

# Zacks Small-Cap Research

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## Myos Rens Tech

(MYOS-NASDAQ)

### MYOS: Several Near-Term Milestones

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 (05/15/18) **\$1.56**  
Valuation **\$3.50**

### OUTLOOK

MYOS reported Q1 '18 financial results and provided a business update. Relative to the financials, revenue was just \$57k, all of which relates to sales of their Qurr product, which launched in April 2017. While revenue remains muted, that was not unexpected as much of MYOS' activities continue to be focused on further expanding the evidence surrounding Fortetropin and its beneficial effects in improving muscle health. This evidence-based approach has the potential to pay dividends in the form of more efficient (and successful) commercialization.

In the meantime, MYOS will look to opportunistically leverage the NSF Certified for Sport designation with their new Yolked product. The certification, which MYOS announced in April, is considered the gold standard for ensuring high quality and verification that the product is free of banned substances – which can be particularly important for competitive athletes that are subject to drug testing (such as college and professional athletes). In late-2017, MYOS entered into a strategic partnership with IMG College to market their products to collegiate athletic programs. Initially, the IMG agreement covers nine Division I colleges (in the NE). Management noted on the Q1 call that they have begun meeting with several of these schools and that initial feedback has been positive.

### SUMMARY DATA

52-Week High **\$2.39**  
52-Week Low **\$1.15**  
One-Year Return (%) **-33.76**  
Beta **1.46**  
Average Daily Volume (sh) **82,696**

Shares Outstanding (mil) **7**  
Market Capitalization (\$mil) **\$11**  
Short Interest Ratio (days) **N/A**  
Institutional Ownership (%) **2**  
Insider Ownership (%) **46**

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

5-Yr. Historical Growth Rates  
Sales (%) **-44.6**  
Earnings Per Share (%) **N/A**  
Dividend (%) **N/A**

P/E using TTM EPS **N/A**  
P/E using 2018 Estimate **-4.0**  
P/E using 2019 Estimate **-3.3**

Zacks Rank **N/A**

### Risk Level

Type of Stock  
Industry

Above Avg.,  
Small-Blend  
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 | \$0.20 E | \$0.25 E | \$0.30 E | \$0.81 E |
| 2019 |          |          |          |          | \$3.04 E |
| 2020 |          |          |          |          | \$4.84 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 | -\$0.08 E | -\$0.09 E | -\$0.07 E | -\$0.35 E |
| 2019 |           |           |           |           | -\$0.39 E |
| 2020 |           |           |           |           | -\$0.41 E |

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

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### **Q1 2018 Update:**

MYOS reported Q1 '18 financial results and provided a business update. Relative to the financials, revenue was just \$57k, all of which relates to sales of their Qurr product, which launched in April 2017. While revenue remains muted, that was not unexpected as much of MYOS' activities continue to be focused on further expanding the evidence surrounding Fortetropin and its beneficial effects in improving muscle health. This evidence-based approach has the potential to pay dividends in the form of more efficient (and successful) commercialization.

In the meantime, MYOS will look to opportunistically leverage the NSF Certified for Sport designation with their new Yolked product. The certification, which MYOS announced in April, is considered the gold standard for ensuring high quality and verification that the product is free of banned substances – which can be particularly important for competitive athletes that are subject to drug testing (such as college and professional athletes). In late-2017, MYOS entered into a strategic partnership with IMG College to market their products to collegiate athletic programs. Initially, the IMG agreement covers nine Division I colleges (in the NE). Management noted on the Q1 call that they have begun meeting with several of these schools and that initial feedback has been positive.

Other initiatives related to MYOS' commercialization efforts include working on a more targeted sales approach as well as the impending launch of a new website which management noted has been designed to better communicate the science-based benefits of Fortetropin. This fits with MYOS' strategy of leading their sales efforts with an evidence-based approach – which we think is critical in order to separate their products from the plethora of protein powders and other supplements that largely lack the efficacy-related evidence that Fortetropin does.

### **Product Development...**

MYOS continues to make progress on the research front as well and currently has four studies ongoing, several of which could have results in the near-term. As a reminder, in just the last 13 months 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, including a randomized, controlled clinical study with University of Berkeley.

- 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. If all goes well, results of the study could be available later this 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. MYOS anticipates the study to start sometime this summer and have results early next year.
- 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 will be 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.
- 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. To-date, 90 dogs have been enrolled in the study and the goal is to test Fortetropin on 100 dogs by mid-2018. If the results are positive, the firm would likely continue developing Fortetropin-based products for pet nutrition as well as humans recovering from musculoskeletal surgeries.

### **Cash**

MYOS continues successfully raise operating funds on favorable terms. MYOS exited Q1 with \$230 in cash and subsequently raised another \$1.2M. This includes ~\$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.

### **Maintaining \$3.50/Share Price Target...**

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 \$1.56/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- $\beta$ ) 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*<sup>1</sup> about their discovery of a novel member of the TGF- $\beta$  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.



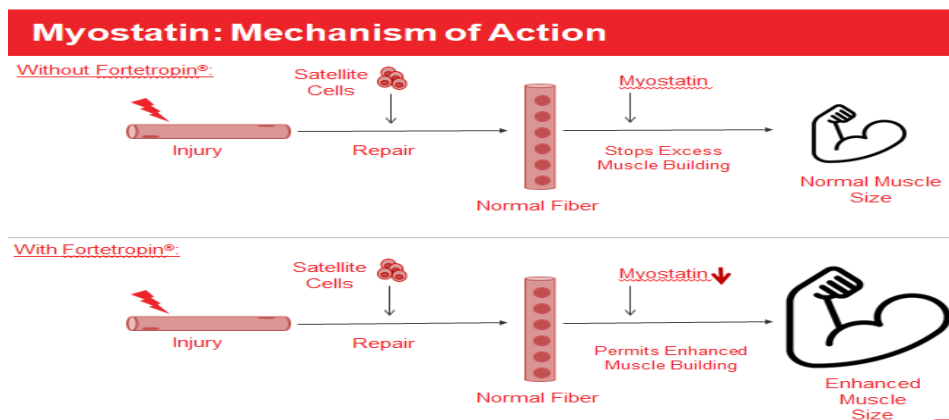
Upper limb muscle mass in myostatin wild-type (left) and myostatin knock-out (right).  
Source: McPherron et al., 1997

(Source: [www.myosrens.com](http://www.myosrens.com))

<sup>1</sup> Nature volume 387, pages 83–90 (01 May 1997)

## 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.



Fortetropin®: Mechanism of Action (Source: [www.myosrens.com](http://www.myosrens.com))

A preclinical study<sup>2</sup> 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](http://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

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.qurr.com](http://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 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 expected to be marketed specifically to competitive athletes. Yolked™ received the Certified for Sport® certification from NSF International.

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:

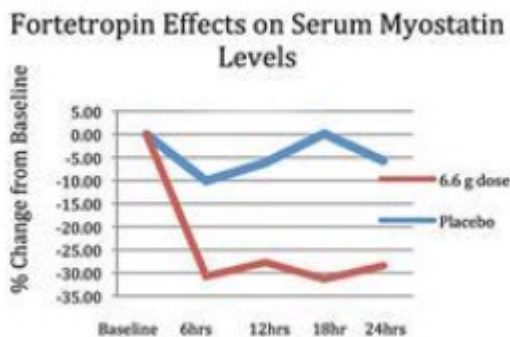
- The ingredients are free of banned substances (270+) as listed by major athletic organizations
- The contents of the product match with what is printed on the label
- There are no harmful levels of contaminants in the products
- The product is manufactured at a GMP facility inspected twice annually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

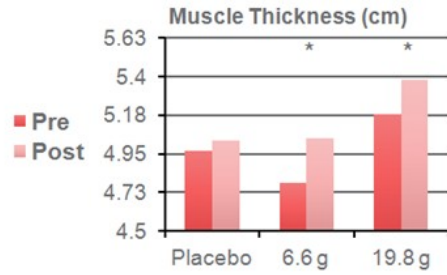
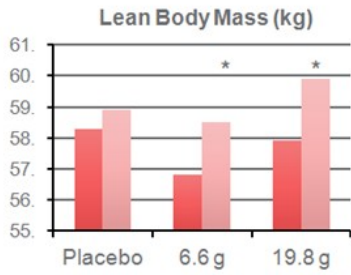
to baseline during the 24-hour period. No study-related adverse events were reported. This study confirmed the beneficial effects of Fortetropin in suppressing free serum myostatin levels.



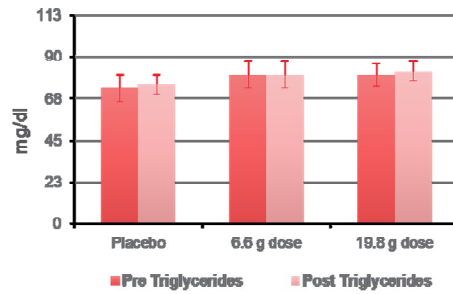
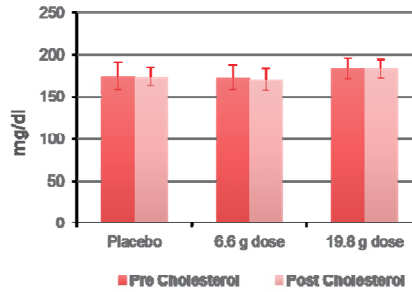
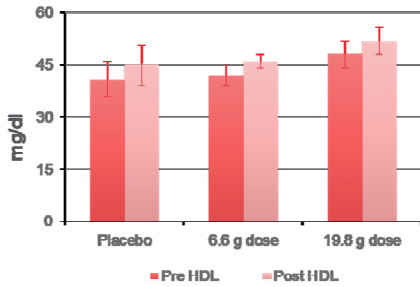
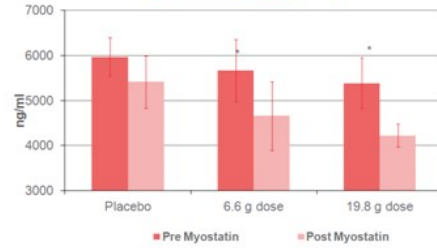
(Source: [www.myosrens.com](http://www.myosrens.com))

- **Study 2<sup>3</sup>**: 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.

<sup>3</sup>J Am Coll Nutr. 2016 Nov-Dec;35(8):679-91.

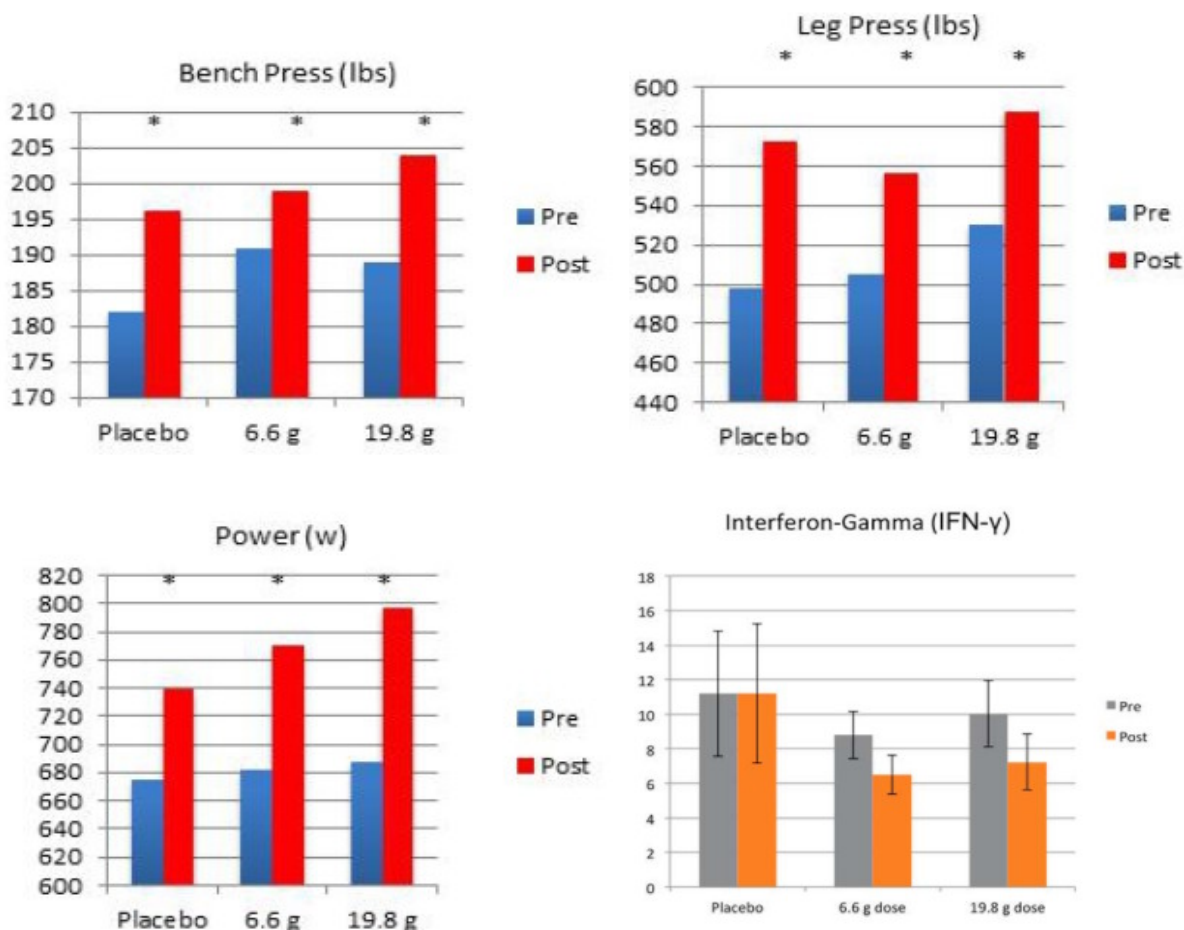


### Myostatin (ng/ml)



(Source: www.myosrens.com)





(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<sup>4</sup> 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

<sup>4</sup>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<sup>5</sup> 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 mortality<sup>6</sup>. These data suggest that muscular strength adds to the protective effect of cardiorespiratory fitness.

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## **REGULATORY COMPLIANCE**

The raw materials for Fortetropin are imported into the U.S. in conformance with United States Department of Agriculture Animal and Plant Health Inspection Service's (USDA APHIS) requirements for egg products, which are designed to exclude pests and diseases. Eggs are considered a major food allergen under the Food Allergen Labeling and Consumer Protection Act of 2004. Hence, the firm is required to label their products that containing Fortetropin to note that they contain egg product. Other statutory obligations include reporting all serious adverse events on a Medwatch Form 3500A. To-date, the firm has not filed a Medwatch Form 3500A with the FDA.

World Anti-Doping Agency (WADA) is a foundation created through a collective initiative that is led by the International Olympic Committee. WADA monitors the fight against drugs in sports. The Banned Substances Control Group (BSCG) is one of the prominent organizations that provides rigorous, independent, ISO-accredited testing to evaluate supplements and their ingredients. They screen for substances prohibited by the WADA and most U.S. professional sports leagues. BSCG Certified Drug Free® program is a comprehensive certification program for the dietary supplement industry. Fortetropin has been awarded this certificate from BSCG.

Fortetropin was granted regulatory approval by Health Canada in 2015 (NPN: 80061148).

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## **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 supplements<sup>7</sup>. 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.

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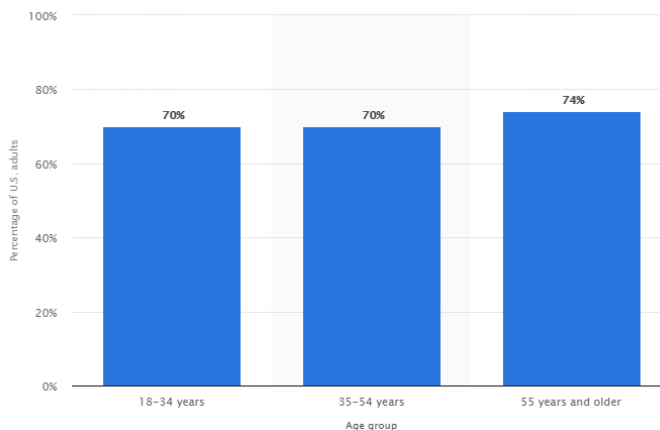
<sup>5</sup> BMJ 2008; 337

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

<sup>7</sup> Nielsen Global Health and Wellness Report - January 2015

➤ **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)

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 activity<sup>8</sup>. 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.

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,

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

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 function<sup>9</sup>. 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. To-date, 76 dogs have been enrolled in the study and the goal is to test Fortetropin on 100 dogs by mid-2018. If the results are positive, the firm would likely continue developing Fortetropin-based products for pet nutrition as well as humans recovering from musculoskeletal surgeries.

The most popular supplement sold for increasing energy and promoting lean muscle growth in canines is K9 Power's Super Fuel Dog Performance and Muscle Recovery Formula. Its main ingredient is chicken followed by whole eggs. Eggs are known to have roughly 95% of biological value (the amount of absorbed protein from food). MYOS' Fortetropin fertilized egg yolk powder is produced via a patented technology which retains the nutrient value and biological integrity of the egg yolk.

➤ **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 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 aging<sup>10</sup>. 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 deposits<sup>11</sup>. 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).

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<sup>9</sup> PLoS Genet 3(5): e79.

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

<sup>11</sup> A Biol Sci Med Sci 2006;61:1059–1064.

### ***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 wasting<sup>12</sup>.
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 mice<sup>13</sup>.
3. Myostatin, a myokine, acts as a molecular mediator of contracting skeletal muscle fibers after exercise<sup>14</sup>.
4. Further studies have shown that genetic deletion of myostatin results in an increase in skeletal muscle mass and function<sup>15</sup>.

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 study<sup>16</sup> 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- $\gamma$  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 patients<sup>17</sup>. 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 survival<sup>18</sup>. 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 pathogenesis<sup>19</sup>.

### ***The role of Myostatin in Cachexia***

Activin A and myostatin belong to TGF- $\beta$  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

<sup>12</sup> Biochem Biophys Res Commun 2003;300:965-971.

<sup>13</sup> Aging Cell 2009;8:573-583.

<sup>14</sup> Bone. 2015 Nov; 80: 115-125.

<sup>15</sup> PLoS Genet 3(5): e79.

<sup>16</sup> J Cachexia, Sarcopenia and Muscle (2016); 7:413-21

<sup>17</sup> Nat Rev Cancer 14(11): 754-762.

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

<sup>19</sup> Ther Adv Med Oncol. 2017 May; 9(5): 369-382.

prolong survival without stimulating tumor growth<sup>20</sup>. Zhou et al. demonstrated in 2010<sup>21</sup> 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 will be 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.

### ***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 peptidobodies, 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.

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## **MARKETING STRATEGY**

All of the raw materials for Fortetropin are sourced from third-party suppliers. Fortetropin is manufactured by a single third-party manufacturer who is in full compliance with cGMP standards set by the FDA. There are multiple vendors for blending, packaging and labeling the products. Fortetropin is available as an over-the-counter (OTC) product.

In February 2014, the company signed an exclusive distribution agreement with Cenegenics for the sale of a proprietary formulation of Fortetropin to their network of age-management centers in the U.S. Cenegenics also promoted Fortetropin through their community of physicians which focused on treating a growing population of geriatric patients. The distribution agreement with Cenegenics expired in December 2016. However, in May 2017, the company received a purchase order from Cenegenics to deliver more products to them.

In addition to MYOS' branded products, the company also plans to sell their proprietary compound as an ingredient in other branded supplements. Since MYOS is attempting to increase its offerings, we believe that the sale of

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

<sup>21</sup> Cell (2010), 142 (4) : 531–543.



Fortetropin as an ingredient in other products is a great strategy to maximize their reach with little incremental sales and marketing spend.

Continuing their brand-awareness strategy, the firm was a sponsor at the IDEA World Convention in Las Vegas in July 2017. Soon after, they announced a partnership with NFL Alumni under its commercial marketing arm, Pro Football Legends, in support of the NFL Alumni NY/NJ Chapter's Optimal Bowl and Wellness Challenge. MYOS, which provided the participants (former NFL players and military veterans) with Qurr products during their workouts, noted that they gained valuable product exposure and alliances for future business opportunities.

Additionally, the company showcased Fortetropin and the Qurr Line of Muscle Health Products at the 2018 Arnold Sports Festival in March. The "Arnold", which is billed as the world's largest multi-sport fitness gathering, is co-promoted by legendary bodybuilder and film star Arnold Schwarzenegger. There were more than 200,000 attendees at this year's event, which featured 20,000 athletes from 80 nations and over 1,000 booths of fitness equipment, apparel and nutrition. MYOS had a strong presence there, offering samples and special EXPO discounted prices for Qurr products.

In continuing their efforts towards building brand awareness through brand partnerships, MYOS inked a sponsorship deal with IMG College, a division of IMG, in November of last year (2017). IMG College represents more than 200 colleges across multimedia rights, licensing and sponsorships. IMG is a global company with deep roots in professional sports. It also owns the Ultimate Fighting Championship (UFC). MYOS commenced marketing its products to collegiate athletic programs. IMG serves as a distribution channel for MYOS' products while helping build brand visibility. We believe the potential to leverage IMG's wide network is substantial.

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## COMPETITIVE LANDSCAPE

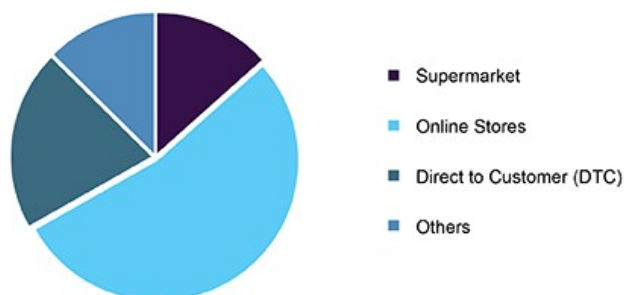
In order to gain a differentiated and premium position in this market segment, manufacturers are offering an expanded suite of nutritional products to widen their target audience. The nutrient-dense, protein-synthesizing product (Fortetropin) is available in multiple forms including powders, puddings and shakes.

Since the market is highly fragmented, brand awareness and consumer loyalty are prime factors for gaining market share. Building brand awareness within their key customer audience by targeting channels such as gyms, fitness and bodybuilding magazines and event sponsorships (such as the Arnold and IDEA World Convention) is a significant focus. Management plans to create brand visibility by building its relationships with brand ambassadors (such as professional athletes), fitness organizations as well as relying on the science behind Fortetropin. Dieticians, athletic trainers and strength coaches are frequently consulted for recommendations on nutritional supplements. The primary sources of information regarding supplements are friends/family members. One study found that a parent or physician is a most influential factor in nutritional supplement purchase decisions<sup>22</sup>.

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<sup>22</sup> Int J Sport Nutr Exerc Metab. 2004 Feb;14(1):104-20.





(Source: [www.grandviewresearch.com/industry-analysis/protein-supplements-market](http://www.grandviewresearch.com/industry-analysis/protein-supplements-market))

The growth in sales from ecommerce is a recent trend that is expected to continue for the foreseeable future. The increase in the number of internet users, easy accessibility and availability to wide options and convenience are the factors driving online sales. Moreover, discussion portals, discounts and other various promotional strategies are expected to further fuel online sales.

According to Grand View Research, online stores accounted for the majority sales in 2016. As per 1010data, Bodybuilding.com and Amazon Direct are the top online retailers of protein powders. Despite GNC and Vitamin Shoppe having a large presence in this sector, the online retail giant Amazon which has multiple sites (Direct, Marketplace and Subscription) accounted for close to 60% of all online protein powder purchases. Amazon Subscription witnessed the fastest growth in 2016. Online sites offer the advantage of being able to carry keyword tags such as “best seller”, “functional food” and have consumer reviews that help entrench a product in the top spot.

While Americans, on average, spend \$55 per month on nutritional supplements, athletes spend almost twice as much (~\$100 per month) and body builders could spend up to \$1000 per month. MYOS’s product is priced at \$130 for one month’s supply. While the product might seem pricey, given the clinically-supported benefits of Fortetropin (and relative lack of evidence supporting almost all other supplements’ ‘claims’), it would seem that athletes/bodybuilders could be price insensitive and quick to adopt such an innovative product.

## INTELLECTUAL PROPERTY

MYOS received patent (U.S. Patent No. 8,815,320 B2) entitled “Process for Producing a Composition Containing Active Follistatin” to cover the proprietary manufacturing of Fortetropin in August 2014 from the USPTO. The patent is valid through early 2033.



# PROJECTED INCOME STATEMENT

## MYOS RENS TECHNOLOGY

| MYOS RENS TECHNOLOGY                   | 2017A            | Q1A              | Q2E              | Q3E              | Q4E              | 2018E                | 2019E            | 2020E            | 2021E            |
|--|------------------|------------------|------------------|------------------|------------------|----------------------|------------------|------------------|------------------|
| <b>Total Revenue</b>                   | <b>\$0.53</b>    | <b>\$0.06</b>    | <b>\$0.20</b>    | <b>\$0.25</b>    | <b>\$0.30</b>    | <b>\$0.81</b>        | <b>\$3.04</b>    | <b>\$4.84</b>    | <b>\$7.97</b>    |
| <i>Y-o-Y Growth</i>                    | 61%              | -62%             | 239%             | 56%              | 91%              | 53%                  | 277%             | 59%              | 65%              |
| Total cost of revenue                  | \$0.31           | \$0.03           | \$0.08           | \$0.10           | \$0.12           | \$0.34               | \$1.06           | \$1.45           | \$1.99           |
| <b>Gross Income</b>                    | <b>\$0.2</b>     | <b>\$0.0</b>     | <b>\$0.1</b>     | <b>\$0.2</b>     | <b>\$0.2</b>     | <b>\$0.5</b>         | <b>\$2.0</b>     | <b>\$3.4</b>     | <b>\$6.0</b>     |
| <i>Gross Margin</i>                    | 41%              | 46%              | 59%              | 60%              | 60%              | 58%                  | 65%              | 70%              | 75%              |
| Selling, Mrktg, Research               | \$0.8            | \$0.4            | \$0.3            | \$0.3            | \$0.3            | \$1.0                | \$2.8            | \$3.7            | \$5.0            |
| <i>% S.M&amp;R</i>                     | 156%             | 691%             | 125%             | 112%             | 100%             | 118%                 | 91%              | 77%              | 63%              |
| Total G&A                              | \$2.0            | \$0.8            | \$0.4            | \$0.5            | \$0.4            | \$2.14               | \$2.5            | \$3.6            | \$5.3            |
| <i>%G&amp;A</i>                        | 383%             | 1481%            | 210%             | 180%             | 143%             | 266%                 | 83%              | 74%              | 66%              |
| Other Expenses                         | \$1.5            | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0                | \$0.0            | \$0.0            | \$0.0            |
| Total operating expenses               | \$4.29           | \$1.24           | \$0.7            | \$0.7            | \$0.7            | \$3.1                | \$5.3            | \$7.3            | \$10.3           |
| <b>Operating Income</b>                | <b>(\$0.4.1)</b> | <b>(\$01.2)</b>  | <b>(\$00.6)</b>  | <b>(\$00.6)</b>  | <b>(\$00.6)</b>  | <b>(\$02.6)</b>      | <b>(\$03.3)</b>  | <b>(\$03.9)</b>  | <b>(\$04.3)</b>  |
| <i>Operating Margin</i>                | -                | -                | -                | -                | -                | -                    | -                | -                | -                |
| Interest income                        | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0                | \$0.0            | \$0.0            | \$0.0            |
| Interest expense                       | \$0.0            | (\$00.0)         | \$0.0            | \$0.0            | \$0.0            | \$0.0                | \$0.0            | \$0.0            | \$0.0            |
| Other income (expense), net            | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0                | \$0.0            | \$0.0            | \$0.0            |
| Loss before provision for income taxes | (\$04.1)         | (\$01.2)         | (\$00.6)         | (\$00.6)         | (\$00.6)         | (\$02.6)             | (\$03.3)         | (\$03.9)         | (\$04.3)         |
| Provision for income taxes             | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0                | \$0.0            | \$0.0            | \$0.0            |
| warrant modification                   | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0            | \$0.0                | \$0.0            | \$0.0            | \$0.0            |
| <b>Net Income</b>                      | <b>(\$04.1)</b>  | <b>(\$01.2)</b>  | <b>(\$00.6)</b>  | <b>(\$00.6)</b>  | <b>(\$00.6)</b>  | <b>(\$02.6)</b>      | <b>(\$03.3)</b>  | <b>(\$03.9)</b>  | <b>(\$04.3)</b>  |
| <i>Net Margin</i>                      | -                | -                | -                | -                | -                | -                    | -                | -                | -                |
| <b>EPS</b>                             | <b>(\$00.69)</b> | <b>(\$00.17)</b> | <b>(\$00.08)</b> | <b>(\$00.08)</b> | <b>(\$00.07)</b> | <b>(\$00.35)</b>     | <b>(\$00.39)</b> | <b>(\$00.41)</b> | <b>(\$00.40)</b> |
| <b>Shares O/ S</b>                     | 5.9              | 7.2              | 7.3              | 7.5              | 7.8              | 7.5                  | 8.5              | 9.6              | 10.8             |
| Source: Zacks Investment Research,     |                  |                  |                  |                  |                  | Anita Dushyanth, PhD |                  |                  |                  |

# HISTORICAL STOCK PRICE



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