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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Awaiting Feedback from FDA regarding pre-IND submission; Phase 2b trial in NASH expected to initiate 2H19…

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 (08/02/19)	$7.57
Valuation	**$24.00**

OUTLOOK

On August 1, 2019, Viking Therapeutics, Inc. (VKTX) announced financial results for the second quarter of 2019 and provided a business update. The company has submitted a pre-IND briefing package to the FDA and is currently awaiting a written response, which we anticipate in the next few weeks, after which the company should be in a position to submit an IND. This should allow for initiation of a Phase 2b clinical trial of VK2809 in NASH patients before the end of 2019. Details regarding the trial design will be announced later in the 2H19, however we anticipate the trial will include biopsy-confirmed NASH patients with F2 and F3 fibrosis, as well as a limited number with F1 fibrosis. We also anticipate multiple doses being tested with at least one dose being lower than 5 mg.

SUMMARY DATA

52-Week High	**$19.65**
52-Week Low	**$7.16**
One-Year Return (%)	**-26.43**
Beta	**2.29**
Average Daily Volume (sh)	**1,166,920**
Shares Outstanding (mil)	**72**
Market Capitalization ($mil)	**$545**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**64**
Insider Ownership (%)	**3**
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	**-17.5**
P/E using 2019 Estimate	**-11.9**

Risk Level	**Above Avg.**
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 A	0 A	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	-$0.07 A	-$0.11 A	-$0.11 E	-$0.12 E	-$0.40 E
2020					-$0.47 E
2021					-$0.50 E

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WHAT'S NEW

Business Update

Phase 2b Trial for VK2809 to Initiate 2H19

Viking Therapeutics, Inc. (VKTX) is currently preparing for the initiation of a Phase 2b clinical trial of VK2809, the company's thyroid beta receptor (TRβ) agonist, for the treatment of nonalcoholic steatohepatitis (NASH). The company has submitted a pre-IND briefing package to the FDA and is currently awaiting written feedback. The pre-IND submission was completely voluntary; the company undertook in an effort to gauge the agency's thoughts regarding the upcoming Phase 2b trial and any potential areas that may require more attention in the IND. The Phase 2a trial (performed under an IND filed with the Division of Metabolic and Endocrinology Products) had restrictive inclusion criteria, thus it was in the company's best interest to gauge whether the Division of Gastroenterology and Inborn Error Products (where the IND for the Phase 2b trial will be filed) had any potential concerns about patient inclusion or other aspects of the company's plan for the trial.

We anticipate that Viking will receive feedback regarding the pre-IND submission in the next couple of weeks. Assuming the FDA has no major issues regarding the company's current thinking on the study design, the IND will be submitted as quickly as possible. Following submission of the IND, the FDA then has 30 days to respond with any concerns, otherwise the company will be free to initiate the trial. It is at this time we anticipate learning the details of the trial regarding number of patients, dosing, treatment length, etc.

Viking cannot finalize details of the trial until after hearing back from the FDA, however we believe that the trial will include biopsy-confirmed NASH patients with F2 and F3 fibrosis (with potentially a small number of F1 fibrosis patients). Based upon the efficacy of the 5 mg dose in the Phase 2a trial, we anticipate at least one dose below 5 mg being tested. When examining data from the 14-day Phase 1 trial, in which doses from 0.25 mg to 40 mg were tested, signs of efficacy were not apparent below the 1 mg dose, thus we don't anticipate the company going below that dose.

We continue to anticipate the trial initiating in the second half of 2019 and based on the length for competitors Phase 2b trials we estimate topline data will be available in the first half of 2021, although the fourth quarter of 2020 is not out of the question. Regarding the pace of enrollment, the company is aware that it could present a potential problem given the number of trials ongoing in NASH and is doing everything possible to mitigate potential competitive issues. In comparison to the Phase 2a trial, management anticipates enrollment proceeding more smoothly.

Data Presentation at EASL Showcases VK2809 Superior Attributes

Following the data presentation at EASL (see our previous report for a full discussion), we view VK2809 as a potential 'best-in-class' treatment for NASH based on its efficacy, potency, and safety.

- The mean relative liver fat reduction in the 5 mg cohort was -53.8% (*P*=0.0001), which compared 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 ≥ 30% reduction in liver fat and 77.8% were 'super-responders', defined as experiencing ≥ 50% reduction in liver fat.
- The results seen with the 5 mg cohort are superior to both of the cohorts in Madrigal Pharmaceuticals' (MDGL) Phase 2b trial, as shown in the table below. For those who may argue that the 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 ≥ 30% reduction in liver fat	16.7%	100.0% (*P*=0.0002)	60.3% (*P*<0.0001)	75.0% (*P*<0.0001)	18.4%

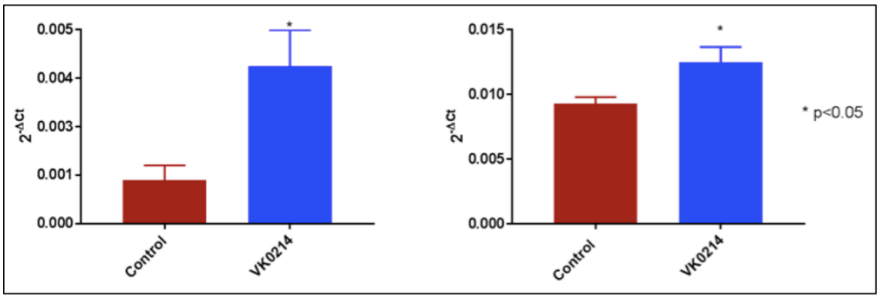
Sources: Viking Therapeutics, Inc.; Madrigal Pharmaceuticals, Inc.; Zacks SCR

- 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. 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. Lastly, treatment with VK2809 resulted in statistically significant decreases in LDL cholesterol, triglycerides, and the atherogenic proteins apolipoprotein B and lipoprotein A. We believe this may be particularly relevant in a NASH population as the most common cause of death for patients with NAFLD is cardiovascular disease (Azzam *et al*., 2015).

VK0214 IND Anticipated in 1H20

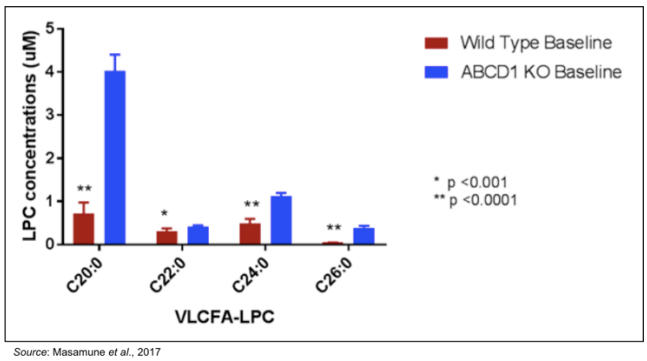
VK0214 is being developed for the treatment of X-linked adrenoleukodystrophy (X-ALD), an orphan neurodegenerative disease that affects approximately 8,000 individuals in the U.S. and 12,000 in Europe. In contrast to VK2809, VK0214 is a TRβ agonist that is activated by carboxyesterases that are ubiquitously 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.



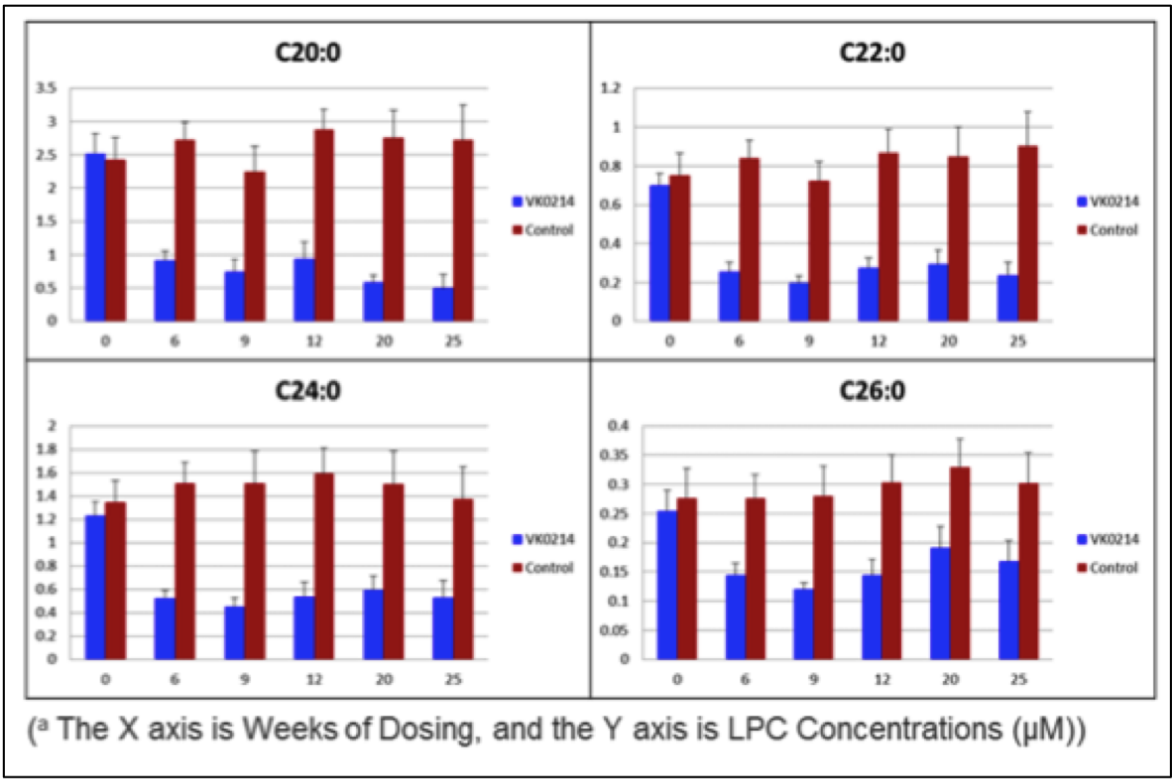
Source: Masamune *et al*., 2017

The company previously reported positive *in vivo* results 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 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.



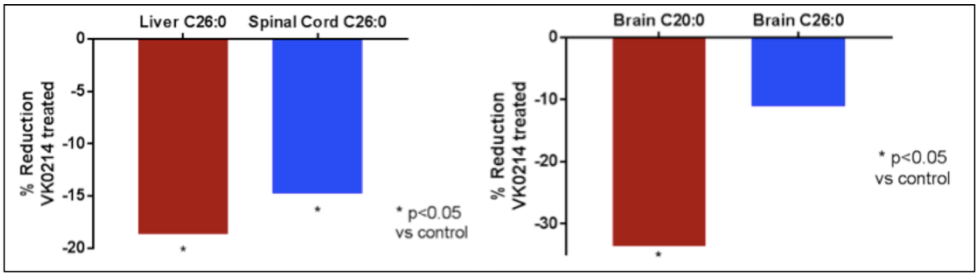
Source: Masamune *et al*., 2017

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 filed such that a proof-of-concept study can be initiated in the first half of 2020.

Financial Update

On August 1, 2019, Viking announced financial results for the second quarter of 2019. As expected, the company did not report any revenues in the second quarter of 2019. The company reported a net loss of $7.7 million, or $0.11 per share, for the second quarter of 2019 compared to a net loss of $6.7 million, or $0.13 per share, for the second quarter of 2018. R&D expenses for the second quarter of 2019 were $7.3 million compared to $5.2 million for the same period of 2018. The increase was primarily due to increased manufacturing expenses, pre-clinical studies, third-party consultants, and stock-based compensation. G&A expenses in the second quarter of 2019 were $2.2 million compared to $1.7 million for the second quarter of 2018. The increase was primarily due to increased stock-based compensation, salaries, and the use of third-party consultants.

As of June 30, 2019, Viking had approximately $292.6 million in cash, cash equivalents, and short-term

investments. As of July 31, 2019, Viking had approximately 72.2 million shares of common stock and when factoring in stock options, warrants, and restricted stock the company has a fully diluted share count of approximately 81.4 million shares.

Conclusion

We're glad to hear that everything remains on track for filing the IND for VK2809 and initiating the Phase 2b clinical trial in the second half of 2019. Investors should not expect any type of announcement regarding the IND or trial initiation until the study is cleared to get underway, thus for the time being "no news is good news". We believe the company is well prepared to get the study started and to execute it as efficiently as possible and while data will likely not be available until the first half of 2021, the potential for partnerships for VK2809, VK5211, and/or VK0214 continues. Our current valuation is $24.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E
VK5211	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
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	$19.0	$4.5	$7.3	$7.5	$8.0	$27.3	$30.0	$32.0
General & Administrative	$7.1	$2.3	$2.2	$2.3	$2.3	$9.1	$9.5	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($26.2)	($6.8)	($9.6)	($9.8)	($10.3)	($36.5)	($39.5)	($42.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$3.7	$1.9	$1.9	$1.8	$1.8	$7.4	$5.0	$5.0
Pre-Tax Income	($22.5)	($4.9)	($7.7)	($8.0)	($8.5)	($29.1)	($34.5)	($37.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($22.5)**	**($4.9)**	**($7.7)**	**($8.0)**	**($8.5)**	**($29.1)**	**($34.5)**	**($37.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.38)**	**($0.07)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.40)**	**($0.47)**	**($0.50)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	57.6	71.8	71.9	72.2	72.4	72.1	73.0	74.0

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

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