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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Data from P2 Trial of VK2809 in 4Q18…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $15/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 (08/13/18)	$10.36
Valuation	**$15.00**

OUTLOOK

On August 9, 2018, Viking Therapeutics, Inc. (VKTX) announced financial results for the fourth quarter of 2018 and provided a business update. The company will be meeting with the FDA in the 3Q18 to discuss the regulatory path forward for VK5211. In addition, the company will be presenting data from the Phase 2 trial of VK5211 in acute hip fracture as part of the oral plenary session at the 2018 ASBMR Annual Meeting.
Another near-term potential catalyst for the stock could be data from GTXi's Phase 2 trial of enobosarm, a SARM molecule like VK5211, in stress urinary incontinence. We expect these results in early 4Q18. In June 2018, the company announced the final patient has been enrolled in the Phase 2 trial of VK2809. We anticipate topline results being announced in either later October or November 2018.

SUMMARY DATA

52-Week High	**$12.74**
52-Week Low	**$1.00**
One-Year Return (%)	**915.69**
Beta	**2.74**
Average Daily Volume (sh)	**1,726,787**
Shares Outstanding (mil)	**61**
Market Capitalization ($mil)	**$628**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**35**
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 A	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	-$0.13 A	-$0.10 E	-$0.10 E	-$0.41 E
2019					-$0.39 E
2020					-$0.40 E

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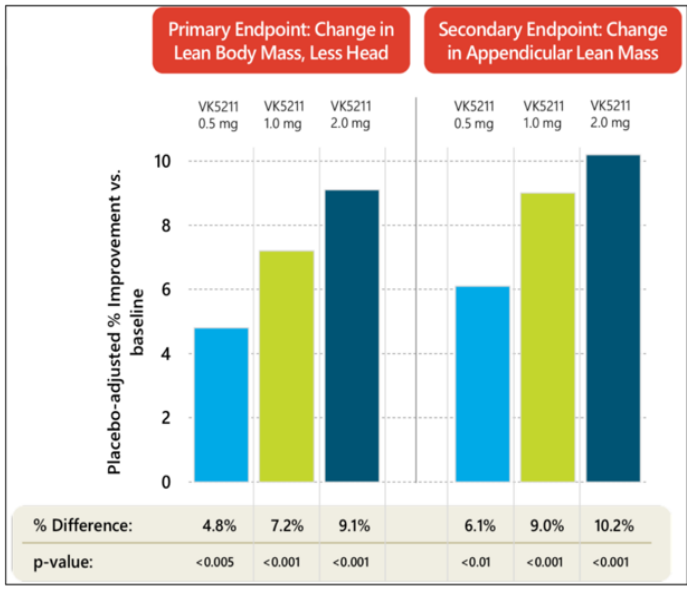
WHAT'S NEW

Business Update

VK5211 Update

In 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.



Source: Viking Therapeutics, Inc.

To put these 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 of enobosarm, a SARM being developed by GTX Inc. (GTXI), that was conducted in healthy older men (>60 years old) and post-menopausal women. 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 currently developing enobosarm for treating stress urinary incontinence and breast cancer. Additional findings from the Phase 2 trial of VK5211 included:

- 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 company will be meeting with the FDA in the third quarter 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 be presented on Sep. 30 during the plenary session at the 2018 American Society for Bone and Mineral Research (ASBMR) Annual meeting. The company won the most outstanding clinical abstract award from the ASBMR conference organizers.

We believe another near-term potential catalyst for the stock in regards to VK5211 is the Phase 2 data that will be reported by GTX Inc. for enobosarm (the SARM mentioned above) in stress urinary incontinence. Results from that study are expected early in 4Q18 (per GTXI guidance). Positive results could lend support for the development of VK5211 in stress urinary incontinence, which may increase its appeal to potential collaborators.

VK2809 Update

On June 5, 2018, Viking announced that the final patient has been enrolled in the Phase 2 trial of VK2809. The Phase 2 trial is a randomized, double blind, placebo controlled study where 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 expect most investors will focus on the drug's effect on liver fat content (see discussion below). Based on the 12-week treatment period and four-week off-treatment period, we are currently estimating for topline results to be released in the mid-October to mid-November timeframe.

Madrigal Data Provides Positive Read-Through for VK2809

On May 31, 2018, Madrigal Pharmaceuticals, Inc. (MDGL) announced positive results from the Phase 2 trial of MGL-3196, the company's thyroid hormone receptor beta (TRβ) agonist, in patients with biopsy confirmed nonalcoholic steatohepatitis (NASH). The following table shows that 56% of patients treated with MGL-3196 experienced a ≥ 2 point reduction in NAS, which increased to 70% when only considering those patients that were MGL-3196 MRI-PDFF responders at week 12 (e.g., had a ≥ 30% reduction in liver fat). This compared to only 32% of placebo-treated patients. In addition, 27% of MGL-3196-treated patients had resolution of NASH compared to only 6% of placebo-treated patients.

	MGL-3196	MGL-3196 MRI-PDFF Responders[1]	Placebo
Number of patients with baseline and end-of-study liver biopsies[2]	73	46	34
≥ 2 Point Decrease in NAS	56%	70%	32%
	p=0.02	p=0.001	
NASH Resolution	27%	39%	6%
	p=0.02	p=0.001	

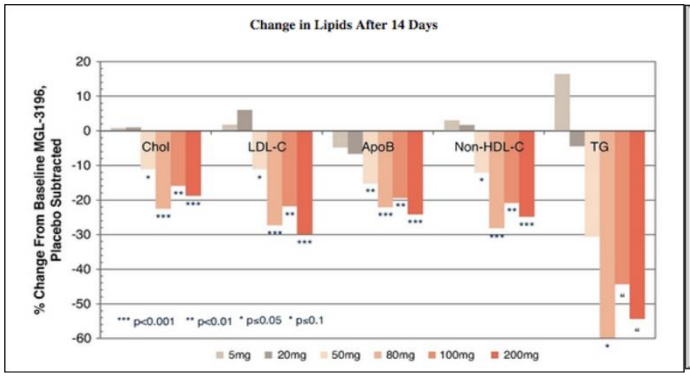
[1]MGL-3196 MRI-PDFF Responders = MGL-3196 treated patients with >=30% relative fat reduction on Week 12 MRI-PDFF

[2]does not include one end-of-study liver biopsy that was inadequate

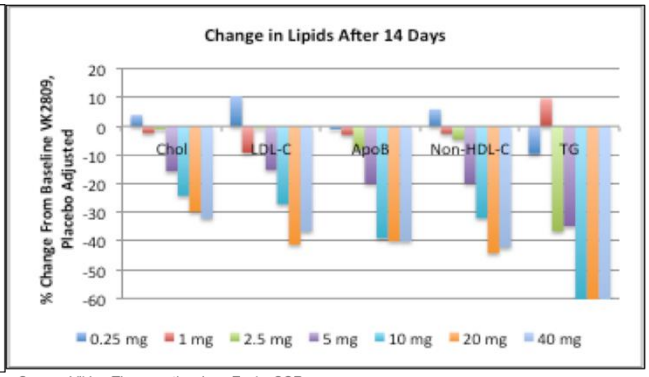
Source: Madrigal Pharmaceuticals, Inc.

There were a number of other positive outcomes that we had anticipated, including continued decreases in liver fat similar to what was seen after 12 weeks of treatment, decreases in patients' lipid profiles (e.g., triglycerides, LDL-C, ApoB, and lipoprotein(a)), and a benign safety profile (although this was not discussed in great detail). Madrigal's stock was up 150% on the news.

While very hard to perform a direct comparison between the two compounds yet, what data we do have shows that VK2809 compares quite favorably with MGL-3196. The following chart shows that reductions in lipid profiles for both MGL-3196 and VK2809 are very similar, and perhaps even slightly favor VK2809. This comparable data, along with the same mechanism of action shared by the two compounds, leads us to believe that VK2809 will have very similar results to MGL-3196 in liver fat reduction. Lastly, with the positive association between liver fat reduction and decrease in NAS and NASH resolution shown in Madrigal's data, we believe VK2809 has enormous potential in treating NASH.



Source: Madrigal Pharmaceuticals, Inc.



Source: Viking Therapeutics, Inc.; Zacks SCR

GSD1a Study to Get Underway

During the second quarter conference call, management indicated that a proof-of-concept study of VK2809 in patients with glycogen storage disease 1a (GSD 1a) will likely initiate this quarter. The company filed an IND earlier in the year in order to initiate the trial, and there have been a few clerical delays that have pushed out the start of the trial to the third quarter. Results from this study are expected in the first half of 2019.

In 2017, Viking announced encouraging results from an *in vivo* study of VK2809 in a mouse model of GSD 1a. The researchers used glucose-6-phospatase catalytic domain knockout mice ($G6PC^{-/-}$) to model the effects seen in patients who have GSD 1a, as they have a mutation that renders glucose-6-phosphatase inactive. The results showed that after four days of treatment with VK2809 there was a statistically significant 69% decrease in mean total liver triglycerides in $G6PC^{-/-}$ mice ($P<0.0001$). This decrease brought the average liver triglycerides to within the range of the wild type control mice. However, there was no effect on liver glycogen concentration. The lack of an effect on liver glycogen is not of concern for treatment with VK2809, as the vast majority of the increase in liver weight due to GSD 1a is from accumulation of lipids.

GSD 1a is 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. The enzyme catalyzes the hydrolysis of glucose-6-phosphate to glucose in the final step of gluconeogenesis and glycogenolysis. The inability of GSD 1a patients to maintain proper glucose levels and to develop hypoglycemia following a short fast is a hallmark of the disease (Chou *et al*., 2002). Patients 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. For those younger than six months of age, nocturnal nasogastric infusion of glucose is utilized to avoid hypoglycemia during the night. For those older than six months, supplemental uncooked cornstarch is used as a slow release glucose source between meals. When followed strictly, dietary strategies typically allow for normal growth and puberty development, however dietary therapy fails to completely prevent the occurrence of hyperlipidemia, hyperuricemia, lactic acidemia, and accumulation of liver fat (Rake *et al*., 2002).

VK0214 Update

In 2017, Viking announced results from a 25-week proof-of-concept study of VK0214 in an *in vivo* mouse model of X-linked adrenoleukodystrophy (X-ALD). 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.

Patients with X-ALD have a mutation(s) in the *ABCD1* gene that renders its product, the adrenoleukodystrophy protein (ALDP), non-functional. ALDP is responsible for transporting 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 induces the expression of ALDR (encoded by the *ABCD2* gene), which is also a VLCFA transporter, thus compensating for the loss of ALDP.

Viking is currently conducting IND enabling work and we anticipate the company filing an IND to initiate proof-of-concept studies in 2019.

Financial Update

On August 9, 2018, Viking announced financial results for the second quarter of 2018. Viking reported a net loss of $6.7 million, or $0.13 per share, compared to a net loss of $5.2 million, or $0.21 per share, in the second quarter of 2017. R&D expenses for the second quarter of 2018 were $5.2 million, compared to $3.7 million for the second quarter of 2017. The increase was primarily due to increased pre-clinical study costs, consultant costs, and stock-based compensation. G&A expenses were $1.7 million for the second quarter of 2018, compared to $1.3 million for the second quarter of 2017. The increase was primarily due to increases in stock-based compensation and salaries and benefit expenses.

As of June 30, 2018, Viking had approximately $142.2 million in cash, cash equivalents, and short-term investments. This was due in part to a public offering in June 2018 of 8.625 million shares at $9.00 per share, which included 1.125 million shares sold based on the underwriter's full exercise of their option to purchase additional shares. Based on the current cash level we believe the company has sufficient capital to fund operations into 2020.

As of July 31, 2018, Viking had approximately 60.6 million shares outstanding and when factoring in outstanding shares of restricted stock, stock options, and warrants the company has a fully diluted share count of approximately 70.6 million shares.

Valuation

The second half of 2018 is setting up to be a very exciting time for Viking as there are a number of catalysts that could have significant effects on the company valuation. The most important of which is likely the results from the Phase 2 study of VK2809, which we anticipate in the late October/November 2018 timeframe. In addition, we anticipate GTX Inc. reporting data on enobosarm in stress urinary incontinence in the early part of the fourth quarter 2018 (which could have implications for the future development of VK5211) and the company providing an update following the meeting with the FDA about the path forward for VK5211 in late September or early October. Lastly, we anticipate the initiation of a proof-of-concept study for VK2809 in GSD 1a during the third quarter of 2018. With a diversified pipeline and plenty of cash to fund operations into 2020, we view Viking as a top pick among smallcap biotech companies and our current valuation is $15.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2017 A	Q1 A	Q2 A	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	$5.2	$4.2	$4.5	$17.0	$18.0	$20.0
General & Administrative	$5.3	$1.8	$1.7	$1.6	$1.6	$6.7	$6.5	$7.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($19.1)	($4.8)	($6.93)	($5.8)	($6.1)	($23.6)	($24.5)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($1.5)	$1.3	$0.3	($0.2)	($0.2)	$1.1	($1.0)	($1.0)
Pre-Tax Income	($20.6)	($3.6)	($6.7)	($6.0)	($6.3)	($22.5)	($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)**	**($6.7)**	**($6.0)**	**($6.3)**	**($22.5)**	**($25.5)**	**($28.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.79)**	**($0.08)**	**($0.13)**	**($0.10)**	**($0.10)**	**($0.41)**	**($0.39)**	**($0.40)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	25.978	44.649	52.767	60.000	61.000	54.604	65.000	70.000

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

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