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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Phase2b Trial of VK2809 Underway…

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 (11/21/19)	$7.07
Valuation	**$24.00**

OUTLOOK

On November 19, 2019, Viking Therapeutics, Inc. (VKTX) announced that the Phase 2b VOYAGE trial of VK2809 in patients with biopsy confirmed nonalcoholic steatohepatitis (NASH) is underway. A total of 340 patients will be randomized to five dosing levels: 1 mg VK2809 daily, 2.5 mg VK2809 daily; 5 mg VK2809 every other day; 10 mg VK2809 every other day; or placebo. There are no restrictions on enrollment for patients with Type 2 diabetes or those on certain cholesterol-lowering medications, such as statins. The primary endpoint is the 12-week change in liver fat as measured by MRI-PDFF with secondary endpoints including histological changes assessed by liver biopsy at 52 weeks. We anticipate enrollment taking approximately 1 year and 12-week liver fat data being available in the first half of 2021.

SUMMARY DATA

52-Week High	**$12.26**
52-Week Low	**$6.38**
One-Year Return (%)	**-42.29**
Beta	**2.29**
Average Daily Volume (sh)	**1,653,901**
Shares Outstanding (mil)	**72**
Market Capitalization ($mil)	**$511**
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	**-18.3**
P/E using 2019 Estimate	**-11.3**

Risk Level	**Average**
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 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

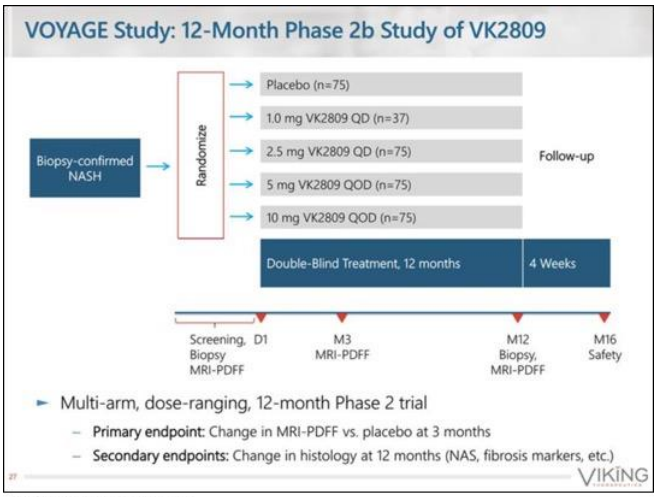
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WHAT'S NEW

Business Update

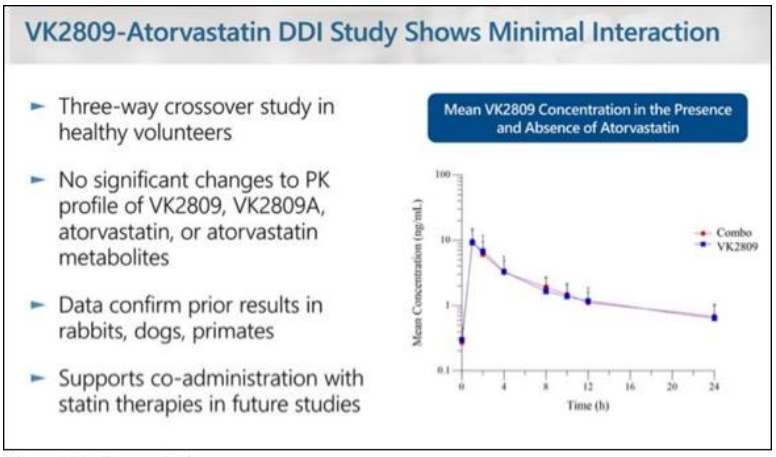
Phase 2b VOYAGE Trial Initiated

On November 19, 2019, Viking Therapeutics, Inc. (VKTX) announced that the Phase 2b VOYAGE trial of VK2809 in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) is underway. 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 potentially 10-15 centers ex-US. An overview of the trial is given below.



Source: Viking Therapeutics, Inc.

Importantly, there were no restrictions placed on patient enrollment like those that were in place for the Phase 2 trial of VK2809 in patients with hypercholesterolemia and fatty liver disease. In that trial, there were restrictions on enrolling diabetic patients and those on statin-type lipid-lowering medications. For the Phase 2b trial, there are no such restrictions, thus the company will be free to enroll patients with comorbidities such as Type 2 diabetes, obesity, and metabolic syndrome, as well as those taking certain cholesterol-lowering medications, including statins. The company recently presented data from a drug-drug interaction study of VK2809 and atorvastatin in healthy volunteers showing that there is no significant change to the pharmacokinetic (PK) profile of VK2809 when dosed in combination with atorvastatin. This is important as many NASH patients are on lipid-lowering medications, thus there should be no issue with treating those patients with VK2809.



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. The company has not yet submitted the 12-month toxicology data to the FDA, thus the trial is currently only approved for 6-months of dosing. However, we anticipate that data being submitted no later than the first quarter of 2020 and following clearance by the FDA patients will receive the full 52 weeks of dosing.

With 340 patients targeted for the study we estimate that enrollment will take approximately 12 months, however once the initial enrollment numbers are known in early 2020 we should have a better sense for when full enrollment will occur. If the trial is enrolled by the end of 2020, we estimate 12-week MRI-PDFF data would be available in the first half of 2021 and full 52-week biopsy data would be available in the first half of 2022.

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 ≥ 30% or ≥ 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 ≥ 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 ≥ 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

Questions Regarding Madrigal's Phase 2b Results in The Lancet

On Nov. 11, 2019, Madrigal announced the publication of results from the company's Phase 2b clinical trial in *The Lancet* (Harrison *et al*., 2019). This was a 36-week randomized, double blind, placebo controlled trial of resmetirom (MGL-3196) in patients with biopsy confirmed NASH (fibrosis stages F1-F3). The primary efficacy analysis was relative change in MRI-PDFF in resmetirom-treated patients compared to placebo at week 12 (NCT02912260). Results showed that resmetirom-treated patients showed a statistically significant reduction in hepatic fat at week 12 (-32.9% vs. -10.4%; *P*<0.0001) and week 36 (-37.3% vs. -8.5%; *P*<0.0001). While resmetirom certainly showed good activity in reducing liver fat in NASH patients, there are a few questions we have following an analysis of the manuscript:

1) Does resmetirom have a PK problem?

   All patients assigned to receive resmetirom got an 80 mg daily dose for the first four weeks. For each patient, a 24-hour resmetirom area under the curve (AUC) was estimated, and on the basis of that value the patient was either lowered to 60 mg daily, maintained at 80 mg daily, or increased to 100 mg daily. Of the 79 patients who completed four weeks of dosing, 37 (47%) had their dose reduced to 60 mg while the remaining 42 either maintained on 80 mg daily (n=37, 47%) or increased to 100 mg daily (n=5, 6%).

Then, for efficacy analysis a 'high exposure group' (AUC ≥ 2700 ng*h/mL) and a 'low exposure group' (AUC < 2700 ng*h/mL) were defined based on the AUC that showed significant lipid lowering effects in a Phase 1 study (Taub *et al*., 2013). The 'high exposure group' consisted of 44 patients while the 'low exposure group' consisted of 34 patients (note: we believe 1 patient who had four weeks of dosing did not get an MRI-PDFF measurement at week 12). While it would make sense that all patients on 60 mg resmetirom would be 'low exposure' and all patients at 80 mg or above would be 'high exposure', we noticed that the number of patients reduced to 60 mg (n=37) does not match the number in the 'low exposure group' (n=34) and that the number of 'high exposure' patients (n=44) does not match the number maintained at 80 mg or moved to 100 mg (n=42). Is the difference simply that two patients at 60 mg were part of the 'high exposure' group and 2 patients from the 80/100 mg group were part of the 'low exposure' group, or were there additional patients whose dosage levels didn't correspond with 'high exposure' and 'low exposure'? We were unable to identify this information in the manuscript.

2) What will the AE profile look like with all patients on 80 or 100 mg resmetirom?

The Phase 2b trial of resmetirom showed that the drug was generally well tolerated, however as shown below 33% of resmetirom patients experienced diarrhea (compared to 7% of placebo patients) and 14% of resmetirom patients experienced nausea (compared to 5% of placebo treated patients). This AE profile occurred with approximately 50% of the resmetirom patients on 60 mg/day (as explained above). We have been unable to locate information regarding a dose titration step in the Phase 3 trial for resmetirom, thus it will be interesting to see what the diarrhea/nausea AE profile looks like when all resmetirom patients are on either 80 or 100 mg per day.

	Placebo, n=41	Resmetirom, n=84
Patients with treatment-emergent adverse events, n (%)	28 (68%)	73 (86·9%)
Severe	2 (5%)	6 (7%)
Moderate	13 (32%)	27 (32%)
Mild	13 (32%)	40 (48%)
Patients with serious adverse events	2 (5%)	5 (6%)
Patients with drug-related serious adverse events	0	0
Adverse events occurring in ≥10%, n (%)		
Diarrhoea (baseline to week 12)	3 (7%)	28 (33%)
Nausea (baseline to week 12)	2 (5%)	12 (14%)
Diarrhoea (week 12–36)	1 (2%)	3 (4%)
Nausea (week 12–36)	1 (2%)	5 (6%)
Headache	6 (15%)	11 (13%)
Urinary tract infection	4 (10%)	9 (11%)
Dizziness	4 (10%)	6 (7%)
Fatigue	4 (10%)	4 (5%)
Grade 3 laboratory changes (CTCAE*)		
Alanine aminotransferase >5 times ULN	3 (7%)	1 (1%)†
Gamma-glutamyl transferase >5 times ULN	5 (12%)	1 (1%)

Data are n (%). Five times ULN was only reported if the value was at least two times greater than baseline. CTCAE=Common Terminology Criteria for Adverse Events. ULN=upper limit of normal. *CTCAE-based assessments were post hoc. †One resmetirom patient took a double dose (160 mg/day) for 2 weeks before the week 2 visit and showed increased liver enzymes to three times baseline at week 2; liver enzymes resolved during the study, with alanine aminotransferase decreasing from 77 IU/L at baseline to 17 IU/L on 80 mg/day.

Source: Harrison *et al*., 2019

3) Why was the definition of NASH resolution changed?

The clinical trial protocol for the Phase 2b trial of resmetirom as posted on clinicaltrials.gov (NCT02912260) lists multiple secondary endpoints, including a ≥ 2 point reduction in NAS and a resolution of NASH defined as a ballooning score = 0 plus an inflammation score = 0 or 1 (which is the definition utilized by the FDA, explained below). However, in Harrison *et al*. NASH resolution is defined as "…at least a 2-point reduction in NAS *plus* [emphasis added] a ballooning score of 0 with lobular inflammation score of 0 or 1." In other words, it appears as though the definition of NASH resolution was changed between the clinical protocol and the manuscript by combining the aforementioned secondary endpoints. Having both a 2-pt reduction in NAS along with a ballooning score of 0 and inflammation score of 0 or 1 is a higher hurdle for placebo patients to clear, as evidenced by the fact that only 32% of placebo patients achieved a 2-pt reduction in NAS in the Phase 2b trial compared with 56% of resmetirom patients. Thus, the effect of resmetirom on NASH resolution may be overestimated by the altered definition due to the fact that only approximately 1/3rd of the comparison group can achieve a 2-pt reduction in NAS.

We note that the Phase 3 trial of resmetirom uses the same definition of NASH resolution used in Harrison *et al*. The FDA guidance on developing drugs for NASH lists two suggested endpoints for Phase 3 trials: 1) resolution of NASH (defined as ballooning = 0, inflammation = 0 or 1, any value for steatosis) plus no worsening of fibrosis or 2) 1 stage or greater improvement in liver fibrosis and no worsening of NAS (no increase for ballooning, inflammation, or steatosis). The FDA makes no mention of including a ≥ 2-point NAS reduction in their definition of NASH resolution. Also of note is that the Phase 3 trials for Intercept's obeticholic acid (NCT02548351) and Genfit's elafibranor (NCT02704403) both define NASH resolution the same as the FDA.

Conclusion

We are glad to see that the Phase 2b trial of VK2809 is underway and that there are no restrictions placed on inclusion criteria such that the company will be able to enroll patients from a much larger population than the Phase 2a trial. Our estimate of one year to enroll the trial is preliminary and we believe it is achievable and perhaps even a bit conservative, but once initial enrollment numbers are known in the first half of 2020 we should be able to better estimate completion of enrollment. We don't think the limitation of 6-month dosing at this point is an issue as the 12-month toxicity data will be submitted within the next few months and we are confident that the FDA will allow dosing up to 12-months once that data is reviewed. 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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