Bumbershoot Holdings LP
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2017-Oct

Viking Therapeutics: Welcome to the Glorious House of Gains

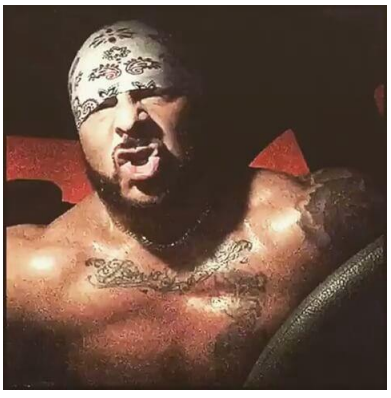
- *Viking Therapeutics is a clinical-stage biotech company that is focused on developing novel therapies to various acute and chronic metabolic and endocrine disorders*
- *A spin-off of Ligand Pharmaceuticals in 2015, Viking maintains a pipeline of four molecular candidates held under an exclusive Master License Agreement. Clinical studies target a broad range of indications to large, underserved markets.*
- *Lead candidate VK5211 is a potent Selective Androgen Receptor Modulator (SARM). Extensive history of efficacy from early clinical trials in animals/humans, as well as testimonials from (illegal) recreational usage as a black-market PED by athletes/bodybuilders.*
- *Currently conducting a Phase II trial for post-operative, hip fracture rehabilitation support in elderly patients. Top-line data expected Q4'17; and recently held panel discussion to outline regulatory steps towards commercialization of $1b+ addressable market.*
- *With funding secure through mid-2018, Viking has line-of-sight on multiple upcoming catalysts over the course of the next 6-12 months that could position the stock to have significant potential upside.*

Introduction

One of the greatest internet personalities (celebrities?) is the indomitable *RobertFrank615*.

For the uninitiated, he is a real-life, pumped-up, Jersey Shore gym rat who is essentially playing a caricature of himself. Loaded with an army of nearly 650k followers, he creates off-kilter, motivational videos that he posts to *Instagram* and *YouTube*.

Put simply, his character's goal in life is to make huge "gainz" at the gym in order to get a "sick pump" for the weekend to then be able to pick up women. In real life ("IRL") though, he co-stars in many of the short videos with his fiancée (yes, it's adorable) and just seems to be a genuine guy that happens to be jacked as all heck and loves to work out.



Jacked, tan, and juicy as Astoria Financial (AF)…

He'll dance to forget the haters. He absolutely despises leg day; and he often comes up with highly entertaining creative expressions such as *International Chest Day* (i.e. Mon-Thurs) or my favorite, the *Glorious House of Gains* (i.e. the gym).

He also happens to be the perfect pop-culture reference for an investment in *Viking Therapeutics* (VKTX:NGS) for two reasons:

1. Viking's lead candidate—a molecule known as *VK5211*—is a potent SARM that has been used as a black-market performance enhancement drug (PED) by athletes and bodybuilders. It is now being positioned clinically as a potential best-in-class treatment for a wide assortment of acute and chronic muscle and bone loss.

2. Its initial area of exploration—rehabilitation support to post-operative elderly patients that suffered a hip fracture—is currently engaged in a Phase II trial, with top-line data expected to be released in Q4'17. With funding secure through mid-2018, to the extent its successful it should propel the stock forward as a major proof of concept towards commercialization.

Said another way, investors in Viking Therapeutics may be positioning—literally and figuratively—to enter into the *GLORIOUS HOUSE OF GAINS* on the back of positive top-line data from the *VK-5211's* Phase II trial results due out later this year.

But I may be getting ahead of myself…

Catabolic Deconstruction

It is easy to *say* that a company has massive upside. It is much harder to *prove* it.

Most of the time it requires building up an investment thesis bit by bit—the fabled "*mosaic*" approach; and in medicine this process is known as *anabolic*.

But here it needs to be broken down into smaller units; and so, in sticking with the bodybuilding and medical theme, what we need is a *catabolic* deconstruction.

Because before we can understand *Selective Androgen Receptor Modulators* (SARM), its crucial to know what it's being selective to and how it can be modulated. (i.e.: Bone, Muscle, and Androgen Receptor specifically.)

Before that though, we'd also need an understanding of tissues, the endocrine system (i.e. hormones), and the ligand-receptor complex more generally.

And by that point we might as well just start at the very beginning…

Start at Conception – Corporate Development

When research scientists at *Ligand Pharmaceuticals* (LGND:NGS) first pioneered the modern era of SARMs back in the 90s, Viking was only a twinkle in their eye.

The company discovered a series of cyclic quinolinones that showed promise in promoting anabolic activity on skeletal muscle with some degree of tissue selectivity.

From these "early efforts" emerged the next generation of non-steroidal SARMs which held immense potential for a wide variety of clinical indications.

But the Great Recession had a funny way of decimating the biotech industry; and while preclinical data results appeared encouraging, clinical trials were put on hold for financial reasons.

In Ligand's case, the stock bottomed below $10/share; and under new CEO John Higgins, it adopted a "never again" policy on drug development internally. Trading in its business for a royalty-license model, it avoided balance sheet risk; and for those investors able to spot that change and time it well, the company was already well on its way into the annals of 10x-bagger history.

But not every bright star in development-stage biotech was to fare as well. For example the lights dimmed on *Metabasis* (formerly MBRX)—a biopharma which had discovered a handful of novel molecules for targeting various metabolic diseases. Forced to be liquidated, it was acquired by Ligand for only $3.2m in Oct-2009.

Brian Lian witnessed all of it with a front-row seat. The former *Amgen* (AMGN:NGS) researcher had made the transition to Wall Street as a Senior Biotech analyst on the sell-side. Covering a handful of businesses in that sector (including *Metabasis*) and sensing opportunity, Lian led a carve-out of the company from Ligand.

After almost two years of due diligence, Viking signed a master license agreement in 2014; and the 'starburst' was completed in 2015 after filing for an IPO.

Today the company is a San Diego-based Biotech firm focused on developing therapies to various metabolic and endocrine disorders.

It has a portfolio of four molecular candidates: *VK5211*, *VK2809*, *VK0214*, and *VK0612*, as well as pre-clinical programs *EPOR* and *DGAT-1*.

The clinical-stage molecular programs are all targeting large, underserved markets "each with global product market opportunities exceeding $1B annually."
—their words, not mine.

Viking Therapeutics – Pipeline

And indeed, the entire pipeline is noteworthy with each drug being interesting in its own right:

VK2809 for example is the molecule most investors are probably most focused on. The drug has shown some extremely promising results *in vivo* for statistically significant reductions in expression of multiple genes associated with *non-alcoholic steatohepatitis* (NASH). Announced Sep-2017, to the extent it can demonstrate similar effect in humans—and no reason to necessarily think it wouldn't—it could prove extremely valuable, particularly given how "hot" an area NASH has become from an investment perspective over the past 1-2 years; and it is a topic I hope to revisit at a later date when I eventually try to tackle *Gilead* (GILD:NGS).

(I'd also endorse the work from PR Research's article *Conquering The Market for Aging Therapies* that was on *SA* comparing it with *Madrigal* (MDGL:NGS)).

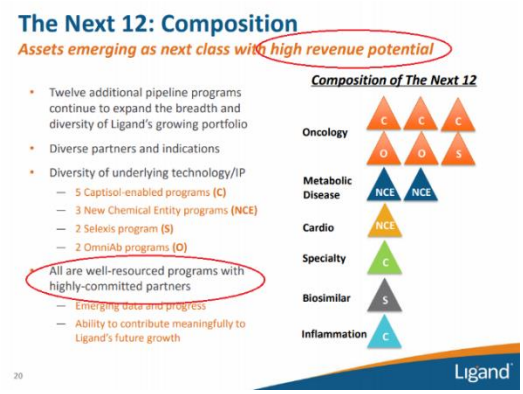
VK0214 has similarly demonstrated some incredible statistical data in the reduction of very-long-chain fatty acids (*VLCFAs*) within plasma levels and key tissues; a marker connected to *X-linked Adrenoleukodystrophy* (*X-ALD*)—a rare/orphan genetic disorder linked to the X chromosome for which there is no approved care.

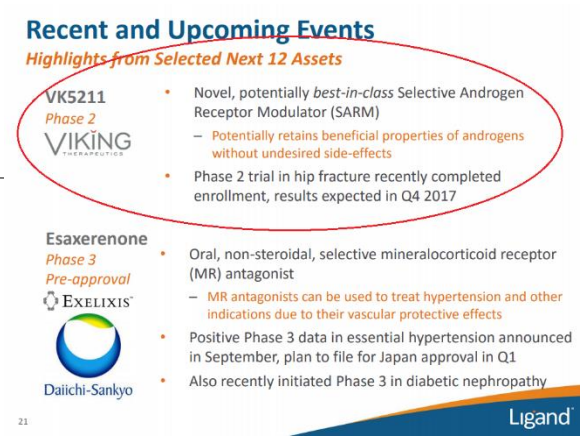
And then there is *VK0612*, the molecule Brian Lian was most interested in at the time which lead to the entire

carve-out. That drug is an inhibitor to a key enzyme of the gluconeogenesis process, which in a Phase IIa study showed to be an effective mechanism for lowering FPG levels (fasting plasma glucose) which could position it as an important treatment in severe type-2 diabetes.

But mostly, I am just interested in *VK5211*… and I seem to be in good company.

Ligand, the former parent company which still owns approx. 25% of Viking's shares, also seems to share my enthusiasm for the drug. While that company reserves somewhat of a "cult status" among biotech investors, for those people less familiar with the business it often uses a "shots on goal" analogy to place into perspective its future growth plans & outlook. Included as part of the "*Next 12*" emerging assets, Viking appears to play heavily into that planning with *VK5211* literally being positioned front-and-center:





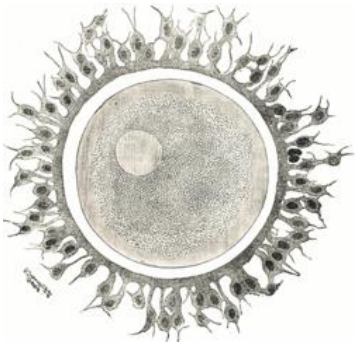
The company also recently held a panel discussion on *Musculoskeletal Therapeutics in Hip Fracture & Other Settings* to present findings and outline the next steps from a regulatory perspective. It also helped to size the opportunity for investors and analysts at well north of $1b annually.

So the rest of this write-up will exclusively focus on *VK5211*, its mechanism of action, and its potential long term opportunity given the upcoming catalyst for top-line data from the drug's Phase II trial.

But first, we still need a bit more background.

Start at Conception – Cellular Development

We enter life as a single, totipotent, eukaryote stem cell known as a *zygote.*[1]



Mitosis begins to kick in and that one cell will start to divide and divide…

And it's from that single fertilized egg—over a journey of almost 9-months—emerges a complexity so baffling that it remains one of biology's "deepest enigmas."[2]

Cells begin to group together into types of tissues—an organizational level between cell & organ. It represents a beautiful ensemble of like-minded cells that together can begin to carry out specific functions.

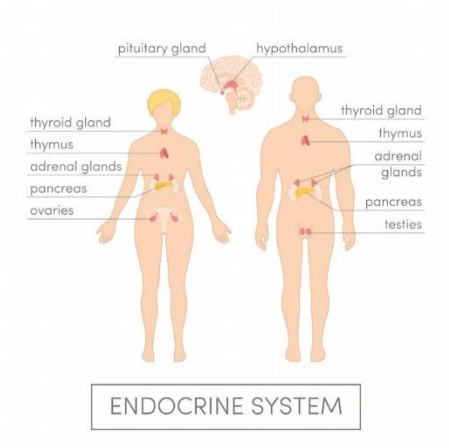
The building continues to form organs, until eventually it coalesces into a conscious living being. …*me*… or *you*. A "pattern integrity"[3] that is as unique as the spaghetti knot living it.

The Endocrine System – Steroid Hormones

Hormones play a huge role in that development.

Formally part of the *Endocrine System*, hormones are signaling molecules produced by various glands. Most typically protein molecules, hormonal signal is passed to a receptor via a binding process that forms a *ligand-receptor complex*.

Steroid hormones are a special sub-class that includes the "sex hormones" (i.e. *gonadocorticoids*).



There are three classes of endogenous sex hormones in humans: *Androgens*, *Estrogens*, and *Progestogens*.

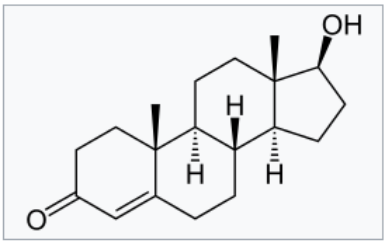
While some are considered more masculine/feminine due to virilization effects, all types of sex hormones are present in any gender, just in different quantities, with *Testosterone* & *Estradiol* being the two most important human derivatives.

Androgens include: *Androstenediol*, *Androstenedione*, *Dehydroepiandrosterone*, *Dihydrotestosterone*, and *Testosterone*.

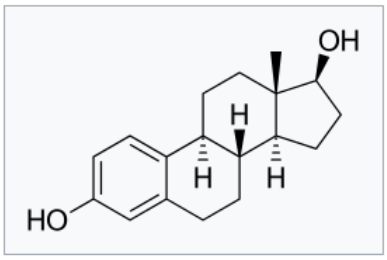
Estrogens include: *Estrone*, *Estradiol*, *Estriol*, etc.

Progestogens include: *Progesterone*, as well as various synthetic *progestins*.

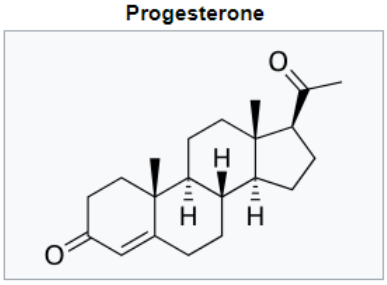
Testosterone



Estradiol



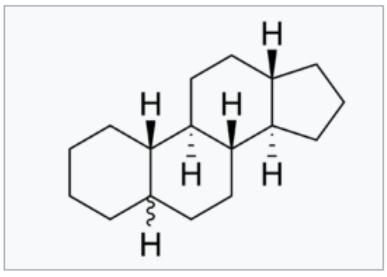
Progesterone



And if they all look similar… it's because they are.

As their name implies, steroid hormones are all based around the same fundamental steroid nucleus called a *Gonane*. It's this structure which then takes on a side-chain through a process known as *steroidogenesis*.

Gonane



Progestogens will act as the crucial intermediate in the production of the other two classes. While Androgens and Estrogens serve the key for biological development and function of the reproductive system, etc.

Links to highly-cited, peer-reviewed articles discussing the relationship between Androgen hormone and bone and muscle, for example, can be seen here:

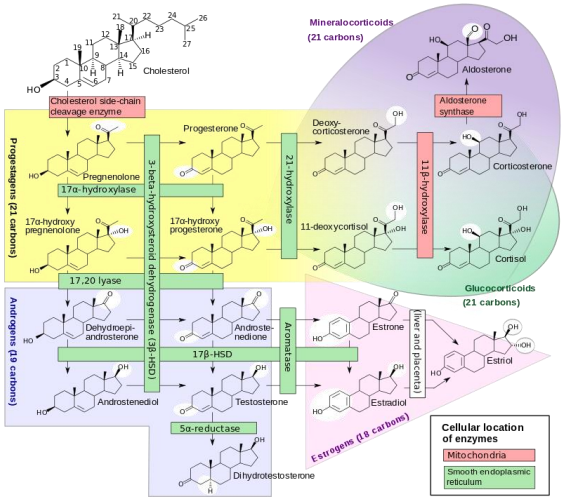
- *Fertility & Sterility* – *Androgen Effects on Bone and Muscle* (Apr-2002, Notelovitz, M.)

  "*Sex steroids are directly involved in modulating osteogenesis and muscle metabolism and function. In this context it can be concluded that androgens —either directly or via aromatization to estrogen— have a profound influence on the presentation of bone and on muscle mass and strength.*"

- *Steroids* – *Androgens and Bone* (2009-Mar, Clarke, B. & Khosla S.)

  "*In summary, testosterone and other androgens exert major beneficial effects on bone cells and skeletal growth and homeostasis, with actions mediated by both androgen receptor and estrogen receptors [...].*"

The progression of the steroid hormones can clearly be seen in the chart below:

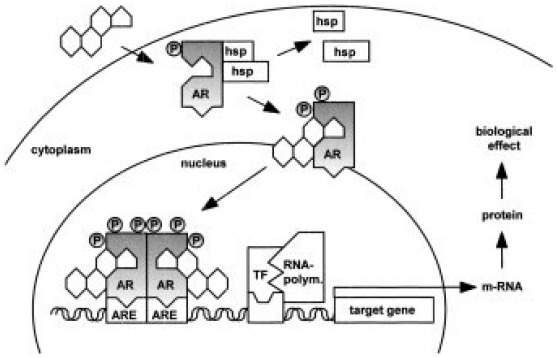


The primary difference between regular hormones and steroid hormones is fat-solubility. That is why it starts with a cholesterol steroid-ring at the top left as input. This fat-solubility allows hormone to traverse through cell membrane without "filtration," essentially making them omnipresent to any receptor throughout the body with specific affinity for it—as long as it's bioavailable.

The Ligand-Receptor Complex

The activation process gets started when the signaling hormone/molecule (known as a *Ligand* and hence the parent company name) binds to a specific target site.

For example, the ligand-receptor complex of *Androgen* hormone is shown below. Androgen will enter into the cell membrane where it will bind with varying affinity to the receptor ('AR') thereby activating it. The receptor drops its protein "floaties" and "sinks" into the nuclear membrane where it lodges into an androgen receptor-complex *receptor* ('ARE'). This will stimulate the cell's transcription factor ('TF') to scribe from the cell's DNA, leading to some intended biological effect or function.

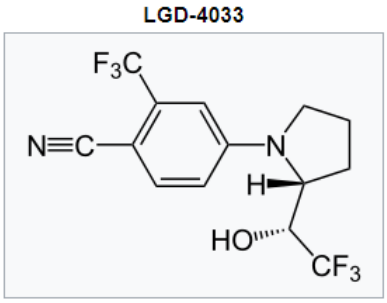


For instance, say a person were to look at the androgen receptors *in* an *osteoblast*—a component of bone tissue with receptors showing affinity for testosterone. When hormone comes into that structure, it will stimulate the intended biological effect of the osteoblast—which is to say synthesizing new bone cells as a part of the overall bone formation/remodeling cycle (i.e.: *ossification*).

This in a nutshell is why hormones of all type play such a vital role in development, maintenance, regulation, etc. throughout our entire lives.

SARMs – The Next Frontier

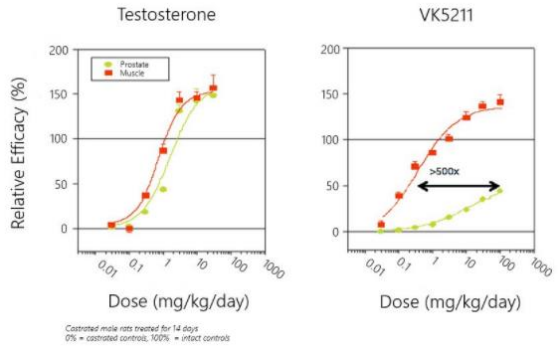
SARMs work the same way, except different...



Meaning that SARM molecules activate the receptor to drive the same biological effect, but is doing so through a different mechanism of action. It is not activating the receptor with a steroid hormone, but rather with a non-steroidal engineered molecule that can show extremely

high affinity to receptors within specific selective types of tissues.

That is why SARMs such as Viking's *VK5211* (formerly known as *LGD-4033*) have demonstrated in studies to have *relative selectively* of approximately **500x** that of exogenous testosterone.



And it's this relative selectivity which allows for doctors and scientists to theorize doing incredible things with them in the future; and positions it as a potential best-in-class therapy for acute/chronic muscle or bone loss.

For example, the concluding quote from the *National Institute of Health's* (NIH) public access paper in 2009 on SARMs as function promoting therapies:

> "*SARMs hold considerable promise as a new class of function promoting anabolic therapies for a variety of clinical indications such as frailty, functional limitations associated with aging and chronic illness, cancer cachexia, and osteoporosis. Although the preclinical data look promising, the efficacy trials of SARMs are just beginning.*"

Fast forward almost a decade later though… and those trials are now here.

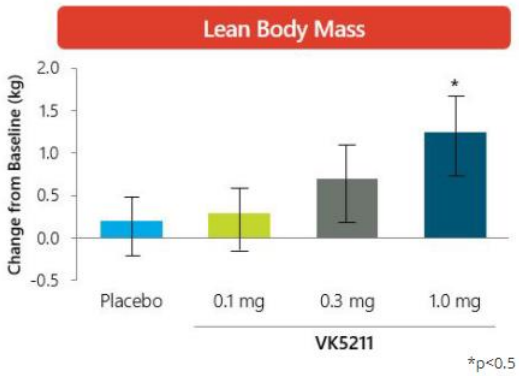
VK5211 – Clinical Trials

VK5211 has undergone considerable preclinical testing and completed multiple Phase I trials to study safety & tolerability while under Ligand's ownership.

Secondary / exploratory data from those trials was key to establishing the first area of interest, positioning the molecule as a therapy for rehabilitation support to hip fractures in post-operative elderly patients.

This is the indication that the company is in the midst of studying as part of a Phase II trial. The 12-week trial, which began in late 2015, finally completed enrollment in Q2'17, putting it on track to release top-line data in Q4'17. The primary end-point of the study is a change in lean body mass (i.e. muscle) as measured by an x-ray absorptiometry ('*DEXA Scan*') reading.

But its extensive clinical history may also shine a light on its chances of success. In particular, the Phase I trial looking at multiple ascending doses in healthy young men that was completed in 2011, showed a clear dose-dependent relationship with statistical significance at the highest (1.0 mg) dosage level.



With that in mind and given that the current Phase II study appears to have been intelligently designed with higher dosage levels, and a longer trial length increased from 3-weeks to 12-weeks, as well as some other minor modifications—it would appear to have de-risked that primary end-point.

While this does not ensure success, intuition would be that study's data should show a strong dose-dependent relationship with statistical significance at most, if not all of the dosage levels.

And that's it!

For Phase II purposes, that is all the top-line data really is… achieving a p-value of less than 0.05; and it's that which seems highly likely, despite what appears to be minimal expectations built into valuation.

So assuming V*K5211* can do what people think/hope it can do… then what?

Target Market – What Could VK5211 Ultimately Be Worth?

So if the science works, what's the *value* of *VK5211* as a *molecule*. Not necessarily value to Viking Therapeutics as it exists today, but its total value as a commercialized therapy.

To evaluate that would need to look at two distinct time periods: *pre-commercialization* (i.e. today and all time in between) and *post-approval*.

Forgetting the former for a moment; and just thinking about commercialization. Irrespective of development timelines, whether it is in 2020 or 2025. Regardless of

ownership structure, royalties, etc. Just what would the drug be worth in its totality to someone in the future.

Well if we just start with the initial indication for hip fractures… that is an enormous market. With almost 300k cases per year in the U.S. alone, hip fractures are one of the leading causes of hospitalizations among the elderly. Given that it causes an immediate and severe impact on function, which is usually accompanied by significant muscle and bone loss, it is an underserved, highly unmet need.

Taking 15%-20% penetration rate of just that domestic market—there are over 1 million cases per year globally—and putting it to a 3-month rehab regimen at $4k per month, in line with other support therapies would peg it to a $550m-$700m+ addressable market; and that would still be fairly bridled expectations considering the overall market size, demographics heading its way, and that the company has already made a compelling case to reconcile a TAM well north of $1bn.

Beyond that initial foray, the market starts to become super enormous as start to consider that the drug could prove similarly useful to other osteoporotic injuries. This would mostly include knee replacements & wrist fractures which would be off-label indications and/or future secondary applications from applying the *same* Phase III trials.

And then there is the holy grail… preventative care. Ongoing chronic support. This is the piece that gets me most jazzed up—not just from a financial perspective, but because it would actually provide patients the most meaningful improvement in medical outcomes. I don't wish to mislead anyone though—this is not on the near-term horizon and I wouldn't want to couch the timeline. But it does present a fairly realistic and very intriguing *eventuality*.

While this step would almost certainly be accompanied by partnership and/or dilution given Viking's financial wherewithal today, it included a substantive and highly thoughtful discussion on the topic as part of Dr. Neil Binkley's presentation in the key opinion leader panel discussion held Oct-9th in NYC.

Interestingly, he compared the natural osteoporotic functional decline from aging with the decline in heart function. Insightfully, he noted that with a *myocardial infarction* (i.e. heart attack) the presumed & accepted medical response is to immediately (or hopefully even *precedingly*) address the underlying "controlling circumstances" [4] which led up to the event. High blood pressure? Stress at work? Perhaps need more exercise or a standing desk. Maybe get you started on a *statin*.

Well with osteoporotic episodes we do none of that. We blame the *fall*. We tend to look past the fact that muscle and bone function are steadily deteriorating, ultimately *leading* to the fall.

And that is the thing about age-related degeneration. Especially when considering the demographics of the *baby boomer* generation—a group of adults that by and large are extremely active. Extremely independent; and not looking to go into a "home" like "Mom & Dad."

This was a large part of Dr. Jack Guralnick's discussion on the panel. He talked about how focus of the medical community is (slowly) shifting to more qualitative and quality-of-life-dependent outcomes—a group of which are being looked at as the secondary/exploratory end-points of the Phase II study.

This could eventually position SARMs/*VK5211* similar to statins… and in that scenario the numbers become *staggeringly large*.

There is only so much an investor can go by at this stage in terms of playing with the odds and outcomes; and blending those risks/rewards together. So I'll just leave you with this: imagine a world in which every person aged 75+ was taking a SARM as a preventative measure to degenerative muscle & bone loss. How much might that be worth? What is the cash flow *Lipitor* generated over the lifetime of the product?

Of course, as said upfront though, that is not equivalent to value in Viking. Value to current Viking shareholders will have to do with *retained* ownership. Which will ultimately be determined by the financial model / cash burn—i.e. all the *pre-commercialized* time in between.

But going back to the initial indication of rehab support for post-operative hip fractures for a moment… even at restrained expectations, with potential to easily cross the $1b mark and most healthcare treatments trading at a multiple of revenue, it might still leave *VK5211* with the chance at being a *multi-billion dollar* molecule.

So in terms of value to Viking—consider a scenario for annual royalty proceeds of $100m based on a "stacked royalty" of ~17% (with Ligand's fee) on sales of $1b per year. With an annuity value, that might still be good for a value to Viking owners of nearly $1b… and that's just one molecule. On a single indication. Under a scenario where a partner is bearing the majority of risk; and that would still represent almost **1500%** upside to the total company enterprise value.

I realize that figure sounds as if it should have me sent me to the loony bin, but if you believe that you may not have studied Viking's target markets very closely…

Financial Model

In terms of the financial model, there is not a whole lot to go by.

The company most recently reported Q2'17 results on Aug-9th. Headline results were negligible and shares had a muted reaction—not surprising given that Viking remains far off of Wall Street's radar.

Looking at the results in more detail, there is still not a lot to see. The company is a *development-stage* biotech so it is pre-revenue (i.e. it's just the expenses). Spendin' money to hopefully make more money later on. At the current run-rate, it will spend ~$15m for the year on R&D, mostly related to the ongoing clinical trials/data collection. It is also pegged to spend ~$5m on general & administrative expenses for the year mostly related to executive salaries & costs of being a public company. A few minor non-cash expenses related to financing, but by and large all reasonable & straightforward; and in sum total represents a cash burn of a few $mm per quarter.

This should leave runway through at least ~mid-2018 given roughly $12m of cash on the balance sheet at the end of the quarter, as well as available liquidity.

In the Q2'17 release, the company also noted that there were ~27.7m shares outstanding as of July-31st, 2017. This would have included the most recent registered offering, but exclude warrants from the both that deal as well as the original, mangled offering in Apr-2016. It also would not account for the most recent privately placed "commitment fee" to Lincoln Park Capital (LPC) as part of the $15m purchase option (at the company's discretion).

So this of course only leaves the time in the middle…

It would be wrong to minimize the "in-between" period since it is both *hugely important* & *unanalyzable* in its effect on residual equity value for current shareholders. The only known piece in the equation is that the higher Viking's stock price is over the next 6-12 months, the more flexibility it will afford it going forward; and the better chance it has to capture a greater percentage of that terminal value for owners without dilution.

While that still leaves many unanswered questions, it does not make the risk/reward break down at $50m of market capitalization when discounted back to present value. To the extent the company is successful, Viking has an enormous runway ahead of it.

That is why it is my best bet for turning into the elusive 100x gain—representing a market cap of ~$3.5bn from my starting point—over the next several years and the coming decade.

Summary

To sum up, I've been waiting almost a year to publish this article. The company finally has line-of-sight from a funding perspective to the release of top-line data on its Phase II trial for *VK5211*. A successful trial with high statistical significance would be a major step forward in the path towards commercialization. With multiple other catalysts on its pipeline of molecules also coming in the next 6-12 months… the time is now.

Or as *RobertFrank* might like to put it:

> *Risk is a 4-letter word.*
> *But so is SARM.*
> *So, get rid of that idea of being a little beta boy;*
> *And grab the 130lbs for a ride on the incline.*
> *Because 'swole' is the goal.*
> *Size is the prize.*
> *Its gains o'clock…*
> *Let's GOOOOOOO!!!!*

ENDNOTES

1. Given the potential religious/political significance of this statement, I do not intend for it to be misinterpreted. "When does life begin?" is a complex question… that is not explained in a single moment. Rather the creation of life begins over time, through a "series of landmark events" in development. [1a]

1a. Slate.com – When Does Life Begin? It's Not So Simple. (http://www.slate.com/…when_does_life_begin…)

2. Discover Magazine – How Does a Single Cell Become a Whole Body? (Nov-1992) (http://discovermagazine…)

3. R. Buckminster Fuller – How Little I Know (Oct-1978) (https://www.bfi.org/publications/…) …and one of my all-time favorites…

4. John Kenneth Galbraith – The Great Crash 1929 (1954) [Introduction to 1988 Edition] (https://www.amazo…)

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Disclosure: Long VKTX, GILD

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