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Zacks Small-Cap Research

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Myos Rens Technology Inc. (MYOS-NASDAQ)

Yolked, MYOS Canine Formula Sales Accelerating. Going Into 2019 w/ New Clinical Evidence and Marketing Initiatives

Based on our 10-year DCF model that uses a 15% discount rate and a 2% terminal growth rate, the target price comes out to roughly $3.50/share. Our assumptions and financial model will be updated based on relevant news.

Current Price (04/01/19)	$1.57
Valuation	**$3.50**

OUTLOOK

MYOS reported Q4'18 financial results and provided a business update. Relative to the financials, revenue remains relatively insignificant, although there are signs of some traction on the topline. Revenue from both Yolked and MYOS Canine Muscle Formula, their two lead products which launched in April and June (2018), respectively, reached new quarterly highs in the period. We expect this trend to continue as MYOS leverages clinical trial evidence in both humans and dogs and expands their presence in Division I and professional sports to drive awareness and uptake of their two lead products. In just the last few quarters the company has made what we think is substantial progress towards putting distribution in place and in building brand awareness of MYOS Canine and Yolked. This includes recent distribution agreements with Miller Veterinary Supply East and The Vitamin Shoppe, an endorsement partnership with Aaron Gordon of the Orlando Magic (Feb 2019), securing courtside advertising during nationally televised college basketball games and a presence in college athletic departments. But perhaps what we find most encouraging is that management continues to stress that the foundation of their growth strategy for their Fortetropin-based products is built around clinical evidence. And MYOS appears determined to further build out their clinical data database.

SUMMARY DATA

52-Week High	**$2.50**
52-Week Low	**$1.04**
One-Year Return (%)	**25.20**
Beta	**0.64**
Average Daily Volume (sh)	**54,948**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**47**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-37.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Consumer-Med**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$0.06 A	$0.09 A	$0.07 A	$0.15 A	$0.36 A
2019	$0.10 E	$0.12 E	$0.20 E	$0.31 E	$0.73 E
2020					$2.37 E
2021					$4.53 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.17 A	-$0.14 A	-$0.12 A	-$0.01 A	-$0.45 E
2019	-$0.14 E	-$0.13 E	-$0.14 E	-$0.14 E	-$0.54 E
2020					-$0.54 E
2021					-$0.41 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Q4 2018 Update: *Yolked, MYOS Canine Formula Sales Accelerating. Going Into 2019 w/ New Clinical Evidence and Marketing Initiatives…*

MYOS reported Q4'18 financial results and provided a business update. Relative to the financials, revenue remains relatively insignificant, although there are signs of some traction on the topline. Revenue from both Yolked and MYOS Canine Muscle Formula, their two lead products which launched in April and June (2018), respectively, reached new quarterly highs in the period. But with the recent shift in focus of efforts and resources towards these two higher-potential products and away from (more) the legacy brands, sales of Qurr and Physician Muscle Health Formula have begun to decelerate.

We expect this trend to continue as MYOS leverages clinical trial evidence in both humans and dogs and expands their presence in Division I and professional sports to drive awareness and uptake of their two lead products. Meanwhile, we think Qurr and Physician Muscle Health Formula will be deemphasized, at least for the near-term, as MYOS remains very diligent towards efficient use of capital and personnel.

In just the last few quarters the company has made what we think is substantial progress towards putting distribution in place and in building brand awareness of MYOS Canine and Yolked. This includes recent distribution agreements with Miller Veterinary Supply East and The Vitamin Shoppe, an endorsement partnership with Aaron Gordon of the Orlando Magic (Feb 2019), securing courtside advertising during nationally televised college basketball games and a presence in college athletic departments.

But perhaps what we find most encouraging is that management continues to stress that the foundation of their growth strategy for their Fortetropin-based products is built around clinical evidence. The most recent data supporting the clinical utility of their products was announced in January and subsequently presented at the North American Veterinary Community (NAVC) / VMX Conference in Orlando. Results (which we discuss below) showed that Fortetropin is associated with a reduction in muscle loss and improvement in overall recovery of dogs that underwent TPLO surgery, which is similar to ACL surgery in humans. This is just the latest data in a growing body of clinical evidence that supports the effectiveness of Fortetropin in reducing muscle loss, increasing lean muscle mass, increasing strength and speeding recovery following surgery.

And MYOS appears determined to further build out their clinical data database. In fact, management noted on the Q4 call that, given the positive results of this Kansas State dog study, that they hope to conduct a (somewhat) similar study in humans – specifically, in patients undergoing total knee replacement surgery. In addition, MYOS indicated that they hope to initiate additional new studies over the coming months.

Q4 2018 revenue was $149k, down 5% yoy (from $157k) but up 126% from Q3'18 (from $66k) and about 24% better than our $120k estimate. Sales of Yolked and MYOS Canine Formula were $89k and $36k, accounting for 60% and 24% of the total, respectively. Both marked new quarterly revenue highs in the period. As the Miller East and The Vitamin Shoppe distribution agreements were penned in November and December, respectively, we think revenue of MYOS's two lead products may have benefitted (at least to some degree) from initial stocking orders.

Meanwhile, revenue from Qurr, MYOS' consumer-focused Fortetropin-based products (puddings, powders and shakes) which launched in April 2017, was $19k in Q4, the lowest quarterly revenue from that product since its introduction. While Qurr has accounted for a substantial portion of the company's revenue over the last two years, including 31% in 2017 and 49% in 2018, it appears MYOS is deemphasizing this brand as the company shifts their focus and resources to their Canine Formula and Yolked.

In the 10-K the company notes that they have accelerated the remaining amortization (which was previously set to amortize through 3/2022) associated with the capitalized costs related to building of the Qurr website to 12/31/19, which matches the expiration date of the remaining Qurr inventory. As such, Qurr sales will likely fall off and conclude during the year. However, as Yolked was launched into the consumer market (including via Amazon and The Vitamin Shoppe) in late-2018, we expect this sales channel to remain well represented by MYOS's Fortetropin products.

Physician Muscle Health Formula, a Fortetropin-based product sold to physicians for their patients which launched in May 2016, generated $5k worth of revenue in Q4. The product had yet to gain much traction, generating just $24k (5% of total) of revenue in 2017 and another $24k (7% of total) in 2018. We expect insignificant revenue from this product going forward and anticipate that it will be discontinued. We think that the physician channel could eventually be reinvigorated with additional human clinical study results – potentially including a planned trial in patients undergoing total knee replacement surgery (discussed below).

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For the full year 2018, revenue was $360k, down 32% from $526k in 2017. The contraction relates to sales to Cenegenics Product and Lab Services, which were $200k in 2017 and $0 in 2018. As a reminder, Cenegenics resold the product through their age management centers and related clinicians. While that distribution agreement ended in December 2016, subsequent purchase orders meant this channel remained a significant contributor to revenue in 2017. We do not model any future sales through Cenegenics.

Combined, Yolked and MYOS Canine Formula generated $219k of sales in 2018, accounting for 45% of the total. During the second half of the year, these two products (which, again, launched in April and June 2018, respectively) generated sales of $146k, or 68% of total revenue.

Yolked appears to continue to be well-received with management indicating that the product is receiving positive feedback from both IMG and the universities themselves. Since its launch in April 2018 it has been detailed to collegiate athletic programs through their strategic partnership with IMG College. As a reminder, initially the IMG agreement covers nine Division I colleges (in the NE). Many of the initial schools that they have worked with began a four-month program in July 2018 – while others started in the Fall. In furthering their collegiate sports related awareness-building efforts, MYOS recently announced that Yolked has had a presence at nationally-televised college basketball games with courtside LED signage. Going into the Fall of 2019, Yolked related advertisements will be visible during college football games.

MYOS has also made a move with Yolked into professional sports. In early February the company announced an endorsement deal with Aaron Gordon, a power forward and prolific scorer of the NBA's Orlando Magic. Gordon will act as a celebrity athlete endorser for Yolked and, per the press release announcing the relationship, "will represent Yolked through a variety of media channels, including social media and traditional formats, and serve as a face of the brand." Noteworthy is that the announcement, which also mentions that this "is the first major endorsement…but will not be the last", indicates that additional similar endorsement deals for Yolked could follow.

MYOS is also now tapping the consumer market with Yolked. In late-2018 the company launched Yolked to the consumer market with distribution established through The Vitamin Shoppe. Yolked was in all of their 775 stores by the close of 2018 and can also be purchased on their website. Yolked can also now be purchased on Amazon.com. In furthering their consumer-facing initiatives, MYOS recently updated the yolked.com website and began implementing formal sales and marketing programs aimed at building awareness and increasing sales.

MYOS Canine Muscle Formula, their first Fortetropin-based supplement for dogs launched in June 2018. MYOS has wasted no time in generating early awareness of the product and in expanding their sales reach. MYOS Canine was featured at the Atlantic Coast Veterinary Conference in Atlantic City, NJ in October. In terms of distribution-reach, upon launch the product had its own website and became available on Amazon.com. Then, in November Miller Veterinary Supply East, which (per their website) provides "licensed veterinarians the equipment, instruments, pet food, pharmaceuticals and supplies needed to run their practices", began carrying MYOS Canine. Miller East affords access to more than 6,000 veterinary hospitals in the eastern U.S.

MYOS Canine is believed to be the first and only evidence-based supplement for supporting muscle health in dogs. MYOS has noted that initial observational studies (including two done at veterinarian hospitals) indicated that their Fortetropin-based supplement may improve mobility. While anecdotal, coupled with positive results of prior studies and highly compelling results of the KSU study (detailed below), the database of evidence continues to grow and fortify.

There is no denying the attractiveness of the domestic pet market. The U.S. pet supplements market is worth approximately $600M and growing rapidly. MYOS has indicated that they expect to leverage the massive growth of the pet-health market. While MYOS Canine Muscle Formula is their first commercial foray into the market, it is not expected to be their last as their intention is to bring additional Fortetropin-based pet products to market. Current customer call-points include veterinarian hospitals, vet practices and direct-to-consumer. Revenue could gain additional traction from the new distribution via Miller East, which came online in Q4'18, as well as from increased awareness as a result of exhibiting and presenting at major veterinarian conferences including the Atlantic Coast Vet conference (October 2018) and the North American Veterinary Community (NAVC) / VMX Conference (January 2019).

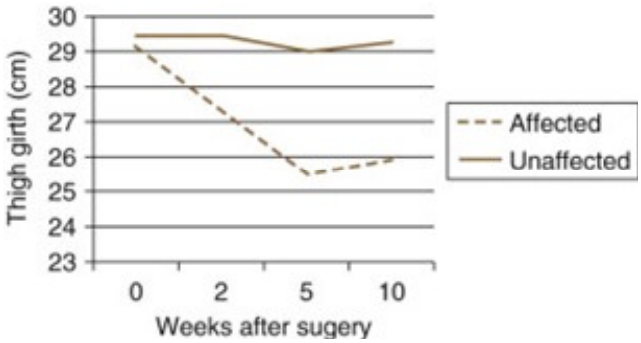
Positive Results of Canine Muscle Recovery Study Following Surgery…

In mid-January MYOS announced positive results of a study conducted at Kansas St. University evaluating the ability of their canine Fortetropin formula to reduce muscle loss in dogs following tibial-plateau leveling osteotomy, or TPLO (i.e. surgery after ligament tear), a common procedure for dogs with cranial cruciate ligament rupture

(CCLR). According to the Journal of the American Veterinary Medical Association, over one million surgeries involving the knee are performed on dogs each year. CCLR is the most common cause of lameness in dogs and one that pet owners are estimated to spend over $1.5B per year to treat (the majority of which relates to surgery).[1,2]

As the leg must be immobilized for weeks following TPLO, muscle loss is a common complication of the procedure. Muscle atrophy is typically evident within two weeks following surgery. And while studies have shown that muscle mass generally begins to return by the fourth week into recovery, significant atrophy remains by week eight. Other studies have shown that affected limbs (i.e. those surgically repaired) maintained just 60% of their muscle mass (as compared to the unaffected limbs) 10 weeks into recovery (chart below) and many dogs show residual muscle atrophy even one year following surgery.[3]

Muscle Loss in Dogs After TPLO[3]



As results of this Kansas St study show, MYOS's Canine Formula appears to significantly reduce this muscle loss common among dogs that undergo TPLO. The double-blinded study included 100 dogs, 50 of which received daily Fortetropin, with the other 50 receiving a macronutrient-matched placebo (i.e. daily cheese powder). The dogs were evaluated on change in muscle mass of the affected and unaffected limbs, as measured by thigh circumference, and change in weight-bearing capacity – both of which are well-established endpoints in TPLO studies. Serum myostatin levels were also evaluated.

The dogs underwent forced exercise restriction during the first eight weeks following surgery. This was followed by a gradual return to activity during weeks 9 through 12. Measurements were taken at baseline, week 8 and week 12. Significance was set at $p<0.1$.

Topline results were announced in a press release on January 15th and, later that same month, the full results were presented by Ken Harkin, Professor & Section Head, Kansas State University College of Veterinary Medicine, at the North American Veterinary Community (NAVC) / VMX Conference in Orlando.

Results showed that;

- Fortetropin prevented loss of muscle mass of the affected limb as measured by the thigh circumference in their affected and unaffected limbs. While there was no statistically different change in thigh circumference (of both the affected and unaffected limbs) of dogs that received Fortetropin, there was a statistically significant decrease in thigh circumference (of both the affected and unaffected limbs) among dogs that received placebo
- Fortetropin-supplemented dogs had a statistically significant greater improvement in the percentage of weight supported by the affected limb as determined by force plate stance analysis (i.e. a more rapid return to normal stance force distribution) as compared to the placebo group from week 0 to week 8 (i.e. during period of exercise restriction)
- Fortetropin prevented a rise in levels of serum myostatin, which is a protein that prevents muscle growth. While there was no statistically significant change in serum myostatin levels among dogs that received Fortetropin, there was a statistically significant increase (from week 0 to week 8 and from week 0 to week 12) in serum myostatin levels among dogs in the placebo group

[1] Coletti et al. Complications associated with tibial plateau leveling osteotomy: A retrospective of 1519 procedures. Can Vet J. 2014 Mar; 55(3): 249–254
[2] Wilke et al. Estimate of the annual economic impact of treatment of cranial cruciate ligament injury in dogs in the United States. J Am Vet Med Assoc. 2005 Nov 15;227(10):1604-7.
[3] Darryl L. Millis. Responses of Musculoskeletal Tissues to Disuse and Remobilization. Canine Rehabilitation and Physical Therapy (Second Edition), 2014

MYOS also noted that there was significant interest in the results from attendees of VMX, which is one of the largest veterinary conferences in the world and attracted over 700 exhibitors last weekend. We think that these results significantly bolster the effectiveness claims of MYOS Canine Formula, which is believed to be the first and only evidence-based supplement for supporting muscle health in dogs. As such, we expect that this most recent study data will likely account for a significant portion of MYOS' marketing message.

Readying for human study in total knee replacement surgery…

As we noted in our update following announcement of the Kansas St study results, given that TPLO recovery in dogs has significant crossover to muscle atrophy experienced by humans following certain orthopedic surgeries, such as ACL repair, we opined that these results could also play a role in helping to guide a similar clinical development program in humans. For example, studies have shown that some muscle fibers of the affected limb may never fully recover following ACL surgery in humans, resulting in chronic loss of quadriceps strength.[4] At the time we noted that we expected to hear more about MYOS' plans for leveraging these Kansas State results for potentially guiding additional human clinical programs.

It was not a long wait as management noted on the Q4 call in late-March 2019 that these Kansas State TPLO results have facilitated their interest in conducting a (somewhat) similar study in humans – specifically, in patients undergoing total knee replacement surgery. The goal will be to demonstrate that Fortetropin supplementation can reduce total recovery time and facilitate rehabilitation. While still in the early stages, management noted that they hope to announce initial details of the planned study in the coming weeks.

Product Development

In addition to the recently completed Kansas State study and the anticipated human knee replacement study, MYOS's recent product development efforts have included collaborations with the University of Berkeley, Weill Cornell Medical College and Rutgers University. In addition to these (detailed below), MYOS is looking to add additional preclinical and clinical studies in their ongoing quest to continue to build their Fortetropin evidence database.

- The study at the University of Berkeley aims to understand the impact of Fortetropin on the rate at which new muscle is synthesized in men and women between 60 and 75 years of age. Positive results from the study could help bolster sales of MYOS' product in the future. MYOS anticipates the study completing in Q2 of this year.
- In May 2018 MYOS contracted with Weill Cornell Medical College for a preclinical study to evaluate Fortetropin in preventing weight and muscle loss associated with lung cancer. Unfortunately, per an update in the 2018 10-K, results did not show that Fortetropin had a significant impact on cancer-related weight and muscle loss and as such, MYOS has decided to not pursue future cachexia-related studies. As outcomes of this study had no consequences on our model, it does not affect our outlook or price target.
- In March 2018 MYOS entered into a research agreement with Rutgers University to develop product candidates for preventing muscle loss (resulting from sarcopenia and cachexia) and improving muscle health. The program is led by Joseph W. Freeman, Ph.D., an Associate Professor in the Department of Biomedical Engineering at Rutgers. Dr. Freeman is also part of the University's Musculoskeletal Tissue Regeneration (MoTR) laboratory which focuses on developing engineering techniques to repair and regenerate musculoskeletal tissue. As of the Q2 call (August 2018) management's guidance was for patient screening to begin shortly and, assuming all went well, for initial data to be available sometime in 2019. Since then the company has not provided updated guidance.

Cash

MYOS continues successfully raise operating funds. Recently this included the sale of ~1.5M common shares at an average price of ~$1.49 for $2.3M in gross proceeds. Joe Mannello (MYOS' CEO) also recently agreed to lend up to $1M in exchange for a 5%, one-year (matures 8/31/19) unsecured promissory note ($1M funded as of year-end 2018. Subsequently, $250k of this was converted to common stock). An in January 2019 MYOS received $1.1M from the sale of its net operating losses through the State of NJ Economic Development Authority.

Maintaining $3.50/Share Price Target…

We have made adjustments to our model following Q4 results. We continue to look for gradual revenue growth over the near term but for that to accelerate as awareness builds of the clinical and real-life benefits of Fortetropin on muscle health (in both humans and pets). The Kansas State TPLO results have the potential to facilitate

[4] Arangio et al., Thigh muscle size and strength after anterior cruciate ligament reconstruction and rehabilitation. J Orthop Sports Phys Ther. 1997 Nov;26(5):238-43.

MYOS's overall marketing message as it relates to the proven benefits of Fortetropin as well as bolster the revenue curve of MYOS Canine Muscle Formula. Positive outcomes of a total knee replacement study (currently in the planning phase) could be a significant catalyst to helping to drive adoption among medical nutrition channels. As such we will be eager to hear updates on the progress of this endeavor.

Meanwhile, beefed-up distribution and new marketing initiatives should benefit sales of Yolked. Celebrity athlete endorsements, The Vitamin Shoppe distribution channel and additional presence in collegiate and professional sports should help to define Yolked's brand. This, along with clinical evidence should aid in separating Yolked from plethora of protein powders and other supplements that largely lack the efficacy-related evidence that Fortetropin does. While these awareness and brand-building initiatives can take time to resonate with consumers, we think these efforts have the potential to carve out Yolked in a niche by itself and to drive revenue for the long term.

We continue to be highly encouraged by management's evidence-based approach towards messaging and product development and, assuming positive results from ongoing (and future) studies, would expect this strategy to result in long-term growth in both revenue and shareholder value.

We incorporate a discount rate of 15% and 2% terminal growth rate. We value MYOS at approximately $3.50/share. This valuation provides more than 100% upside to the current trading price of $1.57/share.

PROJECTED INCOME STATEMENT

MYOS RENS TECHNOLOGY

MYOS RENS TECHNOLOGY	2017A	2018A	Q1E	Q2E	Q3E	Q4E	2019E	2020E	2021E
Total Revenue	$0.53	$0.36	$0.10	$0.12	$0.20	$0.31	$0.73	$2.37	$4.53
Y-o-Y Growth	61%	-32%	77%	36%	205%	105%	102%	225%	91%
Total cost of revenue	$0.31	$0.25	$0.07	$0.07	$0.12	$0.17	$0.43	$1.18	$1.58
Gross Income	$0.22	$0.11	$0.04	$0.05	$0.08	$0.14	$0.30	$1.18	$2.94
Gross Margin	41%	31%	35%	38%	40%	45%	41%	50%	65%
Selling, Mrktg, Research	$0.82	$0.89	$0.13	$0.18	$0.30	$0.35	$0.96	$1.51	$2.08
% S.M&R	156%	248%	129%	150%	149%	114%	132%	64%	46%
Total G&A	$2.01	$3.55	$0.96	$1.00	$1.02	$1.04	$4.02	$4.90	$5.44
%G&A	383%	985%	950%	833%	507%	340%	552%	207%	120%
Other Expenses	$1.45	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total operating expenses	$4.29	$4.44	$1.09	$1.18	$1.32	$1.39	$4.98	$6.41	$7.52
Operating Income	($4.07)	($4.33)	($1.05)	($1.13)	($1.24)	($1.25)	($4.68)	($5.23)	($4.58)
Operating Margin	-	-	-	-	-	-	-	-	-
Interest income	$0.00	$0.00	$0.01	$0.00	$0.00	$0.00	$0.01	$0.02	$0.04
Interest expense	$0.00	($0.01)	($0.02)	($0.02)	($0.01)	($0.01)	($0.06)	$0.00	$0.00
Other income (expense), net	$0.00	($0.00)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Pre-tax income	($4.07)	($4.34)	($1.07)	($1.15)	($1.25)	($1.26)	($4.73)	($5.21)	($4.54)
Income tax	$0.00	($1.12)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
warrant modification	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Net Income	($4.07)	($3.22)	($1.07)	($1.15)	($1.25)	($1.26)	($4.73)	($5.21)	($4.54)
Net Margin	-	-	-	-	-	-	-	-	-
EPS	($0.69)	($0.45)	($0.14)	($0.13)	($0.14)	($0.14)	($0.54)	($0.54)	($0.41)
Y-o-Y Growth	-	-35%	-18%	-12%	12%	1277%	19%	0%	-

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Shares O/S	5.9	7.1	7.7	9.2	9.2	9.2	8.8	9.7	11.0

APPENDIX

BACKGROUND

Headquartered in Cedar Knolls, NJ, MYOS RENS Technology Inc. is an emerging advanced nutrition and biotherapeutics company. Their business is focused on developing and commercializing nutritional supplements, functional foods and therapeutic products aimed at improving muscle health and function. Their flagship product, Fortetropin®, is a bioactive proteo-lipid complex that is developed from fertilized egg yolk using a proprietary process. Fortetropin helps build lean muscle mass by lowering serum myostatin levels, upregulating mTor pathway activity and downregulating ubiqutin proteasome pathway activity.

Mechanism of myogenesis (formation of muscle fibers)

Myogenesis is initiated in myogenic cells that differentiate to form primary skeletal muscle fibers. Clinical studies have highlighted the importance of signaling in satellite cells that are responsible for muscle formation. Satellite cells are

- myogenic stem cells, which proliferate and give rise to new myoblastic cells
- responsible for development, repair and homeostasis of skeletal muscle fibers
- activated in response to stress induced by weight training or injury or in myodegenerative disease states

Satellite cells represent the primary basis of muscle repair in adults, either causing hypertrophy (cells fuse with an existing muscle fiber) or hyperplasia (cells fuse with each other).

What is Myostatin?

Myostatin is a myokine, a naturally occurring protein produced and released by myocytes (muscle cells). Skeletal muscle (striated muscle that excludes heart and digestive tracts) is the primary producer of myostatin. Myostatin is a member of the transforming growth factor beta (TGF-β) protein family. Myosin is formed from the precursor protein, a 375 amino acid dimer that is cleaved by proteases to a 109 amino acid domain (active form of myostatin).

The myostatin peptide binds to one of the two activin type II receptors, ActRIIA and ActRIIB. Binding to the receptors initiates an intracellular signaling cascade that results in an increase in protein breakdown and subsequent inhibition of protein synthesis. Myostatin is responsible for regulating myogenesis. Prior studies in animals with genetic deficiency for producing myostatin have shown an increased muscle mass, suggesting that myostatin is responsible for down-regulating muscle growth and development.

Discovery of Myostatin's role in muscle development…

In 1997, researchers published an article in the journal *Nature*[5] about their discovery of a novel member of the TGF-β family of growth and differentiation factors. This factor was expressed specifically in adult skeletal muscle and referred to as growth/differentiation factor-8 (GDF-8). In order to understand the biological function of GDF-8, they disrupted the GDF-8 gene in some mice. The result was GDF-8 null mice being significantly larger than their wild-type counterparts. Individual muscles of GDF-8 null mice weighed 2-3 times more than those of wild-type animals. GDF-8 null mice showed both muscle cell hypertrophy (increase in muscle size) and hyperplasia (increase in muscle fibers). The GDF-8 null mice were named "mighty mice". Based on the phenotype, the researchers named the discovered protein as myostatin.
(Source: www.myosrens.com)



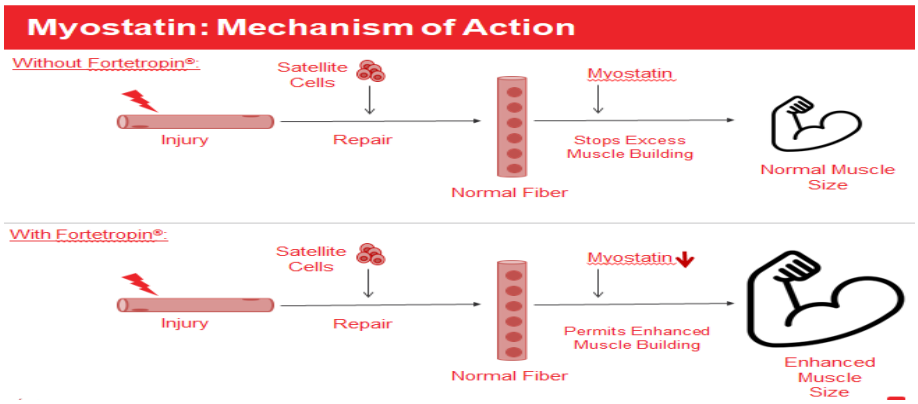
Upper limb muscle mass in myostatin wild-type (left) and myostatin knock-out (right).
Source: McPherron *et al.*, 1997

The science behind Fortetropin...

[5] Nature volume 387, pages 83–90 (01 May 1997)

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Fortetropin is a bioactive proteo-lipid complex. It is isolated from fertilized egg yolk using a patented process that preserves the various proteins and other bioactive molecules and their bioactivity.



Fortetropin®: Mechanism of Action (Source: www.myosrens.com)

A preclinical study[6] of Fortetropin's mechanism of action demonstrated regulatory effects on three important molecular signaling pathways that are responsible for healthy muscle growth.

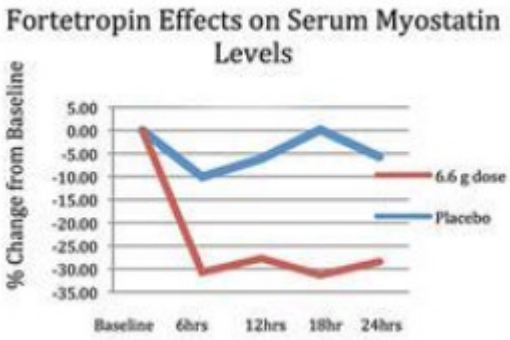
1. Myostatin pathway: We have discussed that Fortetropin® has the ability to reduce serum myostatin levels.

2. mTOR pathway (anabolic signaling): The preclinical data demonstrated that Fortetropin up-regulates the mTOR regulatory pathway. The mTOR pathway is responsible for production of a protein kinase related to cell growth and proliferation that increases skeletal muscle mass. Up-regulation of the mTOR pathway is important in preventing muscle atrophy. The study suggested that Fortetropin-based products could slow down muscle loss post-immobility and/or denervation.

3. Ubiquitin pathway (catabolic signaling): The study also demonstrated that Fortetropin reduces the synthesis of proteins in the Ubiquitin pathway. Over-production in the Ubiquitin pathway is responsible for muscle degradation.

Clinical Studies

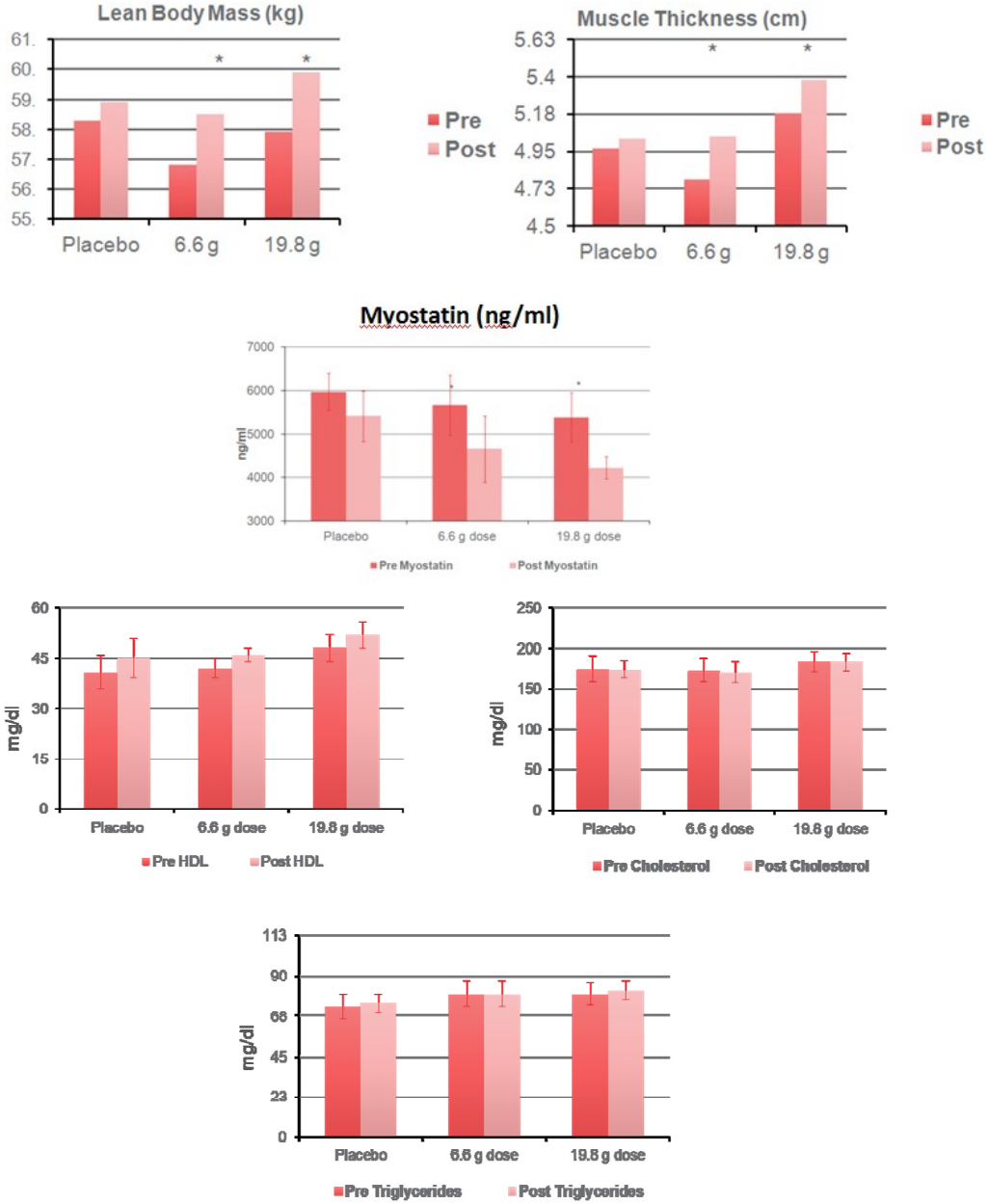
- ***Study 1:*** In March 2013, a double blind, randomized, placebo controlled, parallel, single dose study was conducted involving 24 healthy adult male subjects. Test subjects in the active arm (12 subjects) were administered 6.6g of Fortetropin mixed with vanilla fat-free/sugar-free pudding. An equal amount of vanilla fat-free/sugar-free pudding without Fortetropin was given to the placebo arm (12 subjects). Blood samples were collected at baseline (before dosing) and at 6, 12, 18 and 24 hours post-dosing for measurement of myostatin in blood. Results demonstrated greater than 30% decrease in serum myostatin levels compared to baseline during the 24-hour period. No study-related adverse events were reported. This study confirmed the beneficial effects of Fortetropin in suppressing free serum myostatin levels.



2. Sharp, Matthew H., et al. "The Effects of Fortetropin Supplementation on Body Composition, Strength, and Power in Humans and Mechanism of Action in a Rodent Model." *Journal of the American College of Nutrition* 35.8 (2016): 679-691.

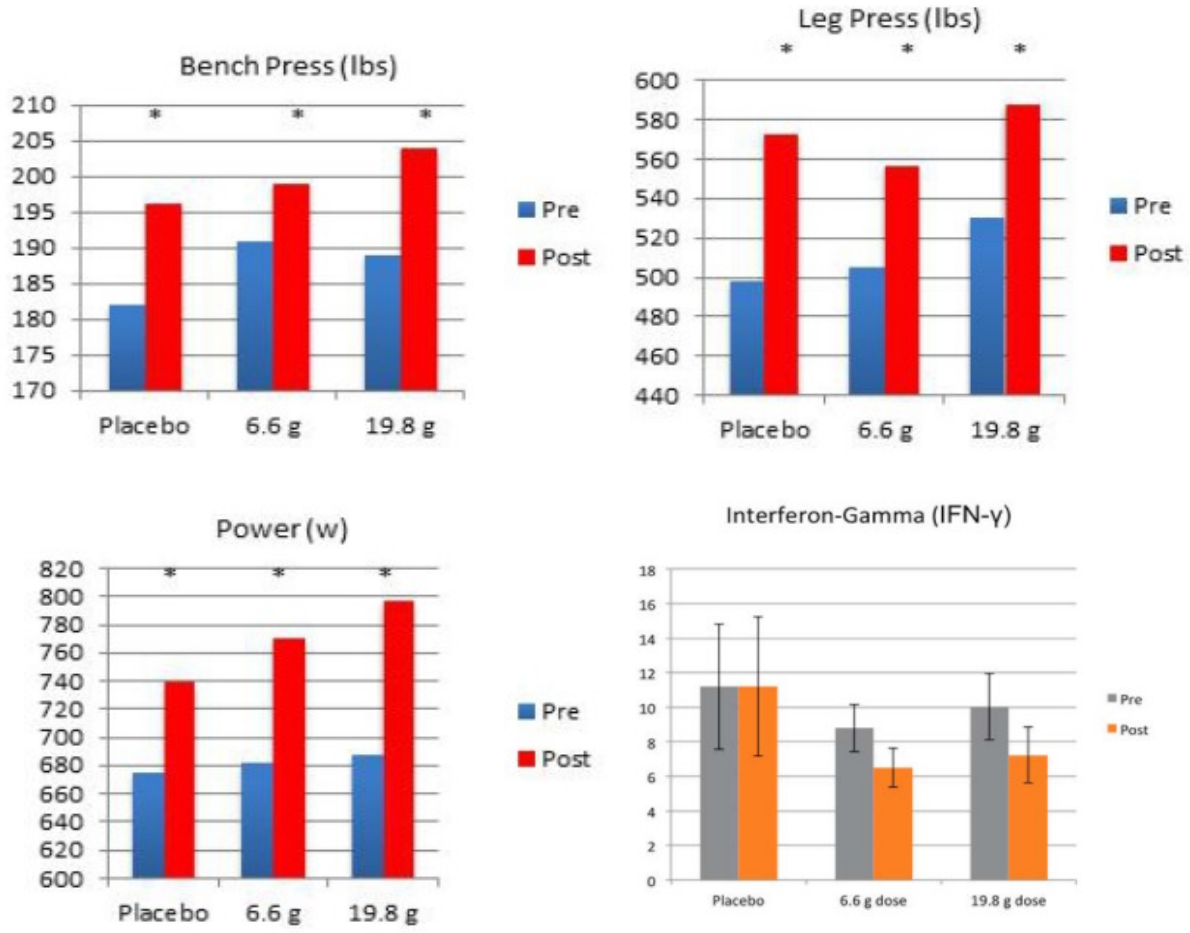
(Source: www.myosrens.com)

- ***Study 2***[7]: Another study was conducted in 2014 to investigate the effects of Fortetropin on skeletal muscle growth and strength in resistance-trained individuals. The study also aimed to investigate the anabolic and catabolic signaling effects of Fortetropin. 37 resistance-trained male subjects of similar age and physique/musculature (i.e. lean muscle mass, body mass, fat mass, muscle thickness) were randomly assigned to receive one of two Fortetropin doses, 6.6g or 19.8g (given as MYO-X), or placebo. All the men followed the same training schedule for 12 weeks. Participants completed a training protocol for muscle hypertrophy on one day and strength-training exercises on another day for two days of each week. Each group performed the same exercises. All subjects were instructed not to consume eggs for the duration of the study. Participants' strength was assessed using one repetition maximum (1RM) lift in leg and bench press exercises. Subjects completed two sets of warmup activities. Following warmup, subjects were instructed to attempt to repeat their 1RM load and allowed five attempts to do so. Anaerobic power was measured with the Monark Wingate cycle test.



(Source: www.myosrens.com)

[7] J Am Coll Nutr. 2016 Nov-Dec;35(8):679-91.



(Source: www.myosrens.com)

Results: The participants who received Fortetropin® had more lean body mass, lost more fat tissue and gained more muscle mass than those that received placebo. In addition, concentration of myostatin decreased in the blood of the participants who had used Fortetropin®. There were no significant differences observed in results of the 6.6g (1 scoop/day) group versus the 19.8g (3 scoops/day) group. Bench press, leg press and Wingate power were used to measure strength and power. The results were significantly increased from baseline in all study groups. No study related adverse events were reported.

The study also evaluated certain biomarkers including IFN-γ inflammatory cytokine, a pro-inflammatory protein that plays a critical role in inflammation and autoimmune diseases. Excess levels of inflammatory cytokines are associated with muscle-wasting diseases such as sarcopenia and cachexia. For subjects in the placebo group, no statistically significant changes in serum levels of IFN-γ were noted. However, subjects in both arms dosed with Fortetropin experienced statistically significant decreases ($p < 0.05$) in serum levels of the IFN-γ inflammatory cytokine.

Conclusion: This study demonstrated that Fortetropin has a positive role in training-induced skeletal muscle adaptation.

- ***Study 3:*** A dose response clinical study[8] was conducted by Jacob Wilson, Ph.D., Professor of Health Sciences and Human performance at the University of Tampa in May 2015. The study's aim was to examine the effects of Fortetropin (given as a supplement) at doses below 6.6g on serum myostatin levels. Researchers intended to determine the minimal effective dose in young adult males and females. In this double blind, placebo controlled clinical study, 80 male and female subjects ranging in ages between 18 and 22 were randomized into one of four dosing groups. Blood samples were collected on day 0 after a 10

[8] frailty-sarcopenia.com/docs/abstracts-2016.pdf

hour overnight fast to assess serum myostatin levels. Participants were categorized and randomly assigned into four groups such that there was no significant difference in serum myostatin concentration between groups. After assignment into the four groups, participants' blood samples were collected to establish baseline values. For one week, every day, three groups were supplemented with a separate dose of Fortetropin (2g, 4g or 6.6g) and the fourth group received a placebo. Blood samples were collected on day 7 after a 10-hour period following final supplementation as well as on day 8, 24 hours following the last supplementation. Results demonstrated that doses of 4g/day and 6.6g/day consumed for 1 week lead to a significant decrease in serum myostatin levels, while placebo and 2g/day did not. The daily use of 4g of Fortetropin, which is approximately 40% lower than the currently-recommended 6.6g dose, resulted in a statistically significant decrease in serum myostatin levels.

Association between Muscular Strength and Mortality

A clinical study[9] was conducted at the Karolinska Institutet's Department of Biosciences and Nutrition at NOVUM, Unit for Preventive Nutrition, in Huddinge, Sweden in 2008 to measure the association between muscular strength and mortality. In this study, 8,762 men aged 20-80 years were evaluated over an average period of 19 years. The data was normalized for age, physical activity, smoking, alcohol intake, body mass index, baseline medical conditions and family history of cardiovascular disease. The study found that there is an inverse relationship between muscular strength and death from all clinical causes and cancer that is independent from the cofounding factors. Other studies have demonstrated that muscular strength is inversely associated with all-cause mortality[10]. These data suggest that muscular strength adds to the protective effect of cardiorespiratory fitness.

[9] BMJ 2008; 337

[10] Eur J Intern Med. 2015 Jun;26(5):303-10

HISTORICAL STOCK PRICE



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