Zacks Small-Cap Research

November 28, 2017
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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Positive Results From Phase 2 Study of VK5211 in Hip Fracture…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $11/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 (11/28/17)	$3.02
Valuation	**$11.00**

OUTLOOK

On November 28, 2017, Viking Therapeutics, Inc. (VKTX) announced positive topline results from the Phase 2 clinical trial of VK5211, a selective androgen receptor modulator (SARM), in patients recovering from hip fracture. The study achieved the primary endpoint showing a statistically significant, dose dependent increase in lean body mass that ranged from 4.8% at the 0.5 mg dose to 9.1% at the 2.0 mg dose. Following receipt of the final clinical data, the company plans to meet with the FDA to determine potential paths forward for a Phase 3 registration program. With a robust data package and efficacy exceeding expectations even at the lowest dose, we believe the company will have many options available for a Phase 3 program. Based on the data, we've raised our valuation to $11 per share.

SUMMARY DATA

52-Week High	**$3.09**
52-Week Low	**$0.93**
One-Year Return (%)	**160.35**
Beta	**1.65**
Average Daily Volume (sh)	**366,795**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$86**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**20**
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 2016 Estimate	**-0.9**
P/E using 2017 Estimate	**-1.1**

Risk Level	**High,**
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)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 A	0 E	0 E
2018					0 E
2019					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.40 A	- $0.22 A	-$0.20 A	-$0.18 A	-$0.90 A
2017	-$0.23 A	-$0.21 A	-$0.22 A	-$0.19 E	-$0.85 E
2018					-$0.72 E
2019					-$0.70 E

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WHAT'S NEW

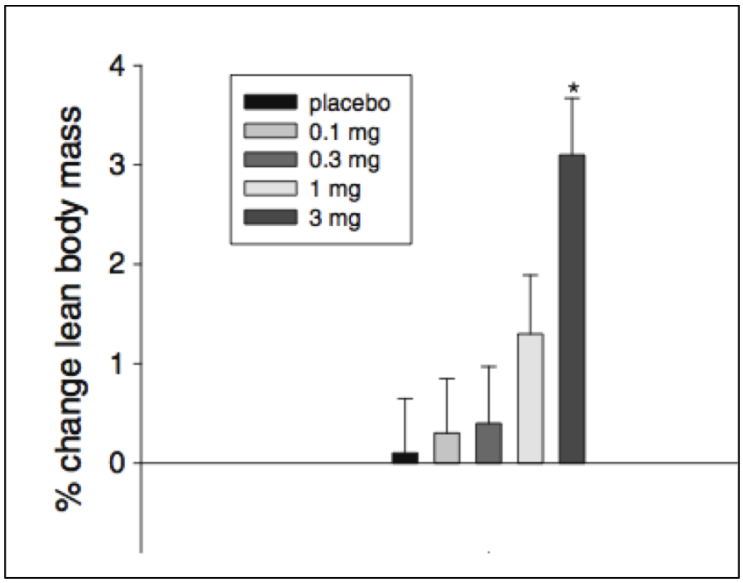
Business Update

Positive Results From Phase 2 Study of VK5211 in Hip Fracture

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 have 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.

The company is still evaluating the data package and will not receive the final data until early 2018 after all study subjects are evaluated at a 12-week follow-up. However, the data presented thus far by the company are very robust and far exceeded expectations:

- 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). 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). The following figure shows that 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.



Source: Dalton *et al*., 2011

- 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.

Following receipt of the final data, likely in early 2018, the company will meet with the FDA to determine the path forward for a Phase 3 registration study. The full data set 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 and joint replacement, although the company is currently only focusing on hip fracture recovery.

Conclusion

The Phase 2 data on VK5211 was better than even the most optimistic expectations, and shows that the drug has robust activity with no safety concerns thus far. We'll be interested to see how the development path evolves once the company is able to fully evaluate the final data package. We believe partnering VK5211 with a larger pharmaceutical company is now much more likely, although with very strong data Viking should be in no rush and can wait for the most optimal terms. Based on the results, we have increased our valuation from $7 to $11 and we continue to believe that Viking's shares are significantly undervalued.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 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	$9.0	$3.5	$3.7	$3.5	$3.8	$14.5	$16.0	$18.0
General & Administrative	$4.8	$1.4	$1.3	$1.2	$1.3	$5.2	$5.7	$6.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.8)	($5.0)	($5.0)	($4.7)	($5.1)	($19.7)	($21.7)	($24.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	($0.3)	($0.2)	($1.4)	($0.1)	($1.9)	($0.5)	($0.6)
Pre-Tax Income	($14.7)	($5.22)	($5.17)	($6.1)	($5.2)	($21.7)	($22.2)	($24.6)
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.7)**	**($5.2)**	**($5.2)**	**($6.1)**	**($5.2)**	**($21.7)**	**($22.2)**	**($24.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.90)**	**($0.23)**	**($0.21)**	**($0.22)**	**($0.19)**	**($0.85)**	**($0.72)**	**($0.70)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.278	22.353	24.119	27.470	28.000	25.485	31.000	35.000

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

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HISTORICAL STOCK PRICE



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