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September 24, 2018
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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Positive Results for Phase 2 Study of VK2809 in NAFLD…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $25/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 (09/24/18)	$18.20
Valuation	**$25.00**

OUTLOOK

On September 18, 2018, Viking Therapeutics Inc. (VKTX) announced positive topline results for the Phase 2 study of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and elevated LDL cholesterol. Treatment with VK2809 reduced liver fat by approximately 58%, and approximately 83% of VK2809-treated patients experienced a decrease in liver fat ≥ 30%. In addition, approximately 65% of VK2809-treated patients experienced a ≥ 50% reduction in liver fat. These results appear to be the best thus far in terms of liver fat reduction amongst oral agents under development for NASH, potentially making VK2809 a "best-in-class" treatment. The company will be meeting with the FDA to map out a registration pathway, which we believe will include a small trial with a biopsy outcome prior to a full registration study.

SUMMARY DATA

52-Week High	**$19.65**
52-Week Low	**$1.24**
One-Year Return (%)	**1209.35**
Beta	**2.86**
Average Daily Volume (sh)	**6,392,001**
Shares Outstanding (mil)	**61**
Market Capitalization ($mil)	**$1,104**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**53**
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	**-22.3**
P/E using 2019 Estimate	**-22.3**

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

Robust Phase 2 Data for VK2809 in NAFLD!

On September 18, 2018, Viking Therapeutics, Inc. (VKTX) announced positive topline results from the Phase 2 study of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and elevated low-density lipoprotein (LDL) cholesterol. The Phase 2 trial was a randomized, double blind, placebo controlled study where patients were treated once daily or every other day with 10 mg VK2809 or once daily with placebo for 12 weeks followed by four weeks off drug. While the primary endpoint of the study was change in LDL cholesterol, the most important endpoints were the secondary ones related to NAFLD that evaluated changes in liver fat content, inflammatory markers, and histological changes.

The following table shows that treatment with VK2809 produced a robust and profound reduction in liver fat content as judged both by relative change in the percentage of liver fat by MRI-PDFF (a non-invasive imaging technique) and the percentage of patients that experienced a ≥ 30% reduction in liver fat.

	VK2809 10 mg QOD (n=15)	VK2809 10 mg QD (n=16)	VK2809 combined (n=31)	Placebo (n=14)
Mean relative change in liver fat by MRI-PDFF	-56.5% (*P*<0.01)	-59.7% (*P*<0.01)	-58.1% (*P*<0.01)	-8.9%
% of pts ≥ 30% liver fat reduction	76.9% (*P*=0.012)	90.9% (*P*<0.01)	83.3% (*P*<0.01)	18.2%

Source: Viking Therapeutics, Inc. / Zacks SCR

These data are particularly impressive when compared to the 12-week data reported by Madrigal Pharmaceuticals, Inc. (MDGL) for their thyroid receptor beta agonist MGL-3196. We understand the inherent difficulties in accurately comparing data across studies, but we view the much higher decrease in liver fat and higher percentage of patients achieving a 30% reduction in liver fat as a clear positive for VK2809, and we believe the data positions VK2809 as a potential "best-in-class" treatment.

	VK2809 10 mg QOD (n=15)	VK2809 10 mg QD (n=16)	VK2809 combined (n=31)	Placebo (n=14)	All MGL-3196 (n=78)	High MGL-3196 (n=44)	Placebo (n=38)
Mean relative change in liver fat by MRI-PDFF	-56.5% (*P*<0.01)	-59.7% (*P*<0.01)	-58.1% (*P*<0.01)	-8.9%	-36.3% (*P*<0.0001)	-42.0% (*P*<0.0001)	-9.6%
% of pts ≥ 30% liver fat reduction	76.9% (*P*=0.012)	90.9% (*P*<0.01)	83.3% (*P*<0.01)	18.2%	60.3% (*P*<0.0001)	75.0% (*P*<0.0001)	18.4%

Source: Viking Therapeutics, Inc. / Madrigal Pharmaceuticals, Inc. / Zacks SCR

During the conference call to discuss the results the company also mentioned what were referred to as "super responders", that is patients who experienced a ≥ 50% reduction in liver fat. Those results showed that 62% of patients treated every other day with VK2809 and 73% of patients treated every day with VK2809 saw liver fat reductions ≥ 50%. While a liver fat reduction of ≥ 30% is shown to increase the chances of a histological response, we find the large percentage of patients experiencing a ≥ 50% reduction in liver fat to be quite impressive and increases the probability of seeing clinically relevant changes in liver histology in future studies.

The safety and tolerability data showed that VK2809 was well tolerated and there were no serious adverse events (SAEs) reported among patients receiving VK2809 or placebo. Importantly, average alanine aminotransferase (ALT) levels for VK2809-treated patients were reduced from baseline in comparison to placebo-treated patients. In addition, there were no clinically meaningful differences in direct bilirubin, indirect bilirubin, alkaline phosphatase, or the thyroid hormone axis in VK2809-treated patients compared to those administered placebo. There were also no issues with tolerability, as gastrointestinal related side effects were numerically higher in placebo-treated patients than in those taking VK2809.

The company has submitted a late-breaker abstract for the 2018 annual meeting of the American Association for the Study of Liver Diseases (AASLD), which is scheduled for Nov. 9-13, 2018, at which time we expect to learn additional details regarding the results from the study. The company also indicated that a separate abstract was submitted regarding only the safety data.

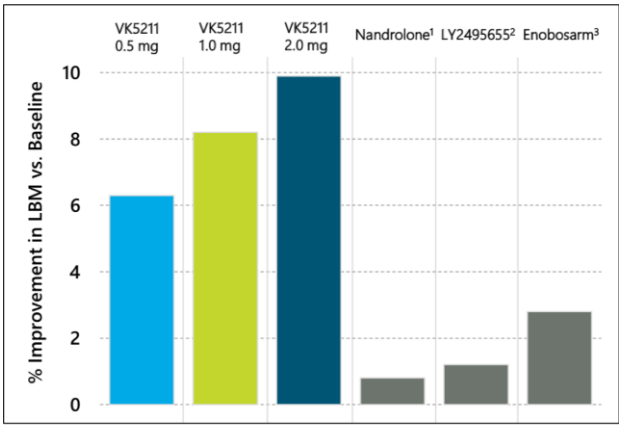
In summary, the data presented by Viking for VK2809 was better than we had anticipated and puts the compound out front as the leader among oral NASH/NAFLD agents that target liver fat. A consistent worry we had heard from investors heading into the data release had to do with potential issues surrounding elevated liver enzymes (which we had attempted to clear up previously here). Since this represented one of the most prominent bear theses against Viking, the fact that there was not only no increase in liver enzyme levels but a reduction should put that argument to rest once and for all.

The next step for Viking will be to meet with the FDA and plot out a regulatory path forward. At this point we believe another small Phase 2 study will likely be necessary since no company has advanced to Phase 3 without biopsy data. However, we would not be surprised if Viking is able to design a combined Phase 2/3 study with a Phase 2 readout on a small group for biopsy data, with those patients then rolled into the Phase 3 portion of the study.

Enobosarm Failure Raises Questions About Potential SUI Indication for VK5211

On September 21, 2018, GTx Inc. (GTXI) announced topline results from the Phase 2 ASTRID clinical trial of enobosarm (which shares the same mechanism of action as VK5211) in stress urinary incontinence (SUI). The study did not achieve the primary endpoint, which was the proportion of patients with >50% reduction in incontinence episodes per day compared to placebo. The results showed that 58.9%, 57.7%, and 52.7% of patients experienced >50% reduction after 12 weeks of treatment in the 3 mg enobosarm, 1 mg enobosarm, and placebo groups, respectively. Adverse events were reported to be similar across treatment groups.

We were surprised that the ASTRID trial failed, as a previous 18 subject Phase 2 study showed a decrease in mean stress leaks from 5.17 to 1.0 per day following 12 weeks of enobosarm treatment along with a 100% responder rate. Viking had never tested VK5211 in SUI and its potential in the indication was presumably predicated on enobosarm showing efficacy in the ASTRID trial. However, Viking (or a partner) may still be warranted in pursuing development of VK5211 in SUI based on the drugs superior ability to increase muscle mass compared to enobosarm, as shown in the following graph, although it is much less likely at this point (note: the VK5211 data is 12-week dosing in hip fracture patients while the enobosarm data is from a cachexia study).



Source: Viking Therapeutics, Inc.

Financial Update

On Sep. 20, 2018, Viking announced the pricing of a public offering of 9.5 million shares of common stock at a price of $18.50 per share. Gross proceeds to the company are expected to be approximately $175.8 million. Viking exited the second quarter of 2018 with approximately $142 million, thus we anticipate Viking will exit the third quarter of 2018 with approximately $310 million, which not only will fund operations for the next couple of years but increases the company's negotiating power in regards to VK5211 and offers flexibility in the development of the company's pipeline.

Conclusion

Viking is in a very good position with excellent clinical data in hand for its two lead assets and more than $300 million in cash. While the results for enobosarm in SUI took away a potential catalyst for the stock price, ultimately it is not a negative for the company as SUI was only one of many potential indications for VK5211 (although it still may not be out of the question, albeit a bit riskier and less likely now).

Based on the results of the Phase 2 trial of VK2809 we have made significant changes to our model, including doubling potential worldwide peak sales for VK2809 (from $2 billion to $4 billion) and increasing the probability of approval to 70%. We feel these changes are warranted given the potential for VK2809 to be a “best-in-class” treatment and the clean safety profile shown in the Phase 2 trial. These changes have resulted in an increase in our valuation to $25 per share. Viking’s stock was up approximately 80% following the release of the VK2809 Phase 2 data, but we feel there is additional upside as the company remains one of our top picks among small-cap biotech stocks.

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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