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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Phase 2b Trial for VK2809 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 (03/14/19)	$8.25
Valuation	**$24.00**

OUTLOOK

On March 13, 2019, Viking Therapeutics, Inc. (VKTX) announced financial results for 2018 and provided a business update. The company will be holding a pre-IND meeting with the FDA this summer to discuss plans for a Phase 2b trial of VK2809 in NASH patients. We anticipate that trial initiating in the second half of 2019. The company is continuing to evaluate next steps for VK5211, which may include exploring opportunities in certain orphan indications, however the company will not pursue any additional trials without a partner. IND enabling work is continuing for VK0214 and we anticipate an IND being filed in 2019 such that a clinical trial can begin in patients with X-ALD. With approximately $300 million in cash, the company is well financed through at least 2021.

SUMMARY DATA

52-Week High	**$19.65**
52-Week Low	**$3.88**
One-Year Return (%)	**47.32**
Beta	**2.73**
Average Daily Volume (sh)	**2,764,061**
Shares Outstanding (mil)	**71**
Market Capitalization ($mil)	**$590**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**66**
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-Value**
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 E	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	-$0.08 E	-$0.08 E	-$0.09 E	-$0.09 E	-$0.34 E
2020					-$0.43 E
2021					-$0.50 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) **VK2809**, which is an oral, liver selective agonist of the thyroid hormone receptor beta (TRβ) and is being developed for the treatment of nonalcoholic steatohepatitis (NASH).
   - We anticipate the company conducting a pre-IND meeting with the FDA in mid-summer 2019 and a Phase 2b study in NASH patients to be initiated in the second half of 2019. Data from the 5 mg cohort of the Phase 2 clinical trial in patients with hypercholesterolemia and fatty liver disease will be presented in April 2019 at the European Association for the Study of the Liver (EASL) 2019 annual meeting.
2) **VK5211**, which is a selective androgen receptor modulator (SARM) and is being developed for orphan muscle wasting indications.
   - Following FDA guidance regarding the clinical path forward for the compound in hip fracture, the company has decided to pursue additional indications for VK5211, which may include various orphan indications. However, the company will not conduct additional clinical studies without a partner.
3) **VK0214**, which a non-tissue selective TRβ agonist and 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 2019.

VK2809 Set for Phase 2b Trial in NASH in 2H19

Viking is set to initiate a Phase 2b clinical trial in patients with nonalcoholic steatohepatitis (NASH) in the second half of 2019. The company has requested a pre-IND meeting with the FDA prior to initiating that trial, which we anticipate occurring in mid-summer 2019. While the full details of the trial are still being considered, we anticipate it will involve at least 150 patients, most with moderate to severe fibrosis (F2/F3), and multiple dosage cohorts over a span of 9-12 months. Guidance on the treatment period is expected at the FDA meeting this summer. Based upon similar trials that have been recently conducted, we estimate that the trial will take between 1.5 – 2 years to complete following enrollment of the first patient, however there are likely to be interim data analyses during the trial, such as liver fat reduction at 12 weeks.

While everyone is focused on the ability of VK2809 (and other TRβ agonists) to significantly decrease liver fat, we believe something that is not fully appreciated for the compound is the potential for anti-fibrotic effects. The current conventional wisdom is that a successful NASH treatment is likely to require a combination therapy, for example a liver fat reducer coupled with an anti-fibrotic agent. However, we aren't convinced that will be the case, and in fact there is evidence that TRβ agonists, particularly VK2809, may be sufficient on their own, even for NASH patients with moderate to severe fibrosis.

In support of this, we remind investors of previous preclinical data Viking presented in 2017 from a diet-induced mouse model of NASH (biopsy confirmed) in which treatment with VK2809 resulted in a significant reduction in plasma and liver lipids. In addition, as the following table shows there was a 50% decrease in liver fibrosis, a 60% decrease in Col1a1 (collagen) content, and a 46% reduction in liver hydroxyproline content in VK2809-treated animals compared to placebo, thus exhibiting VK2809's anti-fibrotic activity. Treatment with VK2809 also caused a potentially beneficial modulation of genes associated with fibrosis, further supporting its ability to positively impact fibrosis.

Species	Change vs. Vehicle Control	p-Value
Change in Fibrosis	-50%	p<0.01
Col1a1 content	-60%	p<0.005
Liver hydroxyproline content	-46%	p<0.01

Source: Lian *et al.*, 2017

Given that the robust liver fat reduction seen in the Phase 2 trial closely mirrored the results seen in this animal study, we believe it validated the model and thus makes it a good proxy for how VK2809 may potentially affect liver fibrosis. Based on this data, we believe it is conceivable that given sufficient time, VK2809 could provide not only a significant reduction in liver lipids (which was shown in the Phase 2 clinical trial), but a reduction in liver fibrosis as well, and could greatly expand the potential patient population amenable to treatment.

VK2809 5 mg Data to be Presented at EASL

During the recent conference call, the company announced that an abstract that includes data from the 5 mg dosing cohort in the Phase 2 clinical trial of VK2809 was accepted for a poster presentation at the European Association for the Study of the Liver 2019 Annual Meeting in April 2019. While we will have to wait for the presentation to get a look at the full data set, management alluded to the fact that the data from the 5 mg cohort is very similar to the 10 mg QOD cohort, including that 9/9 patients were responders, defined as having >30% reduction in liver fat. Management also indicated that it may be possible to further decrease the dose and continue to see good efficacy, implying that VK2809 has a very wide therapeutic window, something we attribute to the liver specificity of the drug. In addition, safety and tolerability continue to be excellent with no new safety signals arising and a tolerability profile that was similar to the 10 mg cohorts.

We note that while Viking is currently discussing having the option to decrease dosing of VK2809 while maintaining good efficacy, Madrigal Pharmaceuticals doses its lead TRβ agonist at 80 mg (8x higher than VK2809 highest dose) with some patients requiring titration to 100 mg for sufficient efficacy (20x higher than the VK2809 5 mg dose). In addition, the 100 mg dose is sometimes accompanied by gastrointestinal side effects, something that has not been seen thus far in trials of VK2809.

VK5211 in Orphan Indications

While Viking previously reported robust efficacy in a Phase 2 trial of VK5211 in patients following hip fracture surgery, including dose dependent increases in lean body mass with encouraging safety and tolerability, following feedback from the FDA regarding a Phase 3 registration pathway Viking has decided that pursuing further development in hip fracture would be too challenging at this time. Due to this, the company is now exploring the potential benefit of using VK5211 in orphan indication where muscle loss plays a role in disease progression and disability (e.g., muscular dystrophy). However, no new clinical studies will be initiated without a partner, and discussions with potential collaborators are currently ongoing.

IND for VK0214 in 2019

VK0214 is being developed for the treatment of 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 March 13, 2018, Viking announced financial results for the fourth quarter and full year 2018. For the fourth quarter of 2018, the company had a net loss of $5.2 million, or $0.07 per share, compared to a net loss of $4.1 million, or $0.14 per share, in the fourth quarter of 2017. The net loss included $5.1 million in R&D expenses, compared to $3.0 million for the same period in 2017, with the increase primarily due to increased pre-clinical studies, manufacturing costs, consultants, and stock-based compensation. G&A expenses for the fourth quarter of 2018 were $1.9 million, compared to $1.4 million in the fourth quarter of 2017. The increase was primarily due to stock-based compensation, salaries, and legal expenses.

For 2018, Viking reported a net loss of $22.5 million, or $0.38 per share. R&D expenses were $19.0 million, compared to $13.7 million in 2017. The increase was primarily due to increased pre-clinical studies, manufacturing costs, consultants, and stock-based compensation. G&A expenses in 2018 were $7.1 million, compared to $5.3 million in 2017. The increase was primarily due to stock-based compensation, salaries, professional services, and the use of consultants.

Viking exited 2018 with approximately $301.5 million in cash, cash equivalents, and short-term investments. We

believe this is sufficient to fund operations at least through 2021. As of Feb. 28, 2019, Viking had approximately 72.0 million shares outstanding, and when factoring in stock options and warrants a fully diluted share count of approximately 81.1 million.

Conclusion

While Viking had previously considered conducting a combined Phase 2/3 clinical trial for VK2809 in NASH, we believe that the choice to move ahead with a Phase 2b trial is the prudent one given the uncertainty in executing a Phase 2/3 trial and the fact that essentially everyone Viking sought council from regarding the matter advised against it. We look forward to learning additional details about the upcoming Phase 2b trial, which we anticipate will occur following the company's pre-IND meeting with the FDA this summer.

We are disappointed that the company has been unable to find a suitable partner for VK5211 thus far, however we are intrigued by the idea of testing the drug in orphan indications and are hopeful that a partnership agreement can occur in 2019. Due to the uncertainty in its clinical path forward we have decreased the value of VK5211 in our model, which has resulted in a slight decrease in our valuation to $24 per share. However, Viking continues to be one of our top picks among small-cap biotech stocks, particularly with the potential for VK2809 to be a best-in-class NASH treatment.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2018 A	Q1 E	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	$5.0	$5.0	$5.1	$5.2	$20.3	$25.0	$30.0
General & Administrative	$7.1	$1.8	$1.8	$1.8	$1.8	$7.2	$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	$1.0	$0.8	$0.6	$0.4	$2.8	$1.0	$1.0
Pre-Tax Income	($22.5)	($5.8)	($6.0)	($6.3)	($6.6)	($24.7)	($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)**	**($5.8)**	**($6.0)**	**($6.3)**	**($6.6)**	**($24.7)**	**($31.5)**	**($37.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.38)**	**($0.08)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.34)**	**($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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