

Viking Therapeutics (VKTX - \$ 7.05)

IND for VK5211 in Post Hip Fracture Surgery Rehabilitation Phase II Study Submitted

Yesterday, VKTX announced an IND submission for initiating VK5211 in a post hip fracture surgery rehabilitation Phase II study. The clinical trial is scheduled to start in 3Q15.

- Details.** The initial portion of the study will evaluate the safety, tolerability, and PK profile of VK5211 in healthy elderly subjects. The subsequent Phase II study will evaluate efficacy, safety and tolerability of VK5211 in patients recovering from recent non-elective hip fracture surgery. The study is a randomized, double-blind, 120-patient, parallel group and placebo-controlled trial. The primary endpoint is the change of lean body mass after 12 weeks of treatment; while secondary endpoints includes assessments of functional performance, quality-of-life and activities of daily living, as well as safety, tolerability, and PK assessments.
- Implications.** We view this announcement a critical step for the company's execution in VK5211's clinical advancement – VKTX's leading clinical asset. We estimate the top-line results could be available in 1H16. Given the Phase II study would be a first proof-of-concept (POC) trial to test efficacy and safety of VK5211 in patients, a positive outcome potentially could be an inflection point for VKTX share value, in our opinion. VKTX could advance VK5211 development in 2H16 or 2017 pending positive data from the Phase II study. As a reminder, VK5211 is a non-steroidal selective androgen receptor modulator (SARM) that has exhibited positive effects in rodent bone models and promising clinical results from a Phase I study in healthy volunteers. For example, the prior Phase I study illustrated a dose dependent lean body mass (LBM) increase but not in fat mass. Further, the 1.0mg VK5211 group demonstrated a statistically significant mean change vs. placebo (p=0.047). Further, VK5211 also demonstrated change (mean value) in leg press strength (Newton) from baseline.
- Action.** We are reiterating our Buy rating and \$20 target price based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. VKTX shares remain undervalued at current levels, in our opinion, since the outcome of the POC clinical studies of the two leading and well-differentiated assets could be available over the next 4 – 5 quarters. If the results are positive, VKTX share value could change significantly, in our opinion.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-1.40A	-0.13	-0.23	-0.32	-1.49	N.A.
FY-14A	-0.07	3.88	-3.01	-2.01	-5.23	N.A.
FY-13A	0.00	-20.39	-5.57	-0.33	-0.07	N.A.
FY-12A	NA	NA	NA	NA	-0.07	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **VKTX**
Rating: **Buy**
Price Target: **\$ 20.00**

Trading Data:

Last Price (07/14/2015)	\$ 7.05
52-Week High (5/5/2015)	\$ 10.23
52-Week Low (7/1/2015)	\$ 6.52
Market Cap. (MM)	\$ 69
Shares Out. (MM)	10

Yale Jen, Ph.D.

Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
VK5211	Hip fracture	Initiate Phase IIa study	3Q15	***
		Report pre-clinical primate data	2H15	***
		Report Phase IIa study results	2Q16	****
VK0214/VK2809	X-Linked Adrenoleukodystrophy (X-ALD)	Complete pre-clinical POC studies	Mid-15	***
		Initiate Phase I POC study	1Q16	***
		Potentially report Phase I study top-line results	Mid-16	****
VK2809	Cholesterolemia	Potentially start Phase II study with additional financial supports	4Q15	***
	NASH	Potentially start Phase II study with additional financial supports	4Q15	***

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company and company presentation

Major Risks

Risks of clinical study failure could have a major impact on VKTX share value. Despite promising aspects of the company's lead products, VK5211 in the post hip fracture surgery rehabilitation and thyroid- agonists (VK2809 / VK0214) in X-ALD, it remains too early to predict the safety and efficacy from the two upcoming Phase I and Phase II studies. Given that clinical validation or POC for these programs has not been established, it would be critical for these studies to demonstrate a positive outcome in order to increase the asset and shareholder value. Negative results of either clinical study could potentially impair their value and have a materially negative impact on shareholder value, especially since success of each study could illustrate the value of VK5211 in hip fracture rehabilitation and thyroid- agonists in X-ALD. Further, it remains too early to predict any potential future success of clinical trials should these programs further advance into next stage clinical stage development. In thyroid- agonists in X-ALD, although it is possible that the drug could reduce or eliminate VLCFA, it remains too early to forecast that the drug could slow and stop the progression of symptoms to provide clinical benefits.

Product may not be approved or reach anticipated sales. Although Viking's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect VKTX shareholder value.

Positive relationship with Ligand is important. Given that Viking is substantially dependent on technologies and drug candidates licensed from Ligand for further development, it would be important for the company to maintain a positive relationship with Ligand. If Viking loses the right to license these technologies and drug candidates or the Master License Agreement with Ligand is terminated for any reason, VKTX's ability to develop existing and new drug candidates would be harmed.

Additional financings could dilute shareholder value. Although the company currently has ~\$23MM cash after recent IPO financing, VKTX could need more financial resources going forward if they want to expand and further develop its pipeline. Should the product not receive FDA approval, or product revenue does not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Limited trading liquidity limits shareholder options. Given VKTX shares only entered the public market recently; daily trading volume and name recognition are relatively modest. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

Figure 1: Income Statement

Viking Therapeutics – Income Statement

(\$',000)	2012	2013	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Revenue														
Product revenue	0.0	0.0	0.0	-	-	-	-	0	0	0	0	88,989	297,528	626,498
Other revenue	0.2	0.0	0.0	-	-	-	-	0	0	0	0	0	0	0
Total revenue	0.2	0.0	0.0	-	-	-	-	0	0	0	0	88,989	297,528	626,498
Costs of goods												10,679	35,703	75,180
Gross sales												78,310	261,825	551,318
Research and development	(69)	(12)	(22,223)	(139)	(702)	(1,509)	(2,022)	(4,371)	(8,612)	(14,898)	(20,709)	(22,573)	(24,378)	(26,085)
General and administrative	(41)	(89)	(1,245)	(322)	(535)	(642)	(751)	(2,249)	(3,351)	(4,490)	(4,715)	(4,950)	(5,198)	(5,458)
Marketing and sales												(31,000)	(54,250)	(59,675)
Total Operating Expenses	(110)	(101)	(23,468)	(461)	(1,236)	(2,150)	(2,772)	(6,620)	(11,963)	(19,389)	(25,424)	(58,523)	(83,826)	(91,218)
Operating Incomes (losses)	(109)	(101)	(23,468)	(461)	(1,236)	(2,150)	(2,772)	(6,620)	(11,963)	(19,389)	(25,424)	30,466	213,702	535,280
Change in fair value of accrued license fees	0	0	(1,822)	4,961	0	0	0	4,961	0	0	0	0	0	0
Change in fair value of debt conversion features	0	21	(391)	83	(200)	(100)	100	(117)	(200)	(500)	(500)	(500)	(500)	(500)
Amortization of debt discount	0	18	558	172	172	172	172	688	344	0	0	0	0	0
Interest expense	1	6	71	35	35	35	35	141	71	0	0	0	0	0
Total other (income) expenses	1	45	(1,584)	5,250	7	107	307	5,672	214	(500)	(500)	(500)	(500)	(500)
Loss before tax	(111)	(146)	(21,884)	(5,711)	(1,244)	(2,258)	(3,080)	(12,292)	(12,177)	(18,889)	(24,924)	30,966	214,202	535,780
Tax	0	0	0	-	-	-	-	0	0	0	0	(11,457)	(79,255)	(198,239)
Net Income (Loss)	(111)	(146)	(21,884)	(5,711)	(1,244)	(2,258)	(3,080)	(12,292)	(12,177)	(18,889)	(24,924)	19,508	134,947	337,542
Net Income (Loss) Applicable to Common Shareholders	(111)	(146)	(21,884)	(5,711)	(1,244)	(2,258)	(3,080)	(12,292)	(12,177)	(18,889)	(24,924)	19,508	134,947	337,542
Net Earnings (Losses) Per Share—Basic	(\$0.07)	(\$0.07)	(\$5.23)	(\$1.40)	(\$0.13)	(\$0.23)	(\$0.32)	(\$1.49)	(\$0.89)	(\$1.21)	(\$1.41)	\$0.86	\$5.96	\$14.90
Net Earnings (Losses) Per Share—Diluted	(\$0.07)	(\$0.07)	(\$5.23)	(\$1.40)	(\$0.13)	(\$0.23)	(\$0.32)	(\$1.49)	(\$0.89)	(\$1.21)	(\$1.41)	\$0.86	\$5.96	\$14.90
Shares outstanding—basic	1,483	2,043	4,187	4,074	9,650	9,652	9,654	8,257	13,654	15,654	17,654	22,654	22,657	22,659
Shares outstanding—diluted	1,483	2,043	4,187	4,074	9,650	9,652	9,654	8,257	13,654	15,654	17,654	22,654	22,657	22,659
Margin Analysis (% of Sales/Revenue)														
Costs of goods												12%	12%	12%
R&D	-33433%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-25%	-8%	-4%
SG&A	-19791%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-6%	-2%	-1%
Operating Income (loss)	-53124%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	34%	72%	85%
Pretax	-537.9223	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	35%	72%	86%
Tax Rate										0%	37%	37%	37%	37%
Net Income	-53792%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	22%	45%	54%
Financial Indicator Growth Analysis (YoY%)														
Total Revenue	NA	-100%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	234%	111%
R&D	NA	-83%	191264%	178%	NA	NA	-91%	-80%	97%	73%	39%	9%	8%	7%
SG&A	NA	119%	1292%	102%	NA	NA	-21%	81%	49%	34%	5%	5%	5%	5%
Marketing and sales					NA	NA							75%	10%
Operating Income (Losses)	NA	-8%	23118%	120%	NA	NA	-88%	-72%	81%	62%	31%	-220%	601%	150%
Pretax Income	NA	32%	14864%	2395%	NA	NA	-86%	-44%	-1%	55%	32%	-224%	592%	150%
Net Income	NA	32%	14864%	2395%	NA	NA	-86%	-44%	-1%	55%	32%	-178%	592%	150%
EPS	NA	-4%	7202%	1855%	NA	NA	-84%	-72%	-40%	35%	17%	-161%	592%	150%

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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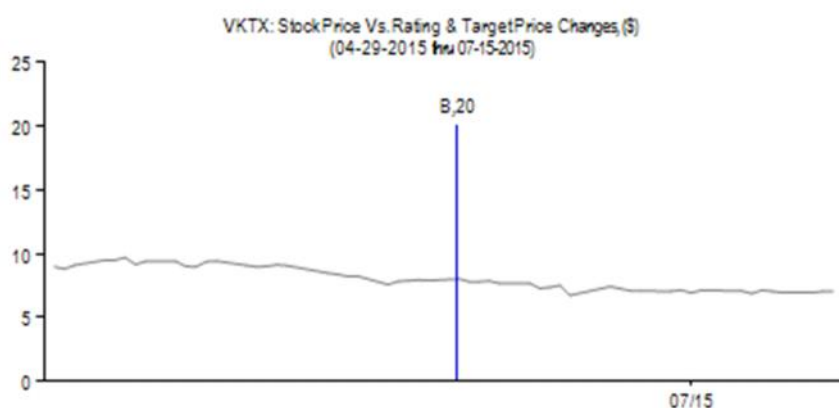
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Date	Rating	Closing Price (\$)
06/08/2015	Buy (B)	8.02

Date	Target Price (\$)	Closing Price, (\$)
06/08/2015	20.00	8.02

Source: Laidlaw & Company

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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