

Zacks Small-Cap Research

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Myos Rens Technology Inc. (MYOS-NASDAQ)

MYOS: Q3 Update: MYOS Canine Initial Sales and Add'l Distribution. Yolked Feedback Positive. Medical Nutrition Could Be Compelling Growth Opportunity

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 (12/04/18) **\$1.15**
Valuation **\$3.50**

OUTLOOK

Relative to the financials, while revenue remains insignificant and has trended somewhat more moderate than our estimates, we continue to like near- and long-term growth fundamentals. We see several catalysts that we expect to come online, or as it relates to certain ongoing efforts, building more substantive momentum that we think have the potential to steepen the revenue growth rate over the next two to three quarters. Near-term catalysts include expanded availability of both MYOS Canine, including through Miller Veterinary Supply East, Amazon.com (where it is designated an "Amazon's Choice product) and MYOS' own dedicated website, as well as Yolked, which is expected to soon be available to the general public (in addition to a growing list of universities). Recently secured CMS reimbursement for MYOS Enteral Nutrition Formula represents another potential immediate-to-near term revenue tailwind. Meanwhile, data from ongoing and expected future pre-clinical and clinical studies continues to be what we think could catalyze sales over the long-term. While anticipated read-out of certain of the ongoing studies has been pushed back a bit, with management now guiding for availability of three study data sets before mid-2019, the wait should not be much longer.

SUMMARY DATA

52-Week High **\$2.50**
52-Week Low **\$1.03**
One-Year Return (%) **-20.57**
Beta **1.15**
Average Daily Volume (sh) **28,273**

Shares Outstanding (mil) **7**
Market Capitalization (\$mil) **\$9**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **2**
Insider Ownership (%) **47**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **-41.8**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2018 Estimate **N/A**
P/E using 2019 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Avg.,**
Type of Stock **Small-Blend**
Industry **Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	\$0.15 A	\$0.06 A	\$0.16 A	\$0.16 A	\$0.53 A
2018	\$0.06 A	\$0.09 A	\$0.07 A	\$0.12 E	\$0.33 E
2019					\$1.12 E
2020					\$3.01 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	-\$0.13 A	-\$0.10 A	-\$0.06 A	-\$0.41 A	-\$0.69 A
2018	-\$0.17 A	-\$0.14 A	-\$0.12 A	-\$0.13 E	-\$0.57 E
2019					-\$0.52 E
2020					-\$0.50 E

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

WHAT'S NEW...

Q3 2018 Update: *MYOS Canine Initial Sales and Add'l Distribution. Yolked Feedback Positive. Medical Nutrition Could Be Compelling Growth Opportunity...*

MYOS reported Q3'18 financial results and provided a business update. Relative to the financials, while revenue remains insignificant and has trended somewhat more moderate than our estimates, we continue to like near- and long-term growth fundamentals. We see several catalysts that we expect to come online, or as it relates to certain ongoing efforts, building more substantive momentum that we think have the potential to steepen the revenue growth rate over the next two to three quarters.

Near-term catalysts include expanded availability of both MYOS Canine, including through [Miller Veterinary Supply East](#), [Amazon.com](#) (where it is designated an "Amazon's Choice product") and MYOS' own [dedicated website](#), as well as Yolked, which is expected to soon be available to the general public (in addition to a growing list of universities). Recently secured CMS reimbursement for MYOS Enteral Nutrition Formula represents another potential immediate-to-near term revenue tailwind.

Meanwhile, data from ongoing and expected future pre-clinical and clinical studies continues to be what we think could catalyze sales over the long-term. While anticipated read-out of certain of the ongoing studies has been pushed back a bit, with management now guiding for availability of three study data sets before mid-2019, the wait should not be much longer. Leading with an evidence-based approach is clearly a focus for the company and, assuming positive results, we would expect MYOS will leverage the data to further enhance their marketing message. This would also further delineate their products from the nutritional supplement space – a general category of which they may be (unfairly) characterized under today.

Product line expansion and diversification into other end-markets could provide even more opportunities for growth. While MYOS Canine Muscle Formula is their first foray into the pet health market, additional products could follow – the ongoing Kansas State study should be informative as to product development related decision-making in pet health. MYOS' Enteral Nutrition Formula is also a first-in-category product for the company – while this represents their initial entry into the medical nutrition space, it may not be their last. In fact, management noted on the Q3 call that they expect to explore additional opportunities in this market – which is one that we think could be particularly attractive given potential for insurance reimbursement.

Q3 revenue of \$66k was down 59% yoy and 25% lower than Q2 of this year. While nothing to get too excited about and nearly 50% less than our \$130k estimate, it did include somewhat of a milestone of sorts – that is, initial sales of MYOS Canine Muscle Formula, which generated \$8k in the quarter. This follows initial sales of MYOS' NSF-certified Yolked product, which made its initial revenue contribution (\$15k) in Q2 and generated another \$13k in Q3.

Meanwhile, revenue from Qurr, MYOS' consumer-focused Fortetropin-based products (puddings, powders and shakes) which launched in April 2017, was \$40k and \$153k in the three and nine months ending June 30, 2018. While Qurr continues to be the majority contributor to the company's top-line, accounting for more than 70% of total revenue through the first nine months of the year, its proportional contribution will likely moderate as MYOS' new products gain traction.

Yolked continues to be well-received with management again noting on the earnings call that the product is receiving positive feedback from both IMG and the universities themselves. As a reminder, Yolked was launched in April of this year and has been detailed to collegiate athletic programs through their strategic partnership with IMG College. 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 – while others started in the Fall. While MYOS has not reported on repeat-order flow, we may know more after these other schools have had a chance to provide feedback. Nonetheless, the anecdotal response has apparently been as-hoped. And a consumer-oriented launch could be imminent with management indicating that they expect to introduce Yolked to the general public before current year-end.

MYOS Canine Muscle Formula, their first Fortetropin-based supplement for dogs launched in June. 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 MYOS announced that Miller Veterinary Supply East, which (per their website) provides "licensed veterinarians the

equipment, instruments, pet food, pharmaceuticals and supplies needed to run their practices”, will carry MYOS Canine and afford it 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 potentially positive results of the ongoing KSU study (which is assessing the impact of Fortetropin on reducing muscle loss in dogs that have undergone surgery after ligament tear), the database of evidence could eventually prove compelling.

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. The product generated initial revenue of \$8k in Q3. Revenue could gain additional traction from the new distribution via Miller East, which came online in Q4, as well as from increased awareness as a result of exhibiting at Atlantic Coast Vet conference.

Management previously mentioned that they had begun to add some personnel as they refine and build out their commercialization strategy. Recent additions include a brand manager and three sales/marketing-focused hires. Importantly, management’s message as it relates to sales, messaging and product development is that they are firm believers in leading with an evidence-based approach - and that commitment is apparent given the number of studies that are ongoing and more that are expected to come online.

Product Development

Relative to their quest to build on the evidence of Fortetropin’s benefits in a variety of conditions (in both humans and pets), MYOS continues to make headway in their various ongoing studies. As a reminder, over the last ~two years MYOS contracted with four universities to conduct as many studies of Fortetropin in different indications. Three of the four research agreements were entered into since December 2017, including a randomized, controlled clinical study with University of Berkeley. While timelines of some of the programs have slipped a little from prior expectations, importantly all remain active and progressing.

- 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 next year.
- The most recent research collaboration came in May when MYOS contracted with Weill Cornell Medical College for a preclinical study that will evaluate Fortetropin in preventing weight and muscle loss associated with lung cancer. Current expectations are that the study will conclude and results will be announced in late Q2 2019.
- 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. Updated guidance was not offered on the Q3 call.
- In April 2017, MYOS initiated a study at Kansas State University, College of Veterinary Medicine, to assess the impact of Fortetropin on reducing muscle loss in dogs that have undergone surgery after ligament tear. Management noted on the Q2 call that enrollment had completed and mentioned on the Q3 call that initial data could be available late in Q1’19. Positive results should not only help to confirm the efficacy of Fortetropin on muscle health in dogs (and enhance myospet’s current marketing message), but also support additional testing in both animals (for pet-related commercial applications) and humans – including potentially a human study in subjects recovering from musculoskeletal surgeries.

Cash

MYOS continues successfully raise operating funds on favorable terms, including \$1.2M in Q2 from the sale of common stock (~\$180k via the ATM program and \$1M through the sale of 806k shares (@\$1.24/share) through a private placement in April – two MYOS Directors participated). Most recently, Joe Mannello (MYOS’ CEO) agreed

to lend up to \$1M in exchange for a 5%, one-year (matures 8/31/19) unsecured promissory note (\$750k funded as of Sept 26th, with the remaining \$250k expected to be drawn in November).

The fact that management continues to provide significant funding (including unsecured debt at a lending rate that is undoubtedly well-below relative risk fixed-income market rates), is certainly a vote of confidence of the growth opportunity for their products. MYOS exited Q3 with \$459k in cash.

Maintaining \$3.50/Share Price Target...

We have made adjustments to our model following Q3 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). MYOS Canine Muscle Formula provides an additional revenue source, which we think similarly will take some time to generate awareness around. The Enteral Nutrition Formula product is a potentially compelling entry into the medical nutrition market. With reimbursement in place we will be particularly interested to see how this product performs – as 'success' could be a harbinger for a greater development focus on this space.

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 \$1.15/share.

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 ubiquitin 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. Myostatin 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*¹ 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.



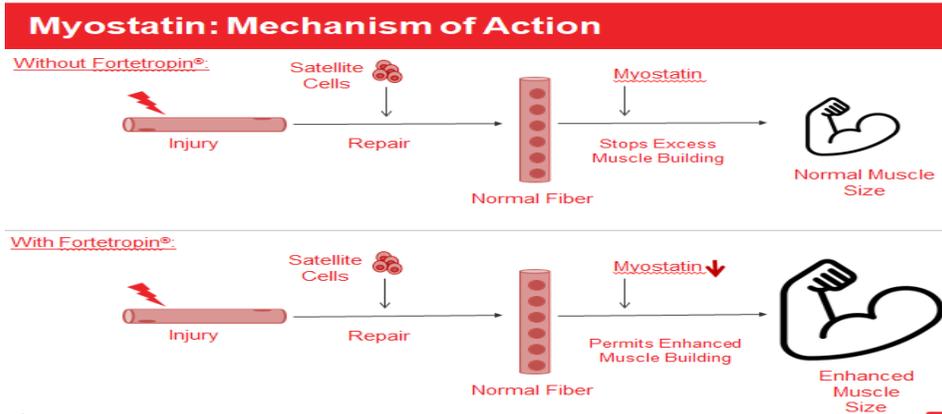
Upper limb muscle mass in myostatin wild-type (left) and myostatin knock-out (right).
Source: McPherron et al., 1997

(Source: www.myosrens.com)

The science behind Fortetropin...

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.

¹ Nature volume 387, pages 83–90 (01 May 1997)



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

A preclinical study² 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.

MYOS' product Fortetropin

In March 2017, the firm commenced sales of Fortetropin®-based products under the brand name Qurr (pronounced, "kyoor") through their online website (www.qurr.com). Qurr products are available in two flavors (chocolate raspberry and vanilla coconut) and in the form of powders, puddings and shakes. Qurr products are positioned for three distinct consumer group demographics in an effort to capture a broader audience:

- "Qurr Well" supports healthy aging by increasing lean muscle
- "Qurr Toned" for promoting healthy muscle which can lead to a lean and toned body
- "Qurr Strong" for athletes hoping to reach their most ambitious training goals



(Source: www.qurr.com)

The site serves a dual purpose: as an educational portal as well as an e-commerce site for both individual product purchases and subscription orders. Qurr products are sold directly to consumers from this site as well as via

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.

Amazon. Qurr products are advertised as low calorie, naturally soy-free and non-GMO, with a recommended daily dose of 6.6g of Fortetropin. As discussed in clinical studies section, a daily dosage of 6.6g of Fortetropin is sufficient for making significant changes to muscle mass and strength. Pricing starts at \$130 per package (four weeks supply containing 28 individual packets) with additional savings for monthly subscriptions or larger quantities. Each packet has 10.4g of supplement powder that contains about 50 total calories and less than 4g of carbohydrates.

Management provided us with samples of the supplement powder. As a part of our research process, we analyzed a few physical characteristics. The texture of the powder is similar to that of breadcrumbs. Because it has a coarsely ground texture, it offers a nice crunchy taste when put directly in the mouth. There is no artificial color added. The sample powder definitely has the aroma of the flavor indicated on the label (vanilla coconut). The powder offers a convenient alternative of eating as is or blending with foods. The powder blends well with water, yoghurt as well as milk. The stevia and monk fruit extract give it a subtle sweet taste. The coconut milk adds a smooth flavor and the taste is not overpowering. Despite being a sweetening agent, the monk fruit sweetener contributes zero calories. There was no gastrointestinal side effect such as stomach discomfort after consumption.

MYOS announced on April 10, 2018 that it has expanded its product line with the addition of Yolked™. This product, also based on Fortetropin®, is marketed specifically to competitive athletes. Yolked™ received the Certified for Sport® certification from NSF International. A consumer-oriented branded product is expected to also come to market – with launch potentially imminent.

NSF International is an independent organization that provides third-party certification of manufacturing systems and processes as well as for food, water and other products. NSF certification is widely accepted across the globe that the product and processes have met the requisite quality and safety standards. NSF’s “Certified for Sport” designation, for dietary and sports supplements, verifies that:

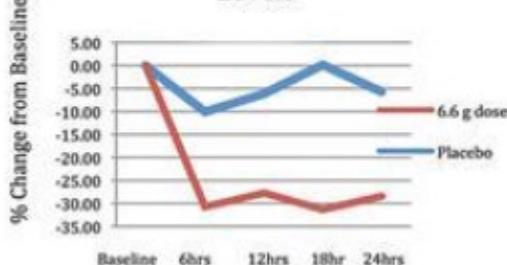
- The ingredients are free of banned substances (270+) as listed by major athletic organizations
- The contents of the product match with what is printed on the label
- There are no harmful levels of contaminants in the products
- The product is manufactured at a GMP facility inspected twice annually for quality and safety

NSF International’s Certified for Sport® program helps athletes make informed decisions when choosing sports supplements. MYOS hopes that Yolked™ will have a major presence in training facilities of collegiate and professional sports teams. Having all of the company’s products as NSF or BSCG certified prevents consumers and athletes from inadvertent doping.

Clinical Studies

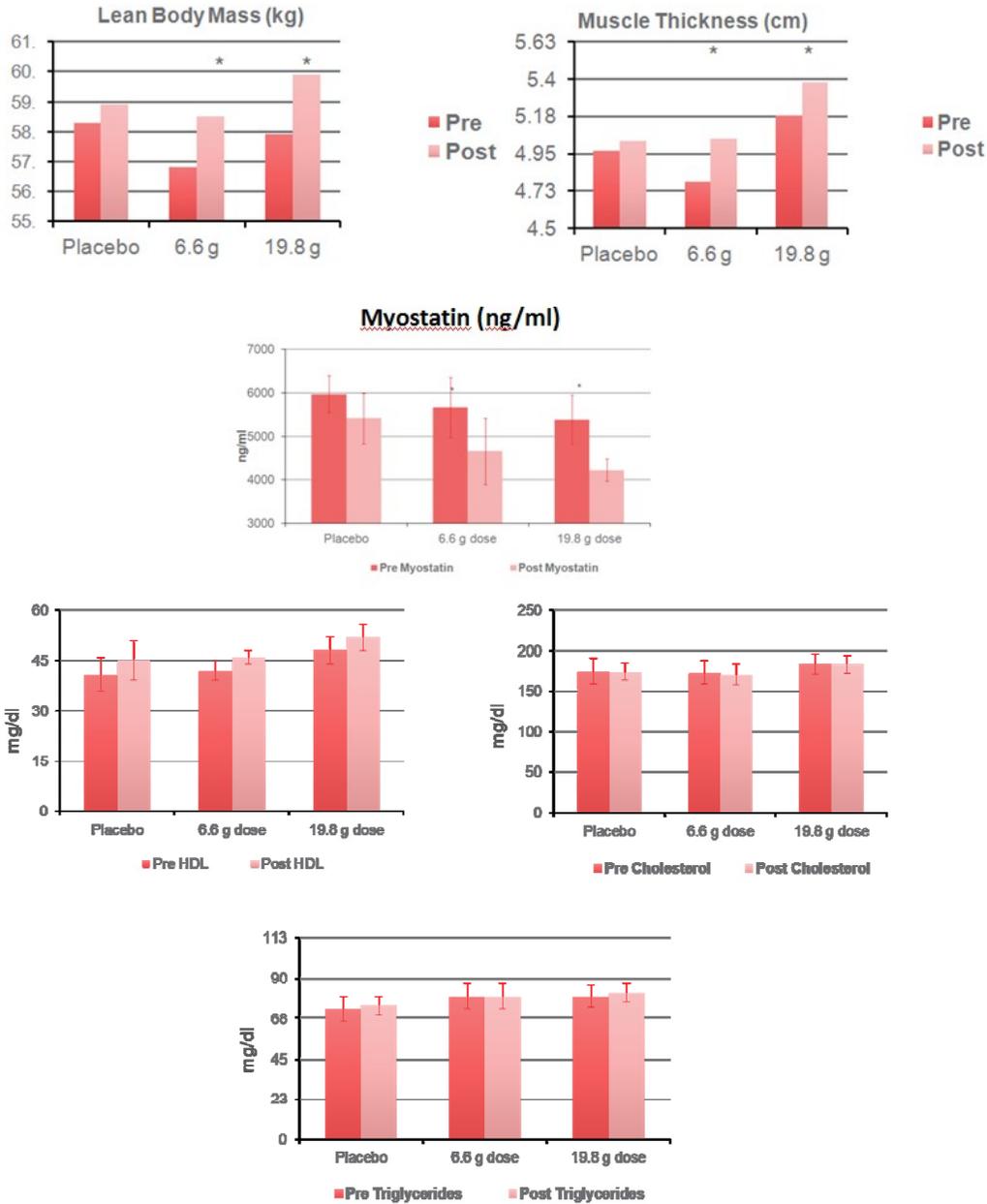
- **Study 1:** In March 2013, a double blind, randomized, placebo controlled, parallel, single dose study was conducted involving 24 healthy adult male subjects. Test subjects in the active arm (12 subjects) were administered 6.6g of Fortetropin mixed with vanilla fat-free/sugar-free pudding. An equal 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.

Fortetropin Effects on Serum Myostatin Levels



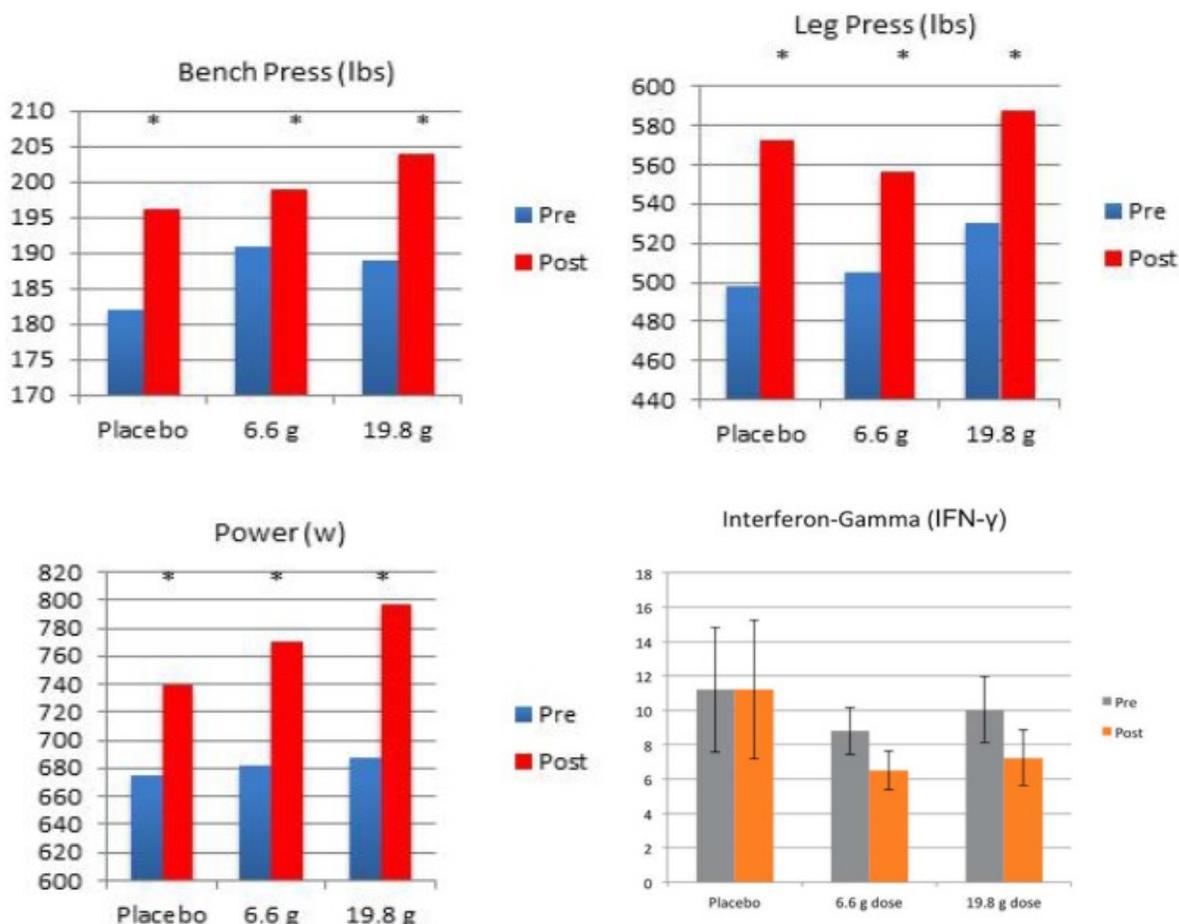
(Source: www.myosrens.com)

➤ **Study 2³**: 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)

³J 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 study⁴ 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

⁴frailty-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

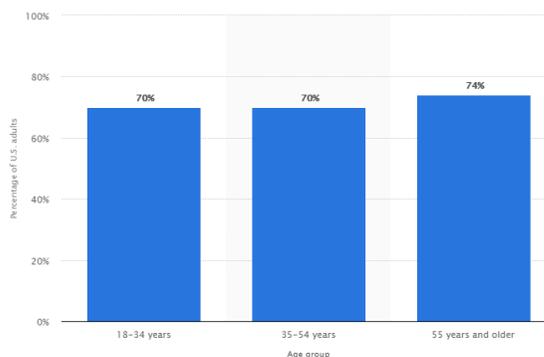
A clinical study⁵ was conducted at the Karolinska Institutet's Department of Biosciences and Nutrition at NOVUM, Unit for Preventive Nutrition, in Huddinge, Sweden in 2008 to measure the association between muscular strength and mortality. In this study, 8,762 men aged 20-80 years were evaluated over 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 confounding factors. Other studies have demonstrated that muscular strength is inversely associated with all-cause mortality⁶. These data suggest that muscular strength adds to the protective effect of cardiorespiratory fitness.

MARKET OPPORTUNITY

In the last decade, sales of vitamins and nutritional supplements have surged. While there are a plethora of products promising muscle building, weight-loss and improved overall health, most supplements lack scientific evidence backing many of these claims. Discerning consumers seek scientific evidence that supports the statements made by the manufacturer when purchasing supplements⁷. MYOS' product proposes to fill this gap. Also, in many disease conditions, which leave the patient temporarily non-ambulatory, muscle-building supplements can play an important role in recovery. Nutritional supplements are gaining traction in the pet nutrition sector as well. It is in these spaces that MYOS intends to gain market share. MYOS' current market focus is in the sports and nutrition sector.

➤ **Sports and Fitness nutrition market**

According to Euro Monitor, the sports nutrition market in the U.S. recorded sales of roughly \$6.5 billion in 2016. Athletes often take nutritional supplements as a way to gain a competitive edge. The most popular supplement within the sports nutritional market is protein powder. Protein also dominates the muscle recovery category. Roughly \$4.5B worth of protein powder is sold in the U.S. every year. Growth in the industry is being catalyzed by greater awareness and interest in the benefits of exercise, nutrition and healthier diets. The remainder of the \$6.5 billion sports nutritional market is comprised of specialty products (such as testosterone boosters, omega-3 fatty acids, etc.), plant-based supplements, herbal and medicinal products, vitamins and mineral supplements.



(Source: Statista.com - Usage of dietary supplements among U.S. adults in 2016)

⁵ BMJ 2008; 337

⁶ Eur J Intern Med. 2015 Jun;26(5):303-10

⁷ Nielsen Global Health and Wellness Report - January 2015

In general, the sports and fitness nutrition market is becoming more fragmented. The retail landscape is evolving with an expanding consumer base. MYOS is not just focused on the core demographic comprised of professional athletes and bodybuilders but also on the larger subset of the health-oriented population that engages in recreational outdoor/physical activities. People over the age of 50 years are subject to age-related loss of muscle strength and function. This segment of the population is willing to spend more on supplements than the average recreationally-active individual to maintain their muscle strength and functionality. The above factors have contributed towards the upswing in the popularity of specialized supplement products.

Consumers are also looking for supplements that are specifically formulated for the different types of physical activity⁸. Further, some consumers want products made with natural ingredients. As consumers emphasize the importance of clarity on labels, manufacturers attempt to be transparent on the ingredients and nutritional benefits of their products. A survey conducted by Ingredient Communications found that more than 70% of consumers are willing to pay a premium for products that are manufactured using ingredients they recognize. Drug-free certification from third-party organizations has become a de facto standard for popular brands selling nutritional supplements. MYOS' product is not a stimulant and contains non-GMO ingredients, is certified Drug Free by BSCG and has clinically proven to generate tangible outcomes in muscle health and function.

➤ **Domestic pet nutrition market (future potential market)**

Largely age-related diseases leading to joint deterioration drive the demand in the pet nutraceutical market. There are about sixty million dog owners in the U.S. Similar to humans, canines undergoing immobilization after surgery to the limb require post-operative care that can include changes to their diet. The Journal of the American Veterinary Medical Association estimated that just over 1 million surgeries involving the knee are performed annually. The average owner spends about \$500 annually in veterinarian visits involving surgery. On average, the post-surgical recovery and rehabilitation period lasts 10-12 weeks. Post-surgical rehabilitation is becoming a commonplace theme in veterinary practice since it decreases recovery time, reduces morbidity, mortality and the risk of wound breakdown. As per the report, *Pet Supplements in the U.S.*, published by Packaged Facts, the pet supplements market witnessed sales of nearly \$600 million in 2016. According to a survey conducted by Packaged Facts, the most frequently purchased supplements include those for joint and digestive health.

MYOS Canine Muscle Formula, their first Fortetropin-based supplement for dogs launched in June. 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 2018. In terms of distribution-reach, upon launch the product had its own website and became available on Amazon.com. Then, in November MYOS announced that Miller Veterinary Supply East, which (per their website) provides "licensed veterinarians the equipment, instruments, pet food, pharmaceuticals and supplies needed to run their practices", will carry MYOS Canine and afford it with 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 potentially positive results of the ongoing KSU study (which is assessing the impact of Fortetropin on reducing muscle loss in dogs that have undergone surgery after ligament tear), the database of evidence could eventually prove compelling.

In a canine, the cranial cruciate ligament (CCL) connects the thigh bone (femur) and the shin bone (tibia). The CCL stabilizes the knee joint in the hind leg. The CCL in dogs is comparable to the anterior cruciate ligament (ACL) in people. CCL rupture is usually caused by a sudden injury or due to factors such as genetics, disease, obesity, poor physical condition or age related changes that weaken the ligament. Surgery has been the best option for the treatment of ruptured CCL. Studies have shown that a mutation to the myostatin gene in whippets, a dog breed for racing, causes an increase in skeletal muscle mass and function⁹. In April 2017, MYOS initiated a study at Kansas State University, College of Veterinary Medicine, to assess the impact of Fortetropin on reducing muscle loss in dogs (n=100) that have undergone surgery after ligament tear. Management noted on the Q2 '18 call in August that enrollment has completed and mentioned on the Q3 call (November) that results could be available in late Q1'19. Positive results should not only help to confirm the efficacy of Fortetropin on muscle health in dogs (and enhance myospet's current marketing message), but also

⁸ <https://ods.od.nih.gov/factsheets/ExerciseAndAthleticPerformance-HealthProfessional/>

⁹ PLoS Genet 3(5): e79.

support additional testing in both animals (for pet-related commercial applications) and humans – including potentially a human study in subjects recovering from musculoskeletal surgeries.

➤ **Clinical nutrition market (future potential market)**

MYOS offers a differentiated product in the emerging niche market targeting age management. According to the U.S. Census Bureau, as of July 1, 2015, 15% of the U.S. population (roughly 50 million) was 65 years of age or older. By 2030, it is expected that one in five people will be 65 years of age or older. Further, the fastest growing segment of the geriatric population is the 85 years of age or older group. A significant portion of the senior population is affluent and educated and often rely on the internet for self-diagnosis before having a dialogue with their physicians. Consequently, product manufacturers are leveraging their websites to bolster their marketing efforts and help educate potential consumers. The Qurr website educates the consumer on Fortetropin and the scientific evidence supporting its health benefits.

Indications:

Decreased or impaired skeletal muscle performance is a common symptom of many age-related diseases and conditions. This can be due to cachexia (i.e. muscle loss and weakness due to chronic diseases) as well as certain orthopedic, neuromuscular and degenerative diseases which can significantly reduce mobility. Additionally, poor mobility is associated with increased hospitalization rates, healthcare costs, and mortality. Therefore, protecting muscle mass and maintaining strength are important to long-term health and survival.

Myostatin upregulation was found to be associated with the pathogenesis of cancer, heart failure and aging¹⁰. Studies have shown that myostatin levels are increased in sarcopenia, cachexia and obesity. The levels decrease with reduced food intake and resistance training. Myostatin is being widely investigated in the regulation of muscle mass.

Sarcopenia

Sarcopenia is a geriatric condition characterized by degenerative loss of skeletal muscle mass and functionality. Aging decreases the size and number of skeletal muscle fibers. Additionally, the ability of skeletal muscle to regenerate itself diminishes with aging and is attributed to a decline in satellite cells' activity.

Muscle weakness in the elderly can occur due to age-related neurological and/or hormonal changes, pro-inflammatory cytokines and fat deposits¹¹. Genetic factors, dietary patterns and the presence of other comorbidities also contribute to the development of sarcopenia. Clinical data supports the premise that an increase in myostatin due to obesity compromises skeletal muscle health and systemic metabolism in a high proportion of older people. Strength decreases with muscle mass which can result in the development of functional limitations. Inhibiting myostatin could prove effective in improving muscular function and strength.

The aging population is comprised of relatively healthy individuals, sufferers of sarcopenia and others who are hospitalized/undergoing post-operative care. Currently, sarcopenia is prevalent in 5%–13% of people over 60 years of age and 50% of those over the age of 80. Currently, there are no FDA-approved medications for the treatment of sarcopenia. The mainstays of treatment are physical activity, resistance exercise training, dietary changes and/or vitamin D supplements. Sarcopenia is recognized by WHO and has an ICD-10 Code (as of October 2016).

The role of Myostatin in Sarcopenia

Myostatin is known to regulate muscle morphology. Whether the activity of myostatin is affected by aging or if it plays a functional role remains to be investigated. Nonetheless, the inhibition of myostatin in adult and older animals significantly increases muscle mass. Clinical studies have demonstrated the following:

1. Myostatin acts as a negative regulator of skeletal muscle growth in postnatal mice. This study suggests therapeutic benefit in diseases associated with muscle wasting¹².
2. Another clinical study examined the systemic and cardiac effects of myostatin deletion in biologically aged mice. Results demonstrated that myostatin deletion does not affect cardiac effects in these mice. In fact, it appeared favorable for bone density, insulin sensitivity and heart function in biologically aged mice¹³.
3. Myostatin, a myokine, acts as a molecular mediator of contracting skeletal muscle fibers after exercise¹⁴.

¹⁰ Journal of Cachexia, Sarcopenia and Muscle (2011), 2(3): 143-151.

¹¹ A Biol Sci Med Sci 2006;61:1059–1064.

¹² Biochem Biophys Res Commun 2003;300:965-971.

¹³ Aging Cell 2009;8:573-583.

4. Further studies have shown that genetic deletion of myostatin results in an increase in skeletal muscle mass and function¹⁵.

All of the above findings support the idea that myostatin could be a potential therapeutic target for sarcopenia. AMAZ-02 (Amazentis SA) is designed as a nutritional supplement to improve muscle function. A randomized, double-blind, single-center, placebo-controlled Phase 2 trial is currently underway. The study aims to investigate the effect of AMAZ-02 on muscle function improvement in the skeletal muscles of elderly patients.

A study¹⁶ published in the *Journal of Sarcopenia, Cachexia and Muscle* in 2016 demonstrated that 12 weeks of supplementing elderly subjects (32 participants between the age of 60-80 years) with a low-dose of creatine combined with resistance training resulted in an increase in lean muscle mass. Despite this increase, it did not translate to a corresponding increase in muscle strength. The clinical study involving resistance trained participants dosed with Fortetropin showed that they gained more lean body mass, lost more fat tissue and increased muscle thickness than those that received placebo. Results from the Fortetropin study also demonstrated statistically significant decreases in serum levels of the IFN- γ inflammatory cytokine, which could help maintain muscle strength and functionality.

Further studies are required to establish the amount of nutritional support needed to restore muscle strength and functionality. In December 2017, the firm announced an agreement with the University of California, Berkeley's Department of Nutritional Sciences & Toxicology to conduct a clinical study. The study 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.

Cachexia

Cachexia is a condition that occurs during the final stages of diseases such as cancer and heart/kidney failure. Muscle wasting in cachexia is the primary cause of death in more than 20% of cancer patients¹⁷. The molecular mechanisms causing cancer cachexia have not been fully understood. Evidence suggests that cachexia could be caused either by increased degradation of muscle protein and/or impaired muscle protein synthesis combined with defective myogenesis or mitochondrial dysfunction. Cancer cachexia is a complex, multifactorial syndrome that is generally characterized by progressive loss of skeletal muscle mass with/without loss of fat mass. It also results in increased protein catabolism and functional impairment. Additionally, it is accompanied by anorexia, weakness, and fatigue. Patients with cancer cachexia have poor tolerance to antitumor treatments and experience reduced quality of life (QOL). The condition has a negative impact on survival¹⁸. Cachexia is estimated to affect 50-80% of cancer patients. Unfortunately, there is no standard treatment for cancer cachexia. Nutritional supplements which modulate inflammation and immune system could counteract molecular mechanisms involved in the disease's pathogenesis¹⁹.

The role of Myostatin in Cachexia

Activin A and myostatin belong to TGF- β family. Activin A binds to ActRIIB, a receptor shared with myostatin. Although myostatin binds to both receptors ActRIIA/B, it has a higher affinity for ActRIIB. In experimental models, ActRIIB decoy receptors have been shown to impede muscle wasting, improve muscle strength and prolong survival without stimulating tumor growth²⁰. Zhou et al. demonstrated in 2010²¹ that treating tumor-bearing mice with an antagonist of ActRIIB and myostatin reverses cancer cachexia. It also dramatically extended survival despite high circulating levels of pro-inflammatory cytokines. This sparked interest for investigators to develop agents targeting the ActRIIB receptor in the field of cancer cachexia. Activin A is overexpressed in a variety of cancers. STM 434 (Santa Maria Biotherapeutics) is being investigated in a Phase 1, open-label study in patients with ovarian cancer and other advanced solid tumors. STM 434 prevents the ActRIIB-mediated signaling and inhibits tumor growth.

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.

¹⁴ Bone. 2015 Nov; 80: 115–125.

¹⁵ PLoS Genet 3(5): e79.

¹⁶ J Cachexia, Sarcopenia and Muscle (2016); 7:413–21

¹⁷ Nat Rev Cancer 14(11): 754-762.

¹⁸ Nutr Clin Pract. 2017 Oct;32(5):599-606

¹⁹ Ther Adv Med Oncol. 2017 May; 9(5): 369–382.

²⁰ Cell (2010), 142: 531–543; Biochem Biophys Res Commun (2010), 391: 1548–1554.

²¹ Cell (2010), 142 (4) : 531–543.

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.

Muscle Dystrophy and Rehabilitation

Muscle atrophy can occur from immobilization, such as following knee surgery, and also as a result of certain diseases that progressively weaken the muscle cells eventually resulting in loss of function as in muscular dystrophy. As per the CDC, there are several different types of muscular dystrophies based on the underlying cellular and molecular mechanisms. Duchene Muscular Dystrophy (DMD), Becker muscular dystrophy, and facioscaplohumeral muscular dystrophy are caused by mutations that affect distinct genes. DMD is a genetic disorder caused by a gene mutation on the X chromosome, thus, affecting more boys than girls. Muscular dystrophies cause degeneration of muscle, impaired mobility and premature death. About 250,000 Americans are estimated to be affected by muscular dystrophy.

The role of Myostatin in Muscular Dystrophy

Multiple molecular mechanisms are responsible for causing muscle wasting in sarcopenia, cachexia and muscular dystrophy. These diseases have overlapping signaling pathways in which myostatin plays a central role. The first human trial involving myostatin inhibitors was conducted in 2004 using MYO-029, a recombinant human antibody. Since then, several myostatin inhibitors such as myostatin antibodies, anti-myostatin peptibodies, activin A antibodies, decoy forms of ActRIIB and ActRIIB antibodies have been in development.

Landogrozumab (LY2495655) is a humanized monoclonal antibody undergoing clinical evaluation by Eli Lilly & Co. for cancer cachexia (completed January 2016) and sarcopenia (completed December 2013). BMS-986089 is a novel fusion protein designed by BMS and licensed by Roche. It is currently being investigated as a treatment option for patients with DMD. PF-06252616 by Pfizer is under development in a Phase 2 trial in ambulatory boys diagnosed with DMD. It has been granted orphan drug and fast track designation in the U.S. and EU.

VALUATION

Maintaining \$3.50/Share Price Target...

We have made adjustments to our model following Q3 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 Fortropin on muscle health (in both humans and pets). MYOS Canine Muscle Formula provides an additional revenue source, which we think similarly will take some time to generate awareness around. The Enteral Nutrition Formula product is a potentially compelling entry into the medical nutrition market. With reimbursement in place we will be particularly interested to see how this product performs – as 'success' could be a harbinger for a greater development focus on this space.

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 \$1.15/share.

PROJECTED INCOME STATEMENT

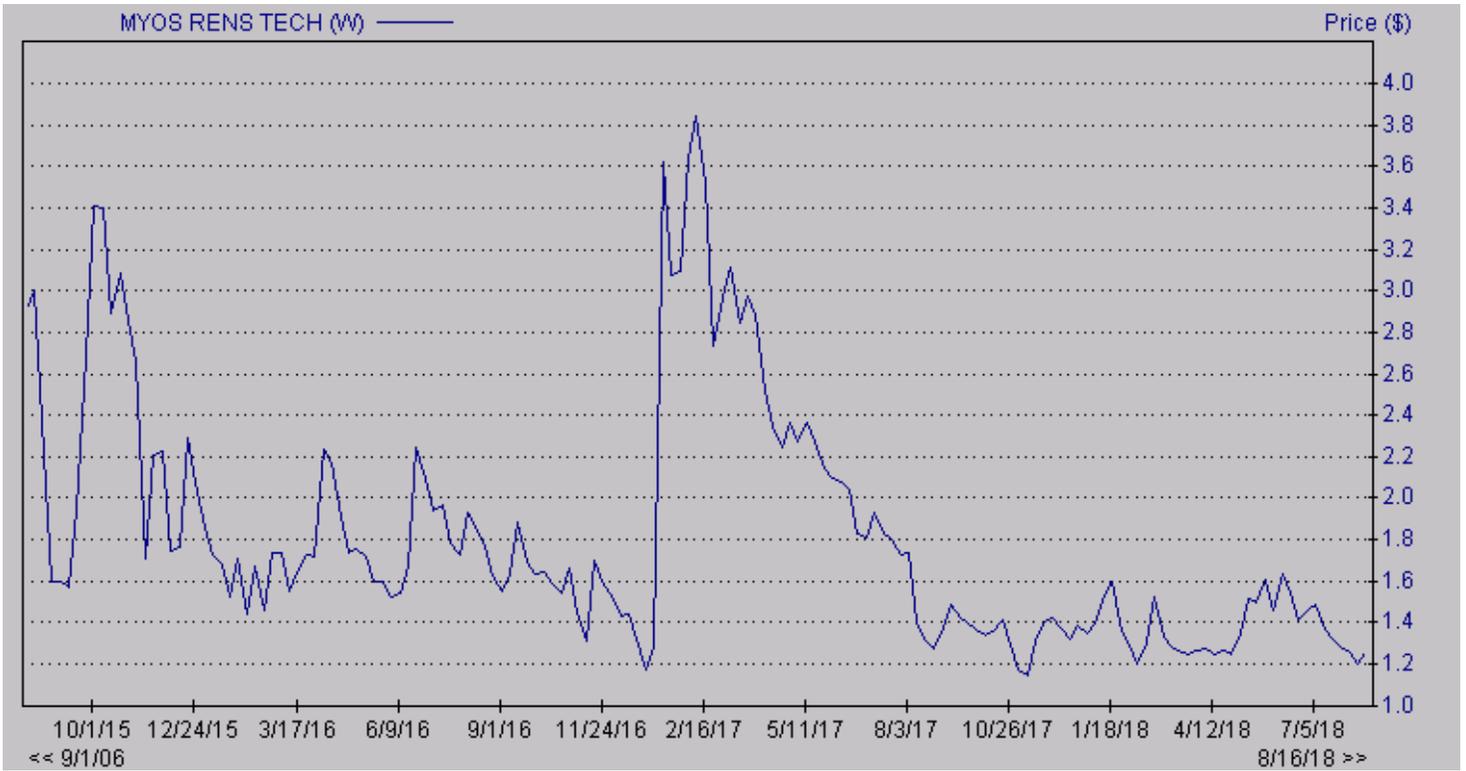
MYOS RENS TECHNOLOGY

MYOS RENS TECHNOLOGY	2017A	Q1A	Q2A	Q3A	Q4E	2018E	2019E	2020E	2021E
Total Revenue	\$0.53	\$0.06	\$0.09	\$0.07	\$0.12	\$0.33	\$1.12	\$3.01	\$4.78
Y-o-Y Growth	61%	-62%	49%	-59%	-24%	-37%	237%	170%	59%
Total cost of revenue	\$0.31	\$0.03	\$0.06	\$0.06	\$0.07	\$0.22	\$0.48	\$1.02	\$1.34
Gross Income	\$0.22	\$0.03	\$0.03	\$0.01	\$0.05	\$0.11	\$0.64	\$1.99	\$3.44
Gross Margin	41%	46%	30%	11%	43%	33%	57%	66%	72%
Selling, Mrktg, Research	\$0.82	\$0.39	\$0.24	\$0.13	\$0.26	\$1.02	\$1.36	\$2.17	\$2.73
% S.M&R	156%	691%	267%	194%	217%	307%	122%	72%	57%
Total G&A	\$2.01	\$0.84	\$0.83	\$0.79	\$0.82	\$3.28	\$3.99	\$4.87	\$4.07
%G&A	383%	1481%	938%	1194%	683%	990%	358%	162%	85%
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	\$1.24	\$1.06	\$0.92	\$1.08	\$4.29	\$5.35	\$7.04	\$6.79
Operating Income	(\$4.07)	(\$1.21)	(\$1.03)	(\$0.91)	(\$1.03)	(\$4.18)	(\$4.72)	(\$5.05)	(\$3.35)
Operating Margin	-	-	-	-	-	-	-	-	-
Interest income	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Interest expense	\$0.00	(\$0.00)	\$0.00	\$0.00	\$0.03	\$0.00	\$0.06	\$0.07	\$0.07
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)	(\$1.21)	(\$1.03)	(\$0.91)	(\$1.00)	(\$4.18)	(\$4.66)	(\$4.98)	(\$3.28)
Income tax	\$0.00	\$0.00	\$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)	(\$1.21)	(\$1.03)	(\$0.91)	(\$1.00)	(\$4.18)	(\$4.66)	(\$4.98)	(\$3.28)
Net Margin	-	-	-	-	-	-	-	-	-
EPS	(\$0.69)	(\$0.17)	(\$0.14)	(\$0.12)	(\$0.13)	(\$0.57)	(\$0.52)	(\$0.50)	(\$0.30)

Y-o-Y Growth	-	-16%	-25%	-6%	-28%	-18%	-	-	-
Shares O/S	5.9	7.2	7.2	7.5	7.5	7.4	9.0	9.9	11.1

Brian Marckx, CFA / Anita Dushyanth, PhD

HISTORICAL STOCK PRICE



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