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David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Viking Therapeutics, Inc.

(VKTX-NASDAQ)

VKTX: Enrollment of Phase 2 Trial of VK2809 Nearing Completion…

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 (05/14/18)	$4.50
Valuation	**$13.00**

OUTLOOK

On May 9, 2018, Viking Therapeutics, Inc. (VKTX) announced financial results for the first quarter of 2018 and provided a business update. The company announced that enrollment for the Phase 2 clinical trial of VK2809 in hypercholesterolemia and fatty liver disease is nearing completion. We continue to anticipate results from this study in the second half of 2018. Partnering discussions for VK5211 are ongoing with several multinational and regional companies. The company is planning to meet with the FDA in the second half of 2018 to hopefully get clarity for the registration pathway for VK5211 in hip fracture. A proof-of-concept study for VK2809 in glycogen storage disease 1a (GSD1a) should initiate in the second quarter of 2018 and IND-enabling studies are ongoing for VK0214 in X-linked adrenoleukodystrophy (X-ALD), with a proof-of-concept study likely to initiate in 2019. The company ended the first quarter with $77.5M in cash, which is enough capital to fund operations beyond multiple important catalysts.

SUMMARY DATA

52-Week High	**$6.93**
52-Week Low	**$0.93**
One-Year Return (%)	**268.85**
Beta	**2.10**
Average Daily Volume (sh)	**823,114**
Shares Outstanding (mil)	**51**
Market Capitalization ($mil)	**$229**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**4**
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 A	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	-$0.08 A	-$0.11 E	-$0.11 E	-$0.12 E	-$0.43 E
2019					-$0.43 E
2020					-$0.40 E

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WHAT'S NEW

Business Update

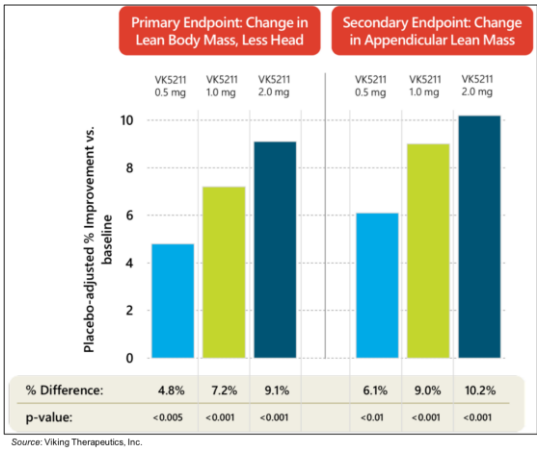
Viking Therapeutics, Inc. (VKTX) is a biopharmaceutical company developing treatments for metabolic and endocrine disorders. The company's lead compounds include:

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 for the second half of 2018. Partnering discussions are ongoing with several multinational and regional companies.
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 as enrollment in the study is nearing completion. We anticipate 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.

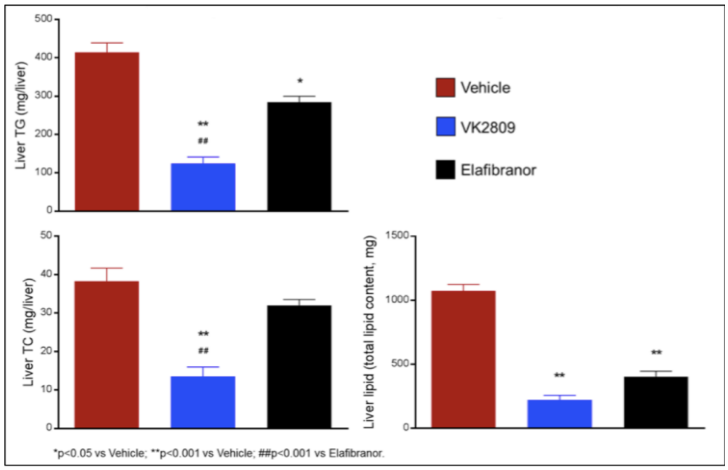
The full data set from the Phase 2 trial will likely be presented at one or more future scientific conferences, such as the 2018 American Society for Bone and Mineral Research (ASBMR) meeting, which takes place in late Sep. 2018. In addition, we believe the data likely opens the door to additional potential indications for VK5211 such as cachexia, sarcopenia, and joint replacement, although the company is currently only focusing on hip fracture recovery.

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 in hip fracture. We do not believe Viking will move VK5211 into a Phase 3 program before entering into a development partnership with a larger pharmaceutical company. Discussions are ongoing with multiple multinational and regional companies. There are a host of factors at play in the partnering discussions, including which indications companies are interested in pursuing and the level of interest in Viking's upcoming meeting with the FDA. Thus, both the likelihood and the timing of a potential partnership is difficult to predict at this point. We are confident that the company will sign a partnership, but caution investors to be patient as it is an evolving situation and could run into late 2018 or early 2019.

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 anticipate topline results in the second half of 2018 as enrollment in the trial is nearing completion.

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.

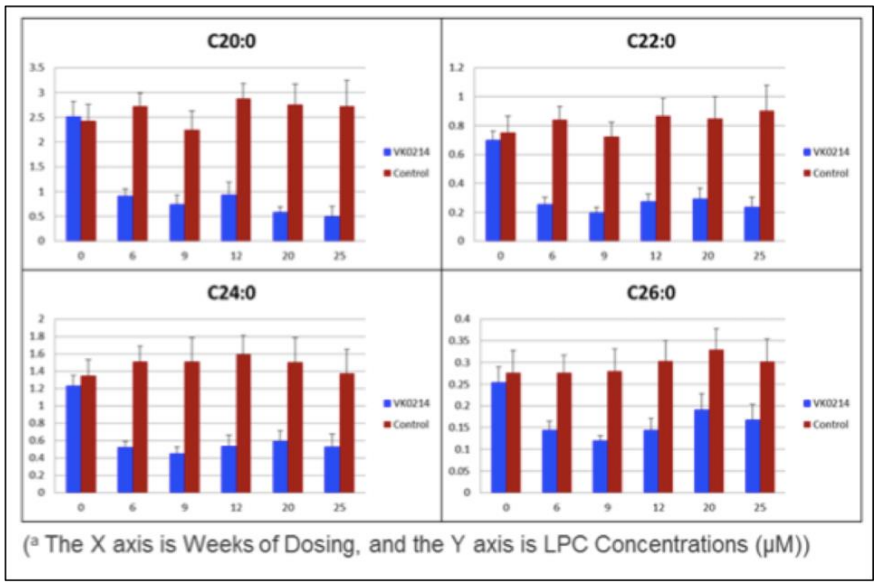


Source: Lian *et al*., 2017

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 May 9, 2018, Viking announced financial results for the first quarter of 2018. The company reported a net loss of $3.6 million, or $0.08 per share, compared to a net loss of $5.2 million, or $0.23 per share, in the first quarter of 2017. R&D expenses for the first quarter of 2018 were $3.0 million, compared to $3.5 million for the first quarter of 2017. The decrease was primarily due to decreased manufacturing expenses and decreased activities related to the VK5211 clinical program. G&A expenses were $1.8 million for the first quarter of 2018, compared to $1.4 million for the first quarter of 2017. The increase was primarily due to increases in stock-based compensation and salaries and benefit expenses.

As of Mar. 31, 2018, Viking had approximately $77.5 million in cash, cash equivalents, and short-term investments. This was due in part to a public offering in February 2018 of 12.65 million shares of common stock that raised net proceeds of $58.7 million. Based on the current cash level we believe the company has sufficient capital to fund operations into 2020. As of April 30, 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

We're glad to see that results for the Phase 2 clinical trial of VK2809 will be available in the second half of 2018. We will better be able to estimate when in the second half of the year the results will be announced once the company enrolls the final patient. We anticipate data being available approximately 4-5 months following the final patient enrollment. Prior to that, a potentially important near-term catalyst will be the release of histology data from Madrigal Pharmaceuticals (MDGL) lead program MGL-3196, which shares the same mechanism as VK2809 (both activate the thyroid beta receptor). Madrigal is expected to announce data from 9 months of treatment in NASH patients sometime this quarter. Positive results could provide an encouraging read-through for VK2809. We note that Madrigal currently trades at a >6x market cap multiple of Viking.

In addition to the data for VK2809, there may be an announcement regarding a partnership for VK5211 in the second half of 2018. However, as discussed earlier there are many different possible partners and various factors that go into the timing of that announcement so it is impossible to estimate accurately when that may take place. Viking has indicated that VK5211 will not be moved into a Phase 3 program without a partnership in place, and we are confident that a partnership will occur, we are just unsure of the exact timing.

After reaching almost $7 per share in Feb. 2018 the stock has retreated approximately 30%, which we credit mostly to an overall negative sentiment for the biotech sector as a whole. We believe investors should view any weakness in the stock as a potential buying opportunity, as Viking is one of the most compelling small-cap biotech opportunities in our coverage universe. Our current valuation remains at $13 per share.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2017 A	Q1 A	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	$3.0	$4.1	$4.2	$4.5	$15.8	$18.0	$20.0
General & Administrative	$5.3	$1.8	$1.5	$1.6	$1.6	$6.5	$6.5	$7.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($19.1)	($4.8)	($5.6)	($5.8)	($6.1)	($22.3)	($24.5)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($1.5)	$1.3	($0.2)	($0.2)	($0.2)	$0.7	($1.0)	($1.0)
Pre-Tax Income	($20.6)	($3.6)	($5.8)	($6.0)	($6.3)	($21.7)	($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)**	**($3.6)**	**($5.8)**	**($6.0)**	**($6.3)**	**($21.7)**	**($25.5)**	**($28.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.79)**	**($0.08)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.43)**	**($0.43)**	**($0.40)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	25.978	44.649	52.000	53.000	54.000	50.912	60.000	70.000

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

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