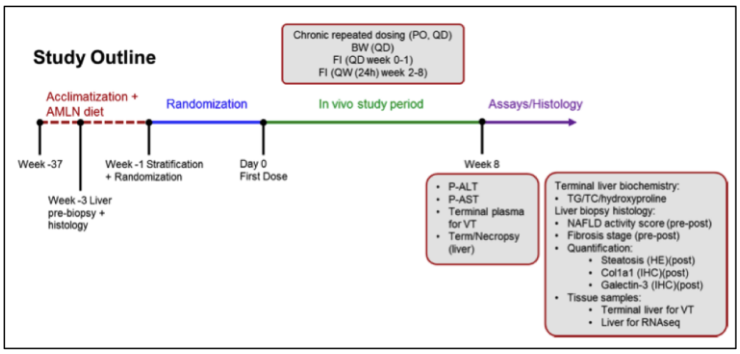
WHAT'S NEW

Business Update

Full Data Set for VK2809 in Diet-Induced NASH Model Presented at AASLD

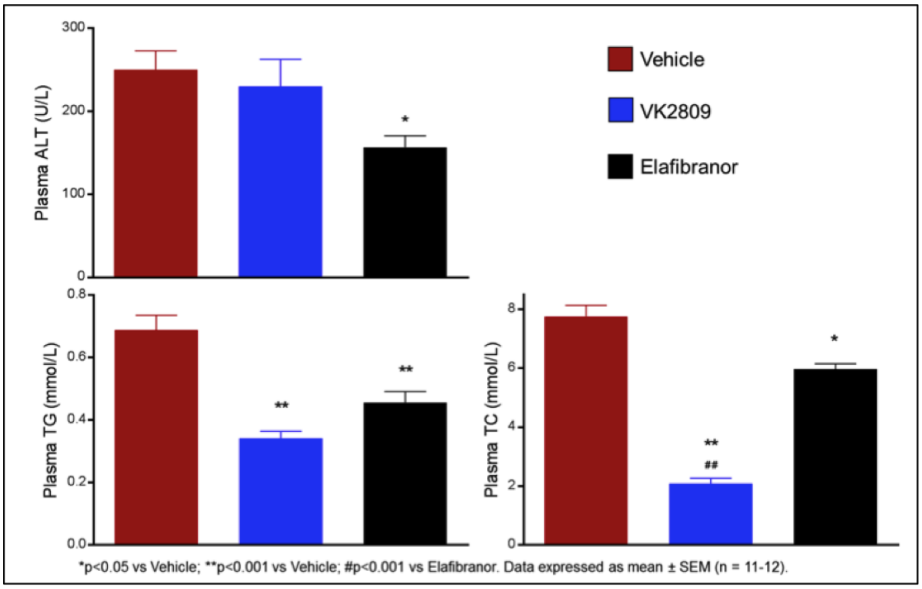
On October 24, 2017, Viking Therapeutics, Inc. (VKTX) announced the presentation of results from a study of VK2809 in an *in vivo* model of non-alcoholic steatohepatitis (NASH). Statistically significant improvements in a number of key measures were seen during the study and gene expression analysis showed statistically significant changes in expression for genes associated with the development and progression of NASH.

Male wild-type C57BL/6J mice were maintained on a high fat diet for 37 weeks prior to initiation of the study. Liver biopsies were performed and the mice were stratified according to steatosis score and fibrosis stage. Treatment with once daily vehicle control, 30 mg/kg elafibranor (active control), or 10 mg/kg VK2809 continued for eight weeks while continuing the high fat diet. At the end of the study, plasma and liver lipids, liver steatosis, collagen, fibrosis, and hydroxyproline content as well as NAFLD activity score (NAS) were all evaluated. RNAseq analysis was performed on liver samples. An outline of the study is provided below.



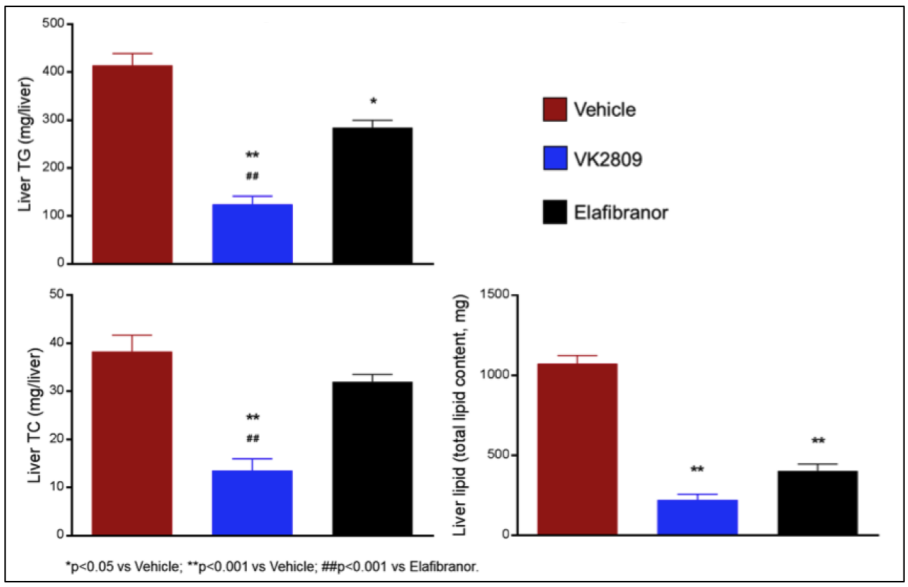
Source: Lian *et al*., 2017

Similar to what was seen in previous studies of VK2809, there was a significant decrease in plasma triglycerides (-50%) and plasma cholesterol (-73%) for mice treated with VK2809 compared to vehicle control. There was also a statistically significant decrease in plasma cholesterol for mice treated with VK2809 compared to elafibranor. There was no significant difference in plasma ALT levels for VK2809-treated mice.



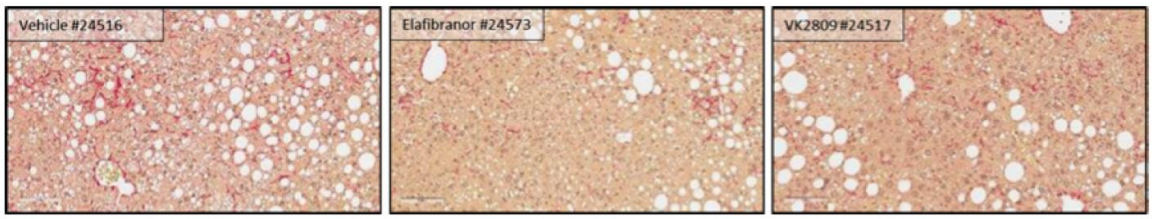
Source: Lian *et al*., 2017

In addition, levels of liver triglycerides (-70%), liver total cholesterol (-65%) and liver total lipid content (-80%) were all significantly lower in mice treated with VK2809 compared to vehicle control mice. The difference in liver triglycerides and liver cholesterol was also significant between VK2809- and elafibranor-treated mice.



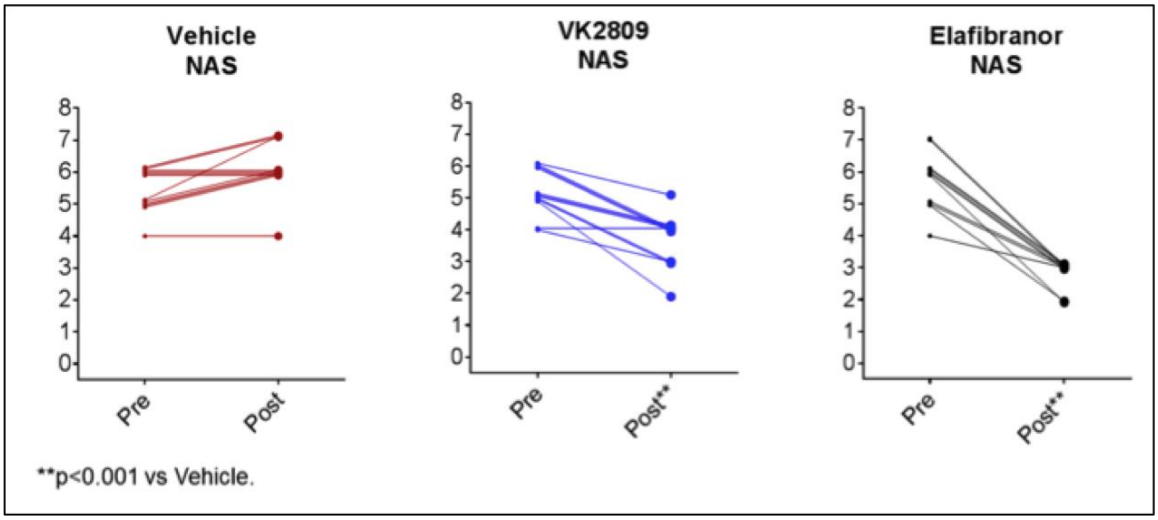
Source: Lian *et al.*, 2017

There was 50% less liver fibrosis in VK2809-treated mice compared to vehicle control-treated mice, as assessed by quantitative histological assessment of picrosirius red stain. The following figures show the level of fibrosis (red areas) in liver sections after eight weeks of treatment.



Source: Lian *et al.*, 2017

Lastly, the changes seen in lipid content and fibrosis translated to improvements in the NAFLD Activity Score (NAS) for mice treated with both VK2809 and elafibranor.

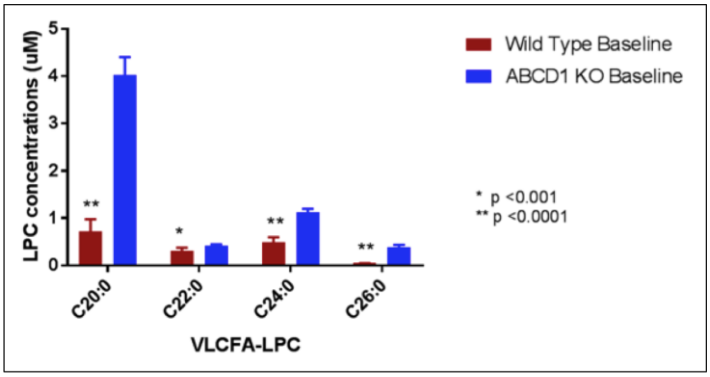


Source: Lian *et al.*, 2017

VK0214 Shows Promise in Treating X-ALD

On Oct. 23, 2017, Viking announced results from a 25-week proof-of-concept study of VK0214 in an *in vivo* model of X-linked adrenoleukodystrophy (X-ALD) were presented at the 87th Annual Meeting of the American Thyroid Association. Treatment with VK0214 led to statistically significant reductions in plasma levels of very long chain fatty acids (VLCFAs) compared to vehicle controls. There was also a reduction seen in brain and spinal cord VLCFAs, an exciting observation as those tissues are especially prone to degeneration in X-ALD.

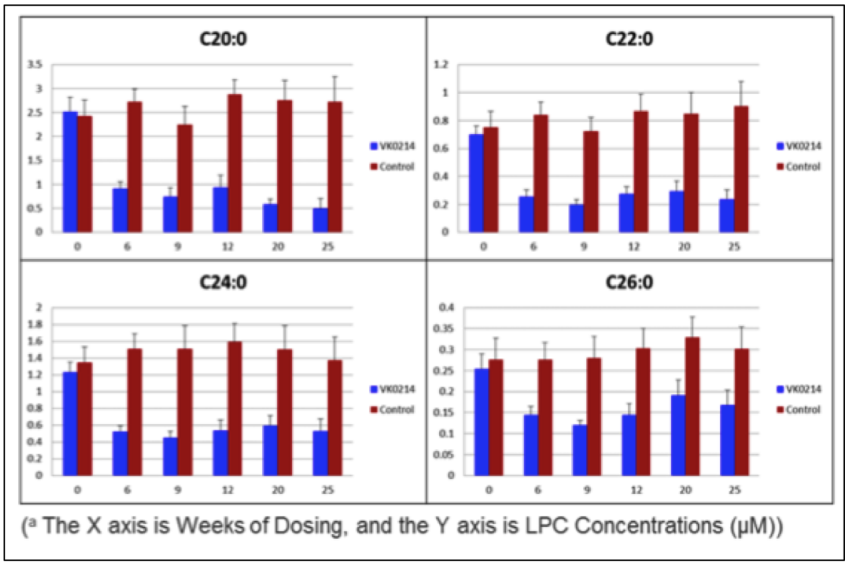
The study used the *Abcd1* knock-out (KO) mouse model, which while not displaying the inflammatory characteristics of the more severe forms of X-ALD, does recapitulate a phenotype similar to those with adrenomyeloneuropathy (AMN), the less severe form of X-ALD. As shown in the following figure, *Abcd1*$^{-/-}$ mice have elevated levels of VLCFAs compared to wildtype mice.



Source: Masamune *et al.*, 2017

Patients with X-ALD have a mutation(s) in the *ABCD1* gene that renders its product, the adrenoleukodystrophy protein (ALDP), non-functional. ALDP is responsible for transporting VLCFAs into peroxisomes for degradation, thus without proper ALDP function the VLCFAs accumulate to toxic levels. The theory behind using VK0214 to treat X-ALD is that it induces the expression of ALDR (encoded by the *ABCD2* gene), which is also a VLCFA transporter, thus compensating for the loss of ALDP.

The following charts show the level of VLCFAs over the course of the 25-week study. Treatment with VK0214 results in a dramatic decrease in VLCFA levels only six weeks after initiating treatment, and this decline is held relatively steady through the entire 25-week treatment period.



Source: Masamune *et al.*, 2017

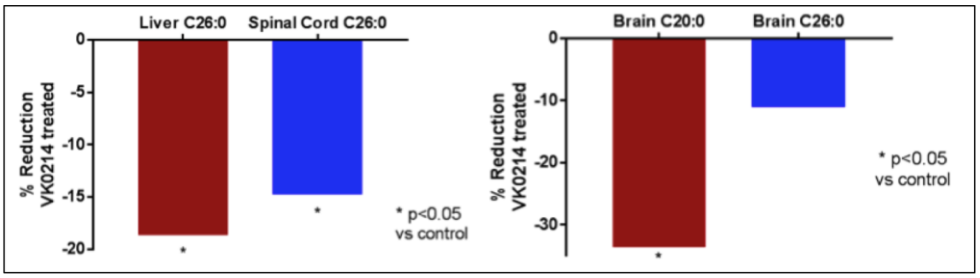
The following table shows that the greatest reductions in VLCFA levels were for shorter chain lengths, as C20:0, C22:0, and C24:0 VLCFAs showed progressive declines from week 12 to week 25, while levels of C26:0 were similar between week 12 and week 25.

VLCA-LPC Subtype	12 Weeks	25 Weeks
C26:0-LPC	-48%	-45%
C24:0-LPC	-51%	-61%
C22:0-LPC	-55%	-74%
C20:0-LPC	-57%	-82%

[a] All values statistically significant (p<0.0001) over control values

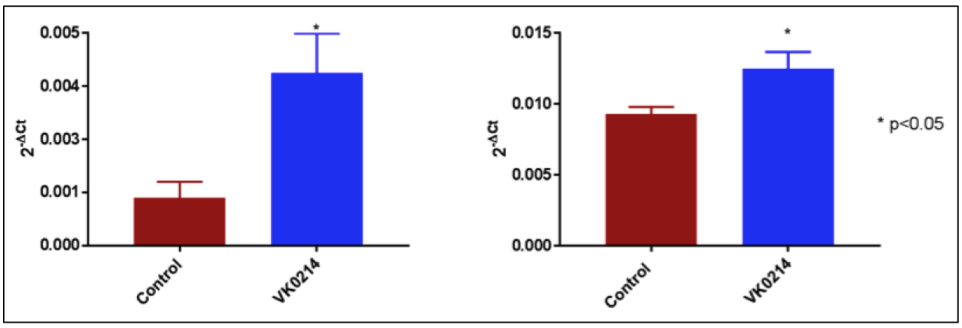
Source: Masamune *et al.*, 2017

Perhaps most importantly, tissue levels of VLCFAs were shown to be lower in mice treated with VK0214 compared to mice treated with vehicle control. The following figure shows there was a statistically significant decrease in the level of C26:0 in both the liver and spinal cord. In addition, in the brain there was a statistically significant decrease in C20:0 and an 11% decrease in C26:0 that trended toward significance (*P*=0.07).



Source: Masamune *et al.*, 2017

Lastly, as would be expected, and supporting the theory behind the use of VK0214 for treating X-ALD, there was a significant increase in the expression of the *Abcd2* gene in both the liver and the cortex.



Source: Masamune *et al.*, 2017

Conclusion

The data presented by Viking for both VK2809 and VK0214 provides nice support to each program. For VK2809, it is clear that the drug is highly effective at altering plasma lipid levels and it is encouraging to see a change in liver lipid levels as well. The fact that there was an improvement in fibrosis and NAS is also important, as one criticism of using a TRβ agonist for NASH was that it would only affect lipid levels and not fibrosis, which is clearly not the case. We will be very interested to review the data from the Phase 2 study of VK2809 in patients with hepatic steatosis/NAFLD, which we anticipate in the first half of 2018.

For VK0214, the theory behind its potential use in X-ALD has been validated through the increased expression of the *Abcd2* gene in *Abcd1*$^{-/-}$ mice along with significantly decreased levels of VLCFAs in both plasma and tissue. These data fully support the continued development of VK0214 and a proof-of-concept study in humans, which we anticipate initiating in 2018.

Viking's stock price has had a nice run over the past couple of months, 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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