Zacks Small-Cap Research

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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Successful Preclinical Data for VK2809 in Glycogen Storage Disease 1a…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $8/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 (02/15/17)	$1.46
Valuation	**$8.00**

OUTLOOK

On February 9, 2017, Viking Therapeutics, Inc. announced initial results from a proof of concept study of VK2809 in an in vivo model of glycogen storage disease 1a (GSD 1a). GSD 1a is a rare, orphan genetic disease that causes excess accumulation of glycogen and lipids and liver tissue. The initial results from the ongoing study showed that treatment with VK2809 caused significant reductions in key metabolic markers of GSD 1a in animals treated with VK2809 compared to those treated with placebo, including liver triglyceride content and liver weight. The full results from the study will be presented at a scientific conference later in 2017.

Viking is planning on submitting an IND application for VK2809 for the treatment of GSD 1a and to initiate a human proof-of-concept study in the second half of 2017. This work will be funded through an agreement with PoC Capital, LLC, which has agreed to fund up to $1.8 million in expenses in exchange for $1.8 million in Viking common stock.

SUMMARY DATA

52-Week High	**$2.15**
52-Week Low	**$0.95**
One-Year Return (%)	**-12.05**
Beta	**0.94**
Average Daily Volume (sh)	**182,814**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
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)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 A	0 E	0 E
2017					0 E
2018					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$1.40 A	- $1.07 A	-$0.53 A	-$0.57 A	-$3.68 A
2016	-$0.40 A	-$0.22 A	-$0.20 A	-$0.24 E	-$0.97 E
2017					-$0.89 E
2018					-$0.93 E

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WHAT'S NEW

Business Update

On February 9, 2017, Viking Therapeutics, Inc. (VKTX) announced successful interim results from a proof-of-concept study of VK2809 in an *in vivo* model of glycogen storage disease 1a (GSD 1a). The study is ongoing, and full results will be presented at an upcoming scientific conference later this year, most likely the International Congress of Inborn Errors of Metabolism in September 2017.

Initial results from the study showed that treatment with VK2809 led to statistically significant reductions in key metabolic markers of GSD 1a, including a reduction in mean liver triglyceride content of more than 60%, a reduction in average liver weight of more than 30%, and a reduction in average liver weight as a percentage of total body weight by approximately 20%. The study utilized a glucose-6-phosphatase knockout mouse model that recapitulates a number of the phenotypic outcomes commonly seen in GSD 1a patients (Lei *et al*., 1996).

Importantly, these data provide the scientific rationale for moving into a proof-of-concept study in humans in the second half of 2017. While final details are yet to be determined, we anticipate the study will likely involve up to 30 patients dosed for four weeks with the primary outcome being the change in plasma triglycerides from the beginning to the end of the study. We would expect the company to assess liver fat as well, potentially as an exploratory endpoint.

GSD 1a

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 as it 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).

VK2809

VK2809 is a novel, orally available, selective thyroid hormone receptor (TR) agonist. There are two major isoforms of TR, TRα and TRβ, which are encoded by separate genes. TRα and TRβ also have markedly different expression patterns, with TRα expression highest in the heart and brain while TRβ expression is highest in the liver (Bookout *et al*., 2006). VK2809 is a prodrug of a potent TRβ agonist that is converted to the active compound through cleavage by the liver specific cytochrome P450 isoenzyme CYP3A4 (Erion *et al*., 2007). The activated form of the drug has approximately 16-fold higher affinity for TRβ (Ki = 2.2 nM) than for TRα (Ki = 35.2 nM).

Thyroid hormones and TR agonists act through a number of mechanisms to modulate triglyceride and cholesterol metabolism, including:

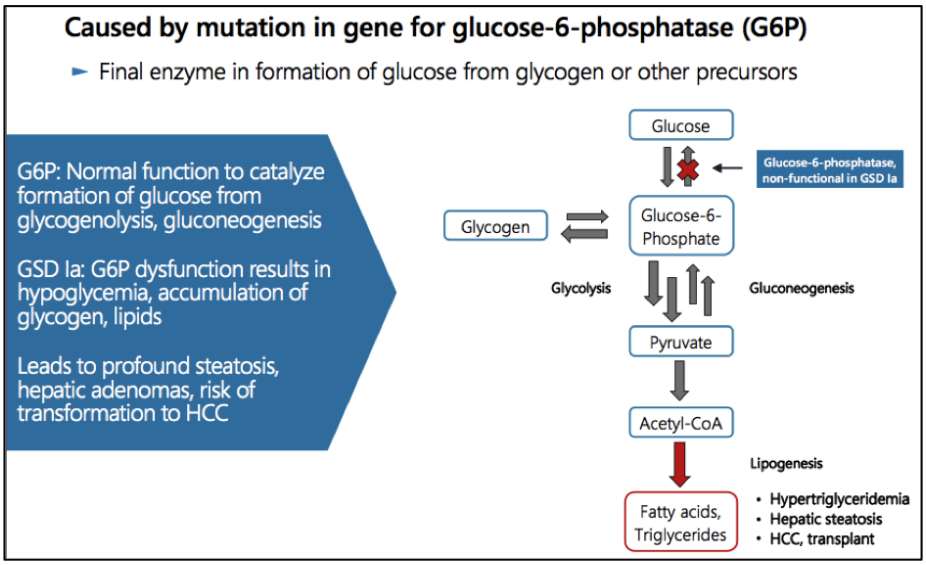
- Increasing expression of LDL receptors, which leads to enhanced clearance of serum LDL (Erion *et al*., 2007)
- Decreasing apolipoprotein B (ApoB) levels, which is the major protein constituent of LDL (Ladenson *et al*., 2010)
- Impacting several aspects of reverse cholesterol transport (Pedrelli *et al*., 2010), the net effect of which is to reduce LDL

- Enhancing synthesis of apolipoprotein A-1, the predominant protein of HDL (Hargrove *et al*., 1999)
- Increasing hepatic uptake of cholesterol from HDL by increasing activity of scavenger receptor class B type-1 (Johansson *et al*., 2005)
- Increasing the activity of liver cholesterol 7α hydroxylase, which converts cholesterol into bile acids for fecal excretion (Johansson *et al*., 2005)
- Inhibiting transcription of sterol regulatory element binding protein-1 (SREBP-1), which decreases fatty acid synthesis and reduces triglycerides (Erion *et al*., 2007)

In addition to lowering plasma cholesterol levels, VK2809 was also shown to reduce hepatic steatosis in rats through increased hepatic fatty acid oxidation, with no evidence of liver fibrosis or other histological liver damage (Cable *et al*., 2009).

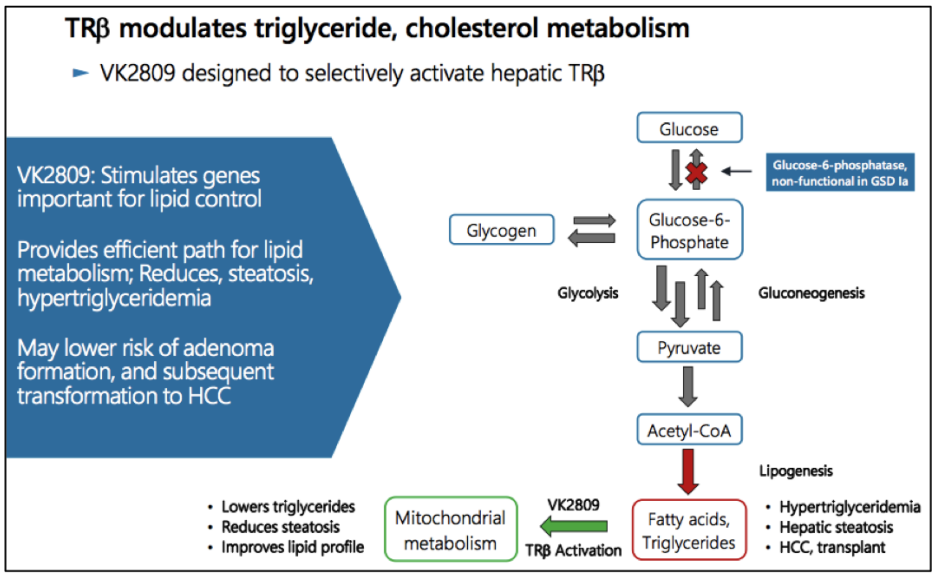
VK2809 for the Treatment of GSD 1a

The following schematic shows how impairment of glucose-6-phosphatase activity leads to accumulation of fatty acids and triglycerides in GSD 1a.



Source: Viking Therapeutics, Inc.

Based on the activity discussed above, administration of VK2809 can theoretically lead to an increase in hepatic TRβ activity, thus increasing the mitochondrial breakdown of lipids and leading to an improved metabolic profile.



Source: Viking Therapeutics, Inc.

PoC Capital to Fund GSD 1a Studies

On February 14, 2017, Viking announced an agreement with PoC Capital, LLC to fund the initial development of VK2809 in GSD 1a. PoC will be responsible for paying up to $1.8 million in expenses associated with VK2809 clinical studies that includes proof-of-concept studies in patients with GSD 1a. Viking will issue up to $1.8 million in common shares to PoC in exchange for the funding.

Conclusion

Viking is pursuing GSD 1a for VK2809 in order to give the company more options for developing the compound as it moves through clinical development. On the one hand, a large pharmaceutical partner could be brought in if the results from the ongoing Phase 2 clinical trial of VK2809 are positive in order to move the compound forward into a registration program for NASH and/or hypercholesterolemia. However, if no partner could be found under reasonable terms, Viking could pursue the development of VK2809 in GSD 1a on its own, as it is an orphan indication that would require a much smaller and less expensive registration program, and the pre-clinical data in a validated model of the disease is quite compelling. It would also compliment the company's pursuit of X-linked adrenoleukodystrophy (X-ALD) for VK0214, which is another orphan indication. While the potential GSD 1a population is small (approximately 3,000 patients in the U.S.), with orphan or ultra-orphan drug pricing it could easily represent a multi-hundred million dollar opportunity.

We remind investors that Viking is set to release data from the company's ongoing Phase 2 clinical trial with VK5211 in hip fracture at the end of 2Q. The company now also expects to release the Phase 2 data from VK2809 in hypercholesterolemia and fatty liver disease in the second half of 2017. These represent clear inflection points for the stock as positive results in one or both of these indications would likely lead to increased interest from larger pharmaceutical partners, with a clear alternate development pathway for VK2809 should the results in hypercholesterolemia and fatty liver disease be negative. Our current valuation is $8 per share, and investors should take a serious look at Viking ahead of data readouts in the second quarter and second half of 2017.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 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	-	-	-	-	-	-	-	-
VK2809/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	$7.0	$1.9	$2.4	$2.1	$2.9	$9.3	$13.5	$16.0
General & Administrative	$5.0	$1.4	$1.2	$1.2	$1.4	$5.2	$5.8	$6.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($12.0)	($3.3)	($3.6)	($3.3)	($4.3)	($14.4)	($19.3)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($11.4)	($0.3)	($0.1)	($0.5)	($0.5)	($1.5)	($2.0)	($3.0)
Pre-Tax Income	($23.4)	($3.6)	($3.7)	($3.8)	($4.8)	($15.9)	($21.3)	($25.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($23.4)**	**($3.6)**	**($3.7)**	**($3.8)**	**($4.8)**	**($15.9)**	**($21.3)**	**($25.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.68)**	**($0.40)**	**($0.22)**	**($0.20)**	**($0.24)**	**($0.97)**	**($0.89)**	**($0.93)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	6.356	9.016	17.105	18.992	20.000	16.278	24.000	27.000

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

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