Zacks Small-Cap Research
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# Viking Therapeutics, Inc. (VKTX-NASDAQ)

***VKTX: Multiple Milestones Upcoming in 2021…***

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $22/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 (01/13/21) | $6.83 |
| **Valuation** | **$22.00** |

## OUTLOOK

Viking Therapeutics, Inc. (VKTX) is developing its lead thyroid receptor beta agonists VK2809 and VK0214 as treatments for non-alcoholic steatohepatitis (NASH) and X-linked adrenoleukodystrophy (X-ALD), respectively. VK2809 is being evaluated in a Phase 2b trial in patients with biopsy confirmed NASH and VK0214 is currently in a Phase 1 trial in healthy volunteers. We recently spoke with management to get an update on the clinical trials currently underway and milestones that will be upcoming in 2021.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$8.11** |
| **52-Week Low** | **$3.45** |
| **One-Year Return (%)** | **-7.20** |
| **Beta** | **2.02** |
| **Average Daily Volume (sh)** | **1,269,213** |
| **Shares Outstanding (mil)** | **73** |
| **Market Capitalization ($mil)** | **$498** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **54** |
| **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** | **-9.1** |
| **P/E using 2019 Estimate** | **-6.7** |

| | |
|---|---|
| **Risk Level** | **Average** |
| **Type of Stock** | **Small-Blend** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

**Revenue**
(In millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2019 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2020 | 0 A | 0 A | 0 A | 0 E | 0 E |
| 2021 | | | | | 0 E |
| 2022 | | | | | 0 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2019 | -$0.07 A | - $0.11 A | -$0.08 A | -$0.10 A | -$0.36 A |
| 2020 | -$0.13 A | -$0.13 A | -$0.13 A | -$0.16 E | -$0.55 E |
| 2021 | | | | | -$0.75 E |
| 2022 | | | | | -$0.89 E |

## WHAT'S NEW

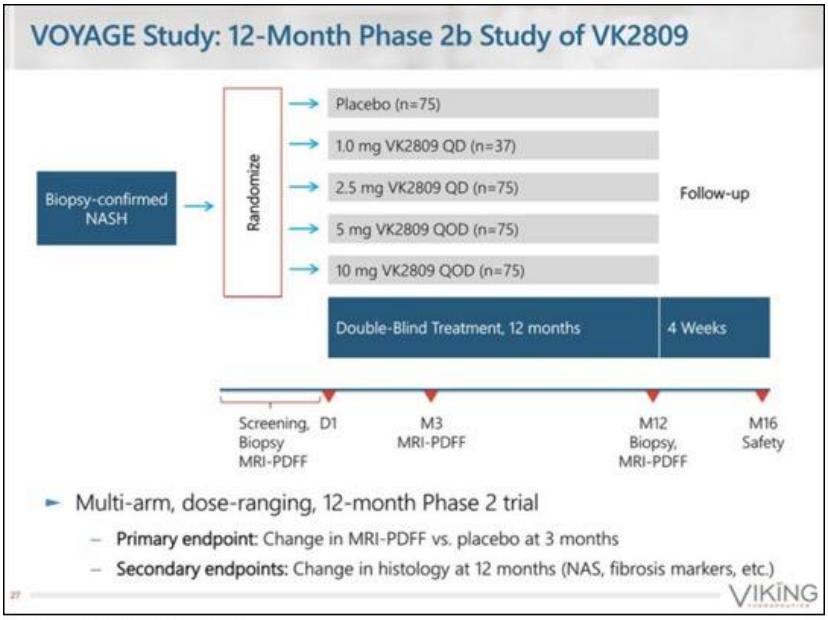
**Business Update**

*Management Provides Update on 2021 Outlook*

We recently spoke to the management team at Viking Therapeutics, Inc. (VKTX), including CEO Brian Lian, regarding the outlook for the company in 2021 and anticipated milestones regarding the ongoing Phase 2b clinical trial of VK2809 in non-alcoholic steatohepatitis (NASH) and the Phase 1 trial of VK0214 in X-linked adrenoleukodystrophy (X-ALD).

VK2809

Viking is currently conducting the Phase 2b VOYAGE trial of VK2809 in patients with biopsy-confirmed NASH (NCT04173065). The randomized, double blind, placebo-controlled trial is expected to enroll approximately 340 patients with fibrosis ranging from stages F1 to F3 across five treatment groups: 1 mg VK2809 daily, 2.5 mg VK2809 daily, 5 mg VK2809 every other day, 10 mg VK2809 every other day, or placebo. We expect approximately 75 patients per arm for the 2.5 mg, 5 mg, 10 mg, and placebo groups and approximately 40 patients in the 1 mg arm. There will be a total of approximately 90 centers enrolling patients worldwide and an approximate 4:1 ratio between U.S. and ex-U.S. sites. An overview of the trial is given below.




*Source*: Viking Therapeutics, Inc.

The primary endpoint of the trial is the 12-week change in liver fat content assessed by magnetic resonance imaging proton density fat fraction (MRI-PDFF) for those treated with VK2809 compared to placebo. A key secondary outcome measure is histological changes assessed by liver biopsy following 52 weeks of dosing.

During our call, management indicated that enrollment in the VOYAGE trial is slow but steady. While a majority of sites had been closed in the spring during the initial COVID lockdown, all the trial sites are currently open even with the increased COVID cases currently occurring in the U.S. A couple of things contributing to slower enrollment right now is patients being apprehensive about joining a clinical trial during the ongoing pandemic and a number of trial sites are having difficulty with staffing due to workers being out due to coronavirus exposure or quarantine. Neither of these issues are specific to Viking and we presume similar headwinds are being encountered by other companies currently conducting trials. As the vaccine roll out continues and winter comes to an end we anticipate case counts decreasing and trial enrollment picking up. In addition, the company is continuing to open additional sites both in the U.S. and ex-U.S. Viking continues to anticipate enrollment completing in the first half of 2021, which could lead to 12-week liver fat data being available by the end of 2021 or early 2022.

VK0214

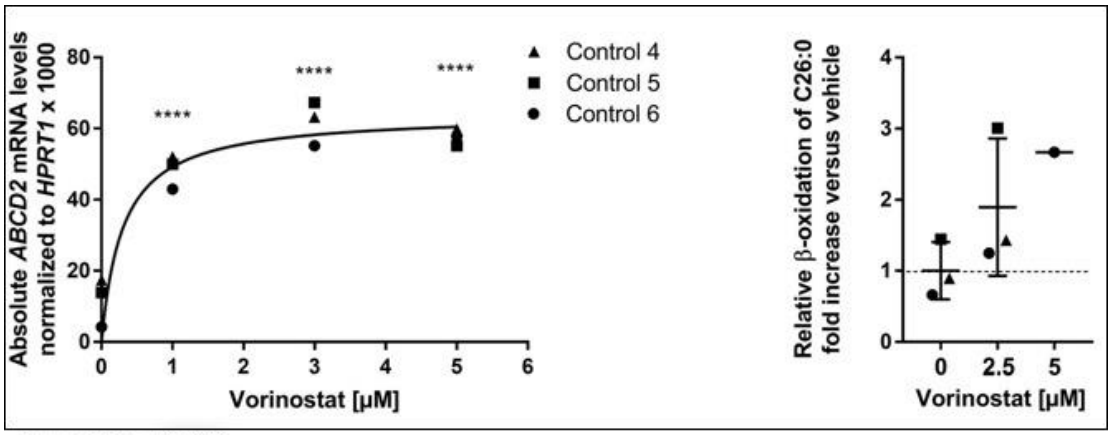
Viking is currently conducting a Phase 1 clinical trial of VK0214 in healthy subjects. It is a randomized, double blind, placebo controlled, single ascending dose (SAD) and multiple ascending dose (MAD) study with the primary objective being the evaluation of VK0214's safety and tolerability along with identifying the proper doses to evaluate in a trial with X-adrenoleukodystrophy (X-ALD) patients.

On our call, management indicated that enrollment in the Phase 1 study was going very well and they are hopeful that data from the SAD/MAD portion of the trial could be available in the first half of 2021, at which time two or three doses will have been identified to take into the Phase 1b portion of the trial in X-ALD patients. Assuming the Phase 1b portion of the study initiates by mid-2021, we anticipate data would be available in late 2021 or early 2022. Assuming positive results from this initial trial the company will need to perform a longer Phase 3 trial that will likely include some type of functional outcome.

X-ALD is an orphan neurodegenerative disease that affects approximately 8,000 individuals in the U.S. and 12,000 in Europe. Like VK2809, VK0214 is a TRβ agonist however it is not designed to be activated in the liver, as opposed to liver-specific activation of VK2809. 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.

X-ALD is caused by a mutation(s) in the *ABCD1* gene, which encodes the adrenoleukodystrophy protein (ALDP). ALDP is responsible for transporting very long chain fatty acids (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 increases the expression of ALDRP (encoded by the *ABCD2* gene), which is also a VLCFA transporter, thus compensating for the loss of ALDP. For additional background, please refer to our previous report discussing the use of VK0214 in a mouse model of X-ALD, which can be found here.

Additional support for the use of a compound that can augment expression of the *ABCD2* gene in patients with X-ALD comes from a study of vorinostat (Zolinza®), a histone deacetylase inhibitor that is approved for the treatment of cutaneous manifestations in patients with cutaneous T cell lymphoma (CTCL) (Zierfuss *et al*., 2020). Researchers discovered that expression of *ABCD2* in macrophages is controlled through histone modifications in the *ABCD2* promoter region, specifically a high level of histone 3 lysine 27 acetylation (H3K27ac). Thus, macrophages from X-ALD patients were treated *in vitro* with vorinostat, and as shown in the following figure there was a dose dependent increase in *ABCD2* expression (lower left), which led to a subsequent increase in the β-oxidation of C26:0 (a type of VLCFA, lower right).




Source: Zierfuss *et al*., 2020

While VK0214 and vorinostat are not in the same class of drugs, we feel that the data above shows a compound that is able to induce expression of the *ABCD2* gene (which both VK0214 and vorinostat are able to do) can lead to the desired phenotype, namely an increase in the β-oxidation of VLCFAs. Zierfuss *et al*. attempted treatment of advanced cerebral adrenoleukodystrophy (CALD) patients with vorinostat but were unsuccessful in halting progression of the disease, however they did note decreases in the plasma levels of C26:0 and improvements in other inflammatory markers. We are encouraged by the clinical application of a compound that increases *ABCD2* expression in X-ALD patients and believe this further supports testing VK0214 in this population.

## Conclusion

We thank Viking's management for speaking with us and for providing an update on upcoming milestones in 2021. We are hopeful that enrollment will be completed in the VOYAGE trial by the end of the second quarter of 2021 and we look forward to seeing the 12-week liver fat data, which could be available before the end of 2021. This timeline would lead to histology data being announced in the second half of 2022. We don't believe many investors are focused on VK0214, however there could be multiple data readouts for that program this year with a Phase 3 program possibly initiating in 2022. With no changes to our model, our valuation remains at $22.

## PROJECTED FINANCIALS

**Viking Therapeutics, Inc.**
Income Statement

| Viking Therapeutics, Inc. | 2019 A | Q1 A | Q2 A | Q3 A | Q4 E | 2020 E | 2021 E | 2022 E |
|---|---|---|---|---|---|---|---|---|
| **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 | $23.6 | $8.0 | $7.8 | $7.1 | $10.4 | $33.3 | $50.0 | $60.0 |
| General & Administrative | $9.1 | $3.0 | $2.8 | $2.7 | $2.5 | $11.0 | $10.5 | $11.0 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($32.7) | ($10.9) | ($10.6) | ($9.8) | ($12.9) | ($44.3) | ($60.5) | ($71.0) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Non-Operating Expenses (Net) | $6.9 | $1.3 | $1.0 | $0.6 | $1.3 | $4.2 | $5.0 | $5.0 |
| Pre-Tax Income | ($25.8) | ($9.7) | ($9.6) | ($9.3) | ($11.6) | ($40.1) | ($55.5) | ($66.0) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($25.8)** | **($9.7)** | **($9.6)** | **($9.3)** | **($11.6)** | **($40.1)** | **($55.5)** | **($66.0)** |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.36)** | **($0.13)** | **($0.13)** | **($0.13)** | **($0.16)** | **($0.55)** | **($0.75)** | **($0.89)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 72.0 | 72.4 | 72.5 | 72.6 | 73.0 | 72.6 | 74.0 | 74.0 |

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

## HISTORICAL STOCK PRICE


Source: Zacks SCR

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