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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Phase 1 Trial of VK0214 Underway…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $22/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 (10/30/20)	$5.58
Valuation	**$22.00**

OUTLOOK

On October 28, 2020 Viking Therapeutics, Inc. (VKTX) announced financial results for the third quarter of 2020 and provided a business update. The company recently initiated a Phase 1 clinical trial of VK0214, the company's second thyroid beta receptor agonist, in healthy volunteers to test its safety, tolerability, and pharmacokinetic profile. Following completion of that study, we anticipate a Phase 1b trial in patients with X-linked adrenoleukodystrophy, which we expect to initiate in the first half of 2021.

Enrollment continues in the company's Phase 2b VOYAGE trial of VK2809 in patients with biopsy confirmed NASH, and we continue to expect enrollment to be completed during the first half of 2021.

SUMMARY DATA

52-Week High	**$8.73**
52-Week Low	**$3.45**
One-Year Return (%)	**-13.76**
Beta	**2.02**
Average Daily Volume (sh)	**1,105,013**
Shares Outstanding (mil)	**73**
Market Capitalization ($mil)	**$407**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**55**
Insider Ownership (%)	**4**
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 2018 Estimate	**-9.4**
P/E using 2019 Estimate	**-6.7**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.07 A	- $0.11 A	-$0.08 A	-$0.10 A	-$0.36 A
2020	-$0.13 A	-$0.13 A	-$0.13 A	-$0.16 E	-$0.55 E
2021					-$0.75 E
2022					-$0.89 E

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WHAT'S NEW

Business Update

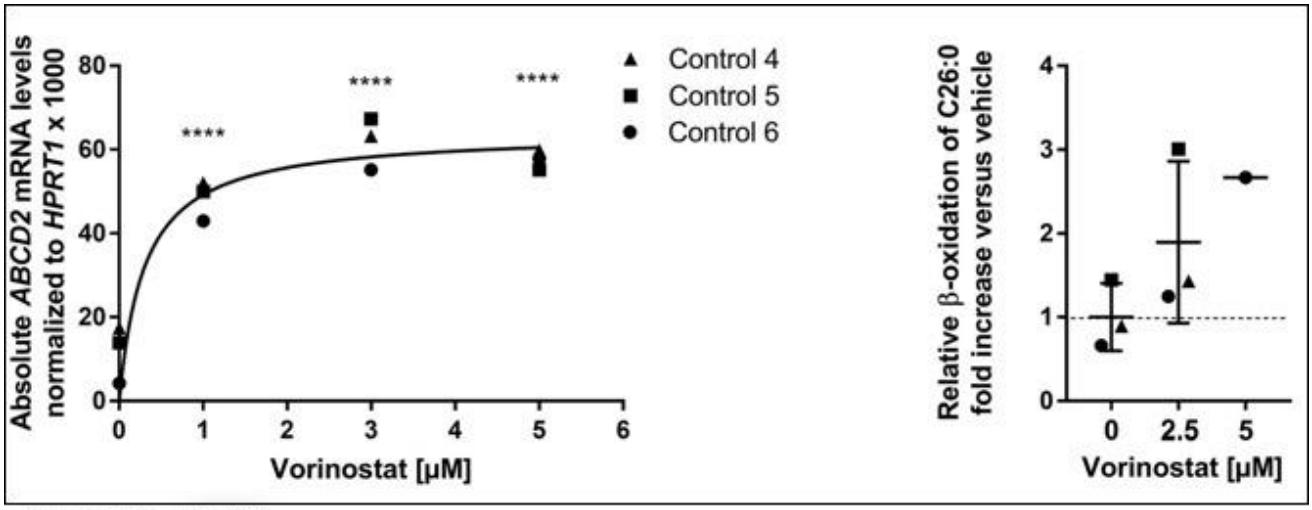
VK0214 Phase 1 Trial Initiated

In September 2020, Viking Therapeutics, Inc. (VKTX) announced the initiation of a Phase 1 clinical trial of VK0214, the company's second thyroid beta (TRβ) receptor agonist. It is a randomized, double blind, placebo controlled, single ascending dose (SAD) and multiple ascending dose (MAD) study in healthy subjects. The primary objective of the study is to evaluate the safety and tolerability of VK0214 and to identify the proper doses to evaluate in a trial with X-adrenoleukodystrophy (X-ALD) patients.

X-ALD is an orphan neurodegenerative disease that affects approximately 8,000 individuals in the U.S. and 12,000 in Europe. In contrast to VK2809, VK0214 is a TRβ agonist that is activated by carboxyesterases that are ubiquitously expressed in the body. The drug also has a different pharmacokinetic and pharmacodynamic profile than VK2809, thus potentially making the drug more suitable for a disease such as X-ALD, which is more diffuse than NASH.

X-ALD is caused by a mutation(s) in the *ABCD1* gene, which encodes the adrenoleukodystrophy protein (ALDP). ALDP is responsible for transporting very long chain fatty acids (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 increases the expression of ALDRP (encoded by the *ABCD2* gene), which is also a VLCFA transporter, thus compensating for the loss of ALDP. For additional background, please refer to our previous report discussing the use of VK0214 in a mouse model of X-ALD, which can be found here.

Additional support for the use of a compound that can augment expression of the *ABCD2* gene in patients with X-ALD comes from a study of vorinostat (Zolinza®), a histone deacetylase inhibitor that is approved for the treatment of cutaneous manifestations in patients with cutaneous T cell lymphoma (CTCL) (Zierfuss *et al*., 2020). Researchers discovered that expression of *ABCD2* in macrophages is controlled through histone modifications in the *ABCD2* promoter region, specifically a high level of histone 3 lysine 27 acetylation (H3K27ac). Thus, macrophages from X-ALD patients were treated *in vitro* with vorinostat, and as shown in the following figure there was a dose dependent increase in *ABCD2* expression (lower left), which led to a subsequent increase in the β-oxidation of C26:0 (a type of VLCFA, lower right).



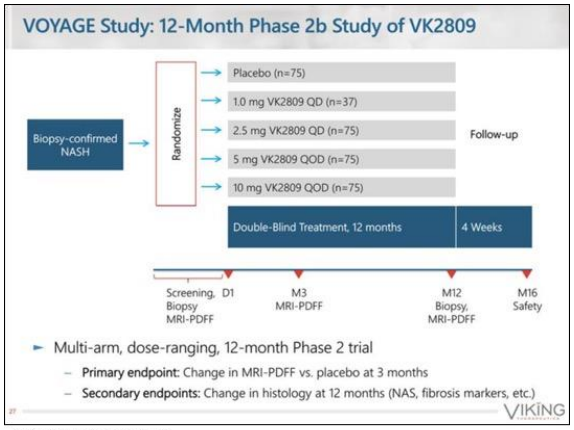
Source: Zierfuss *et al*., 2020

While VK0214 and vorinostat are not in the same class of drugs, we feel that the data above shows a compound that is able to induce expression of the *ABCD2* gene (which both VK0214 and vorinostat are able to do) can lead to the desired phenotype, namely an increase in the β-oxidation of VLCFAs. Zierfuss *et al*. attempted treatment of advanced cerebral adrenoleukodystrophy (CALD) patients with vorinostat but were unsuccessful in halting

progression of the disease, however they did note decreases in the plasma levels of C26:0 and improvements in other inflammatory markers. We are encouraged by the clinical application of a compound that increases *ABCD2* expression in X-ALD patients and believe this further supports testing VK0214 in this population.

Enrollment in Phase 2b VOYAGE Trial Continues

Viking is currently conducting the Phase 2b VOYAGE trial of VK2809 in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH). The randomized, double blind, placebo-controlled trial is expected to enroll approximately 340 patients with fibrosis ranging from stages F1 to F3 across five treatment groups: 1 mg VK2809 daily, 2.5 mg VK2809 daily, 5 mg VK2809 every other day, 10 mg VK2809 every other day, or placebo. We expect approximately 75 patients per arm for the 2.5 mg, 5 mg, 10 mg, and placebo groups and approximately 40 patients in the 1 mg arm. There will be a total of approximately 90 centers enrolling patients worldwide and an approximate 4:1 ratio between U.S. and ex-U.S. sites. An overview of the trial is given below.



Source: Viking Therapeutics, Inc.

The primary endpoint of the trial is the 12-week change in liver fat content assessed by magnetic resonance imaging proton density fat fraction (MRI-PDFF) for those treated with VK2809 compared to placebo. A key secondary outcome measure is histological changes assessed by liver biopsy following 52 weeks of dosing.

During the third quarter conference call, management indicated that enrollment has continued despite very difficult conditions (e.g., COVID19), however the company has expanded the total number of planned enrollment sites to 90 (up from 80) and the ex-U.S. sites are expected to open very soon. Thus, at this point we continue to anticipate enrollment being completed in the first half of 2021.

New Data Presented at EASL 2020

In August 2020, Viking announced new data from the Phase 2 clinical trial of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and elevated low density lipoprotein (LDL) cholesterol were presented at EASL 2020. The new results showed that patients treated for 12 weeks with VK2809 continued to show a statistically significant decrease in liver fat at Week 16, which was four weeks after the last dose was administered. In addition, consistent liver fat reductions were seen in patients regardless of baseline characteristics or the presence of various NASH risk factors.

The following table shows the results for median relative percent change in liver fat, mean absolute percent change in liver fat, and the percentage of patients who experienced a ≥30% reduction in liver fat at Week 12 and at Week 16. Dosing for this study concluded at the end of Week 12 and patients then came in to get another MRI scan at Week 16 to determine the durability of effect after dosing was concluded. Some of the patients were not able to come back for the scan at Week 16, which is why the number of patients for the placebo and VK2809-treated groups is lower for Week 16. The results show that at Week 16 there continues to be a statistically significant decrease in liver fat in patients treated with VK2809 compared to placebo. The increases seen in the placebo group at Week 16 are due to 3 'non-responders' for whom a Week 16 MRI was not available. This had the effect of enriching the placebo group with responders, but should not be confused with an actual increase in underlying response among placebo patients relative to VK2809-treated patients. For example, at Week 12, 2/12 (16.7%) placebo patients had a ≥30% reduction in liver fat while at Week 16 it was 2/9 (22.2%). Not included in this table but disclosed by the company is that 100% of the patients receiving 5 mg VK2809 daily were still responders at Week 16.

	Placebo Wk 12 (n=12)	VK2809 combined Wk 12 (n=33)	Placebo Wk 16 (n=9)	VK2809 combined Wk 16 (n=27)
Median relative % change in liver fat by MRI-PDFF	-9.4%	-56.5% (*P*<0.0001)	-18.7%	-45.4% (*P*=0.0053)
Mean absolute % change in liver fat by MRI-PDFF	-1.1%	-9.4% (*P*=0.0007)	-2.0%	-7.5% (*P*=0.0027)
% of pts ≥ 30% reduction in liver fat	16.7%	87.9% (*P*<0.0001)	22.2%	70.4% (*P*=0.0083)

Source: Viking Therapeutics, Inc. / Zacks SCR

In addition to examining results at Week 16, the company also presented data on liver fat reductions in patients stratified by various baseline characteristics and the presence of common risk factors for NASH. Regardless of increased alanine aminotransferase (ALT), a high body mass index (BMI), hypertension, and Hispanic ethnicity, the decrease in liver fat was consistent and statistically significant compared to placebo.

Mean Relative % Change in Liver Fat at Week 12

	Placebo	VK2809 Combined
Baseline ALT>xULN	-2.1%	-57.4% (*P*=0.0001)
BMI ≥ 30	-7.8%	-51.3% (*P*=0.0151)
Hypertension (BP≥140 mmHg)	6.2%	-54.9%. (*P*=0.017)
Hispanic Ethnicity	-7.2%	-49.0% (*P*=0.0054)

Source: Viking Therapeutics, Inc. / Zacks SCR

Financial Update

On October 28, 2020, Viking announced financial results for the third quarter of 2020. As expected, the company did not report any revenues in the third quarter of 2020. Viking reported a net loss of $9.3 million, or $0.13 per share, in the third quarter of 2020 compared to a net loss of $5.7 million, or $0.08 per share, for the third quarter of 2019. R&D expenses in the third quarter of 2020 were $7.1 million, compared to $5.3 million for the third quarter of 2019. The increase was primarily due to increased expenses related to clinical trials, salaries and benefits, and stock-based compensation. G&A expenses for the third quarter of 2020 were $2.7 million, compared to $2.2 million for the third quarter of 2019. The increase was primarily due to increased stock-based compensation, salaries and benefits, and insurance expenses.

Viking exited the third quarter of 2020 with approximately $255 million in cash, cash equivalents, and short-term investments and we believe the company is continuing to be fiscally prudent with its resources. As of October 15, 2020, Viking had approximately 73.0 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 82.7 million.

Conclusion

We are glad to see the Phase 1 trial for VK0214 is underway and we expect results from that trial to be reported in the first half of 2021 prior to the company moving into the Phase 1b trial in X-ALD patients. We continue to anticipate enrollment in the Phase 2b VOYAGE trial of VK2809 completing in the first half of 2021, and are glad to see the company is slightly increasing the total number of enrollment sites to help meet that goal. While enrollment has continued thus far through the coronavirus epidemic, investors should be aware that increased lockdown measures this winter could have an impact on the study and delay the projected completion of enrollment, but at this point we are hopeful that will not be the case. With no changes to our model, our valuation remains at $22.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
VK2809	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK0214	$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	$23.6	$8.0	$7.8	$7.1	$10.4	$33.3	$50.0	$60.0
General & Administrative	$9.1	$3.0	$2.8	$2.7	$2.5	$11.0	$10.5	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($32.7)	($10.9)	($10.6)	($9.8)	($12.9)	($44.3)	($60.5)	($71.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.9	$1.3	$1.0	$0.6	$1.3	$4.2	$5.0	$5.0
Pre-Tax Income	($25.8)	($9.7)	($9.6)	($9.3)	($11.6)	($40.1)	($55.5)	($66.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($25.8)**	**($9.7)**	**($9.6)**	**($9.3)**	**($11.6)**	**($40.1)**	**($55.5)**	**($66.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.36)**	**($0.13)**	**($0.13)**	**($0.13)**	**($0.16)**	**($0.55)**	**($0.75)**	**($0.89)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	72.0	72.4	72.5	72.6	73.0	72.6	74.0	74.0

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

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