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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Pre-IND Meeting with FDA in Summer 2019; Phase 2b NASH Trial 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 (05/03/19)	$8.15
Valuation	**$24.00**

OUTLOOK

On May 2, 2019, Viking Therapeutics, Inc. (VKTX) announced financial results for the first quarter of 2019 and provided a business update. During the conference call, the company announced that a pre-IND meeting will be conducted this summer with the FDA, after which an IND will be filed so that a Phase 2b clinical trial of VK2809 can be initiated in the second half of 2019. Details regarding the trial design have yet to be finalized, however the trial will include biopsy-confirmed NASH patients with F2 and F3 fibrosis, as well as a limited number with F1 fibrosis. Given the efficacy seen with the 5 mg dose in the Phase 2a trial, we anticipate multiple doses being tested with at least one dose being lower than 5 mg. The company also announced pre-IND studies are continuing for VK0214 and we anticipate an IND being filed later in 2019.

SUMMARY DATA

52-Week High	**$19.65**
52-Week Low	**$4.04**
One-Year Return (%)	**96.86**
Beta	**2.56**
Average Daily Volume (sh)	**3,031,611**
Shares Outstanding (mil)	**72**
Market Capitalization ($mil)	**$587**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**65**
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	**-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 A	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	-$0.07 A	-$0.08 E	-$0.09 E	-$0.09 E	-$0.33 E
2020					-$0.43 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). A pre-IND meeting will be conducted with the FDA in mid-summer 2019, after which an IND will be filed such that the trial can be initiated in the second half of 2019. While details of the trial have yet to finalized, we do anticipate the trial including biopsy-confirmed NASH patients with F2 and F3 fibrosis (although there are likely to be a small number with F1 fibrosis).

Regarding the upcoming trial, based on the length for competitors Phase 2b trials we estimate that if started in the second half of 2019 topline data would probably be available in the first half of 2021, although 4Q20 isn't 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.

As far as potential doses to be studied in the Phase 2b trial, based on 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 it likely wouldn't make sense to test any doses below that.

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 Update

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. IND-enabling studies are currently ongoing for VK0214, and we anticipate an IND being filed in 2019 such that a proof-of-concept study can be initiated.

Financial Update

On May 2, 2019, Viking announced financial results for the first quarter of 2019. As expected, the company did not report any revenues in the first quarter of 2019. The company reported a net loss of $4.9 million, or $0.07 per share, for the first quarter of 2019 compared to a net loss of $3.6 million, or $0.08 per share, for the first quarter of 2018. R&D expenses for the first quarter of 2019 were $4.5 million compared to $3.0 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 first quarter of 2019 were $2.3 million compared to $1.8 million for the first quarter of 2018. The increase was primarily due to increased stock-based compensation, salaries, and the use of third-party consultants.

As of Mar. 31, 2019, Viking had approximately $298.7 million in cash, cash equivalents, and short-term investments. As of April 30, 2019, Viking had approximately 72.0 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 82 million shares.

Conclusion

Even with the excellent efficacy and safety data for VK2809, Viking's stock continues to languish. We believe this is partly due to the large number of shorted shares, although this number has come down recently. As of Apr. 15, 2019, there were approximately 28.7 million shares sold short, representing approximately 47% of the float. We continue to be flummoxed by the large number of Viking's shares sold short, particularly since 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 and for it to potentially cause cardiac toxicity here.

One very large potential catalyst for the stock could be the announcement of a partnership for VK2809, although we admit it is difficult to handicap the possibility for one at this point. Fortunately, Viking is in very strong financial shape and is able to move forward with development of VK2809 on its own, but with the stellar efficacy and safety of the drug we believe it is a very attractive partnership opportunity. Our valuation remains $24.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2018 A	Q1 A	Q2 E	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	$5.0	$5.1	$5.2	$19.8	$25.0	$30.0
General & Administrative	$7.1	$2.3	$1.8	$1.8	$1.8	$7.7	$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)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$3.7	$1.9	$0.8	$0.6	$0.4	$3.7	$1.0	$1.0
Pre-Tax Income	($22.5)	($4.9)	($6.0)	($6.3)	($6.6)	($23.8)	($31.5)	($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)**	**($6.0)**	**($6.3)**	**($6.6)**	**($23.8)**	**($31.5)**	**($37.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.38)**	**($0.07)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.33)**	**($0.43)**	**($0.50)**
YOY Growth	-	-	-	-	-	-	-	-
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*

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