Viking Therapeutics

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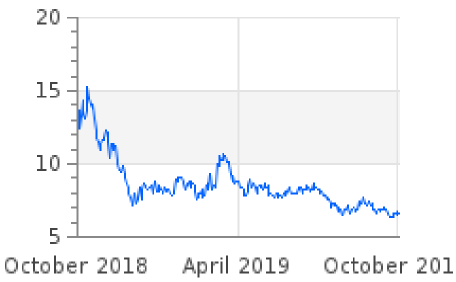
Why Viking Therapeutics isn't waiting for a white knight

Price:	6.59
Market Cap:	$475.87 m

1 Year Share Price Graph



Share Information

Code:		VKTX
Listing:		NASDAQ
52 week	**High**	**Low**
	15.68	**6.155**
Sector:		**Pharma & Biotech**
Website:		**www.vikingtherapeutics.com**

Company Synopsis:

Viking Therapeutics is a clinical-stage biotherapeutics company focused on the development of novel, first-in-class or best-in-class therapies for metabolic and endocrine disorders.

action@proactiveinvestors.com

In a little over three weeks, Viking Therapeutics Inc (Nasdaq: VKTX) will present its Phase 2 study results for its potential blockbuster drug VK2809. The data, already known by the market, comes from the recently completed Phase 2 clinical trial, but the meeting will be important to gauge the temperature of institutions and big pharma.

While strong Phase 2 results ? which Viking achieved, and we'll review shortly ? open the gate of optimism, it's no guarantee of approval. In fact, a Phase 2 trial achieving its endpoints only equals to a slightly more than 50% chance of success in Phase 3.

Let's step back momentarily and examine what it is that Viking does, what VK2809 is and what opportunities the companies may have in its future.

Viking Therapeutics is a small-cap, clinical-stage biotech company focused on the development of therapies for metabolic and endocrine disorders with three metabolic therapeutics in development.

1. VK2809: The company is currently working to prevent both nonalcoholic fatty liver disease (NALFD) and nonalcoholic steatohepatitis (NASH) via its small molecule thyroid beta agonist called VK2809

2. VK5211: Viking strives to create significant improvements in measures of lean body mass via VK5211. The therapy currently targets patients recovering from hip fractures.

3. VK0612: Oral treatment for type 2 diabetes that is currently in Phase 2 development.
Overall, the company holds exclusive worldwide rights to five therapeutic programs in clinical trials or preclinical studies including the three outlined above, but the lead drug right now is VK2809.

VK2809 is a liver-selective thyroid receptor beta agonist that successfully demonstrated the ability to statistically reduce LDL-C (low-density lipoprotein cholesterol) in patients with non-alcoholic fatty liver disease (NAFLD) as compared with placebo.

The real excitement came in the form of the trial's secondary endpoint as VK2809-treated patients experienced statistically significant reductions in liver fat content compared with placebo.

Based on these results, after being treated with just 10 mg of VK2809, more than half the patients achieved liver fat reductions of 59.7% versus only 8.9% for the placebo group. Additionally, more than 90% of the patients achieved a 30% reduction in liver fat versus just 18.4% of the placebo group.

This is significant because NALFD is a precursor to NASH, which is the leading cause of liver transplants in American women. This is a chronic condition that can last for years, or even for life. Currently, there is no treatment approved by the US Food and Drug Administration.

It is estimated that 6% to 8% of US adults have NASH, but what's more astonishing is 30% to 40% of US adults have NAFLD. This translate to a huge TAM (total addressable market).

Conservative estimates place the number of adults with NAFLD between 70 million and 100 million and the number of adults suffering from NASH between 14 million and 22 million adults in the United States alone.

Put those two together and Viking's VK2809 has the chance to capture a solid percentage of the $35 billion untreated NAFLD and NASH market.

Sizing up the competition
But Viking isn't without competitors in this market.

Madrigal Pharmaceuticals Inc (NASDAQ:MDGL) also has a thyroid receptor beta agonist for treatment of NASH. While Viking's VK2809 produced superior Phase 2 results on the surface, the trials weren't apples for apples as Viking's trial group didn't include any signs of liver damage while Madrigal's group had biopsy-proven NASH. Madrigal is likely to be Viking's major competitor.

Size-wise, Gilead may be the largest early player in the space. The company holds a strong NASH pipeline, but its focus is on combination therapies rather than a monotherapy. This makes Gilead a logical buyer of either Viking or Madrigal. At one-third the market cap of Madrigal, Viking may offer more value.

Finally, Intercept Pharmaceuticals Inc (NASDAQ:ICPT) will likely be the first company with an FDA-approved treatment, but the treatment comes with significant safety concerns. Expect it to serve a Band-Aid until either Viking or Madrigal (or both) come to market.

Fortunately, the sheer potential size of the NASH and NAFLD permits multiple players in the space, all with blockbuster potential.

READ: Viking Therapeutics stock rises on positive trial results for treatment of hip fractures
Viking Therapeutics also has VK5211 ready for a pivotal Phase 3 trial. VK5211 increases lean body mass, and it currently targets patients recovering from hip fractures. This therapy faces a slightly tougher road to blockbuster status since it competes with testosterone.

The company plans to meet with the FDA to discuss the best steps moving forward to ensure the success of VK5211; however, it should be noted that Viking will need large coffers to support both a Phase 3 trial of VK5211 along with a Phase 3 trial of VK2809.

Each year, approximately 300,000 Americans break their hip, so the current total addressable market for VK5211 is significantly smaller than VK2809. One should conclude Viking will give priority to VK2809.

As much as Viking would prefer a larger partner to pocket these expensive trials, given the current competition to get to market as soon as possible, management is not waiting for a white knight.

The company's recent secondary offering raised $175 million at $18.50 per share, significantly higher than the mid-October stock price trading almost 20% below that price.

The survival of small biotech companies depends on their potential to produce at least one successful drug. The caveat is financing. Many biotech firms fail not because a drug fails, but because they simply run out of money.

Viking appears to have addressed any near-term financial concerns or need for a white knight while it develops not one but two potential blockbuster therapies. It still must prove through successful Phase 3 trials that its therapies are more than simple potential and competition will be strong, but Viking has made all the right moves up until this point.

At the time of publication, Tim Collins had no positions in the stocks mentioned.

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