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Viking Therapeutics (VKTX-NASDAQ)

VKTX: Data from Phase 2 Study of VK2809 in NASH in 2H18; Sufficient Cash to Fund Operations to 2020…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $13/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 (03/09/18)	$5.63
Valuation	**$13.00**

OUTLOOK

On March 7, 2018, Viking Therapeutics, Inc. (VKTX) announced financial results for the fourth quarter and full year 2017 and provided a business update. Viking is planning on presenting data from the Phase 2 trial of VK5211 in hip fracture patients at a scientific conference in the second half of 2018. The company has indicated that it will not pursue a Phase 3 trial for VK5211 without first entering into a partnership with a larger pharmaceutical company.

The company's Phase 2 clinical trial of VK2809 in nonalcoholic steatohepatitis (NASH) is continuing to enroll patients and we now anticipate results in the second half of 2018. A Phase 1 trial of VK2809 in patients with glycogen storage disease 1a (GSD1a) will initiate in 2Q18.

SUMMARY DATA

52-Week High	**$6.93**
52-Week Low	**$0.93**
One-Year Return (%)	**333.08**
Beta	**1.81**
Average Daily Volume (sh)	**1,506,160**
Shares Outstanding (mil)	**51**
Market Capitalization ($mil)	**$287**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**20**
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	**-7.0**
P/E using 2019 Estimate	**-7.4**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 E	0 E	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.23 A	- $0.21 A	-$0.22 A	-$0.14 A	-$0.79 A
2018	-$0.11 E	-$0.11 E	-$0.11 E	-$0.12 E	-$0.45 E
2019					-$0.43 E
2020					-$0.40 E

WHAT'S NEW

Business Update

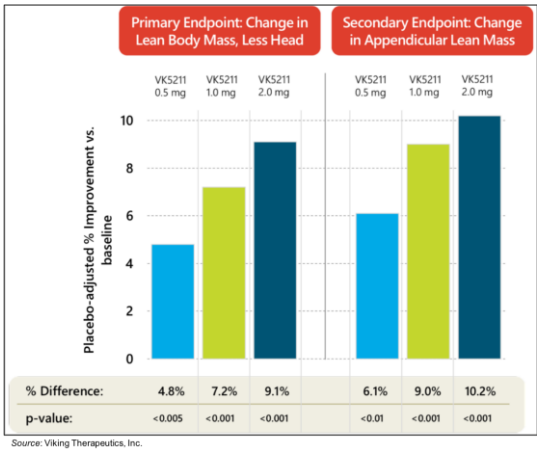
Viking Therapeutics, Inc. (VKTX) is a biopharmaceutical company developing treatments for metabolic and endocrine disorders. The company's lead compounds include:

1) **VK5211**, which is being developed for acute rehabilitation following non-elective hip fracture surgery.
   - The company announced positive topline data from a Phase 2 trial in Nov. 2017 and we anticipate the full data set being presented at a scientific conference in the second half of 2018. The company plans to request a type C meeting with the FDA, after which the company anticipates entering into a development partnership with a larger pharmaceutical company to move the compound into a Phase 3 program.
2) **VK2809**, which is being developed for the treatment of hypercholesterolemia and fatty liver disease, along with the orphan disease glycogen storage disease type Ia (GSD Ia).
   - Viking anticipates data from the ongoing Phase 2 study of VK2809 in fatty liver disease in the second half of 2018. A human proof-of-concept study in GSD Ia will initiate in the second quarter of 2018.
3) **VK0214**, which is being developed for the treatment of X-linked adrenoleukodystrophy (X-ALD).
   - IND-enabling studies are currently underway and we anticipate an IND being filed in the fourth quarter of 2018.

VK5211

On November 28, 2017, Viking Therapeutics, Inc. (VKTX) announced positive topline results from the Phase 2 study of VK5211, a selective androgen receptor modulator (SARM), in patients recovering from hip fracture. This was a multicenter, randomized, double blind, placebo controlled trial that enrolled a total of 108 subjects (83 women and 25 men) age ≥ 65 years of age who had suffered a hip fracture within the past three to seven weeks. Subjects were administered placebo or 0.5 mg, 1.0 mg, or 2.0 mg of VK5211 once-daily for 12 weeks (NCT02578095). The primary outcome of the trial was the change in lean body mass, less head, after 12 weeks of treatment. Secondary and exploratory endpoints included assessments of functional performance, quality-of-life, and activities of daily living.

- Placebo-adjusted increases in lean body mass, less head, were 4.8% (or 1.6 kg) at 0.5 mg (*P*<0.005), 7.2% (or 2.5 kg) at 1.0 mg (*P*<0.001), and 9.1% (or 3.1 kg), as shown in the following figure.



To put this data into context, it's reported that in the first year after hip fracture lean body mass decreases by up to 11% (Fox *et al.*, 2000). Also, the company's scientific advisors had stated that a 2-4% increase in lean body mass, less head, would be considered a positive outcome, thus even the lowest dose performed better than those assumptions. Lastly, these results also appear to be superior to those seen in a Phase 2 study in healthy men >60 years of age of enobosarm, a SARM being developed by GTX Inc. (GTXI). In that study, the highest dose of enobosarm (3 mg) resulted in an ~3% increase in lean body mass, which is less than that seen for the lowest dose of VK5211 in a similar population (Dalton *et al.*, 2011). GTXI is developing enobosarm for treating stress urinary incontinence and breast cancer.

- Subjects experiencing at least a 5% increase in lean body mass, less head, were 19% with placebo, 61% at 0.5 mg (P<0.01), 65% at 1.0 mg (P<0.01), and 75% at 2.0 mg (P<0.01).

- While not powered for efficacy, numerical advantages were seen in various functional secondary endpoints, including the 6-minute walk test and short physical performance battery. These analyses were included in order to look for signals in potential outcomes for future clinical trials.

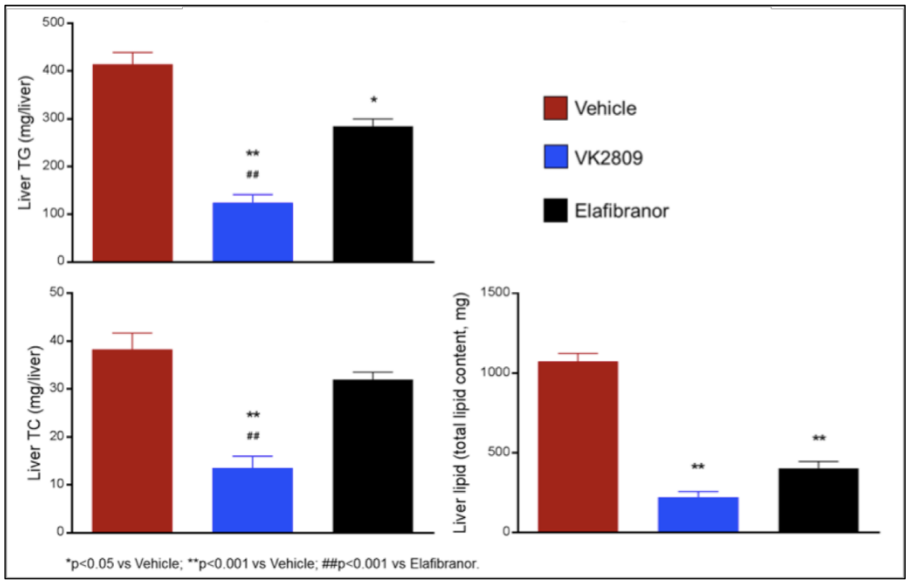
- There were no safety signals observed, as there were 0 drug-related serious adverse events and no difference in adverse events between placebo and active groups or between the different dosages.

We anticipate the company meeting with the FDA in the second half of 2018 to determine the path forward for a Phase 3 registration study, however we do not believe Viking will move VK5211 into a Phase 3 program before entering into a development partnership with a larger pharmaceutical company. The full data set from the Phase 2 trial will likely be presented at one or more future scientific conferences, such as the 2018 American Society for Bone and Mineral Research (ASBMR) meeting, which takes place in late Sep. 2018. In addition, we believe the data likely opens the door to additional potential indications for VK5211 such as cachexia, sarcopenia, and joint replacement, although the company is currently only focusing on hip fracture recovery.

VK2809

Viking is currently testing VK2809, the company's thyroid hormone receptor beta (TRβ) agonist, in a Phase 2 clinical trial in patients with hypercholesterolemia and fatty liver disease. Patients are being treated once daily with Vk2809 or placebo for 12 weeks followed by four weeks off drug. The primary endpoint will assess changes in LDL cholesterol, with exploratory endpoints evaluating changes in liver fat content, inflammatory markers, and histological changes. We now anticipate topline results in the second half of 2018.

In October 2017, Viking announced the presentation of results from a study of VK2809 in an *in vivo* model of non-alcoholic steatohepatitis (NASH). Statistically significant improvements in a number of key measures were seen during the study and gene expression analysis showed statistically significant changes in expression for genes associated with the development and progression of NASH. The following figure shows levels of liver triglycerides (-70%), liver total cholesterol (-65%) and liver total lipid content (-80%) were all significantly lower in mice treated with VK2809 compared to vehicle control mice. The difference in liver triglycerides and liver cholesterol was also significant between VK2809- and elafibranor-treated mice.



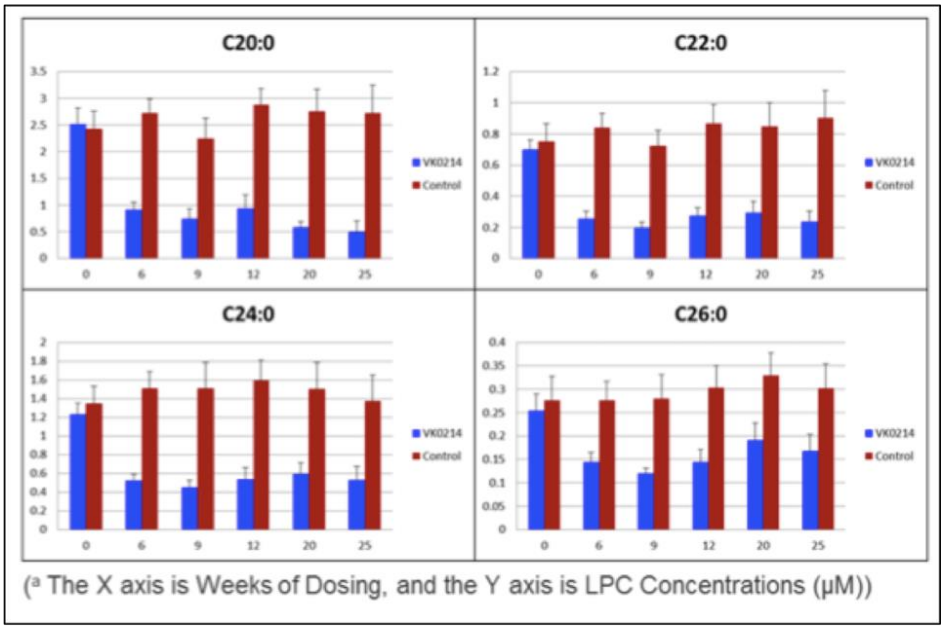
Source: Lian *et al.*, 2017

VK2809 will also be tested as a treatment for glycogen storage disease 1a (GSD 1a), a rare, orphan genetic disease caused by mutations (thus far, 84 have been identified) in glucose-6-phophatase, a key enzyme involved in the maintenance of glucose homeostasis. Patients with GSD 1a accumulate excess glycogen in the liver and kidney, which results in progressive hepatomegaly and nephromegaly. Additional metabolic consequences include hypercholesterolemia, hypertriglyceridemia, hyperuricemia, and lactic acidemia. Accumulation of fats in the liver

also contributes to hepatomegaly. There is no cure for GSD 1a and dietary augmentation is the current standard of care for patients. Viking had previously announced encouraging results from an *in vivo* study of VK2809 in a mouse model of GSD 1a, which included a statistically significant 69% decrease in mean total liver triglycerides. We anticipate a Phase 1 trial in GSD 1a patients initiating in the second quarter of 2018.

VK0214

IND-enabling studies have been initiated for VK0214, another TRβ agonist that is activated by carboxyesterases that are ubiquitously expressed in the body. In October 2017, Viking announced results from a 25-week proof-of-concept study of VK0214 in an *in vivo* model of X-linked adrenoleukodystrophy (X-ALD) showing that treatment with VK0214 led to statistically significant reductions in plasma levels of very long chain fatty acids (VLCFAs) compared to vehicle controls. There was also a reduction seen in brain and spinal cord VLCFAs, an exciting observation as those tissues are especially prone to degeneration in X-ALD. The following charts show the level of VLCFAs over the course of the 25-week study. Treatment with VK0214 resulted in a dramatic decrease in VLCFA levels only six weeks after initiating treatment, and this decline was held relatively steady through the entire 25-week treatment period.



Source: Masamune *et al*., 2017

Financial Update

On March 7, 2018, Viking announced financial results for the fourth quarter and full year 2017. For the fourth quarter of 2017, the company had a net loss of $4.1 million, or $0.14 per share, compared to a net loss of $3.6 million, or $0.18 per share, in the fourth quarter of 2016. The loss included $3.0 million in R&D expenses, compared to $2.6 million for the same period in 2016, with the increase due to increased activities related to the VK2809 clinical program. G&A expenses totaled $1.4 million, compared to $1.1 million for the fourth quarter of 2016, with the increase due to increases in salaries and benefits-related expense.

For the full year, the company reported a net loss of $20.6 million, or $0.79 per share. R&D expenses were $13.7 million, compared to $9.0 million for 2016, with the increase due to increased expenses related to clinical trial activity for VK5211 and VK2809 along with increased preclinical expenses for VK0214. G&A expenses totaled $5.3 million, compared to $4.8 million in 2016. The increase was due to increased salaries and benefit expenses partially offset by a decrease in non-cash stock compensation.

Viking exited 2017 with approximately $20.6 million in cash and cash equivalents. Subsequent to the end of the year, Viking sold a total of 12.65 million shares of common stock for gross proceeds of $63.3 million in a public offering. We believe the company has sufficient capital to fund operations into 2020. As of Feb. 28, 2018, Viking had approximately 50.9 million shares outstanding (of which Ligand owns approximately 14.9%) and when factoring in outstanding shares of restricted stock, stock options, and warrants the company has a fully diluted share count of approximately 65.1 million shares.

Conclusion

While not ideal, we don't believe pushing back the results for the Phase 2 trial of VK2809 to the second half of 2018 is a cause for concern. We still have a high degree of confidence in that study, as discussed in our previous update comparing VK2809 to Madrigal Pharmaceuticals MGL-3196.

In addition to that data, we anticipate a potential partnering of VK5211 in the second half of 2018. Viking has indicated that VK5211 will not be moved into a Phase 3 program without a partnership in place, which we believe is most likely to occur following presentation of the full dataset from the Phase 2 trial at a scientific conference and a type C meeting with the FDA in the second half of 2018. The company has yet to decide whether to release the 24-week follow up data from that study, which should be received this month, or hold off to present it during the scientific conference.

Any weakness in the stock based on the delay in releasing data for the hypercholesterolemia and fatty liver disease trial should be viewed as a buying opportunity for investors as positive data from that trial will cause a significant revaluation in the shares. We are maintaining a $13 valuation.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2017 A	Q1 E	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
VK5211 (Hip Fracture)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK2809 (Hypercholesterolemia)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK0214 (ALD)	$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	$13.7	$4.0	$4.1	$4.2	$4.5	$16.8	$18.0	$20.0
General & Administrative	$5.3	$1.5	$1.5	$1.6	$1.6	$6.2	$6.5	$7.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($19.1)	($5.5)	($5.6)	($5.8)	($6.1)	($23.0)	($24.5)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($1.5)	($0.2)	($0.2)	($0.2)	($0.2)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	($20.6)	($5.7)	($5.8)	($6.0)	($6.3)	($23.8)	($25.5)	($28.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($20.6)**	**($5.7)**	**($5.8)**	**($6.0)**	**($6.3)**	**($23.8)**	**($25.5)**	**($28.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.79)**	**($0.11)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.45)**	**($0.43)**	**($0.40)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	25.978	51.000	52.000	53.000	54.000	52.500	60.000	70.000

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

HISTORICAL STOCK PRICE

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