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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Slight Delay in Enrollment in Phase 2b NASH Trial Due to Ongoing Pandemic…

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 (05/05/20)	$6.34
Valuation	**$22.00**

OUTLOOK

Viking Therapeutics, Inc. (VKTX) recently announced financial results for the first quarter of 2020 and provided a business update. The coronavirus pandemic has caused a slowdown in enrollment of the ongoing Phase 2b VOYAGE trial of VK2809 in patients with nonalcoholic steatohepatitis (NASH), however the trial is continuing and has not had to put a halt on enrollment. The company is now estimating that enrollment will complete in the first half of 2021. In the 3Q20, we anticipate an IND being filed for VK0214 such that the company can initiate a Phase 1 trial first in healthy volunteers and then in patients with X-linked adrenoleukodystrophy (ALD). The company exited the first quarter of 2020 with approximately $269 million in cash, cash equivalents, and short term investments and thus is well capitalized to finance operations through multiple milestones.

SUMMARY DATA

52-Week High	**$8.91**
52-Week Low	**$3.45**
One-Year Return (%)	**-28.84**
Beta	**2.05**
Average Daily Volume (sh)	**1,590,139**
Shares Outstanding (mil)	**73**
Market Capitalization ($mil)	**$460**
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	**-9.6**
P/E using 2019 Estimate	**-8.2**

Risk Level	**Average**
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 E	0 E	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 E	-$0.15 E	-$0.16 E	-$0.57 E
2021					-$0.75 E
2022					-$0.89 E

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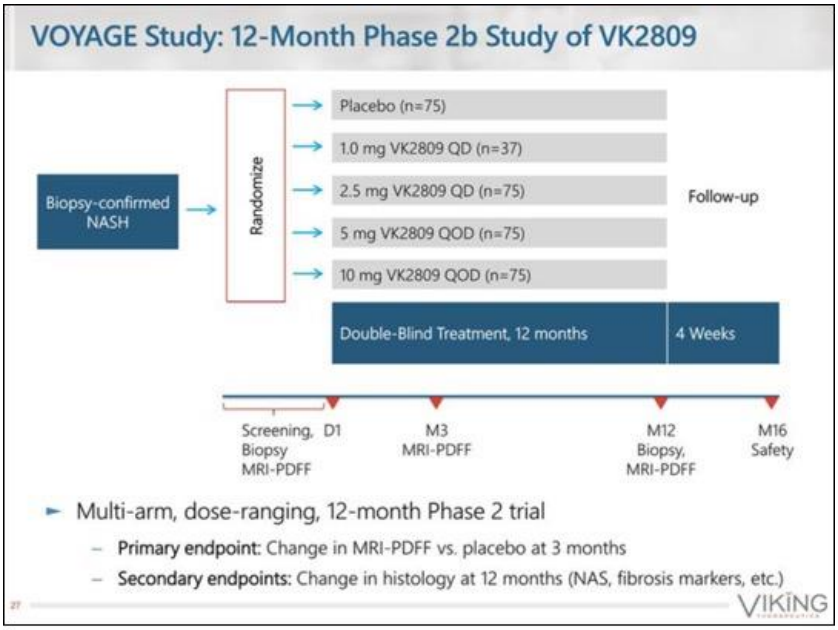
WHAT'S NEW

Business Update

Slight Delay in Enrollment for VOYAGE Trial

Viking Therapeutics, Inc. (VKTX) 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 70 centers enrolling patients in the US and we expect approximately 10-15 ex-U.S. centers opening beginning in the third quarter of 2020. 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 first quarter conference call update, management indicated that the ongoing coronavirus pandemic has caused a slowdown in enrollment, however patients are continuing to be enrolled and those enrolled are continuing to be treated. Varying degrees of disruptions are occurring at most all of the clinical sites, however the company believes they have reached a plateau in those disruptions. Based on the current situation, the company now estimates completion of enrollment in the first half of 2021.

The company also announced during the call that the 12-month toxicology data has been submitted to the FDA in February 2020. As a reminder, 6-month toxicology data had originally been submitted with the IND and the FDA had requested the 12-month toxicology data when it became available. The trial was allowed to commence with six months of dosing when the IND was approved. There isn't a formal mechanism in place for the company to hear back from the FDA regarding the 12-month toxicology data, and so we view this as a "no news is good news" situation and unless the FDA gets back to them with concerns (which we don't have any reason to believe will occur), we anticipate dosing to go out to 12 months as originally planned.

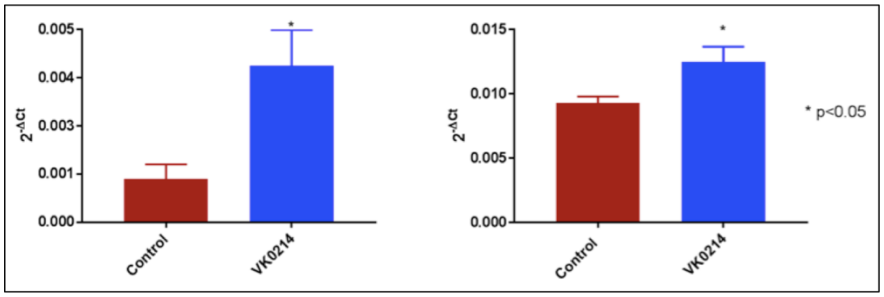
Presentation at EASL

In February 2020, Viking announced that an abstract describing additional data from the Phase 2 trial of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and hypercholesterolemia was selected for an oral presentation at the 2020 International Liver Congress, which is hosted by the European Association for the Study of the Liver (EASL). The meeting has been postponed to Aug. 25-28, 2020, however we would not be surprised to see it go virtual as other scientific meetings have done. Full details of the abstract have not been disclosed, however the company did say that it will include data for patients that had a liver MRI performed at week 16 of the trial (4 weeks after dosing stopped) along with an examination of various subsets and patient characteristics.

VK0214 IND to be Filed in 3Q20

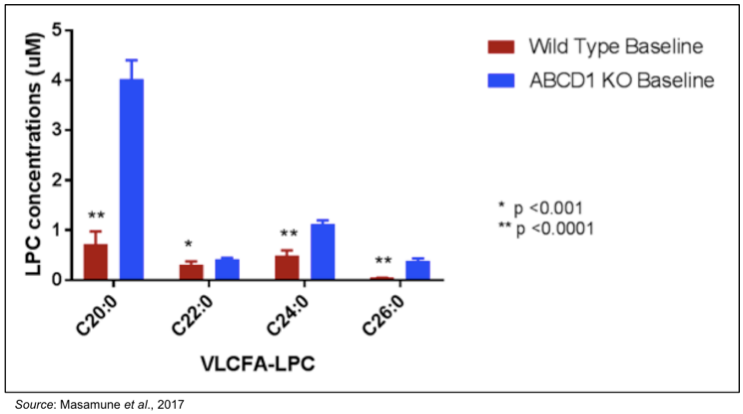
VK0214 is being developed for the treatment of X-linked adrenoleukodystrophy (X-ALD), an orphan neurodegenerative disease that affects approximately 8,000 individuals in the U.S. and 12,000 in Europe. In contrast to VK2809, VK0214 is a TRβ agonist that is activated by carboxyesterases that are ubiquitously 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 ALDR (encoded by the *ABCD2* gene), which is also a VLCFA transporter, thus compensating for the loss of ALDP. The following graph shows that VK0214 induces the expression of the *Abcd2* gene in mice.



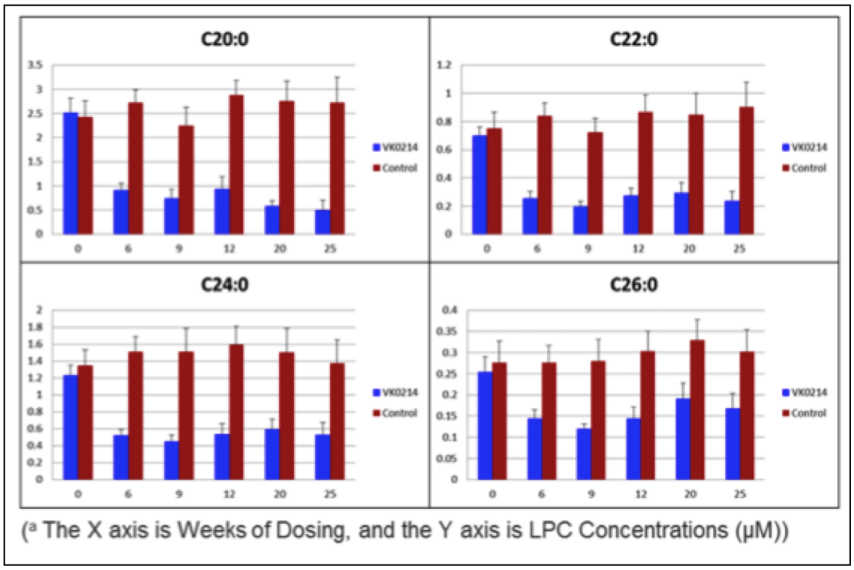
Source: Masamune *et al.*, 2017

The company previously presented positive *in vivo* results at the 87th Annual Meeting of the American Thyroid Association from a study involving 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 biochemical 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.



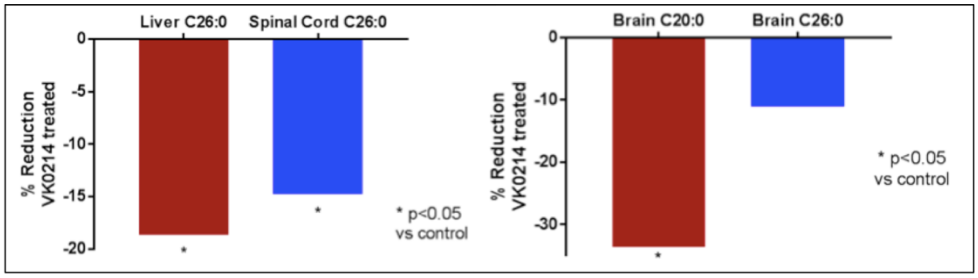
Source: Masamune *et al.*, 2017

Treatment with VK0214 resulted in a dramatic decrease in VLCFA levels in plasma only six weeks after initiating treatment, and this decline held relatively steady through the entire 25-week treatment period.



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

IND-enabling studies are currently ongoing for VK0214, and we anticipate an IND being submitted in the third quarter of 2020 and a Phase 1 proof-of-concept study being initiated shortly thereafter. The trial will likely involve a single-ascending dose study in healthy volunteers followed by a multiple ascending dose study also in healthy volunteers and then finally a multiple dose study in X-ALD patients. The company will be looking at 28-day dosing and will examine VLCFA levels before and after treatment. If those results are positive, the company would then meet with the FDA to discuss the regulatory path forward.

Financial Update

On April 30, 2020, Viking announced financial results for the first quarter of 2020. As expected, the company did not report any revenues in the first quarter of 2020. Viking reported a net loss of $9.7 million, or $0.13 per share, in the first quarter of 2020 compared to a net loss of $4.9 million, or $0.07 per share, for the first quarter of 2019. R&D expenses in the first quarter of 2020 were $8.0 million, compared to $4.5 million for the first quarter of 2019. The increase was primarily due to increased expenses related to the initiation of the VOYAGE trial, increased costs associated with preclinical studies, and manufacturing of drug candidates. G&A expenses for the first quarter of 2020 were $3.0 million, compared to $2.3 million for the first quarter of 2019. The increase was primarily due to increased stock-based compensation, legal expenses, and salaries.

Viking exited the first quarter of 2020 with approximately $269 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 April 15, 2020, Viking had approximately 72.6 million shares outstanding, and when factoring in stock options and warrants a fully diluted share count of approximately 82.7 million.

Conclusion

We're disappointed to see the delay in enrollment due to the coronavirus pandemic, but this is something almost all companies are experiencing so it is not that surprising. Thankfully, the trial is still enrolling patients and there hasn't been a need to pause enrollment. In addition, the company believes it has reached the peak of disruptions, which is encouraging.

We've previously discussed the fact that in terms of news flow this year is likely to be quiet for Viking. Company-specific news we anticipate in the third quarter of 2020 includes the IND filing for VK0214 and the EASL presentation. The company may also provide an update on enrollment of the VOYAGE trial, but that is very dependent on how the coronavirus pandemic evolves.

Regarding NASH-specific news, the FDA will be deciding on the fate of Intercept Pharmaceuticals (ICPT) NDA for obeticholic acid (OCA) for the treatment of NASH. The Advisory Committee (AdComm) meeting originally scheduled for Apr. 22, 2020 has been moved to June 9, 2020 and the PDUFA date is June 26, 2020. Two important points that will be very relevant for the NASH market as a whole that investors should pay attention to are: 1) will the FDA put a requirement for a biopsy in the label? (we view this as unlikely); and 2) will payers require a biopsy prior to authorizing treatment? (this could differ from one payer to the next).

With the delay in VOYAGE we have pushed out our timelines a bit for VK2809, which has resulted in a slight decrease in our valuation to $22. However, our enthusiasm for VK2809 has not waned as we continue to believe it will be a 'best-in-class' therapy for NASH.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2019 A	Q1 A	Q2 E	Q3 E	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	$8.3	$9.5	$10.4	$36.2	$50.0	$60.0
General & Administrative	$9.1	$3.0	$2.4	$2.5	$2.5	$10.4	$10.5	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($32.7)	($10.9)	($10.7)	($12.0)	($12.9)	($46.5)	($60.5)	($71.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.9	$1.3	$1.4	$1.3	$1.3	$5.3	$5.0	$5.0
Pre-Tax Income	($25.8)	($9.7)	($9.3)	($10.7)	($11.6)	($41.3)	($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)**	**($9.3)**	**($10.7)**	**($11.6)**	**($41.3)**	**($55.5)**	**($66.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.36)**	**($0.13)**	**($0.13)**	**($0.15)**	**($0.16)**	**($0.57)**	**($0.75)**	**($0.89)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	72.0	72.4	72.7	72.9	73.0	72.7	74.0	74.0

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

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