

Viking Therapeutics, Inc.

(VKTX-NASDAQ)

VKTX: VK2809 5 mg Data Presented at EASL...

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at \$24/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 (04/12/19) **\$9.97**
Valuation **\$24.00**

OUTLOOK

On April 11, 2019, Viking Therapeutics, Inc. (VKTX) presented new data from the company's Phase 2 study of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and hypercholesterolemia at The International Liver Congress 2019. Included was data showing that patients receiving 5 mg daily doses of VK2809 had a mean reduction in liver fat of 53.8% ($P=0.0001$), which was quite comparable to the value seen for those taking 10 mg every other day (-56.5%; $P=0.0018$) and 10 mg ever day (-59.7%; $P=0.0004$). In addition, all 9 patients in the 5 mg cohort were responders, defined as a $\geq 30\%$ relative reduction from baseline in liver fat at Week 12. The company is now planning for a Phase 2b trial of VK2809 in patients with biopsy confirmed nonalcoholic steatohepatitis (NASH), which we anticipate initiating in the second half of 2019.

SUMMARY DATA

52-Week High **\$19.65**
52-Week Low **\$3.88**
One-Year Return (%) **97.04**
Beta **2.75**
Average Daily Volume (sh) **4,559,754**

Shares Outstanding (mil) **72**
Market Capitalization (\$mil) **\$718**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **65**
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 **-22.5**
P/E using 2019 Estimate **-16.1**

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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 E	0 E	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-\$0.08 A	-\$0.13 A	-\$0.11 A	-\$0.07 A	-\$0.38 A
2019	-\$0.08 E	-\$0.08 E	-\$0.09 E	-\$0.09 E	-\$0.34 E
2020					-\$0.43 E
2021					-\$0.50 E

WHAT'S NEW

Business Update

Additional P2 Data for VK2809 Presented at EASL

On April 11, 2019, Viking Therapeutics, Inc. (VKT) [announced](#) the presentation of new data from the Phase 2 clinical trial of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and hypercholesterolemia. Included in the poster presentation were details about the cohort of patients that received 5 mg daily doses of VK2809. Results showed that the mean relative liver fat reduction in the 5 mg cohort was -53.8% ($P=0.0001$), which compares quite favorably to the cohorts receiving 10 mg every other day (-56.5%; $P=0.0018$) and 10 mg every day (-59.7%; $P=0.0004$). In addition, all nine patients in the 5 mg cohort experienced $\geq 30\%$ reduction in liver fat and 77.8% were 'super-responders', defined as experiencing $\geq 50\%$ reduction in liver fat. The results are summarized in the table below.

	Placebo (n=12)	VK2809 5mg QD (n=9)	VK2809 10mg QOD (n=13)	VK2809 10mg QD (n=11)	VK2809 combined (n=33)
Median relative % change in liver fat by MRI-PDFF	-9.4%	-53.8% ($P=0.0001$)	-56.5% ($P=0.0018$)	-59.7% ($P=0.0004$)	-56.5% ($P<0.0001$)
Median absolute % change in liver fat by MRI-PDFF	-1.1%	-8.7% ($P=0.014$)	-8.9% ($P=0.013$)	-10.6% ($P=0.0030$)	-9.4% ($P=0.0007$)
% of pts $\geq 30\%$ reduction in liver fat	16.7%	100.0% ($P=0.0002$)	76.9% ($P=0.0048$)	90.9% ($P=0.0006$)	87.9% ($P<0.0001$)
% of pts $\geq 50\%$ reduction in liver fat	16.7%	77.8% ($P=0.0092$)	61.5% ($P=0.041$)	72.7% ($P=0.012$)	70.0% ($P=0.014$)
Maximum observed reduction	52.8%	77.9%	72.4%	75.6%	77.9%

Source: Viking Therapeutics, Inc. / Zacks SCR

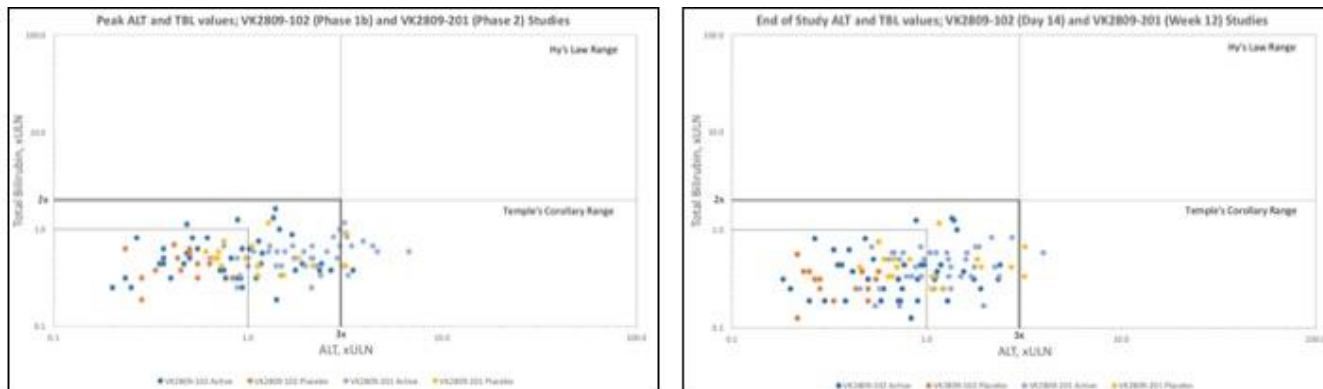
We remind investors of Madrigal Pharmaceutical's (MDGL) 12-week liver fat data for its lead compound MGL-3196 (a TR β agonist like VK2809) to again show that even the VK2809 5 mg cohort showed superior results to both of the MGL-3196 cohorts. For those who may argue that the two patient populations are too dissimilar to offer a valid comparison, we believe that the very similar placebo responses seen in both outcomes in the table below indicate that the two populations are in fact quite similar. In addition, we have yet to see data on the proportion of MGL-3196 'super responders', or data from patients who received and stayed on the 80 mg starting dose of MGL-3196, or data from patients receiving either the up- or down-titrated doses of MGL-3196. Rather, the only MGL-3196 data that have been presented have been pooled results from patients receiving "high exposure" to the drug, without further explanation with respect to dose level or corresponding statistical relevance.

	Placebo (n=12)	VK2809 5mg QD (n=9)	All MGL-3196 (n=78)	High MGL-3196 (n=44)	Placebo (n=38)
Median relative % change in liver fat by MRI-PDFF	-9.4%	-53.8% ($P=0.0001$)	-36.3% ($P<0.0001$)	-42.0% ($P<0.0001$)	-9.6%
% of pts $\geq 30\%$ reduction in liver fat	16.7%	100.0% ($P=0.0002$)	60.3% ($P<0.0001$)	75.0% ($P<0.0001$)	18.4%

Sources: Viking Therapeutics, Inc.; Madrigal Pharmaceuticals, Inc.; Zacks SCR

Viking presented new safety data in the form of 'eDISH' (evaluation of Drug-Induced Serious Hepatotoxicity) plots from the company's completed Phase 2 trial as well as a prior 14 day Phase 1 study (where doses were as high as 40 mg daily). The most specific indicator of drug-induced liver injury in a clinical trial is when subjects experience elevated serum levels of both alanine aminotransferase (ALT) and total bilirubin (TBL) with no significant elevation in serum alkaline phosphatase (AP). Thus, the eDISH plot graphically displays ALT and TBL values for each subject in a clinical trial and can provide valuable information on drug-induced liver toxicity and/or injury. The logarithmic plots use the generally accepted cutoffs of 3X upper limit of normal (ULN) for ALT and 2X ULN for TBL. In addition,

the plot can show any potential Hy's law cases (ALT > 3X ULN, TBL > 2X ULN, AP < 2X ULN) ([FDA Guidance for Industry: Drug-Induced Liver Injury](#)). The eDISH plots showing maximum values for ALT and TBL (lower left) and after either 14 days or 12 weeks of treatment (lower right) are as follows.



Source: Loomis et al., 2019

A couple of interesting things are readily apparent from the eDISH plots: 1) there were no cases in the 'Hy's Law Range' – thus, VK2809 showed no liver toxicity in both the Phase 1b and 2 studies and any worries about potential liver toxicity for VK2809 are completely unfounded; 2) It appears that eight patients in the Phase 2 study experienced an ALT level > 3X ULN at some point, however this number drops down to one after 12 weeks of dosing (however we don't know their dose cohorts). Three placebo patients had ALT level > 3X ULN at some point during the study and that only dropped to two after 12 weeks of dosing. Clearly, VK2809 is having a positive effect on ALT levels in treated patients.

Additional safety and adverse event data showed that there were no serious treatment-emergent adverse events (TEAEs) and that a greater percentage of VK2809-treated patients completed the study compared to those receiving placebo. In addition, there were similar proportions of VK2809- and placebo-treated patients experiencing cardiovascular (CV)-related AEs and no changes to CV toxicity markers (troponin, CK-MB, NT-proBNP) were reported, thus further supporting the cardio safety of VK2809.

Conclusion

Our confidence in the potential for VK2809 to be a 'best-in-class' drug continues to grow as Viking continues to present additional data on the drug (including an abundance of safety and toxicity data that exceed comparable disclosures related to MGL-3196). VK2809 has shown the greatest liver fat reduction of any oral NASH candidate currently in clinical testing, and it also produces significant reductions in low density lipoprotein cholesterol as well as improvements in atherogenic proteins such as apolipoprotein B and lipoprotein (a). Given that the most common cause of death for patients with NAFLD is cardiovascular disease ([Azzam et al., 2015](#)), we believe the reduction in cardiovascular risk factors is a clear differentiator for VK2809 in a crowded NAFLD/NASH field.

We would be remiss to not mention the fact that Viking's stock is currently one of the most shorted stocks on the Nasdaq (as a % of its float), with approximately 32.1 million shares short as of Mar. 29, 2019. This represents approximately 50% of the company's current float. Why Viking's stock is so heavily shorted remains a complete mystery to us, as we believe most of the 'bear theses' surrounding the stock have been rendered moot. For example, we discussed the unfounded concerns for VK2809 to potentially cause liver toxicity [here](#) (which was further supported by the data discussed above) and for it to potentially cause cardiac toxicity [here](#). One argument we continue to hear against VK2809 is that it is approximately three years behind MGL-3196 in development. However, we don't believe that is a sufficient reason for such a high short percentage. Regardless, we believe investors should at least be aware of the issue.

Viking is continuing to plan for the upcoming Phase 2b clinical trial of VK2809 in patients with biopsy-confirmed NASH. We anticipate that trial initiating in the second half of 2019. While we believe VK2809 is an excellent partnering opportunity for a larger biopharma company, Viking is in very strong financial shape and is able to move forward with development of the drug on its own. Our valuation remains \$24.

PROJECTED FINANCIALS

Viking Therapeutics, Inc. Income Statement

Viking Therapeutics, Inc.	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
VK5211	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
VK2809	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
VK0214	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$19.0	\$5.0	\$5.0	\$5.1	\$5.2	\$20.3	\$25.0	\$30.0
General & Administrative	\$7.1	\$1.8	\$1.8	\$1.8	\$1.8	\$7.2	\$7.5	\$8.0
Other Expenses	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Operating Income	(\$26.2)	(\$6.8)	(\$6.8)	(\$6.9)	(\$7.0)	(\$27.5)	(\$32.5)	(\$38.0)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$3.7	\$1.0	\$0.8	\$0.6	\$0.4	\$2.8	\$1.0	\$1.0
Pre-Tax Income	(\$22.5)	(\$5.8)	(\$6.0)	(\$6.3)	(\$6.6)	(\$24.7)	(\$31.5)	(\$37.0)
Income Taxes Paid	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$22.5)	(\$5.8)	(\$6.0)	(\$6.3)	(\$6.6)	(\$24.7)	(\$31.5)	(\$37.0)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.38)	(\$0.08)	(\$0.08)	(\$0.09)	(\$0.09)	(\$0.34)	(\$0.43)	(\$0.50)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	57.6	71.8	72.0	72.2	72.4	72.1	73.0	74.0

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



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