Zacks Small-Cap Research

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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Potential of VK2809 in NASH Treatment Shown in Diet-Induced Mouse Model…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $8/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 (06/07/17)	$1.26
Valuation	**$8.00**

OUTLOOK

On June 6, 2017, Viking Therapeutics, Inc. (VKTX) announced results from a preclinical study of VK2809 in a diet-induced mouse model of non-alcoholic steatohepatitis (NASH). As opposed to most other NASH models, the one utilized by Viking results in all of the key physiological hallmarks of the disease, most notably liver fibrosis.

Results showed that treatment with VK2809 resulted in statistically significant reductions in liver triglyceride content, liver cholesterol content, liver fibrosis, liver collagen, and liver hydroxyproline compared to vehicle control. In addition, VK2809 also performed better than an active control on all of those outcomes. Data from a Phase 2 study of VK2809 in patients with fatty liver disease are expected in the fourth quarter of 2017.

SUMMARY DATA

52-Week High	**$1.69**
52-Week Low	**$0.95**
One-Year Return (%)	**-2.33**
Beta	**1.07**
Average Daily Volume (sh)	**69,512**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
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 E	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	-$0.16 E	-$0.16 E	-$0.16 E	-$0.70 E
2018					-$0.63 E
2019					-$0.65 E

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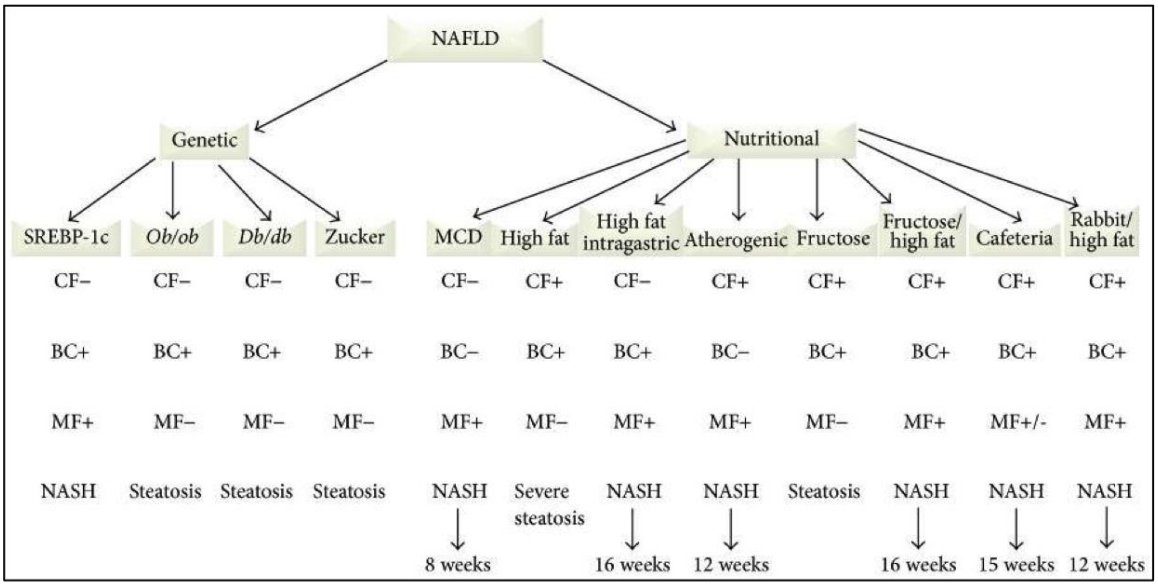
Business Update

On June 6, 2017, Viking Therapeutics, Inc. (VKTX) announced promising results from an *in vivo* study of VK2809 in a mouse model of diet-induced non-alcoholic steatohepatitis (NASH). Animals treated with VK2809 had statistically significant reductions in a number of key measures related to the development and progression of NASH, including liver triglyceride content, liver cholesterol content, liver fibrosis, liver collagen content, and liver hydroxyproline content. VK2809 also performed better (though not all reached statistical significance) in those parameters than an undisclosed active control, which is a metabolic-targeting agent currently in late-stage development. These data are the first to demonstrate a histological benefit from a thyromimetic agent in a NASH model. We continue to expect data from a Phase 2 study of VK2809 in patients with hypercholesterolemia and fatty liver disease in the fourth quarter of 2017.

Diet-Induced Mouse Model of NASH

Several animal models have been developed to represent the various pathophysiologic changes, morphologic changes, biochemical changes, and clinical features of NASH (Sanches *et al*., 2015). These models can be classified as nutritional (diet-induced), genetic, or a combination of nutritional and genetic. A robust model should recapitulate all of the hallmarks of the disease, including changes in metabolic profile, steatosis, inflammation, hepatocellular ballooning, fibrosis, and tumor susceptibility. The genetic models are typically best at inducing biochemical changes seen in NASH (e.g., increases in liver triglyceride and cholesterol), while the different nutritional models typically result in histopathological changes that are consistent with NASH, but lack the biochemical changes. The following chart shows the different animal models currently utilized to study NASH, with the fructose/high-fat diet-induced model best able to recapitulate the main clinical features (CF), biochemical changes (BC), morphological findings (MF), and the occurrence of NASH. We believe it is important for investors to understand that there are a number of different NASH models, thus while some compounds may show robust activity in a certain NASH model, if that model does not best represent what is seen in the clinic it is likely of little use.



Source: Sanches *et al*., 2015

Viking utilized a mouse model of NASH using wild-type mice fed a diet that consisted of 40% fat (18% trans fat), 40% carbohydrate (20% fructose), and 2% cholesterol (Clapper *et al*., 2013). This diet has previously been shown to induce steatosis, steatohepatitis with fibrosis, and cirrhosis and mimics what may be seen in individuals with poor dietary habits. Following 33 weeks on the diet, a biopsy was performed to confirm the presence of disease characteristics, including fibrosis. Mice were then treated for eight weeks with VK2809 (10 mg/kg/day), vehicle

control, or an undisclosed active control that is in late-stage clinical development for NASH. Results from a study using this same model to examine the effects of treatment with liraglutide, elafibranor, and obeticholic acid were recently presented (Feigh *et al*., 2017), thus we believe the active comparator may be one of those compounds.

VK2809 Shows Robust Activity in NASH Model

While we will have to wait for the full data set to be presented later this year at a scientific conference, the preliminary data that Viking disclosed is quite impressive. The following table shows the results obtained with VK2809 compared to both vehicle control and active control. For all parameters, VK2809 performed statistically significantly better than vehicle control. Compared to active control, VK2809 was statistically significantly better than for liver triglyceride and liver cholesterol content, and there were clear trends toward significance for liver collagen and hydroxyproline. A recent presentation showed that liver collagen significantly correlated with fibrosis in patients with non-alcoholic fatty liver disease (NAFLD), a precursor to NASH (Buzzetti *et al*., 2017). Fibrosis is a known risk-factor for adverse outcomes in patients with NAFLD (Angulo *et al*., 2015).

Parameter	VK2809 Compared to Vehicle Control	*P* value	VK2809 Compared to Active Control	*P* value
Liver Triglycerides	↓ 70%	<0.0001	↓ 56%	<0.0001
Liver Cholesterol	↓ 65%	<0.0001	↓ 58%	<0.0001
Liver Fibrosis	↓ 50%	0.01	↓ 21%	0.3
Liver Collagen	↓ 60%	<0.005	↓ 49%	0.07
Liver Hydroxyproline	↓ 46%	0.01	↓ 36%	0.06

Source: Viking Therapeutics, Inc. / Zacks SCR

VK2809 was also superior in a number of other outcomes. Animals treated with VK2809 experienced a 40% mean improvement in non-alcoholic fatty liver disease activity score (NAS; a composite measure of disease activity that is comprised of steatosis, ballooning, and inflammation) compared to animals treated with vehicle (P<0.0001). Fifty percent of VK2809-treated animals improved by at least two points in NAS, compared to no vehicle-treated animals (P=0.01), and no animals treated with VK2809 experienced a worsening in NAS while 60% of vehicle-treated animals did (P<0.0001). Lastly, there were no unexpected or abnormal laboratory findings for VK2809-treated animals and all animals received all scheduled doses of drug.

VK2809 Phase 2 Clinical Trial

Viking is currently conducting a Phase 2 clinical trial of VK2809 as a treatment for both hypercholesterolemia and fatty liver disease. The company is enrolling patients with elevated cholesterol, fatty liver disease, and at least three risk factors for metabolic syndrome, which is considered a major driver for the onset of NASH. The primary endpoint will assess changes in LDL following 12 weeks of treatment, with exploratory endpoints evaluating changes in liver fat content, inflammatory markers, and histological changes. Upon conclusion, the company hopes to be in a position to move forward in either hypercholesterolemia or NASH. Thus, it could be viewed as a two-in-one study – confirmatory on LDL and exploratory for fatty liver disease. We anticipate topline results in the fourth quarter of 2017.

Conclusion

As a reminder, Viking is expected to announce additional results from a long-term *in vivo* study of VK0214 in a model of X-linked adrenoleukodystrophy (X-ALD) in the second quarter of 2017, and results from the Phase 2 study of VK5211 in hip fracture in late summer 2017.

The preliminary data regarding VK2809 in a diet-induced model of NASH are very encouraging, particularly since the compound was better than another drug in late stage clinical trials for NASH in a number of different parameters. We hope to learn the identity of the active comparator later in the year when the company presents the full data set at a scientific conference. Results from the ongoing Phase 2 clinical trial of VK2809 in hypercholesterolemia and fatty liver disease are expected in the fourth quarter of 2017, and if those results are similar to what was seen in the *in vivo* model, then the company's valuation is likely to increase significantly from what is now a perplexingly low $30 million. Our current valuation is $8/share.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2016 A	Q1 A	Q2 E	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	$2.5	$2.6	$2.8	$11.4	$14.0	$16.0
General & Administrative	$4.8	$1.4	$1.2	$1.2	$1.2	$5.0	$5.0	$6.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.8)	($5.0)	($3.7)	($3.8)	($4.0)	($16.5)	($19.0)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	($0.3)	($0.1)	($0.1)	($0.1)	($0.6)	($0.5)	($0.6)
Pre-Tax Income	($14.7)	($5.2)	($3.8)	($3.9)	($4.1)	($17.0)	($19.5)	($22.6)
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)**	**($3.8)**	**($3.9)**	**($4.1)**	**($17.0)**	**($19.5)**	**($22.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.90)**	**($0.23)**	**($0.16)**	**($0.16)**	**($0.16)**	**($0.70)**	**($0.63)**	**($0.65)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.278	22.353	23.500	25.000	26.000	24.213	31.000	35.000

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

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