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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: VK2809 IND Filed; P2b Trial to Initiate in 4Q19…

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 (11/06/19)	$7.82
Valuation	**$24.00**

OUTLOOK

On November 5, 2019, Viking Therapeutics, Inc. (VKTX) announced financial results for the third quarter of 2019 and provided a business update. The company has filed the Investigational New Drug (IND) application for VK2809 such that a Phase 2b clinical trial can initiate in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH), with plans to initiate the trial before the end of 2019. Details of the trial design will be announced once the study gets underway, but we anticipate at least two doses of VK2809 given for up to 12 months in patients with F2 or F3 fibrosis, although a few F1 fibrosis patients may be included as well.
Additionally, IND-enabling work is continuing for VK0214 and we anticipate an IND being filed and a P1 proof-of-concept trial to initiate in the first half of 2020.

SUMMARY DATA

52-Week High	**$15.30**
52-Week Low	**$6.38**
One-Year Return (%)	**-53.44**
Beta	**2.29**
Average Daily Volume (sh)	**999,523**
Shares Outstanding (mil)	**72**
Market Capitalization ($mil)	**$474**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**62**
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	**-14.2**
P/E using 2019 Estimate	**-9.5**

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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	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	-$0.08 A	-$0.12 E	-$0.37 E
2020					-$0.47 E
2021					-$0.50 E

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WHAT'S NEW

Business Update

IND Filed for VK2809; P2b Trial to Initiate in 4Q19

On November 5, 2019, Viking Therapeutics, Inc. (VKTX) provided a business update, which included the announcement that the Investigational New Drug (IND) application for VK2809 has been submitted to the FDA such that a Phase 2b clinical trial in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) can be initiated.

The company had previously studied VK2809 in a Phase 2a clinical trial in patients with hypercholesterolemia and nonalcoholic fatty liver disease (NAFLD), which was performed under an IND filed with the Division of Metabolic and Endocrinology Products. Thus, since the company is now focused on NASH patients, it was necessary to file an IND with the Division of Gastroenterology and Inborn Error Products. While we are unsure of the exact timing of the IND submission, we are confident that the FDA will clear the IND (which usually takes 30 days, although given the size and scope of the VK2809 IND submission we would not be surprised if it takes a little bit longer) and that the company will get the Phase 2b trial initiated before the end of 2019.

Once the trial gets underway we anticipate learning additional details about the study design, including the number of patients, the number of doses being tested, and the length of treatment. We would consider the Phase 2b trial currently being conducted by CymaBay Therapeutics (CBAY) as a good template for what investors should ultimately expect regarding Viking's Phase 2b trial. CymaBay is currently conducting a Phase 2b trial testing the efficacy of seladelpar, a peroxisome proliferator-activated receptor δ (PPARδ) agonist, in 181 patients with biopsy-confirmed NASH. Based upon CymaBay's trial, we anticipate the following feature's in Viking's trial:

- Approximately 150-200 biopsy-confirmed NASH patients, the majority of which with F2 or F3 fibrosis (although there is likely to be a small cohort with F1 fibrosis)
- Multiple doses of VK2809 will be tested, most likely 5 mg daily along with at least one dose below 5 mg
- Enrollment will likely take 9-12 months (CymaBay finished enrollment in nine months)
- 12-week MRI-PDFF data approximately four months following completion of enrollment with the potential for 26-week MRI-PDFF data (if collected) approximately five months later
- 52-week MRI-PDFF and biopsy data approximately 14 months following completion of enrollment

With the trial set to initiate in the fourth quarter of 2019, we estimate that enrollment could complete during the third quarter of 2020, 12-week MRI-PDFF data could be available in late fourth quarter of 2020 or early first quarter 2021, and 52-week biopsy and MRI-PDFF data could be available in the fourth quarter of 2021.

VK2809 Results Point to Potential Best-in-Class Activity

Based upon the data that has been presented thus far by Viking and Madrigal Pharmaceuticals, Inc. (MDGL), which is currently studying resmetirom in a Phase 3 trial for the treatment of NASH, we view VK2809 as a potential 'best-in-class' treatment for NASH based on its efficacy, potency, and safety. Like VK2809, resmetirom is a thyroid hormone receptor (TR)-β agonist.

The following table shows the mean relative liver fat reduction, mean absolute liver fat reduction, and the percentage of patients that experienced a $\geq$ 30% or $\geq$ 50% reduction in liver fat following 12 weeks of treatment with either VK2809 or resmetirom. VK2809 shows superior efficacy to resmetirom across all doses tested, including 100% of patients treated with 5 mg VK2809 experiencing a $\geq$ 30% reduction in liver fat. For those who may argue that the patient populations are too dissimilar to offer a valid comparison (VK2809 was tested in a NAFLD population while resmetirom was tested in a biopsy-confirmed NASH population), we believe that the very similar placebo responses seen in both trials indicate that the two populations were in fact quite similar. In addition, the fact that we have yet to see 'super responder' data from Madrigal (the percentage of patients experiencing a $\geq$ 50% reduction in liver fat following 12 weeks of treatment) indicates to us that a negligible percentage of patients likely achieved that level of response.

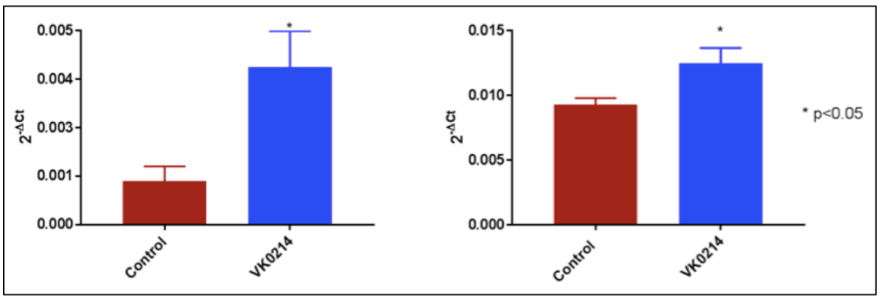
	Placebo (n=12)	VK2809 5mg QD (n=9)	VK2809 10mg QOD (n=13)	VK2809 10mg QD (n=11)	VK2809 combined (n=33)	All MGL-3196 (n=78)	High MGL-3196 (n=44)	Placebo (n=38)
Mean relative % change in liver fat by MRI-PDFF	-9.4%	-53.8% (*P*=0.0001)	-56.5% (*P*=0.0018)	-59.7% (*P*=0.0004)	-56.5% (*P*<0.0001)	-36.3% (*P*<0.0001)	-42.0% (*P*<0.0001)	-9.6%
Mean 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)	-7.6% (*P*<0.0001)	-8.8% (*P*<0.0001)	-1.6%
% of pts ≥ 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)	60.3% (*P*<0.0001)	75.0% (*P*<0.0001)	18.4%
% of pts ≥ 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)	Not Reported	Not Reported	Not Reported

Source: Viking Therapeutics, Inc. / Madrigal Pharmaceuticals, Inc. / Zacks SCR

IND-enabling Work Continuing for VK0214; IND to be Submitted 1H20

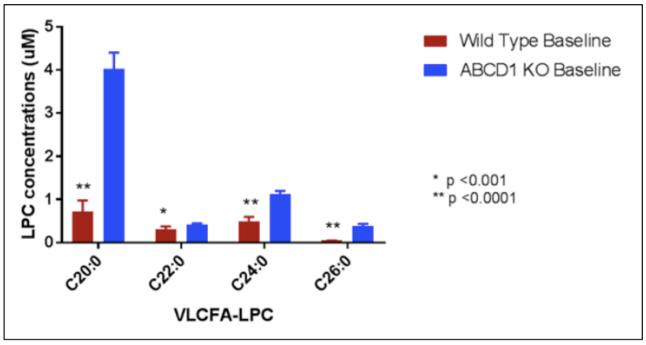
VK0214 is being developed for the treatment of X-linked adrenoleukodystrophy (X-ALD), an orphan neurodegenerative disease that affects approximately 8,000 individuals in the U.S. and 12,000 in Europe. In contrast to VK2809, VK0214 is a TRβ agonist that is activated by carboxyesterases that are ubiquitously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



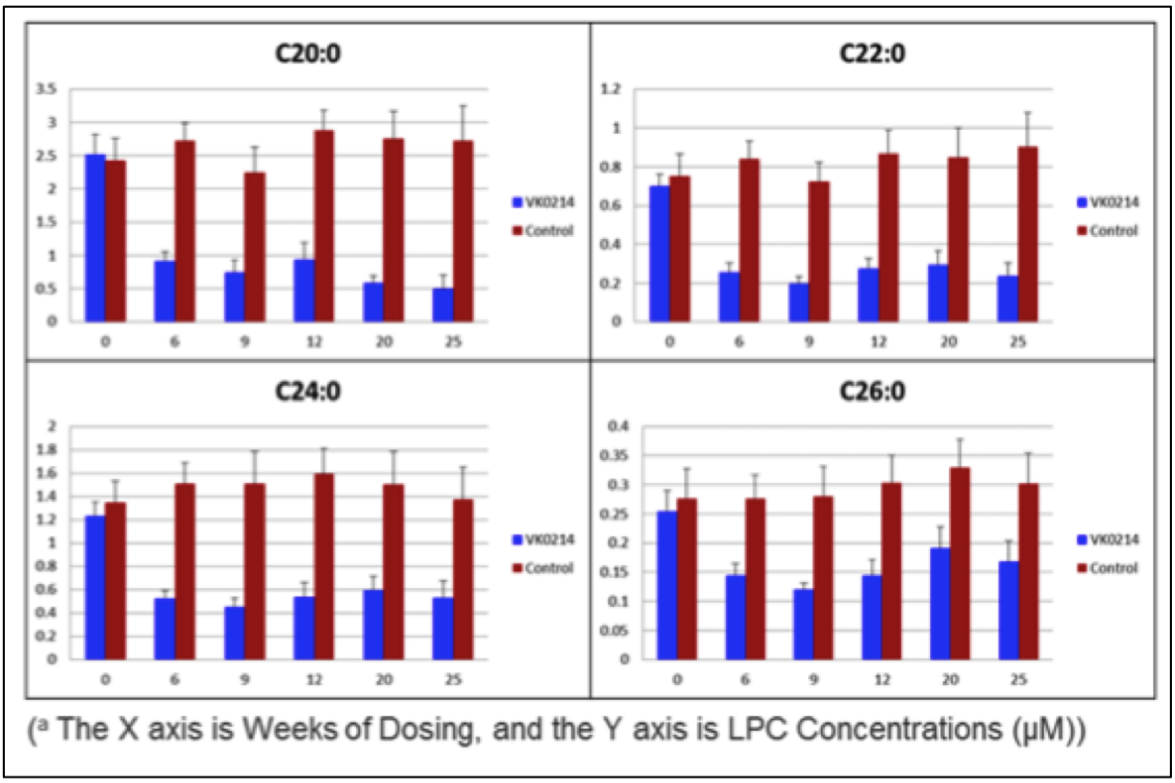
Source: Masamune *et al.*, 2017

The company previously presented positive *in vivo* results at the 87th Annual Meeting of the American Thyroid Association (Masamune *et al*., 2017) 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.



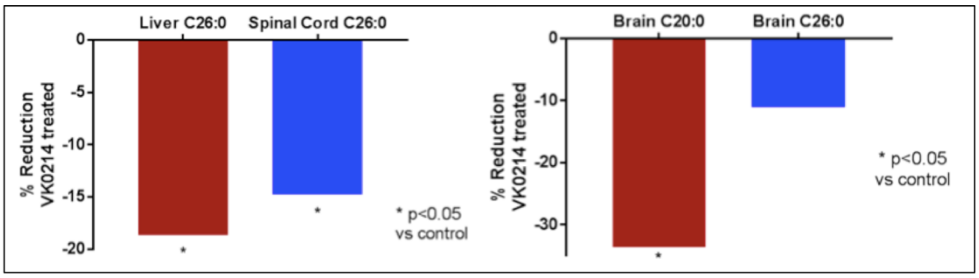
Source: Masamune *et al.*, 2017

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 and a proof-of-concept Phase 1 study being initiated in the first half of 2020.

Financial Update

On November 5, 2019, Viking announced financial results for the third quarter of 2019. As expected, the company did not report any revenues in the third quarter of 2019. The company reported a net loss of $5.8 million, or $0.08 per share, compared to a net loss of $6.6 million, or $0.11 per share, in the third quarter of 2018. R&D expenses in the third quarter of 2019 were $5.3 million compared to $5.7 million in the third quarter of 2018. The decrease was primarily due to decreased stock-based compensation and manufacturing costs. G&A expenses for the third quarter of 2019 were $2.2 million compared to $1.7 million for the third quarter of 2018. The increase was primarily due to stock-based compensation and consultant fees.

As of September 30, 2019, Viking had approximately $288.1 million in cash, cash equivalents, and short-term investments and approximately 72.3 million shares outstanding. When factoring in stock options, warrants, and restricted stock the company has a fully diluted share count of approximately 81.5 million shares.

Conclusion

Now that the IND is submitted the company is awaiting any feedback from the FDA and clearance to initiate the Phase 2b trial, which typically takes 30 days following submission. At this point we see the only real question mark regarding the trial as being what type of restrictions, if any, the FDA will place on enrollment. Based on the safety data reported thus far we would be surprised to see any type of restrictions on patient enrollment. Once the trial is underway we anticipate learning additional details of the study, after which estimates of the trial timeline should become clearer. Our valuation remains at $24.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2018 A	Q1 A	Q2 A	Q3 A	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	$5.3	$8.0	$25.1	$30.0	$32.0
General & Administrative	$7.1	$2.3	$2.2	$2.2	$2.3	$9.0	$9.5	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($26.2)	($6.8)	($9.6)	($7.4)	($10.3)	($34.1)	($39.5)	($42.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$3.7	$1.9	$1.9	$1.6	$1.8	$7.2	$5.0	$5.0
Pre-Tax Income	($22.5)	($4.9)	($7.7)	($5.8)	($8.5)	($26.9)	($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)**	**($5.8)**	**($8.5)**	**($26.9)**	**($34.5)**	**($37.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.38)**	**($0.07)**	**($0.11)**	**($0.08)**	**($0.12)**	**($0.37)**	**($0.47)**	**($0.50)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	57.6	71.8	71.9	72.0	72.1	72.0	73.0	74.0

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

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