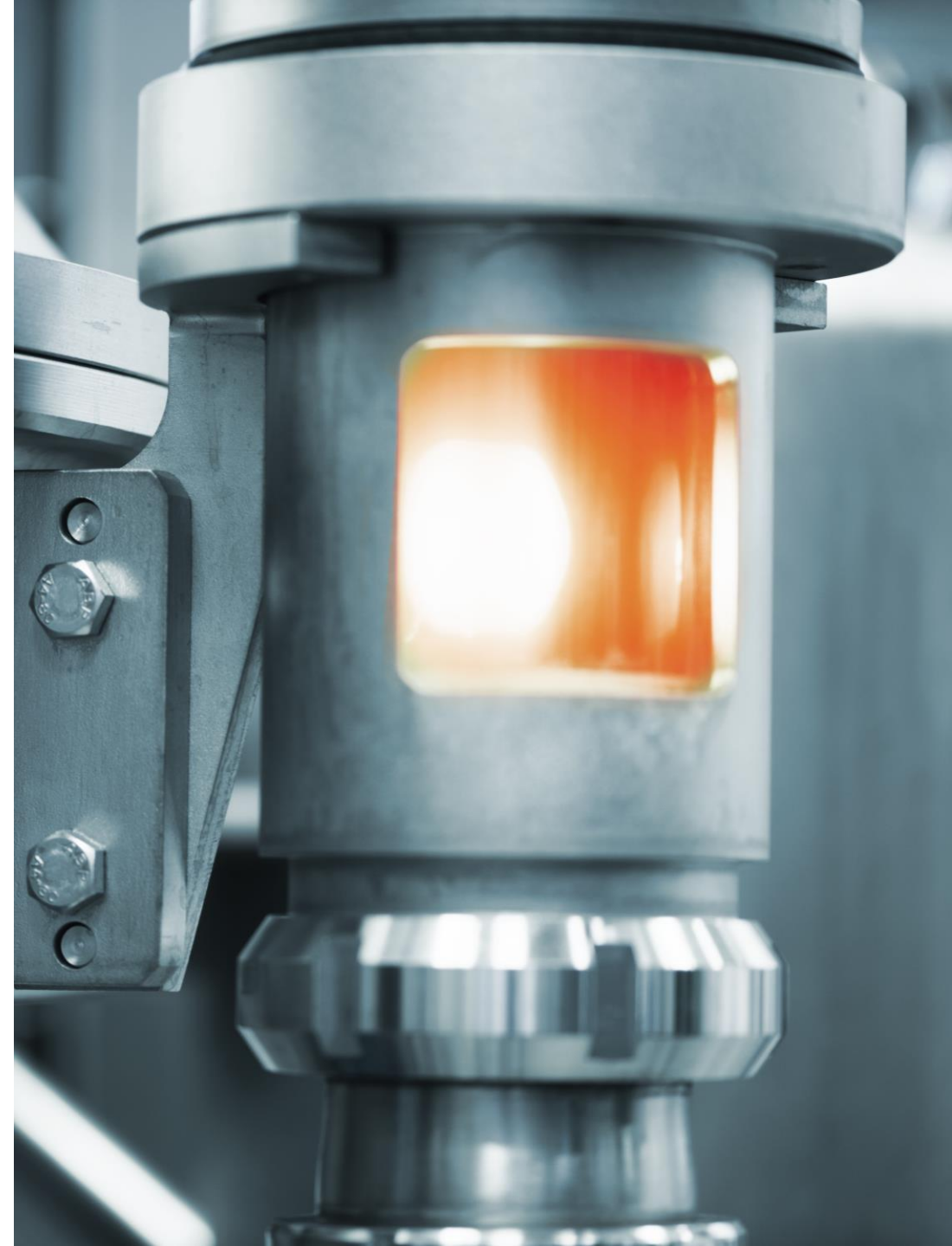


The medicine of tomorrow

Hofseth BioCare business presentation

Date:

15.10.2020



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Turning fish “waste” into high value **UNIQUE** consumer health products



**SALMON OIL
OMEGO®**

Fresh, unprocessed
Unrefined
Natural fish oil
Full spectrum of omegas
Low TOTOX
100% triglyceride



**SALMON PROTEIN
PROGO®**

Only protein hydrolysate with
NO bitterness;
High bioavailability (98%)
Benefits beyond nutrition
including correction of
anemia and weight loss



**SALMON COLLAGEN CALCIUM
CALGO®**

Natural source of calcium
enabling better uptake to bone &
collagen II, trace elements and
natural bone growth factors



**PHP
PETGO SALMON MEAL™**

Pet feed

HBC: turning fish industry waste to high value products



Proprietary enzymatic hydrolysis process protected by patents and trade secrets now covering the processing of all marine sources of off-cuts



Sales mix moving away from low margin animal feed towards high margin human grade products



Diversified R&D pipeline focussed on treatment of anemia, inflammatory bowel disease, BMI reduction, asthma & COVID-19, bone & joint health



Sustainability lies at the heart of the business model: waste to value

Farming



- Annual harvest volume of around 10-12,000 tons salmon/trout
- No GMO, no antibiotics

Processing

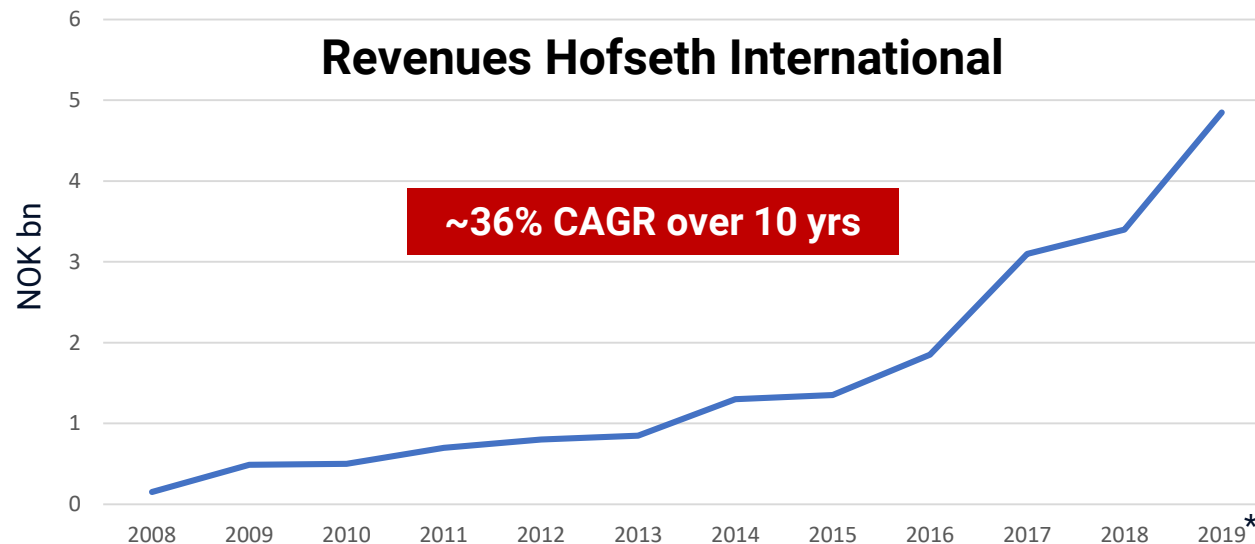


- Three processing facilities with a total capacity of 100,000 tons
- Global customer base (Costco, Lidl, Aldi, Coles)

Waste to value

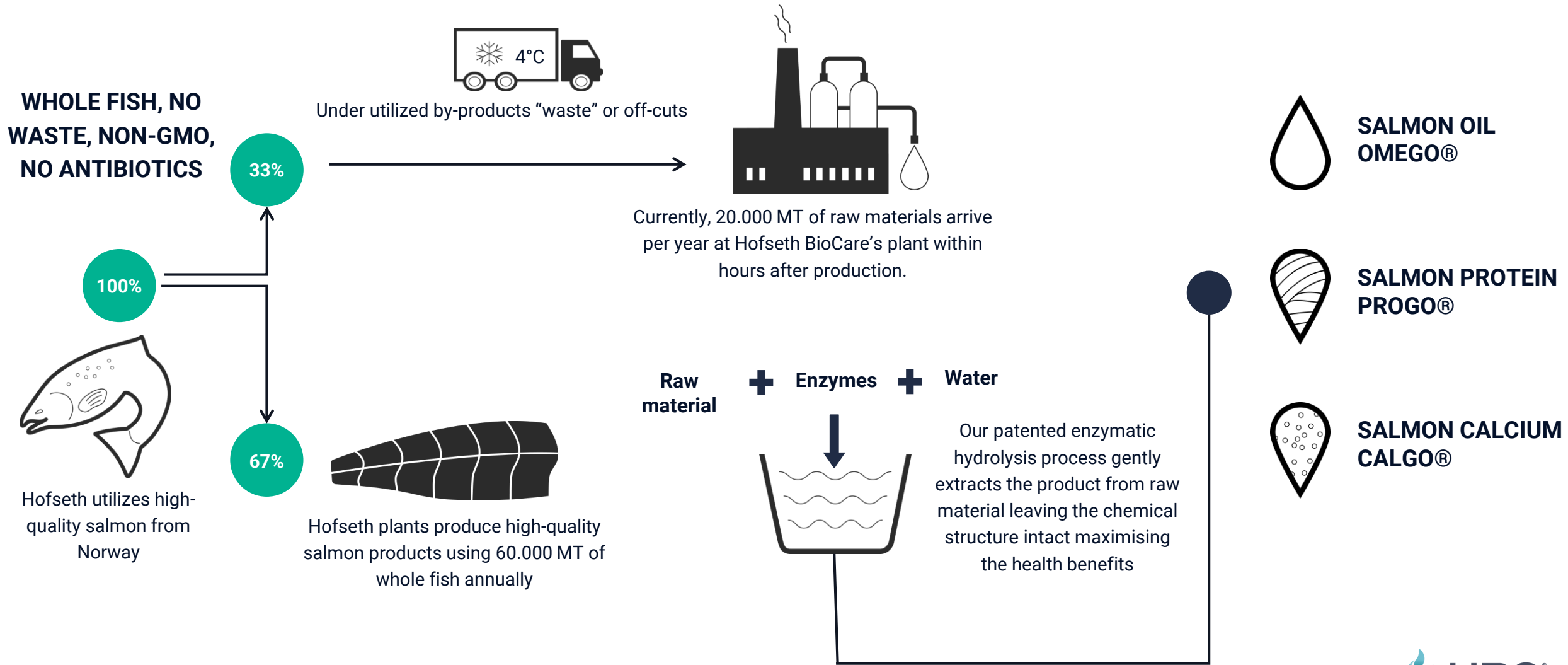


- **Using off-cuts from the processing division to produce high value products for pets & humans**
- State-of-the-art production facilities
- Manufacturing process protected by patents & trade secrets
- Current manufacturing capacity at Midsund of 25,000 MT
- Strategically located close to multiple sources of fresh salmon supply
- Replacement cost manufacturing facilities \$150m



*Estimated sales for 2019

The enzymatic hydrolysis production process



Our plants

- FSSC 22000 certified
- GMP+ certified
- Friend of the Sea certified
- Kosher certified
- Approved establishment by Norwegian Food Safety Authority
- FDA-approval
- Halal certification possible on request

Unrefined salmon oil

Full spectre of omega fatty acids

Product name:

OmeGo®

Fat content:

More than 99.1 %

Lipo-peptides:

Less than 0.9 %

FFA:

Less than 1 %



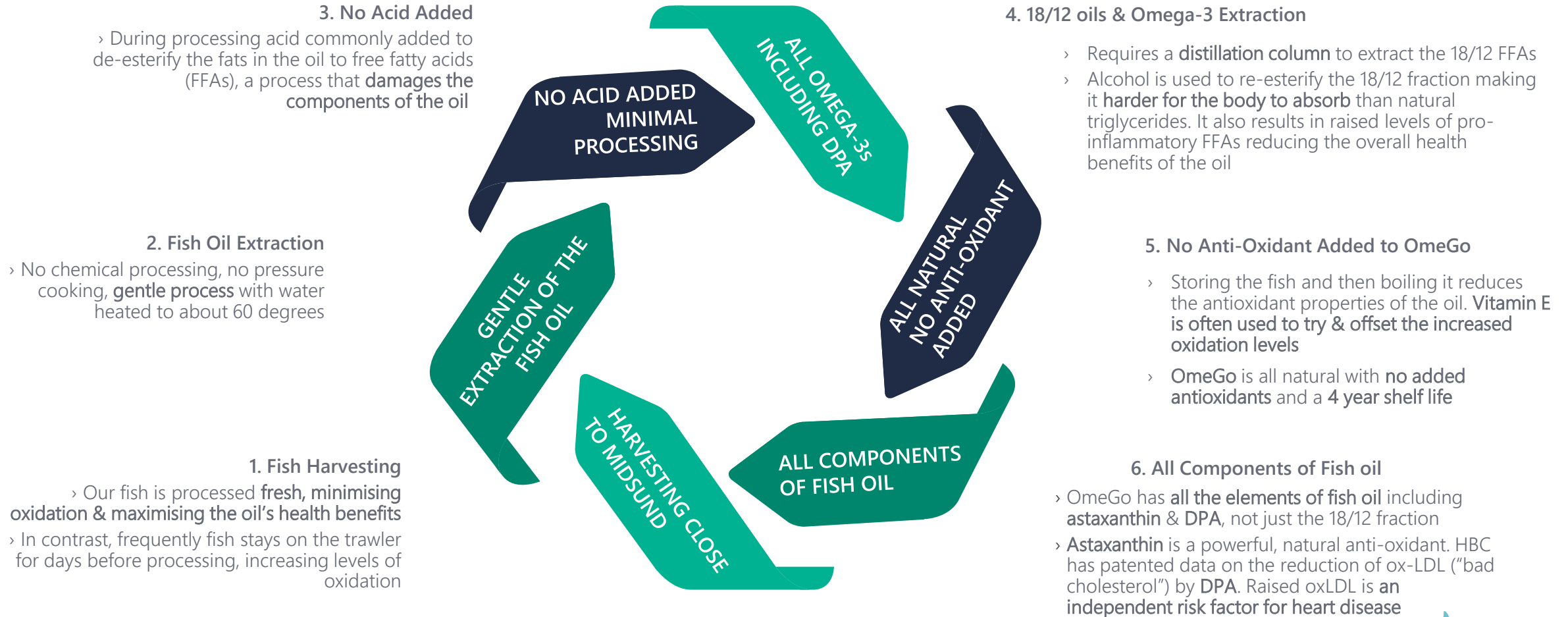
OmeGo® Salmon oil

- Unrefined, fresh Natural Norwegian Salmon Oil, so...
- ...it contains all the fish omegas, not just 18/12, providing all the benefits of fresh fish
- ...it's anti-inflammatory with low tottox levels, no added antioxidants & 4 years shelf life
- ...it has broad benefits on blood lipids & cardiovascular health*
- ...it contains a non-Omega fraction that could provide a new treatment for eosinophilic asthma**
- ...it has FFA levels of less than 1%
- ...& minimal processing significantly reduces the cost of production

* Journal of Nutrition & Food Science 2013

** The Journal of Functional Foods in Health and Disease (FFHD)

HBC's oil – minimal processing



OmeGo®

Fresh, minimally processed, all the benefits of whole fish

OmeGo provides full spectre of omega-3s (including DPA) and **all other PUFAs** contained in fresh fish:

- contains DHA/EPA at 75mg/1000mg, the same level as in whole fish
- contains all 13 omegas including DHA, EPA & DPA for total omega-3 level of 170mg/1000g. **DPA reduces oxLDL** – an independent marker of CV disease risk

NOTE **18/12 oil** contains 300mg/1000mg DHA & EPA but only 50% is absorbed as in unnatural ethyl-ester form, so 150mg/1000mg bioavailable & **NO DPA**. Manufacturing process results in raised levels of **FFAs** which are pro-inflammatory

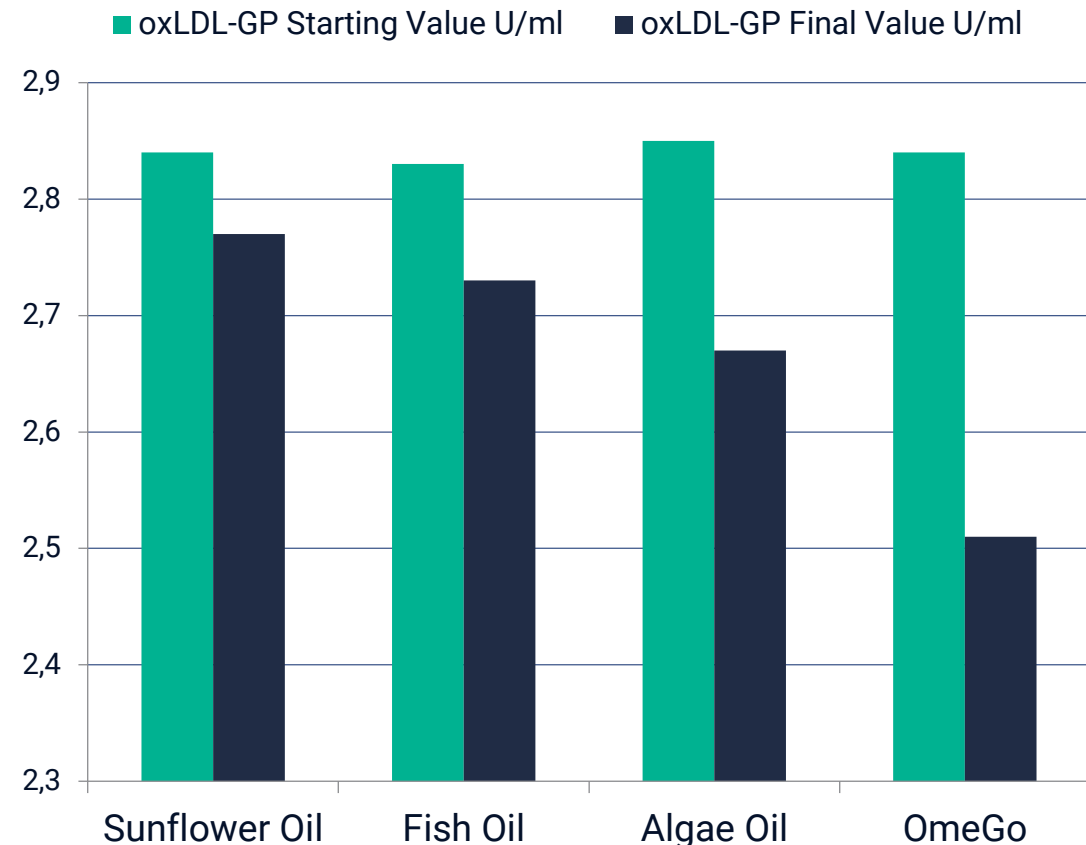
OmeGo®

Cardiovascular health

- Full spectrum of Omega-3s (DHA, EPA, DPA) providing all the benefit of fresh fish including anti-inflammatory & antioxidant benefits. No added antioxidant, stable, natural product with 4 years shelf-life.
- Significantly greater reduction in oxLDL a highly inflammatory form of “bad cholesterol” & independent marker of CV risk
- Chronic inflammatory diseases including atherosclerosis are a major cause of morbidity and mortality worldwide

Source: Journal of Nutrition & Food Sciences, Sen & Framroze, 3:5 (2013)

Healthy human reduction in serum oxLDL



Fresh, minimally processed, maximising antioxidant benefits

Fresh, minimal processing = OmeGo has very low oxidation / Totox (aka rancidity) levels:

- Low TOTOX levels are essential to maximise the health benefits of fish oil;
- The time to extract the oil and the quality of manufacturing is key;
- Natural antioxidant astaxanthin = no need to add vitamin E - OmeGo is a stable, fresh, natural product with **4 years shelf life**
- Minimal processing significantly reduces the cost of production vs 18/12 oil and Krill oil

HBC's oil & respiratory health

HBC's R&D work continues to identify medically important & differentiated health benefits:

HBC has identified a **minor lipid-soluble non-PUFA element** that modulates eosinophil effector function (EEF) invitro and in animal models of eosinophilic inflammation (patent pending).

Eosinophils are a white blood cell that help to fight infection. However in some individuals they become overactive and can cause ill health.

For instance, eosinophils are an important driver of inflammation in up to 40% of asthmatics.

STOCK ANNOUNCEMENT

Preclinical research with OmeGo® demonstrates potential to treat eosinophilic asthma

15.05.2020

STOCK ANNOUNCEMENT

HBC starts its accelerated COVID-19 Phase 2 clinical trial of OmeGo® salmon oil to decrease Acute Respiratory Distress Syndrome and the need for assisted respiration

30.06.2020

STOCK ANNOUNCEMENT

New study highlights the potential of OmeGo® as a prophylactic therapy for Asthma and COPD

01.09.2020

Targeting steroid treatment-resistant asthma

7-8% population suffers asthma with up to **40% driven by eosinophils**

Eosinophilic asthma typically requires higher doses of steroids & increased risks of side effects including **osteoporosis, weight gain, hypertension, diabetes, cataracts**.

Less likely to have good asthma control with increased risk of exacerbations & hospitalization

Ultimate goal = control inflammation & reduce in steroid intake

Asthma market

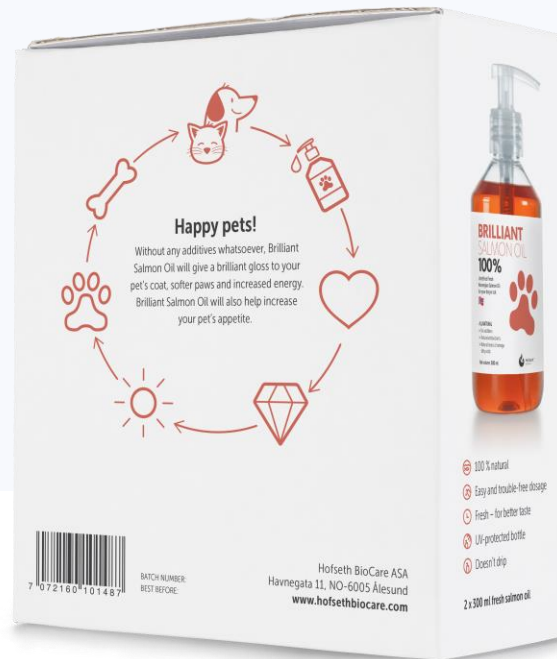
Inhaled: Bronchodilators & steroids: >\$7bn market

Oral: Singulair had \$5bn peak sales despite only moderate effectiveness; Steroids useful but long-term side effect issues; CRTH2 agents in development but recent failure Novartis' fevipiprant

Injectable biologics: Anti-IL-5: Fasrena (AstraZeneca) & Nucala (GSK); Anti-IL-4/-13 Dupixent (Sanofi/Regeneron), Anti-IgE (allergic asthma) Xolair (Roche / Novartis) >\$3bn sales but HIGH PRICE

This is different

Process description	Other salmon oils	Anchovies oils	Concentrated fish oils	OmeGo [®] 
No pressure cooking and high physical stress on the biomass to extract the oil	×	×	×	✓
No bleaching (caustic)	×	×	×	✓
No winterization	×	×	×	✓
No acid hydrolysis to FFA	✓	✓	×	✓
No high temperature fraction distillation to concentrate EPA-DHA	✓	✓	×	✓
No re-esterification to TG or EE (only 90-95%)	✓	✓	×	✓
No deodorization (acid or base)	×	×	×	✓
No re-blending to replace destroyed active components i.e. astaxanthin	×	✓	✓	✓



Brilliant Salmon Oil is now available at Costco stores across the UK, Spain, Iceland and in over 1,000 retail stores in the US

Salmon protein hydrolysate

98 % pure protein

Product name:
ProGo®

Protein content:
More than 97 %

Fat content:
Less than 0.5 %

Ash content:
Less than 2.5 %





Pure Salmon Protein Hydrolysate

98% protein, fat content less than 0.5%, ash content less than 2.5%

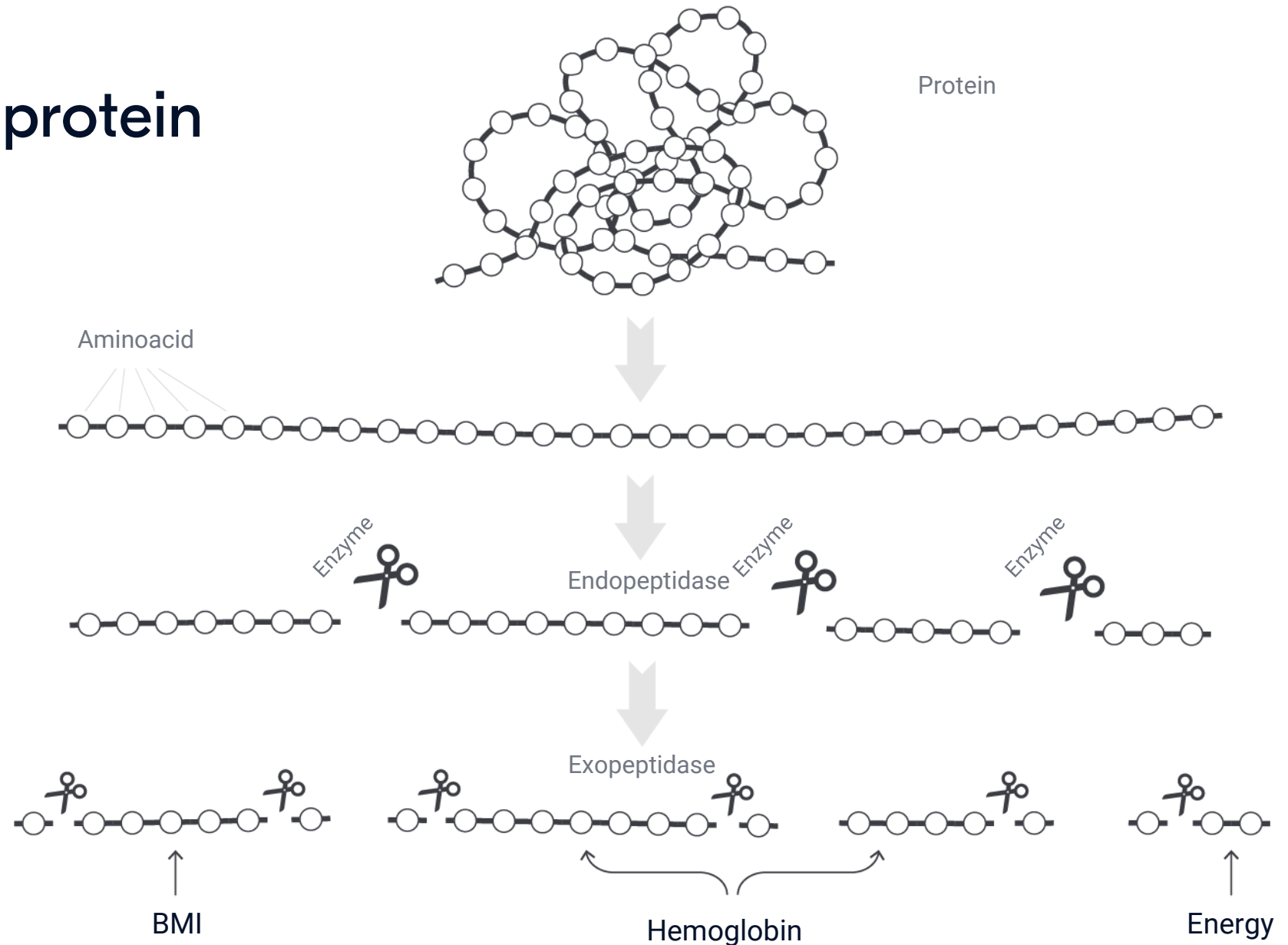
Enzymatic hydrolysis to peptides and amino acids eases GI absorption

Antioxidant and anti-inflammatory effects demonstrated in trial work

Broad utility from post-exercise recovery to recovery from a bout of illness

Hydrolyzing a protein

HBC's proprietary patented technology delivering easily absorbed bioactive peptides & amino acids from HBC's proprietary tailored enzyme technology

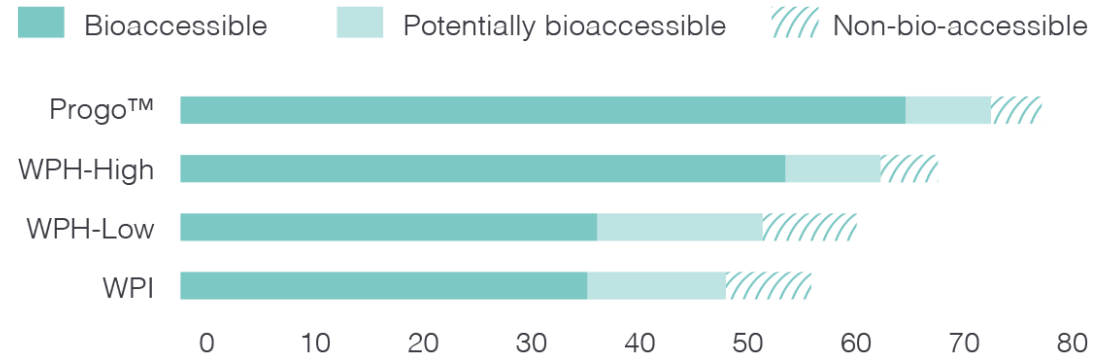


ProGo®

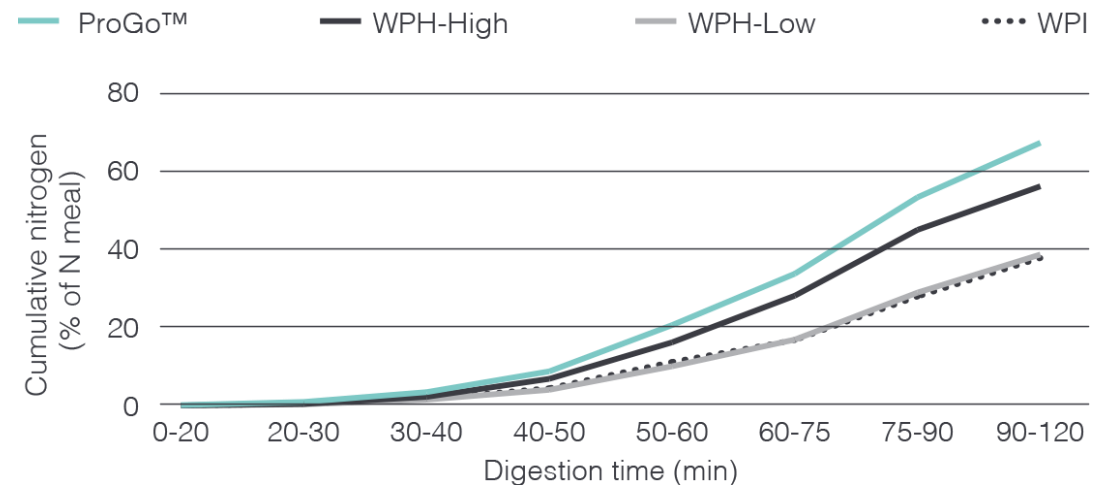
TIM-1 Study

- Fastest uptake of nitrogen into the body
- Highly soluble in water due to low molecular size
- More than 98% digestibility, and rapid digestion time
- Proven ability to increase red blood cells in anemic individuals
- Proven ability to reduce BMI
- Hypo allergenic

Bioaccessibility



Digestion times



ProGo®

Anemia study shows 15 % rise in hemoglobin levels



16g once a day of SPH bioactive peptides resulted in normal levels of ferritin and near normal levels of Hb after 6 weeks treatment.

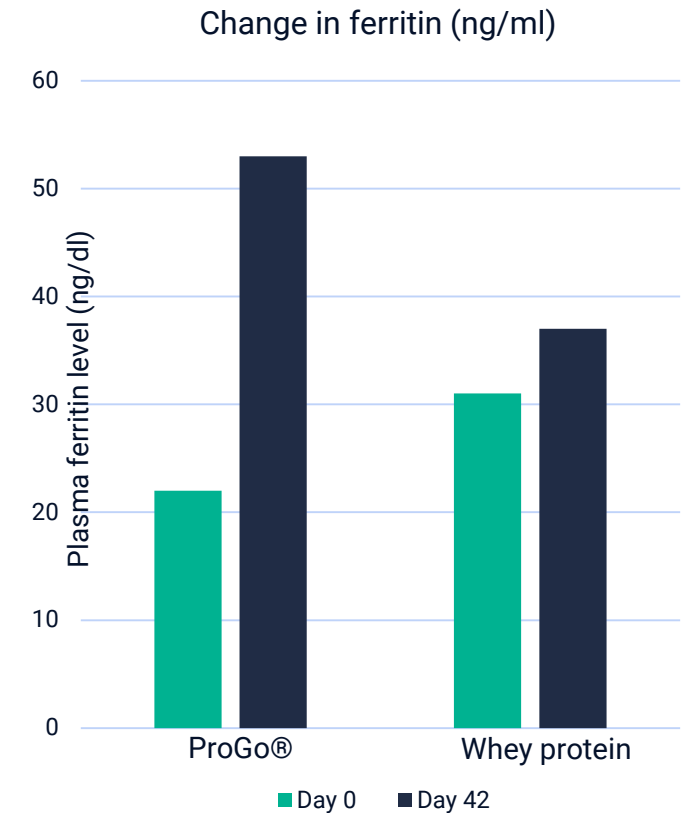
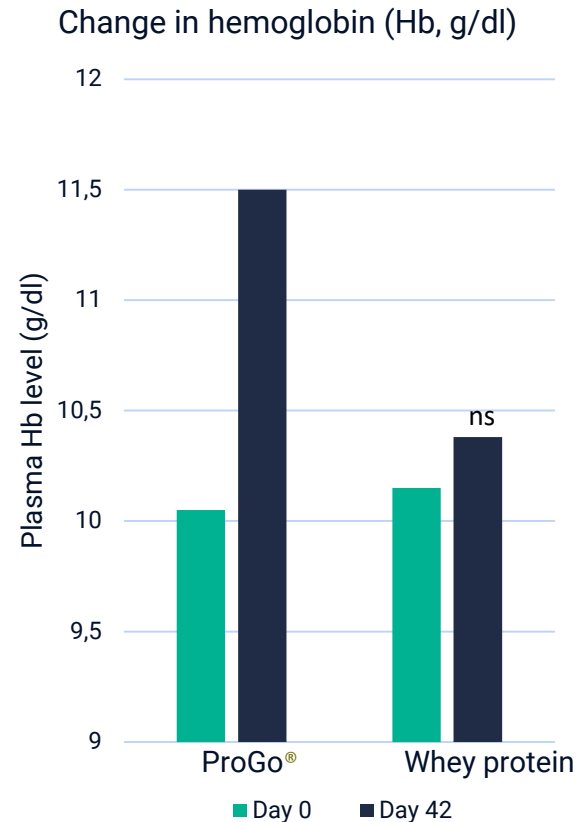


The bioactive peptides driving the hemoglobin increase have been identified with the potential for encapsulation as well as application for new chemical entity (NCE) status.



Anticipate the initiation of clinical trial work for the treatment of iron deficiency anemia during 2021.

Change in hemoglobin (+15 %) and serum ferritin (+140 %) after 6 weeks of treatment



CURRENTLY NO NUTRACEUTICAL HAS AN FDA LABEL FOR ANEMIA



Bioactive peptides to treat Iron Deficiency & Iron Deficiency Anemia (IDA) - Health Labels pending.

Late stage regulatory process with Health Canada for claim for correction of iron deficiency anemia (IDA) & *provision of antioxidant effects*.

This would be a unique claim as ProGo contains neither iron nor antioxidants: the action of the bioactive peptides upregulating antioxidant gene protective systems including FTH1

- WHO estimates anemia affects over 25% of the global population, half of these cases caused by IDA
- Currently IDA \$3bn market (>\$1bn US alone) although treatment options limited to iron supplementation
- New treatment options needed to improve outcomes & expand the market
- We have identified the active peptide fraction* driving the IDA correction to enable encapsulation of the relevant peptides

Broad applicability for health and wellness, the correction Iron Deficiency & recovery from ill health

*via size exclusion chromatography

Bioactive peptides to treat Iron Deficiency & Iron Deficiency Anemia (IDA) - Health Labels pending.



Bioactive Peptides is a patented formulation that has been clinically shown to help maintain healthy levels of ferritin and hemoglobin. This supports Red Blood Cell production, helps maintain iron-rich blood, promotes energy utilization and supports a healthy response to gut inflammation.

Directions: Mix one sachet with 10 oz of cold water. Do not exceed recommended dosage unless directed by your healthcare practitioner. Allow for 15 days of continued use for effect.

Storage: Keep in dry place.

Flavor: Mango and Orange.

Warning: If pregnant or nursing, taking other nutritional supplements or medications, consult your healthcare provider before use. Keep out of reach for children.

Notice: This product contains artificial sweetener (Sucralose).

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Bioactive Peptides

Helps Maintain Iron-Rich Blood*

* Supports Healthy Ferritin and Hemoglobin Levels

Supports Red Blood Cell Production

Promotes Energy Utilization

Supports Gastrointestinal and Immune System Health

Nutrition Facts

15 servings per container

Serving size 1 sachet (20g)

Amount per serving

Calories 76

% Daily Value*

Total Fat 0.5g 1%

Saturated Fat 0.1g 1%

Cholesterol 0mg 0%

Sodium 100mg 4%

Total Carbohydrate 0.6g 0%

Total Sugars 0g

Protein 16.6g 33%

Not a significant source of trans fat, dietary fiber, added sugars, vitamin D, calcium, iron and potassium.

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Bioactive Peptides (85.5%), acidity regulator (malic acid), flavor, emulsifier (soy lecithin), sweetener (sucralose), anticaking agent (tricalcium phosphate) and color (beetroot powder, carotenes).
Contains: Fish (Salmon) and Soy.



Batch:



Made in Norway

Best before:

Hofseth BioCare ASA
Havnegata 11, NO-6005 Ålesund
www.hofsethbiocare.com



15 doses

Stick pack format for convenient dosing

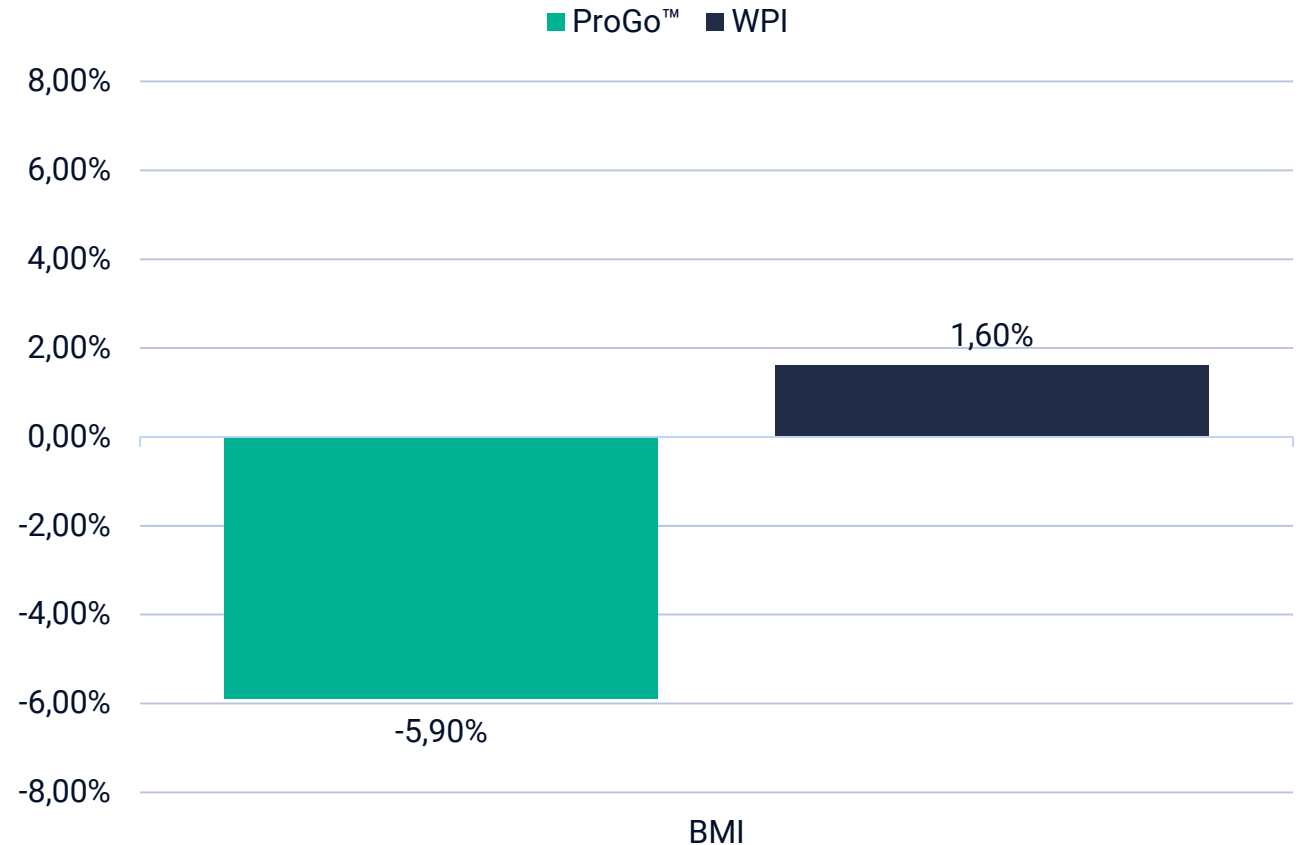


ProGo®

BMI Decrease study

- Obesity is a major global health problem with over 3 million adults dying each year from obesity related complications
- 16 g / day ProGo™ treatment for 6 weeks showed a 5.9% decrease in Body Mass Index
- For a 75kg person this would equate to ca.4kg loss of weight after 42 days
- Salmon protein hydrolysate powder in supplemental doses could be a useful tool in the long-term management of obesity.

Change in BMI and metabolism serum biomarkers after 6 weeks of treatment

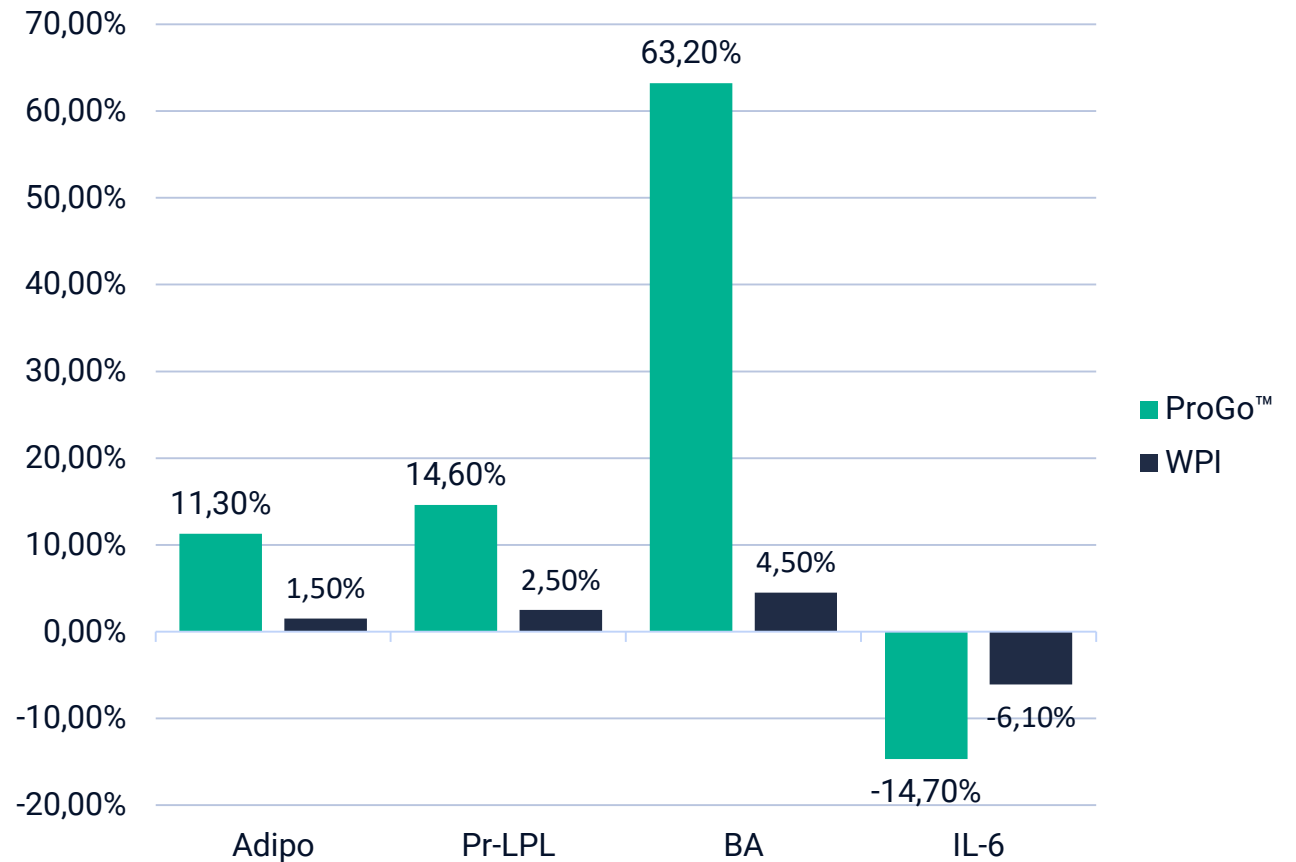


* All results above were significantly different between protein drinks ($p < 0.05$)

BMI Decrease study - biomarkers

- Adiponectin (Adipo)
 - is a plasma protein derived from adipose tissue. It has anti-atherogenic and insulin-sensitizing activities
 - it is closely associated with the metabolic syndrome & an elevated plasma adiponectin may be a useful biomarker of the effectiveness of obesity treatment
- Preheparin Lipoprotein lipase (Pr-LPL)
 - is a lipolytic enzyme regulated by insulin and its serum level reflects insulin sensitivity
- Bile acids (BA)
 - are essential for solubilization of dietary fats & have been reported to reduce plasma and liver triacylglycerol (TG) levels in animal and human trials
- Human Interleukin 6 (IL-6)
 - is a 184 amino acid pro-inflammatory polypeptide. The reduction of circulating IL-6 could be viewed as a biomarker of improved metabolic function with obesity treatment

Change in BMI relevant serum biomarkers after 6 weeks of treatment



* All results above were significantly different between protein drinks ($p < 0.05$)

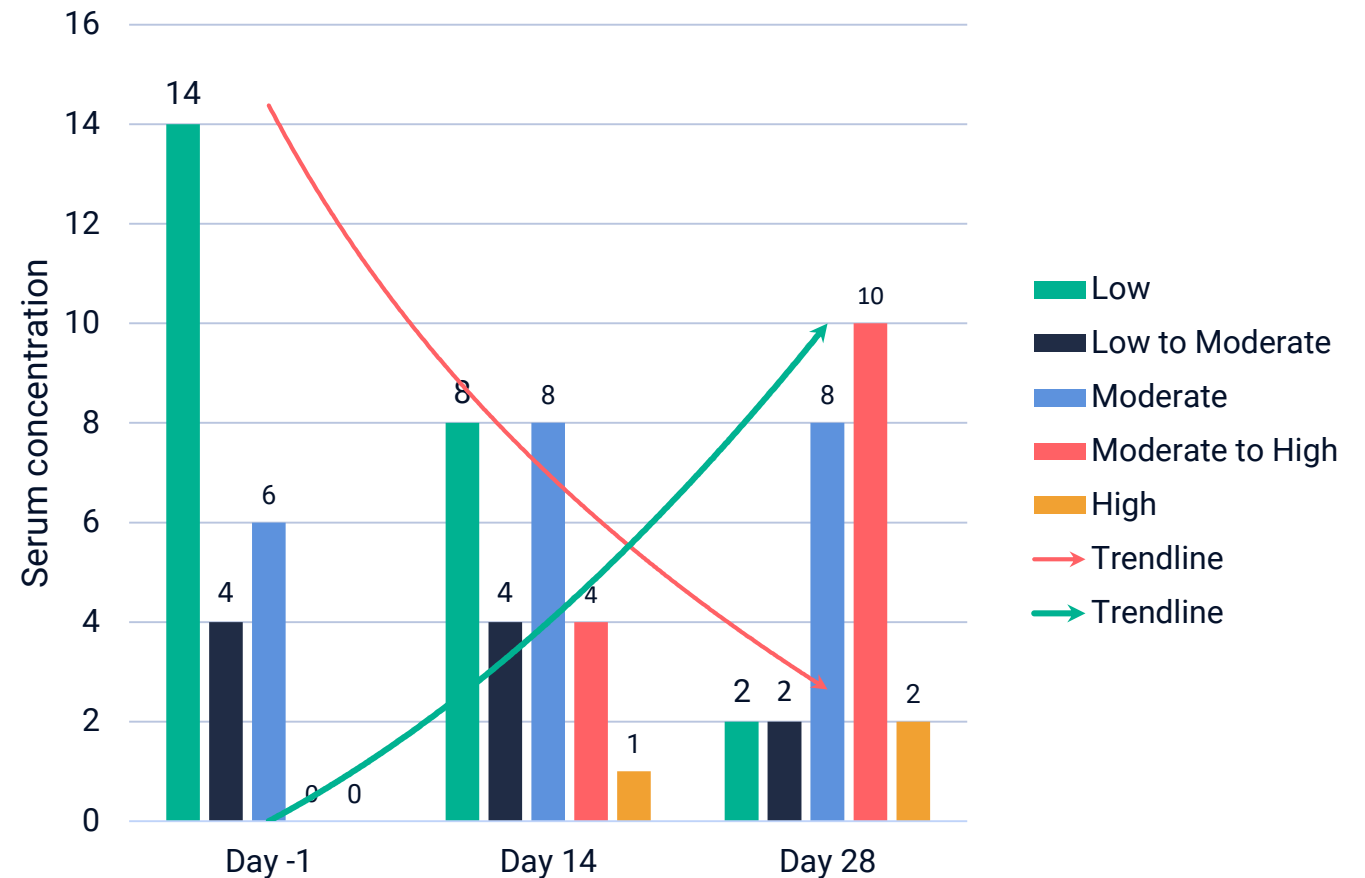
Opportunities in weight management

- **Over two thirds of the US population** is overweight (BMI 25+) or obese (BMI 30+) i.e. **>200M**
- Overweight / obesity results in an inflammatory state with increased inflammatory cytokines
- **Moderate weight loss (>5%)** has **clear health benefits** including reducing the risk of
 - Diabetes
 - Cardiovascular disease, hypertension, dyslipidaemia
 - Cancer
 - Fatty liver disease
 - Osteoarthritis
- **Limited options:** calorie restriction & exercise; pharmacotherapy but expensive & frequent self pay
- **ProGo®** also has a positive effect on vitality & anemia which could further aid weight management

Endurance, Energy and Vitality Study

- 21 out of 24 subjects showed a 90% confidence level statistically significant increase in energy and vitality scoring from Day 1 baseline results at the end of the 4 week trial.
- After the two week washout period, 5 out of the 11 subjects who showed statistical improvement in energy and vitality still showed an improvement but not at 90% confidence level.

Change in energy and vitality after just 2 weeks of treatment



By one tailed student T-test statistically significant at 90 % confidence level.

CollaGo® Collagen Peptide

- > 25 % collagen
- Collagen Type I from skin tissue
- Collagen might contribute to
 - Reduce signs of aging
 - Faster healing of wounds
 - Anti-inflammatory effect
 - Increase mineral density in bones
 - Improved skin
 - Improved nails
 - Improved hair



Bioactive peptides for hair, nails, skin & antioxidant benefits - Health Labels pending

- Bringing the structural benefits of type I & III collagen and the bioactive antioxidant effects of the peptide mix
- 18-week study in healthy adults showed*
 - Increase in energy levels
 - Improvement in hair, nails & skin quality
 - Reduction in oxidative stress / free radical activity (ROS/RNS) via the upregulation of natural defense systems in the body
 - Reduction in inflammatory cytokines and general markers of inflammation



*Study on energy increase, improvements in hair/nail/skin health and anti-inflammatory modulation:

http://www.hofsethbiocare.com/upload_images/BE451834DD9B4925A9B1E39247EEADF6.pdf

Calcium bone powder

Natural marine calcium



Product name:
CalGo®

Elemental calcium:
More than 17 %

Elemental phosphorus:
More than 8 %

Collagen:
More than 24 %

CalGo®

Natural Marine Bone Powder

Highly bioactive with potential to enhance joint and bone health

- No additives
- Rich in Type II Collagen, 24% by weight
- Microcrystalline hydroxyapatite form of calcium
- Natural source of phosphorus
- Clinical trial work in joint health and osteoporosis to commence in 2020

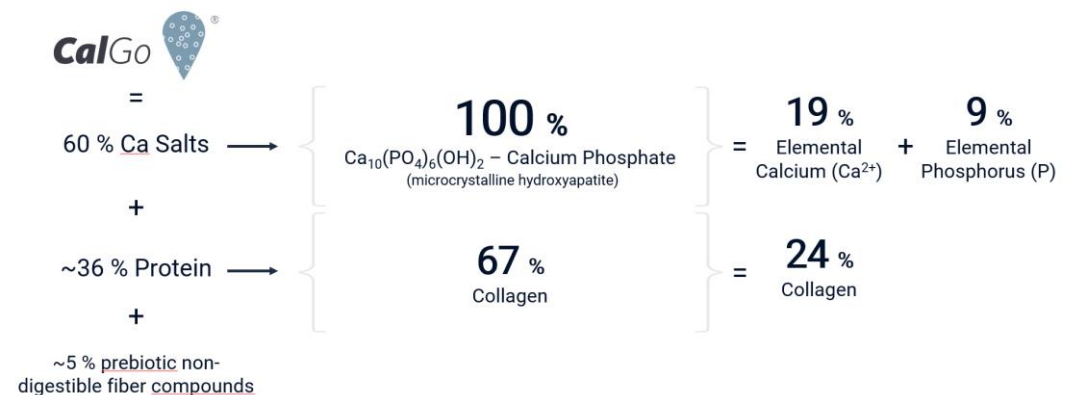
CalGo® contains the key elements of bones & joints: collagen, calcium & trace elements

STOCK ANNOUNCEMENT

STRENGTHENS R&D FUNCTION
WITH THE HIRING OF DR. ERLAND
HERMANSEN AS MEDICAL
DIRECTOR FOR CLINICAL
DEVELOPMENT

26.08.2020

Dr. Hermansen is a qualified Orthopaedic surgeon based in Ålesund, Norway where he was Head of the Surgical department Ålesund Hospital, Møre and Romsdal Hospital Trust.



CalGo®

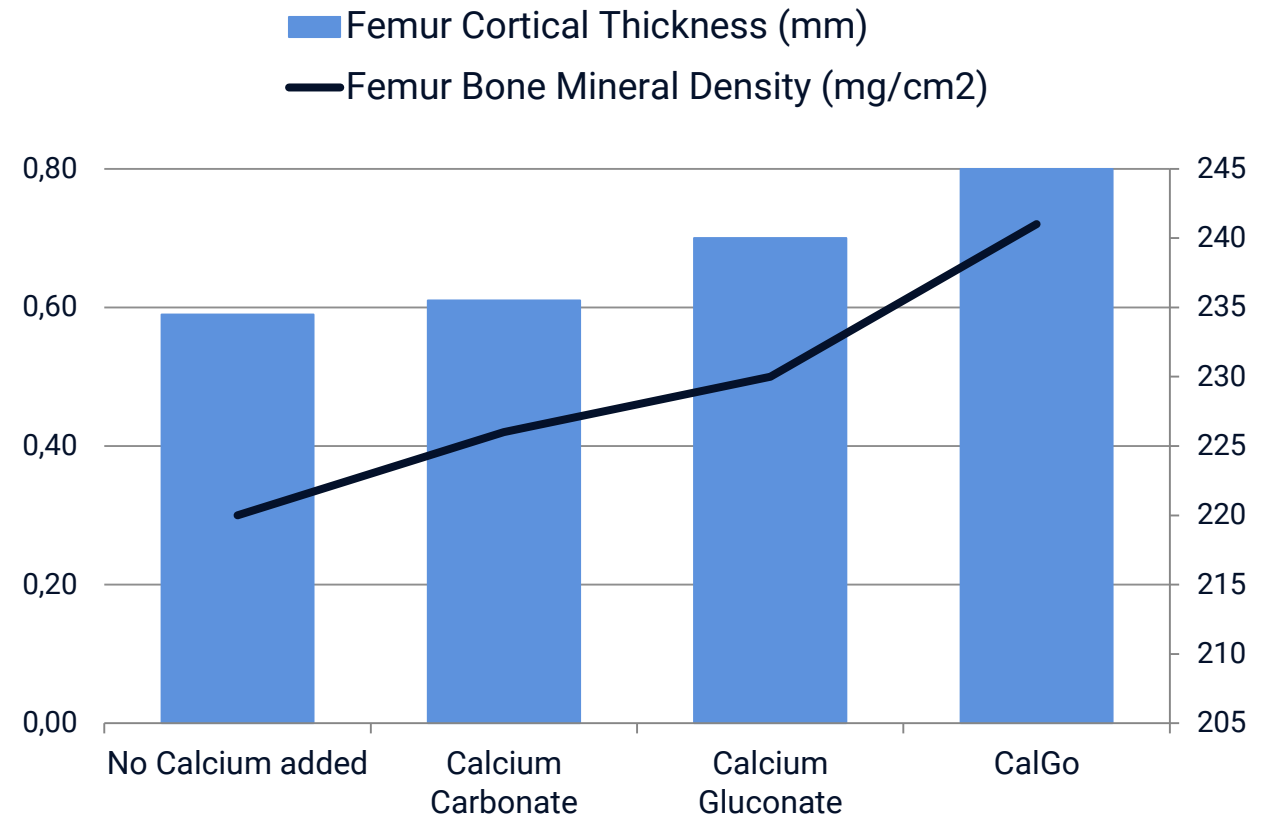
CalGo® Natural bone collagen

- Increased cortical thickness (strength) by 33%* & bone mineral density / BMD by 9% vs placebo (no calcium added)*
- The cortical thickness increase was almost double the increase with gluconate vs placebo & more than double for gluconate's BMD change vs placebo
- Changes in BMD & cortical thickness with calcium carbonate were non-significant

*both statistically significant

Source: *J Nutr Food Sci* (2015), 5:348

CalGo™ effect on femur after 8 weeks (rat model)



NØRE

- HBC brand launched in Norway
- Logistics & website in-place
- Initial uptake very favourable – strong traction with primary care physicians



Bone & joint health market

Osteoarthritis affects 40%+ of over 65's

Ageing population & obesity resulting in rising prevalence

Osteoporosis typically seen in post-menopausal women with >2M osteoporotic fractures pa in US alone

Skeletal health market

Calcium supplementation:

- Multi-billion \$ market led by calcium carbonate despite limited effectiveness
- Health trends away from dairy leaves many with inadequate calcium intake*

Joint health:

- Multi-billion \$ market despite mixed data on effectiveness
- Chondroitin & glucosamine
- Hyaluronic acid
- Hydrolysed collagen, mainly bovine & porcine with issues over sustainability & suitability

*The Dietary Guidelines report 2015-2020 from the US departments of HHS & DOA

Yield & Revenue Sensitivities



**SALMON OIL
OMEGO®**



**SALMON PROTEIN
PROGO®**



**SALMON CALCIUM
CALGO®**



**PHP
PETGO™**

This is Different and Simple: marked gearing potential

- Current processing volumes 20,000 MT pa, at Midsund Plant
- New spray drying facility at Midsund will improve both product yield and quality: completion Q4 2020

INGREDIENT	YIELD	PRODUCTION COST	B2B PRICE	B2C	MEDICAL NUTRITION 2021
OmeGo 	20.5%	9	-	200+	Asthma, COVID, CVD pricing tbc
BRILLIANT SALMON OIL 	-	9		60	
ProGo 	5%	50	100 - 170	300-500	Anaemia, IBD pricing tbc
CollaGo 	-	50	200 - 300	400-500	Antioxidant effects, skin health Pricing tbc
CalGo 	3%	40	130	350-1500	Osteoporosis, osteoarthritis
PetGo 	5%	26	26 - 30		

Future capacities and world opportunities

Berkåk

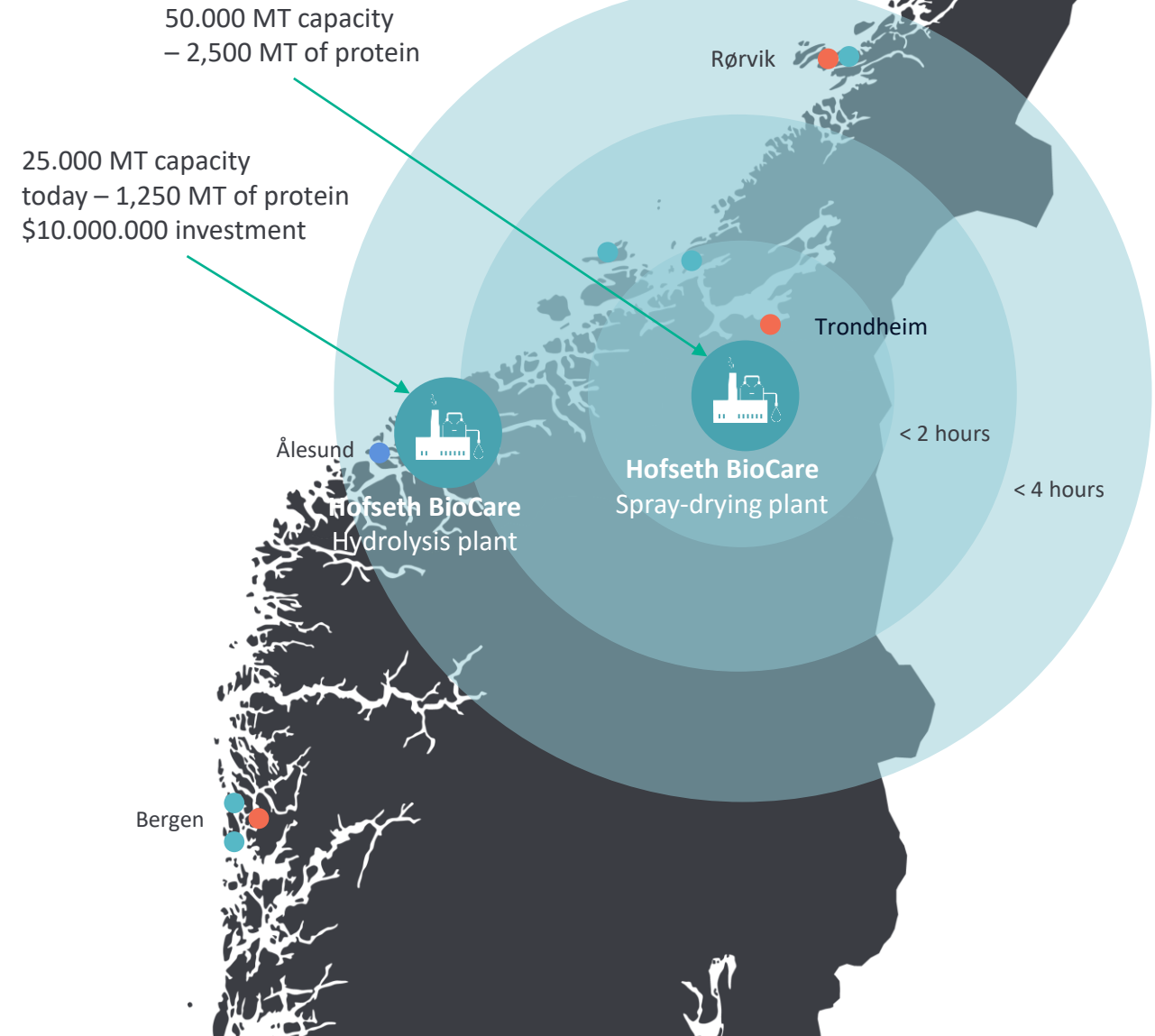
Turning our second factory into a hydrolysis plant

Norway

- > Total market of salmon in Norway is 1.3 million MT, of which Hofseth processes 60.000 MT
 - > **430,000 MT of raw material**
 - > **Translates to 21,000 MT of protein hydrolysates**

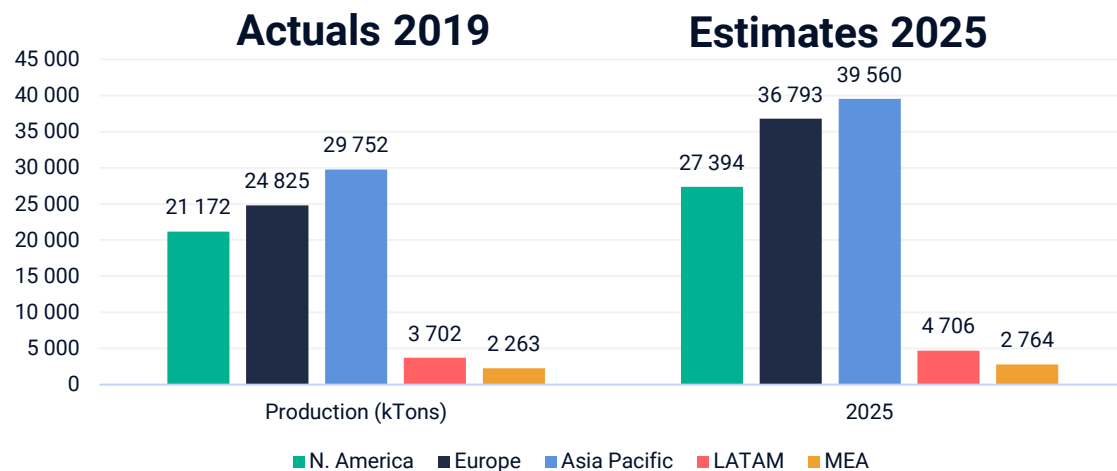
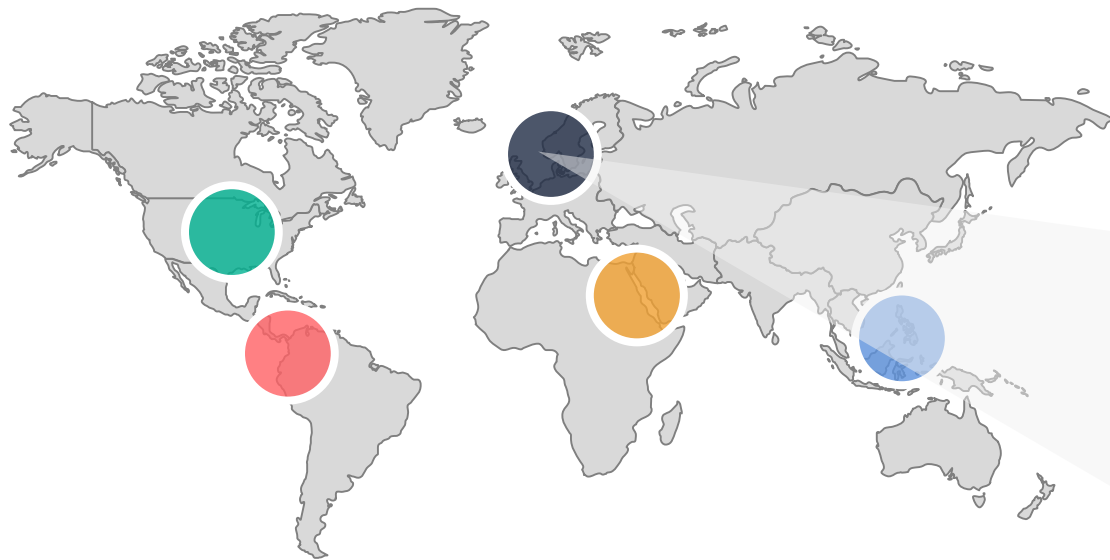
Global

- > 40 million MT of (all species) marine by-products
 - > **Translates into 2 million MT of additional protein**



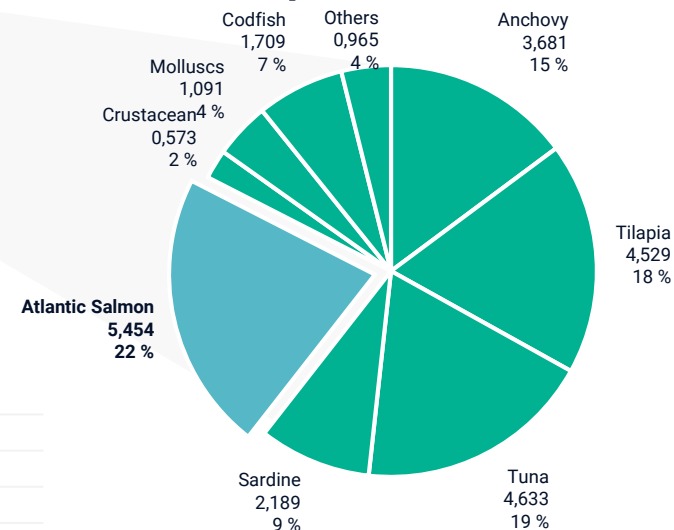
World, Europe and Hofseth BioCare production forecasts

Production of Fish Protein Hydrolysates

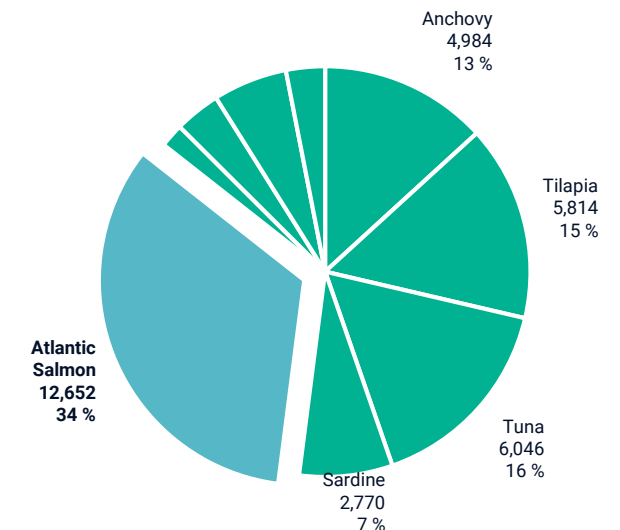


Total European Fish Protein Hydrolysates Market of 24,825 (Kilo Tons) in 2019

Actual production 2019



Estimates 2025



European Fish protein hydrolysates are expected to grow from 2019 to 2025 with a CAGR of 4.5 %

HBC will grow faster than the market and is expected to produce 5,400 metric tons of SPH by 2025, representing 42.7 % of the Atlantic salmon protein hydrolysate production and 14.3 % of the total European (all species) production

Atlantic Sapphire Joint Venture

- November 1st 2019 announced the signing of a Letter of Intent to establish a joint venture in Miami, Florida, USA.
- The intention of the JV is to build and operate a facility in Miami, FL to produce valuable by-products from salmon off-cuts supplied by Atlantic Sapphire.
- HBC's proprietary intellectual property will be leveraged to produce refined products such as salmon oil, proteins and calcium products for the feed, pet and human consumption market.
- Atlantic Sapphire and HBC aim to enter into a definitive agreement in Q1 2020, begin limited production in Q4, 2020 and increase output once Atlantic Sapphire begins 20,000t (HOG) annual production.
- AS are targeting 220KT of salmon output by 2030, equivalent to nearly 10% of global supply. This would imply 70KT of off-cuts that would need to be processed by then.

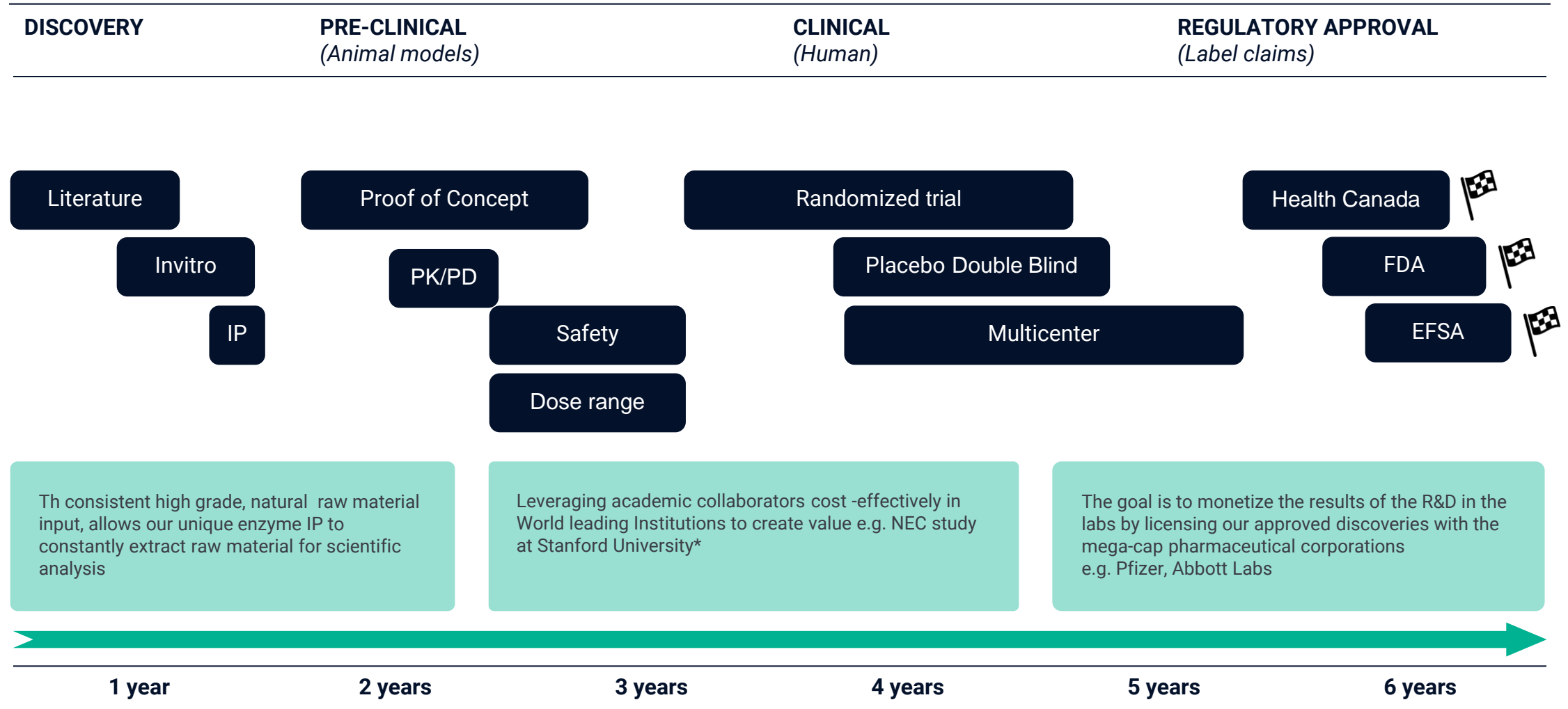


THIS IS DIFFERENT

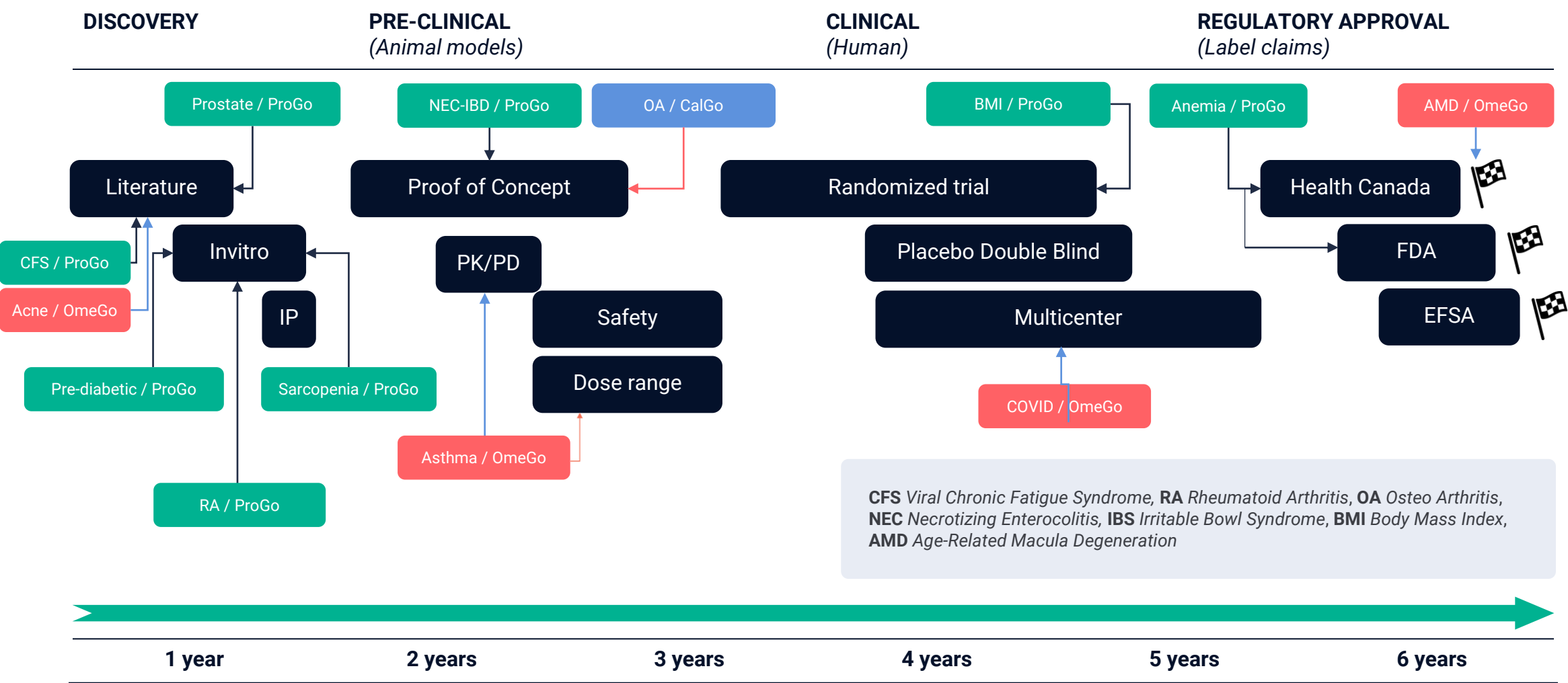
AN EMERGING BIOTECHNOLOGY COMPANY



R&D in HBC



R&D Project Timelines



HBC's R&D

FOCUS ON ANTI-INFLAMMATORY & ANTIOXIDANT BENEFITS

OmeGo® ProGo® CollaGo® CalGo®

- Key to health & healthy ageing
- From healthy subjects to chronic diseases the body is trying to balance inflammation
- Preventative health through to the targeted treatment of chronic disease
- Leading potential indications
 - **correction iron deficiency anaemia** with upcoming label anticipated from Health Canada Aug-20
 - **mild to moderate ulcerative colitis** with ongoing collaboration at Stanford University
 - **steroid-resistant asthma, COVID-19** with COVID trial initiated at Mount Sinai Hospital, Toronto
 - **osteoporosis & osteoarthritis** with clinical trials set to commence in 2020

HBC's medical research pipeline

Product	Product Fraction	IP	Discovery (~1y)	Pre-Clinical (~2y)	Clinical (~2-3y)	Regulatory approval (~1-2y)
Salmon Protein Hydrolysate (SPH) ProGo® & CollaGo®	SPH-FTH1	✓	Iron Deficiency Anemia Treatment			Health Canada (filed) → FDA S/F claim
	SPH-CollaGo	✓	Skin Health Treatment & Antioxidant			Health Canada (filed) →
	SPH-HO1	✓	Gastrointestinal Health			
	SPH-ProGo	✗	Healthy Weight loss			
	SPH-XX	⌛	Sarcopenia ¹⁾			
	SPH-XX	⌛	Pre-Diabetic Co-treatment			
	SPH-XX	⌛	Rheumatoid Arthritis ²⁾			
Salmon Oil (SO) OmeGo®	SO	✓	Improved AREDS Formulations for AMD Treatment			
	SO-LP	✓	Asthma Co-treatment			
	SO-LP	⌛	Acne treatment			
	SO-OxLDL-Gp1	✓	Cardiovascular Health			
	SO-CoV19	⌛	COVID-19 Co-Treatment			
Salmon Bone Powder CalGo®	SBP-XX	⌛	Osteo Arthritis			
	SBP-CalGo	⌛	Osteoporosis Treatment			






1) Age-Related Sarcopenia Treatment
2) Rheumatoid Arthritis Co-Treatment

✓ Filed/Approved
 ✗ Not applicable
 ⌛ In progress




Initiated
 Ongoing
 Approved

Value creation in these Future Indications



Salmon Peptide Hydrolysate, ProGo[®]

-  Reducing gastrointestinal (GI) inflammation: necrotizing enterocolitis & ulcerative colitis
-  Increasing hemoglobin and reducing iron deficiency anemia
-  Weight Management - BMI Reduction
-  Reduction of Sarcopenia Muscle Loss
-  Prediabetic co-treatment

Salmonid oil, OmeGo[®]

-  COVID-19 anti-inflammatory co-therapy
-  Eosinophilic Asthma co-treatment
-  oxLDL-GP reduction for Cardiovascular Health

Marine bone powder, CalGo[®]

-  Osteoporosis & osteopenia
-  Joint health in early osteoarthritis

ProGo[®] bioactive peptides & treatment GI inflammation

- Our GI research work continues with Stanford University with a new two-year collaboration announced recently.
- Preclinical research continues in necrotising enterocolitis (NEC) & ulcerative colitis (UC).
- Clinical trial work is planned to start in 2021 in adult subjects with mild to moderate ulcerative colitis
- Oxidative stress is a common mechanism for many diseases associated with the gastrointestinal (GI) tract.
- ProGo[®] has been shown to up-regulate protective antioxidative stress genes and lower pro-inflammatory cytokines offering a potential GI-protective role for the peptides.



Two-year research collaboration contract signed with Stanford on the use of Salmon Protein Hydrolysate peptides for the treatment of GI tract diseases in children and adults

11.05.2020

Background to ulcerative colitis (UC)



Chronic inflammation of the colon with diarrhoea, pain, fever, weight loss

>1mn patients in US & EU5 with onset in 20's & 30's

Treatment advances have been focused on injectable, biologic therapies for severe UC

Unmet need = control symptoms & limit long-term side effects in mild to moderately severe UC

Ulcerative colitis market

Oral / topical:

- 5-ASA agents incl. Lialda, Pentasa & Asacol with >\$2bn sales at peak
- Steroids but long-term consequences incl. osteoporosis, hypertension, diabetes, cataracts
- Azathioprine, 5-mercaptopurine but safety risks including infections, lymphoma, skin cancer
- JAK inhibitor Xeljanz but risk serious infections, cancer and blood clots

Injectable:

- Anti-TNFs: Humira, Remicade, Simponi multi-billion \$ sales but risk serious infections & cancer
- Anti-integrin Entyvio annual sales >\$3bn but risk infections and potential PML risk

Background to NEC

- Prevalence of ca 7% in infants with a birthweight of 500-1500g & risk increases with diminishing birth weight.
- Significant morbidity and mortality: 10%-50% in infants weighing less than 1500g.
- No improvements in outcome in recent years but the understanding of the underlying process has greatly increased including an immature intestinal barrier & immune system and bacterial translocation.
- The end result: a dysregulated inflammatory response which can spread through the body with long term consequences including neurodevelopmental impairments & death.
- A deficiency in heme oxygenase (HO) activity appears an important element in the inflammatory process with activation of HO resulting in:
 - An increase in blood supply to the gut
 - An increase in regulatory T-cells (Tregs) and reduction in effector T-cells (Teffs) to rebalance mucosal immuno-activity
 - Improved GI barrier function

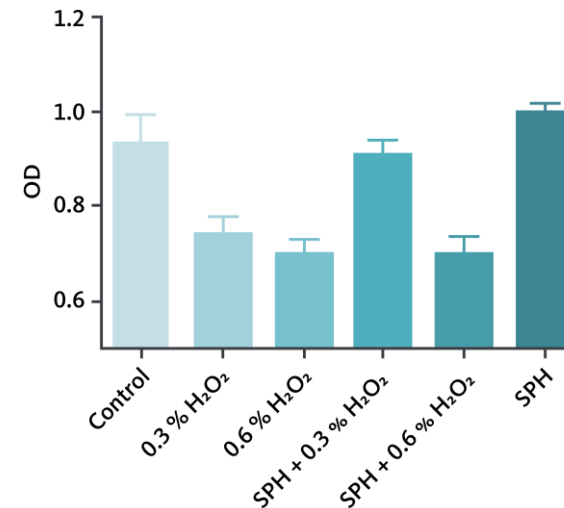
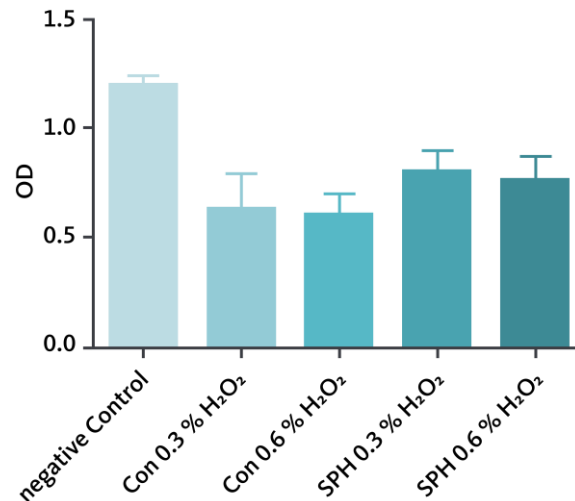
Preclinical work in Necrotising Enterocolitis (NEC)

- Our collaboration with Stanford University has assessed ProGo[®] in an animal model of NEC.
- Tissue injury was assessed biochemically & compared between ProGo-pretreated mice and their controls.
- The results are very exciting: a protective effect of ProGo[®] in neonatal mice was consistently shown with a significant reduction in gut injury from chemically-induced oxidative-stress.
- Gene expression analyses are ongoing; previous study work with ProGo[®] showed a significant upregulation in genes associated with protection against oxidative stress including **heme oxygenase** (HO), an enzyme system deficient in NEC.

NEC-study results: GI-protection in a mouse model

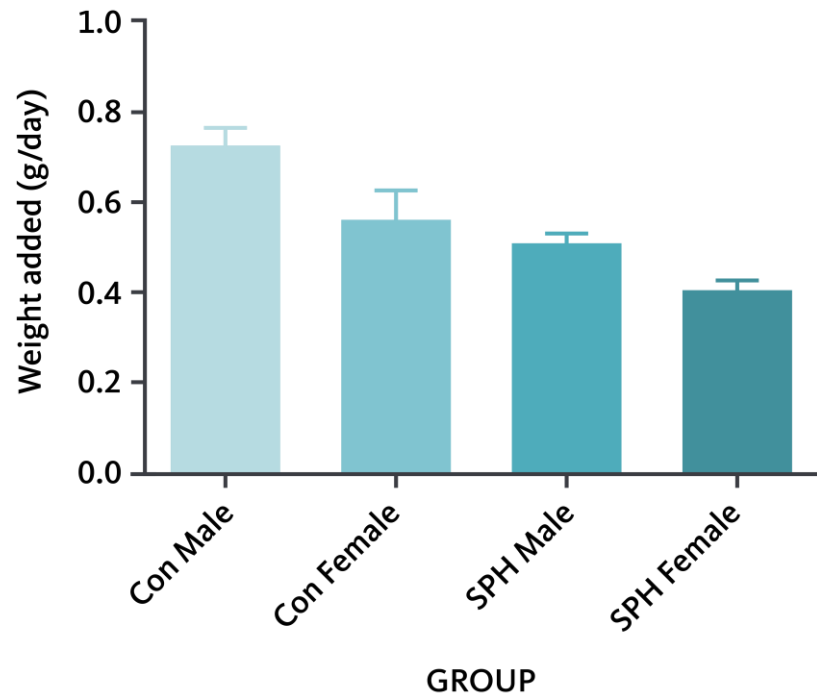
Protective effect on GI tract demonstrated with ProGo using a mouse model of NEC

- Oxidative stress-induced gut injury with 0.3% hydrogen peroxide (H_2O_2) measured via keratin 8 (K8) fecal protein level
- K8 is a structural protein within the epithelial lining of the gut and therefore a biochemical marker for injury to the epithelium
- Injury to the epithelium reduces GI barrier function with a disturbance in water & electrolyte movement & potential for immune sensitization to luminal antigens further raising levels of inflammation
- ProGo® pre-treatment diminished oxidative stress (0.3 % H_2O_2)-induced gut injury in neonatal mice
- Note optical density / OD (in the graphs below) is reversely related with fecal K8 protein level so lower the OD the greater the GI damage



NEC-study: GI protection & bioactive peptides

Weight gain in neonatal mice in NEC study

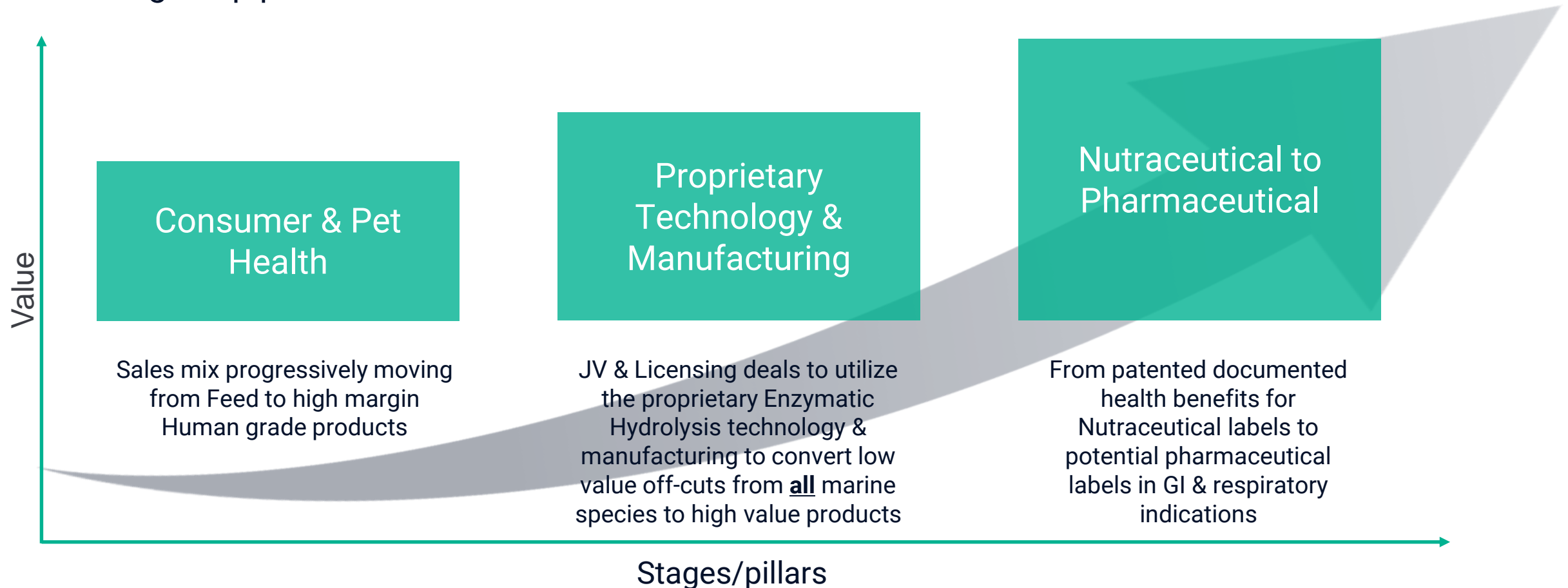


- Control animals gained more weight compared to mice who received ProGo[®] & H2O2
- This would suggest that the mechanisms of GI-protection by ProGo are unlikely nutritional, rather a bioactive effect
- ProGo peptides upregulate a number of oxidative protective stress genes including HMOX1 which encodes heme oxygenase (HO)
- A deficiency in HO has been seen in premature infants with NEC
- In animal models, an increase in HO activity has been noted to increase the proportion of Treg* cells thereby reducing inflammation
- Treg cells have also been shown to protect against NEC development in neonatal mice

*Treg = regulatory T-cell, a cell that modulates the immune system activity

3 Pillars for Long Term Value Creation

Long-term goal to monetize the results of the R&D in the lab by licensing discoveries with large-cap pharma & biotech



HBC trial publications

Study on digestion and bioavailability:

http://www.hofsethbiocare.com/upload_images/E11E92222C3A42E9967E7A41EEDA2372.pdf

Study on hemoglobin increase:

http://www.hofsethbiocare.com/upload_images/5B82602E6CF04155960F1D9361B2CDF0.pdf

Study on BMI reduction:

http://www.hofsethbiocare.com/upload_images/738BC74F60104FFE82197A78A519471E.pdf

Human uptake study:

http://www.hofsethbiocare.com/upload_images/983564E49ECE4758BE50428DA31DB6B5.pdf

Study on energy increase, improvements in hair/nail/skin health and anti-inflammatory modulation:

http://www.hofsethbiocare.com/upload_images/BE451834DD9B4925A9B1E39247EEADF6.pdf

Study on cardiovascular health:

http://www.hofsethbiocare.com/upload_images/479C92CC1C3C4F3EB35B74183CD07D36.pdf

Study on bone growth and bone density:

http://www.hofsethbiocare.com/upload_images/3B83D8AF0AE846C9B3D99CA4B7AA8BF3.pdf

Study on human osteoblast cell proliferation:

http://www.hofsethbiocare.com/upload_images/D2CA82B1D7164AC18C1AA48ED49675F4.pdf

This is different

- Only sustainable, naturally manufactured salmonid oil, hydrolyzed protein and marine calcium
- The only marine-based products from fish off-cuts with patented health benefits
- Total barriers to entry via patent protection (on all marine species) & trade secrets
- Scalability at low cost & via licensing of technology
- Fast growing consumer & pet health businesses
- Vast growth potential in aquaculture & global protein demand

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This is different™