

# Initiating Research Coverage

# healthyextracts





# Healthy Extracts, Inc.

(OTC:GRCK)

**Report Date: 09/30/20** 

12-24 month Price Target: \$.17

**Allocation: 4** 

Closing Stock Price at Initiation (Closing Px: 09/29/20): \$.06

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**Disclosure:** Portions of this report are excerpted from Healthy Extract's filings, website(s), presentations or other public collateral. We have attempted to identify those excerpts by *italicizing* them in the text.

## **Company Overview**

Healthy Extracts, Inc. ("HE") was incorporated in the state of Nevada in 2014 as Grey Cloak Tech, Inc. The Company entered the nutraceutical space via the February 2019 acquisition of BergaMet NA, LLC, a Delaware limited liability company ("BergaMet" or "BMNA"). BergaMet was an operating enterprise at the time of the acquisition and it represents one of the Company's two major wholly owned business units. Further, in 2020, the Company acquired Ultimate Brain Nutrients, LLC ("UBN"). UBN now represents the Company's second major business unit. As a result of these transactions, Healthy Extracts is now focused on the development and commercialization of science-based nutraceutical products, and their strategy includes a multipronged marketing approach.

Specifically, bergamot, or citrus bergamia, is a rare citrus fruit native to the Calabrian region of Southern Italy. Due to sensitivity to the weather and soil conditions, this region accounts for 80 percent of the worldwide production of bergamot. This superfruit has been used for decades in the Calabrian regions for its beneficial effects in promoting overall health particularly in support of cholesterol, cardiovascular, and metabolic health. We will provide additional information below regarding the potential health benefits of bergamot. While BergaMet is not the only company currently marketing a bergamot-based nutraceutical, as we understand it, the Company does have an exclusive arrangement with a large Italian bergamot producer named H&AD. The arrangement provides HE with a higher potency product, which the Company believes (and studies support) allows them to provide a higher quality and more effective product than perhaps other bergamot-based products in the marketplace. While the Company has been selling bergamot-based products for some time, they have just recently developed the infrastructure, as well as several new products to scale those marketing efforts. We will discuss that further as well.

In addition to the bergamot line, the Company recently acquired Ultimate Brain Nutrients ("UBN"). *UBN is a science-based company that develops unique*, *plant-based superior health technology neuro-products that improve brain health, including memory, cognition, focus and neuro-energy. UBN's proprietary formulations target brain activity, focus, migraine headache and cognitive behavior and provide multiple intellectual property license opportunities for monetizing the company's portfolio. Sales and licensing opportunities include multiple beverage formats, individual products, proprietary mixtures and other food platforms. <i>UBN has five unique formulation patents – one issued and four pending – targeting brain activity, focus, migraine headache and cognitive behavior.* Like BergaMet, UBN was an established enterprise at the time of the acquisition, and HE's charge is to further develop the brand and scale the marketing efforts around it.

As we noted, each of the Company's two brands were established and operating at the times they were acquired. There is a bit of back story to that nuance, which we will cover in the segments below, but from the "10,000 foot view" the business really involves combining these pieces and layering on some people with proven marketing success, as well as capital provided by the public platform. The Company's view is that the combination of these elements, with what they believe are natural supplements with science-based efficacies that address a handful of pervasive and growing health problems including those impacting cardiovascular and brain health, will provide the basis for success that will translate into higher valuations for the reconstructed public vehicle.

In the past, we were fortunate enough to get involved early in another public nutraceutical story that like HE shares our Colorado roots. We are constructive on the prospects that we have perhaps discovered another of those opportunities.

# **Industry and Regulatory Overview**

#### Market Size and Market Share

The nutraceutical industry is large and growing. As with most large international industries, the estimates of the size and anticipated growth are a matter of methodology, interpretation and opinion, but, for a point of reference, most estimates put the current international market somewhere between \$200-\$300 billion, and most seem to believe that the industry will achieve CAGR's in the 6% to 8% range. Again, the global industry is large and growing.

The term "nutraceutical" was apparently coined in 1989 by Dr. Stephen L. DeFelice, founder and chairman of the Foundation of Innovation Medicine (<a href="https://fimdefelice.org/">https://fimdefelice.org/</a>). Obviously, the term is a blending of the words nutrition and pharmaceutical. Interestingly, over the years, Dr. Felice's work has focused on what is ultimately some of the "rub" in terms of the perceived efficacy and perhaps even the safety of many nutraceuticals, especially in the context of pharmaceuticals that are ultimately subjected to significant clinical rigors that nutraceuticals generally are not. We will address some of that "rub" as well as some of the regulatory nuances below, but first, recognize that today the term nutraceutical is a largely generic term that includes a host of products that make up the multi-billion-dollar industry. While people inside and outside the industry have different ways of dividing it up, it is often broken down into two categories: "Supplements" (vitamins, herbs, proteins etc.) and "Functional Foods/Drinks", which include a number of natural foods, but also foods that have been fortified with proteins, probiotics and many others. As we will demonstrate, we think the Company is positioned in each of these. To that point, Company collateral includes the following graphic with respect to the market for its bergamot-based supplements:

#### TARGET MARKET SEGMENTS

within the \$140b U.S. Supplements Industry



The above market segments represent a Total Addressable Market for the Company's Bergamot SuperFruit™ supplements of more than \$65b.

There are many large players in the nutraceutical space, and they include large food and drink companies, as well as divisions of large pharmaceutical companies. Not surprisingly, the large pharma players (Abbott Laboratories, Bayer and Pfizer for instance) tend to focus on the supplement side, while large food and beverage companies (Coca-Cola Co., Kraft Heinz Company, General Mills, Inc., Kellogg Company and many others) tend to occupy the Functional food end of the industry. Further, the industry also includes several sizeable "native" players as well including names like Nu Skin Enterprises, Amway; USANA Health Sciences, Inc. and many others.

While there are certainly many large companies involved in different aspects of the industry, much of the industry research on the space still regards it as generally fragmented with many small players. For instance, a 2013 Business Insider article noted that "...in 1994, about 600 supplement companies were producing about

4,000 products ... but that market has since ballooned; today, close to 6,000 companies pump out about 75,000 products". Further, a more recent article from <a href="https://www.creativethirst.com">www.creativethirst.com</a>, notes that there are "over 432 sports nutrition brands selling dietary supplements online".

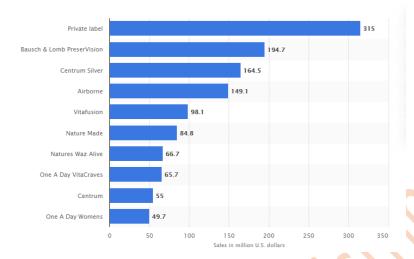
The above said, despite the many small players, we suspect the largest players in the space collectively dominate market share. For example, <a href="https://www.byclue.com/nutritional-supplement-overview/us-supplements-industry/">https://www.byclue.com/nutritional-supplement-overview/us-supplements-industry/</a> notes the following:

The U.S. is the world's biggest nutritional supplement market: the biggest sales volume, the greatest number of manufacturers and brands, and the most developed market in terms of number of ingredients and finished products. Large companies benefit from economies of scale of manufacturing, research, and marketing. Small companies can compete effectively by specializing in niche nutritional products, or through advanced product development efforts. The U.S. supplement industry is highly concentrated: the top 50 companies account for more than 80% of revenue. The below chart (from <a href="https://www.woodstockvitamins.com">www.woodstockvitamins.com</a>) illustrates a list of major players:

# The 14 Mega-Corporations That Own Your Supplement Brands



We submit, we do not vouch for the accuracy of the "more than 80% of revenue" estimate above, but looking at the players and the brands, we think it may certainly be in the ballpark. By way of example, as most will notice, many of the brands listed above are mass market brands sold at mass market retailers. For instance, Bayer's "One A Day" and Pfizer's "Centrum" are widely recognizable multi-vitamins while Japan's Otsuka Pharmaceutical owns Nature Made, which is a well-known vitamin line and other supplements brand often found in grocery stores and other large retail chains. According to industry research firm Statista (www.statistia.com), while in 2019 private label supplements represented the largest "portion" of the US supplement market, the three aforementioned brands alone collectively outsold the entire private label group:



With respect to Healthy Extract's opportunities, we would reiterate two items from above. First, "small companies can compete effectively by specializing in niche nutritional products, or through advanced product development efforts" and second, while large heavily marketed brands may collectively dominate the space, "private label supplements represent the largest "portion" of the US supplement market".

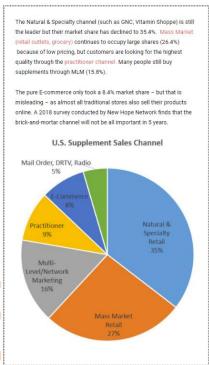
#### • Market Segments and Sales Channels

The "nutraceutical industry" includes participants all along the supply chain. There are large integrated players like the pharma and food/beverage giants we noted above, that have the resources to research, develop, manufacture and market supplements and functional foods at scale. Further, some of these companies are also able to leverage their brand and adjunct relationships (distribution for instance), to drive awareness and ultimately consumer demand for their products.

On the other end of the spectrum, there are numerous smaller players focused on one end of the supply chain or another, or on various points in-between. For instance, there are companies that produce and sell the raw materials that go into supplements, developers/manufacturers that develop their own proprietary blends that others can white label, contract manufactures that will manufacture the proprietary blends for others and enterprises that may utilize one of more combinations of these to create products that they brand and then market themselves. There are also companies in the industry that may do all or other combinations of those things and while some of these companies may serve portions of the supply chains of some large pharma and F&B players like those we mentioned previously, many of these companies service the smaller participants that do not have the scale or the resources to support fully integrated operations. Again, to compete, these smaller players generally need to develop more specialized/niche products, and at least in our experience, those products may need to include more science-based development that can help differentiate them in the marketplace. As an alternative (or better yet an adjunct), smaller players, especially on the downstream (consumer product) end of the spectrum have also managed to succeed in the industry by developing and executing savvy marketing campaigns, processes, and platforms, which brings us to our next point.

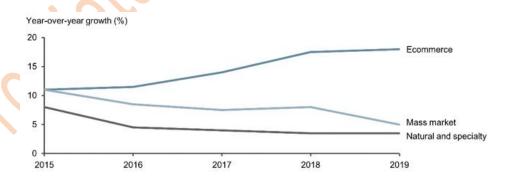
While the nutraceutical supply chain is diverse, the sales channels within the industry are equally fragmented. As we suggested above, some of the industry's large integrated players typically rely more on some of their more traditional and established distribution conduits like grocery and/or drug store chains as well as other large mass retailers.

Absent those types of big box relationships, smaller companies may need to rely on one or more of the other available sales channels to succeed. Again, in our experience, finding the "right" channel or perhaps synergistic combination of channels is generally paramount to the success of these participants. Moreover, we have seen instances where (ultimately) successful companies started off (and failed) selling through a particular channel, specialty retail for instance, and then pivoted their marketing efforts into another channel like multilevel/network marketing and became quite successful. Frankly, we are not sure if that implies that one channel may necessarily be optimal for one formulary or indication versus another, we just know that some organizations end up doing better in some channels than in others and as such, finding that "right" channel(s) is important. As we will delineate further in this report, HE has developed and is deploying a multi-channel approach that they believe will prove effective.



Sales Channel

As an extension of the above, while Mass Market Retail has represented a significant channel for the nutraceutical industry, that reality may say more about the clout of some of the industry's larger players than it does the overall effectiveness of the channel. Clearly, some of that dynamic is driven by the notion we raised prior, which is that large pharma, as well as large food & beverage companies in the space have substantial distribution, slotting and other marketing advantages in the big box retail theatre that smaller nutraceutical brands simply do not have. While that factor bodes well for those larger companies, it is perhaps ominous for the smaller brands. However, as the graphic below suggests, over the past few years the nutraceutical Ecommerce channel has experienced more robust growth than both mass retail and specialty retail. Moreover, the Covid19 pandemic has driven more sales of just about everything online, and while there is no way of ascertaining how sticky that dynamic might prove to be post pandemic, we suspect the industry trend may continue to favor online sales versus traditional mass retail. We will discuss the impact of Covid19 further below.

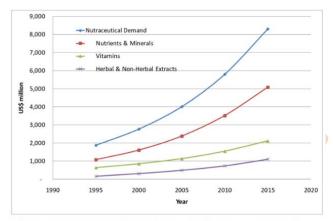


\*Other channels include MLM, Practitioner, Mail/DRTV/Radio and are ~25% of 2019 VMS sales

Source: Nutrition Business Journal (NBJ) https://www.lek.com/insights/ei/impact-covid-19-vitamins-minerals-and-supplements

#### Consumers

Not uniquely, the nutraceutical industry is driven by consumer attitudes, perceptions and demands that are shaped by the prevailing environment, which is in turn impacted by a host of influences including economics, government, media, industry marketing and others. From our perspective, the current pandemic has taught us quite a lot about the influence that some of these factors have on citizens/consumers. Specifically, since the time that Dr. DeFelice coined the phrase in 1989, consumer acceptance/demand for nutraceuticals has risen markedly. A (2018) News Medical Life Sciences article notes:



Nutraceutical demand by product group (US\$millions). Source: Freedonia Group, 2006. World Nutraceuticals industry forecasts to 2010 & 2015.

Although nutraceuticals as an industry emerged in the early 1990s, the world has witnessed its explosive growth in the first decade of this century. From 1999 to 2002 the industry grew at an annual average growth rate of 7.3 percent, while in this century the rate doubled to 14.7 percent.

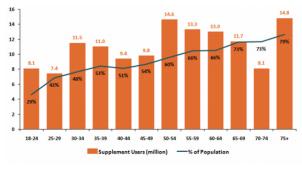
 $\underline{https://www.news-medical.net/health/Nutraceutical-ndustry.aspx \#: ":text=From\%201999\%20to\%202002\%20the, estimated\%20at\%20117\%20billion\%20USD.$ 

The above noted, it begs the question, "given the robust sustained growth of the industry, which groups of consumers are taking all these nutraceuticals and why?". It turns out, the question to those two questions are "most of them", and "for a variety of reasons". As the graphics below regarding supplements illustrate, nearly 4 in 5 U.S. adults take a supplement, and while historically, those number tend to increase with age, they include nearly every adult demographic:

# Who Takes Dietary Supplements? And Why? 770 of U.S. adults take dietary



2019 CRN Consumer Survey on Dietary Supplements www.crnusa.org/2019survey



http://greencirclecap.com/vms-nutra-value-nov-2017-white-paper/

Source: Simmons Market Research, Winter 2016 Simmons NCS Adult Study 12-Month

The top reason Americans take supplements is for overall health and wellness benefits followed by:

24% Energy

20% Immune health

19% To fill nutrient gaps

18% Healthy aging

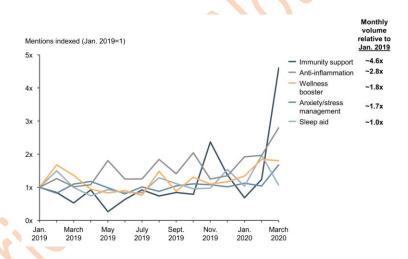
18% Heart health

2019 CRN Consumer Survey on Dietary Supplements www.crnusa.org/2019survey

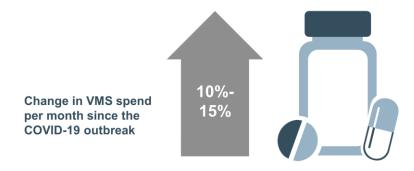
Further, there are various reasons consumers use supplements and the weighting of some of those reasons are diverse and we suspect that some of these tend to be more topical to certain demographic groups. For instance, "Healthy Aging" is probably a more popular response from older portions of the population, while perhaps "To Fill Nutrient Gaps" might be more topical to younger groups whose busy lifestyles may negatively impact their eating habits and general nutrition. Moreover, emerging macro variables also shape the general as well as specific demand of the industry. For example, as some of the graphics/narrative below indicate, the Covid19 pandemic has had a marked effect on recent demand for many supplements.

The following graphics and narrative provide some interesting insights regarding the (start of the) pandemic and supplement perception and demand. From: <a href="https://www.lek.com/insights/ei/impact-covid-19-vitamins-minerals-and-supplements">https://www.lek.com/insights/ei/impact-covid-19-vitamins-minerals-and-supplements</a> ("VMS" is Vitamins, Minerals and Supplements)

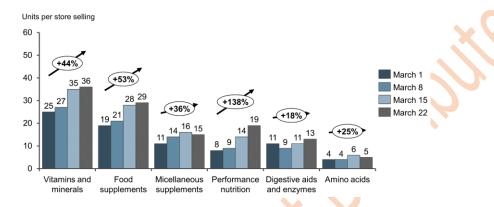
"...Over the past two months as COVID-19 has affected the U.S., consumers have increasingly turned toward VMS products, expressing greater interest in and engagement with the category. Analysis of social media activity related to VMS use cases (see Figure 2) clearly reflects this increasing engagement as customers look to boost their overall health and wellness as a precaution against illness".



"...Based on L.E.K. Consulting's recent consumer research in partnership with Civis Analytics (3/31-4/2), consumer interest in VMS on social media is translating into behavior. On average, consumers are reporting an increase in monthly spend on VMS products of 10%-15% since the pandemic began (see Figure 4)".



"...Unsurprisingly, the bulk of activity has occurred in products related to immune health. Consumer chatter about vitamin C, vitamin D, elderberry and echinacea spiked by 3x-16x in March. Manufacturers along these value chains are experiencing this pull-through, with suppliers reporting demand increases of more than 20%. Surprisingly, recent sales data suggests that the growth has extended beyond immune health. Based on SPINS data from a recent NBJ webinar, overall vitamins and minerals, food supplements, performance nutrition, digestive aids and enzymes, and amino acids all experienced growth in weekly sales of approximately 20%-140% over the final three weeks of March":



Again, we have no idea if this will persist post Covid19, or for that matter whether this phenomenon has something to do with consumers being isolated etc. However, in our view, we are more inclined to believe that people will be more likely to look to supplements for thing likes boosting their immunity because of Covid19 than perhaps would have had Covid19 never happened. We think that may be true of other co-morbidities that seem to be associated with more acute Covid19 outcomes. For instance, we think the pandemic will likely drive demand for supplements that might improve known covid19 co-morbidities like cardiovascular disease and diabetes.

## Regulation

The regulation of nutraceuticals is a bit of a hot button issue. Certainly, some of the consternation around the industry has to do with the federal regulation (or in some views the lack thereof) of nutraceuticals.

First, much of the regulation around the nutraceutical industry stems from the **Dietary Supplement Health** and **Education Act of 1994 ("DSHEA")**. Recognize, the Act essentially defines nutraceuticals as "foods" rather than drugs. The Act largely places labeling/disclosure responsibilities on sellers that require that statements regarding the nutritional value supplements must include disclaimers on the product label. Those disclaimers must include language that notes the supplement "has not been evaluated by the FDA" and that the product is not intended to "diagnose, treat, cure or prevent any disease."

The language of the Act includes the following definition.

Dietary Supplement Health and Education Act of 1994 - Amends the Federal Food, Drug, and Cosmetic Act to define a "dietary supplement" as a product: (1) other than tobacco, intended to supplement the diet that contains a vitamin, mineral, herb or botanical, dietary substance, or a concentrate, metabolite, constituent, extract, or combination of the above ingredients; (2) that is intended for ingestion, is not represented as food or as a sole item of a meal or diet, and is labeled as a dietary supplement; (3) that includes an article approved as a new drug, certified as an antibiotic, or licensed as a biologic and that was, prior to such approval, certification or licensure, marketed as a dietary supplement or food, unless the conditions of use and dosages

are found to be unlawful; and (4) excludes such articles which were not so marketed prior to approval unless found to be lawful. Deems a dietary supplement to be a food. Excludes a dietary supplement from the definition of the term "food additive."

(Sec. 4) Deems food to be adulterated if it is a dietary supplement or contains a dietary ingredient that: (1) presents a significant or unreasonable risk of injury; (2) is a new dietary ingredient for which there is inadequate information to provide assurance that such ingredient does not present such risk; (3) poses an imminent hazard to public health or safety; or (4) contains an ingredient that renders it adulterated.

(Sec. 5) Provides that a publication shall not be defined as labeling when used in connection with the sale of dietary supplements when it: (1) is not false or misleading; (2) does not promote a particular manufacturer or brand of supplement; (3) is displayed so as to present a balanced view of the available scientific information; (4) is displayed physically separate from such supplements; and (5) does not have appended to it any information by sticker or other method. Places the burden of proof on the United States in establishing that such matter is false or misleading.

- (Sec. 6) Sets forth conditions under which nutritional claims may be made with respect to such supplements.
- (Sec. 7) Deems a dietary supplement misbranded unless its labeling meets specified guidelines.
- (Sec. 8) Deems a dietary supplement which contains a new dietary ingredient adulterated unless: (1) such supplement contains only ingredients which have been present in the food supply as articles used for food in a form in which the food has not been chemically altered; or (2) there is a history of use or other evidence of safety regarding such supplement.
- (Sec. 9) Authorizes the Secretary of Health and Human Services to prescribe good manufacturing practices for dietary supplements to be modeled after those for food.
- (Sec. 12) Creates the Commission on Dietary Supplement Labels. Authorizes appropriations.
- (Sec. 13) Establishes an Office of Dietary Supplements within the National Institutes of Health. Authorizes appropriations.

Recognize that the FDA is primarily tasked with much of the enforcement of the Act, which largely includes the labeling of products as well as oversight of good manufacturing practices ("GMP"). It also places the burden of proof on the Food and Drug Administration to demonstrate that a product is unsafe. However, *the advertising* of nutraceuticals falls under the jurisdiction of the Federal Trade Commission. The FTC describes its symbiosis with the FDA as follows:

The Federal Trade Commission ("FTC") and the Food and Drug Administration ("FDA") work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

In 1994, the Dietary Supplements Health and Education Act (DSHEA) significantly changed the FDA's role in regulating supplement labeling. 2 Although DSHEA does not directly apply to advertising, it has generated many questions about the FTC's approach to dietary supplement advertising. The answer to these questions is that advertising for any product — including dietary supplements — must be truthful, not misleading, and substantiated. Given the dramatic increase in the volume and variety of dietary supplement advertising in recent years, FTC staff is issuing this guide to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising.

To a lesser extent, the industry is also regulated by the <u>Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006</u>, which essentially requires that nutraceuticals marketed/sold in the U.S. require labeling which includes "a domestic address or domestic phone number through which the responsible person ... may receive a report of a serious adverse event with such dietary supplement." Obviously, the goal of the Act is to provide a framework through which adverse effects can be identified and then communicated to the public.

Clearly, the objective of nutraceutical regulation is to first "do no harm". That is, unless the FDA determines and proves otherwise, with some nuance, nutraceutical companies are free to develop and market formularies from known safe foods, including vitamins, herbs, minerals etc. (those that are not "adulterated") without conducting rigorous scientific trials aimed at establishing clear efficacy. On the other hand, because of that lack of scientific rigor, those companies are limited in terms of what/how they can label and otherwise advertise those products with regards to their effectiveness in addressing specific ailments or diseases.

Generally speaking, outside of the "adulterated" wrinkle, the FDA essentially takes the position of *no position* on the effectiveness of nutraceuticals. That is clearly quite different than the means or the end to the FDA approval process it applies to drugs. However, the FDA does have processes that allow nutraceutical companies to present scientific data that may support the basis for providing more definitive claims regarding the efficacy of their products. The FDA refers to these designations as "Authorized Health Claims" and/or "Qualified Health Claims". The following descriptions and examples of each are from the FDA, www.fda.gov.

#### Authorized Health Claims

To be approved by the FDA as an authorized health claim, there must be significant scientific agreement (SSA) among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship.

An example of an authorized health claim is, "Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life."

When the FDA evaluates a health claim, the agency considers the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles). If there is significant scientific agreement (SSA) among qualified experts that the claim is supported by the evidence, the agency will authorize by regulation a health claim for the substance/disease relationship.

The FDA has provided just 12 Authorized Health Claims since 1990.

#### Qualified Health Claims

Qualified health claims are supported by some scientific evidence, but do not meet the significant scientific agreement standard. To ensure that they are not false or misleading to consumers, qualified health claims must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. Qualified health claims are currently evaluated under the FDA's interim guidance for such claims.

An example of a qualified health claim is, "Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2."

In response to litigation that raised First Amendment challenges to the significant scientific agreement standard, the FDA in 2000 announced its intention to exercise its enforcement discretion with regard to certain categories of dietary supplement health claims that may not meet this standard. In 2002, the FDA extended this approach to health claims on conventional foods. The assumption underlying this approach is that disclaimers will remedy any potential harm caused by potentially misleading claims.

As we will illuminate further in this report, the Company currently has data in front of the FDA seeking a Qualified Health Claim designation.

#### The Rub

Recognize, the nutraceutical industry has its share of detractors, and most of those are of the view that the industry lacks appropriate oversight and regulation. Some view the industry as largely "snake oil" with little or no *scientific proof* of its efficacy and in some cases too little attention paid to potential safety concerns over at least some of the industry's thousands of products/iterations.

On the other hand, there are others, many with considerable appropriate credentials, who believe that the entire FDA approval process is too onerous and too expensive, and as a result impedes the availability of supplements, formularies etc., with demonstrable efficacy and safety profiles that collectively *could* improve healthcare outcomes and reduce healthcare costs. In short, there are many of the view that just because a supplement or formulary has not been subjected to standard FDA approval rigors, does not mean that it is not effective. Further, they also believe that just because studies (or even anecdotal summaries) of some of those same supplements and formularies were not conducted via the same standards as those typically followed in an FDA approval process, does not make them worthless or otherwise unworthy of consideration. Frankly, we have seen some similar division in the medical community recently with things like hydroxychloroquine and even with respect to vaccines and other potential virus prophylactics. Clearly, some view FDA rigors as the firewall between "snake oil" nutraceuticals and the unwitting public, while others view the FDA as the mote that protects the lifeblood and profits of big pharma. The reality is probably somewhere in between.

The above said, what we find particularly interesting about the nutraceutical/pharmaceutical "rub" is the public's apparent collective perceptions of each. Oddly enough while most of the arguments from the nutraceutical detractors fall under the guidelines of protecting the public from fraud, nearly 4 out of 5 adult consumers take some sort of supplement. That apparently suggests that most people are not convinced that they are being "protected". We submit, there are not a lot of things that 80% of U.S. adults agree on.

Conversely, a September 22, 2020 Axios/Ipsos survey (<a href="https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index">https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index</a>) notes that just 39% of those asked said they would be willing to receive a first generation covid19 vaccine. So

then, *nearly* 80% are comfortable taking a supplement that is not confirmed and approved via FDA rigors, but *less than* 40% are comfortable taking a vaccine that is. People can glean whatever they would like from that, but to us, it suggests that the public is more skeptical about pharmaceuticals and approvals than some of the experts who insist on the same.



#### **Brand and Product Overview**

To reiterate, the Company currently operates two wholly owned subsidiaries, each focused on building a suite of formulations around a science-based lead ingredient, and each is focused on particular disease indications and/or physiologies. We will briefly discuss each of these subsidiaries as well as their science, technology, and products. As we noted above, the first of these companies, BergaMet NA was purchased in February 2019, while the second, Ultimate Brain Nutrients, was purchased in April 2020. There is a backstory to these transactions that we think is worth noting.

The largest shareholder of Health Extracts is a successful Denver, Colorado businessman by the name of Jay Decker. Mr. Decker has a long and successful history in the Colorado energy industry. Here is his bio:

From 1996 until its sale to Nobel Energy in 2006 for \$3.4 billion, Jay W. Decker served in various capacities for Patina Oil & Gas including President, COO and director. He was formerly the Executive Vice President and a Director of Hugoton Energy Corporation, a public independent oil company since 1995. From 1989 until its merger into Hugoton Energy in 1995, Mr. Decker was the President and Chief Executive Officer of Consolidated Oil & Gas, Inc., a private independent oil company and President of a predecessor company. Prior to 1989, Mr. Decker served as Vice President of Operations for General Atlantic Energy Company and in various capacities with Peppermill Oil Company, Wainoco Oil & Gas and Shell Oil Company. Mr. Decker received his Bachelor of Science Degree in Petroleum Engineering from the University of Wyoming.

Mr. Decker came across Bergamot while trying to find alternatives/adjuncts to statins he was taking to try to control his own hyperlipidemia. His results after using bergamot were "astounding". In short, Mr. Decker became focused on the notion of spreading the bergamot word and ultimately purchased BergaMet NA as his platform to do that. Mr. Decker's nutraceutical endeavors in that regard, also lead him to UBN, which he also purchased. We believe Mr. Decker's collective personal investment in those two assets is between \$8.5 - \$9 million. Today, because of Healthy Extract's acquisitions of BMNA and UBN, we believe Mr. Decker directly owns approximately 65% of Healthy Extract's outstanding shares.

# BergaMet NA

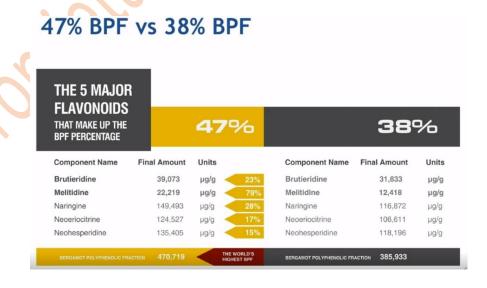
According to Company collateral:

Bergamot, or citrus bergamia, is a rare citrus fruit native to the Calabrian region of Southern Italy. Due to sensitivity to the weather and soil conditions, this region accounts for 80 percent of the worldwide production of bergamot. This superfruit has been used for decades in the

Calabrian regions for its beneficial effects in promoting overall health - particularly, in support of cholesterol, cardiovascular, and metabolic health. Citrus bergamot contains five unique antioxidant polyphenols in unusually concentrated amounts, which help protect your body's trillions of cells from free radical damage. The juice and albedo of bergamot has a unique profile of flavanoid and glycosides, such as neoeriocitrin, neohesperidin, naringin, rutin, neodesmin, rhoifolin, and poncirin. Naringin has been shown to be beneficial in animal models of atherosclerosis, while neoeriocitrin and rutin have been found to exhibit a strong capacity to prevent LDL from oxidation. Importantly, bergamot juice is rich in brutieridine and melitidine with an ability to inhibit HMG-CoA reductase, which inhibits the liver's ability to produce LDL, resulting in reduced cholesterol levels in liver cells.

To edify, today the BMNA side of the business includes five products. We will detail those later in this report. These five products all include different formularies aimed at different groups of customers. For instance, one is focused on women and another on athletes. However, each of these formularies, and we suspect any new formularies they develop going forward, have a common element, and that element is bergamot. Further, as the narrative above suggests, bergamot is only native to a small handful of regions around the world, the most prolific of which is Calabria, Italy, which is located at the country's most southern tip.

The Company sources its bergamot from a Calabria (Italy) based company called Herbal & Antioxidant Derivatives ("H&AD"). H&AD is a fully integrated producer of bergamot extracts, and they indicate that they are the leader in the space. H&AD produces many natural extracts which it sells in 20 countries around the world, and 4 of those products are bergamot based. These 4 products differ in terms of form (powders, oils etc.) as well as in terms of processing and other additives one to the next. One of those 4 products is referred to as "BPF"® or more technically, bergamot polyphenolic fraction 100%. This is the specific product that BMNA purchases from H&AD. As we understand it, BMNA has a long-term agreement with H&AD, which includes the exclusive North American rights to a high concentration version of BPF® that is 47% pure versus the standard 38%. For reference, H&AD refers to this iteration as "BPF Gold". This is an important distinction because there are a few other companies that sell bergamot based nutraceuticals in the U.S., but according to H&AD, BPF Gold is sold exclusively to BMNA in North America (thus the "NA" in BergMet NA). As we will delineate, studies suggest that bergamot may be efficacious in mitigating certain diseases, and it also suggests that dosing is topical to that success. As a result, along with other formulary nuances, we think this exclusive arrangement may differentiate BMNA's bergamot products from other competitors. The graphic below from the Company addresses the advantage of BPF Gold versus the standard form:



#### ➤ The Science

As we have alluded to, our experience in the nutraceutical space is that specific science is an important factor in the differentiation and ultimately the success of many supplements, and we think that is certainly true of niche or other *targeted* formularies/products (as opposed to more generic vitamins and minerals). In the case of bergamot, there is a considerable amount of research that has been conducted and specifically on BPF. For the sake of brevity, we are not going to try to summarize each of these studies. The Company provides links to each on their site, and we have provided a screen shot of them below for reference. The URL to these is provided as well. Notice, these studies address BPF efficacy on several disease states including Metabolic Syndrome ("MO"), hyperlipidemia (high cholesterol), diabetes, non-alcoholic steatohepatitis fatty liver disease ("NASH") and others. Just to edify, according to webMD, "...Metabolic syndrome is not a disease in itself. Instead, it's a group of risk factors -- high blood pressure, high blood sugar, unhealthy cholesterol levels, and abdominal fat". Also, for those not familiar with NASH, it is implicated in both liver cirrhosis and liver cancer, and there is currently no drug to treat it. However, both MO and NASH are generally linked to obesity and poor eating habits.

- Study shows that bergamot may help support cardiovascular and metabolic health // view The effect of bergamot polyphenolic fraction in patients with non alcoholic liver steato-hepatitis and metabolic syndrome
- Study determines which flavonoids (or polyphenols) are contained in citrus bergamot // view: Characterization of flavonoids in Citrus bergamia (Bergamot) polyphenolic fraction by liquid chromatography—high resolution mass spectrometry (LC/HRMS)
- Study determines possible benefits of particular flavonoids contained in citrus bergamot // view: Molecular mechanisms of lipid- and glucose-lowering activities of bergamot flavonoids
- Study identifies potential cardioprotective benefits of polyphenols in citrus bergamot // view: Studies on the protective role of Bergamot polyphenols in doxorubicin-induced cardiotoxicity.
- Study shows that citrus bergamot may assist in pain management // view: The protective role of bergamot polyphenolic fraction on several animal models of pain
- Study suggests that citrus bergamot may inhibit cholesterol absorption in the gut // view: Citrus bergamot improves atherogenic lipoprotein particle characteristics in patients with non-alcoholic fatty liver disease and metabolic syndrome
- Study suggests that citrus bergamot may help support a healthy liver // view: The Hepatic Effects of Citrus Bergamot Polyphenol Fraction (BPF) on Patients with Non-alcoholic Fatty Liver Disease and Metabolic Syndrome
- Study on rats shows that citrus bergamot may have a positive effect on liver health in rats // view: Bergamot Polyphenol Fraction Prevents Nonalcoholic Fatty Liver Disease via Stimulation of Lipophagy in Cafeteria Diet-Induced Rat Model of Metabolic Syndrome
- Study suggests that citrus bergamot may positively impact cardiometabolic health // view: The Effect of Bergamot-Derived Polyphenolic Fraction on LDL Small Dense Particles and Non Alcoholic Fatty Liver Disease in Patients with Metabolic Syndrome
- Study shows polyphenols specific to bergamot may help support cholesterol health // view: Bergamot polyphenolic fraction enhances rosuvastatin-induced effect on LDL-cholesterol, LOX-1 expression and protein kinase B phosphorylation in patients with hyperlipidemia
- Study suggests citrus bergamot may have support healthy aging and immune system // view: Telomere and telomerase modulation by bergamot polyphenolic fraction in experimental photoageing in human keratinocytes
- Study shows bergamot may help reduce growth rate of certain types of harmful cells // view: Hypolipemic and hypoglycaemic activity of bergamot polyphenols: from animal models to human studies
- Study suggests bergamot may help support healthy blood lipid levels // view: The Use of Bergamot-Derived Polyphenol Fraction in Cardiometabolic Risk Prevention and its Possible Mechanisms of Action
- Study suggests bergamot may support healthy cholesterol levels in certain patients // view: Use of a novel and natural antioxidant compound in the management of statine intollerance

#### https://bergametna.com/pages/clinical-studies-2

While again, providing the specifics of the numerous studies relevant to the potential efficacy of BPF is beyond the scope of this document, we have provided some sample abstracts of a few of these studies.



Contents lists available at ScienceDirect

#### PharmaNutrition

journal homepage: www.elsevier.com/locate/phanu



#### Review

## Molecular mechanisms of lipid- and glucose-lowering activities of bergamot flavonoids



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#### ABSTRACT

Bergamot (Citrus bergamia Risso et Poiteau) juice has a particularly high content and a unique composition of flavonoids. Neoeriocitrin, neohesperidin, naringin, melitidin and brutieridin represent  $more\ than\ 95\%\ of\ Bergamot\ Polyphenol\ Fraction\ (BPF),\ while\ rhoifolin,\ diosmin,\ poncirin\ and\ others\ can$ be found in the remaining 5%. The brilliant performance of BPF in clinical practice against as a treatment for hyperlipidemia and moderate hyperglycemia in metabolic syndrome, awaits a plausible mechanistic explanation. Considering the overwhelming scientific evidence, it is likely that flavonoid components of BPF are responsible for majority of pharmacological effects. Here, we will review the scientific evidence showing that flavonoids, in particular citrus flavonoids present in bergamot fruits, influence lipid and sugar metabolism at the molecular level. Anti-diabetic and dyslipidemia-correcting effects of bergamot polyphenols may be explained by their ability to activate AMP kinase (AMPK), which is a central regulator  $of glucose\ and\ fatty\ acids\ metabolism\ and\ inhibit\ cAMP\ phosphodies terases\ (PDE),\ involved\ in\ regulation$ of lipolysis in adipocytes and liver. Importantly, certain polyphenols can act as 3-hydroxy-3methlglutaryl coenzyme A (HMG-CoA) reductase inhibitors, thereby mimicking statins action. In addition, flavonoids bind and act as natural inhibitors of quinone oxidoreductase 2 (QR2/NQO2) and other enzymes with potential roles in metabolic regulation. Finally, pleiotropic and possible synergistic effects may account for enhanced nutraceutical effects of natural flavonoid mixtures, such as BPF as compared to purified flavonoids

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https://www.sciencedirect.com/science/article/pii/S2213434415300220



# Journal of Metabolic Syndrome

Gliozzi, et al., J Metabolic Synd 2014, 3:2 DOI: 10.4172/2167-0943.1000143

#### Bergamot Polyphenols: Pleiotropic Players in the Treatment of Metabolic Syndrome

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#### Abstract

Metabolic syndrome (MS) represents a clustering of risk factors related to an elevated incidence of cardiovascular disease (CVD) and type 2 diabetes. Despite the possibility of multiple pharmacological interventions to treat metabolic changes related to MS, these therapeutic strategies often exhibit several side effects and inadequately prevents CVD. Among nutraceutical compounds presenting potential efficacy in this regard, bergamot polyphenols, via their multi-action properties, have been shown to positively modulate several mechanisms involved in MS suggesting their benefits as therapy. The purpose of this review is to discuss the beneficial effects of bergamot polyphenols providing a new therapeutic approach in the treatment of MS.

https://www.hilarispublisher.com/open-access/bergamot-polyphenols-pleiotropic-players-in-the-treatment-2167- $\underline{0943.1000143.pdf\#:\text{``:text=Bergamot\%20Polyphenols\%3A\%20Pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%28IRC-pleiotropic\%20Players\%20in\%20the\%20Treatment\%20of,\%20in\%20the\%2$ FSH%29%2C%20University%20of%20Catanzaro%20%E2%80%9CMagna%20Graecia%E2%80%9D%2C%20Catanzaro%2C%20Italy The next two papers address bergamot's ability to address nitric oxide ("NO") production. As the second of these notes, NO is presumed to be critical to homeostasis. Further NO is directly related to sports performance/recovery. As we will reflect below, the Company has a sports performance/recovery product.







#### Research Article

# Bergamot Polyphenolic Fraction supplementation improves metabolic balance, endothelial function and maximal oxygen uptake in athletes

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Keywords: Bergamot polyphenolic fraction; Nitric oxide; Endothelial function; Physical exercise

#### Abstract

Background: The study aimed to evaluate the effects of a 4-week Bergamot Polyphenolic Fraction (BPF Gold; Bergamet Sport) supplementation on serum nitric oxide (NO), asymmetric dimethyl-arginine (ADMA), Endopat indices of endothelial function and maximal oxygen uptake (VO2max) of athletes.

**Methods:** The effects of dietary supplementation (BPF Gold, 650 mg twice a day for 4 weeks) and placebo administration on flow-mediated dilatation (via Endopat measurements), serum markers (NO, ADMA), lipid profile, and VO<sub>2max</sub> were analysed in 30 athletes both before and after dietary protocols.

Results: Significant differences between pre- and post-intervention baseline NO levels were observed after BPF Gold dietary protocol. Higher post-intervention baseline NO level was observed after BPF Gold diet compared with placebo. Moreover BPF Gold Sport increased baseline NO concentration ( $\Delta$ NO). The positive correlation was observed between baseline post-intervention NO concentration and maximal oxygen uptale and also between  $\Delta$ NO and  $\Delta$ VO $_{2max}$  in response to BPF Gold supplementation. There was an association between a higher Edopat values of endothelial function and higher VO $_{2max}$  after Bergamet Sport diet compared with lower values of placebo.

**Conclusion:** These findings suggest that an increase in NO release in response to BPF Gold Sport supplementation may play a central role in cardiovascular adaptive mechanisms and enhanced exercise performance in athletes.

https://www.heighpubs.org/jsmt/pdf/jsmt-aid1027.pdf



Future Sci OA. 2015 Aug; 1(1): FSO48. Published online 2015 Aug 1. doi: 10.4155/FSO.15.48 PMCID: PMC5137939 PMID: 28031863

# Nitric oxide enhancement strategies

Nathan S Bryan\* 1

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This article has been cited by other articles in PMC.

#### Abstract

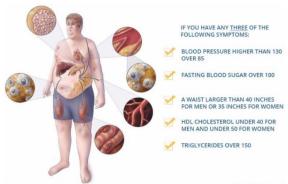
It is becoming increasingly clear that many diseases are characterized or associated with perturbations in nitric oxide (NO) production/signaling. Therapeutics or strategies designed to restore normal NO homeostasis will likely have broad application and utility. This highly complex and multistep pathway for NO production and subsequent target activation provides many steps in the endogenous pathway that may be useful targets for drug development for cardiovascular disease, antimicrobial, cancer, wound healing, etc. This article will summarize known strategies that are currently available or in development for enhancing NO production or availability in the human body. Each strategy will be discussed including exogenous sources of NO, use of precursors to promote NO production and downstream pathways affected by NO production with advantages and disadvantages highlighted for each. Development of NO-based therapeutics is and will continue to be a major focus of biotech, academia as well as pharmaceutical companies. Application of safe and effective strategies will certainly transform health and disease.

#### https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5137939/

In addition to the above, the following is some narrative from the Company's Italian bergamot manufacturer. It references some studies (these are among the list we provided above) that provide some compelling data. Following that, we have provided some other summations of study data and we have provided links to those studies.

Bergamot Polyphenolic Fraction 100% (BPF®) improves overall biomarkers of hyperlipemia via reduction of serum cholesterol, triglicerydes, LDL (the "bad" cholesterol) and small dense lipoproteins and increase of HDL (the "good" cholesterol). BPF® exerts also positive effect in the maintenance of normal serum glucose concentrations by reducing insuline-resistance.

BPF® is the most widely studied extract of the Bergamot fruit's juice and albedo, which has a unique profile of flavonoids and glycosides, such a



unique profile of flavonoids and glycosides, such as neoeriocitrin, neohesperidin, naringin, rutin,

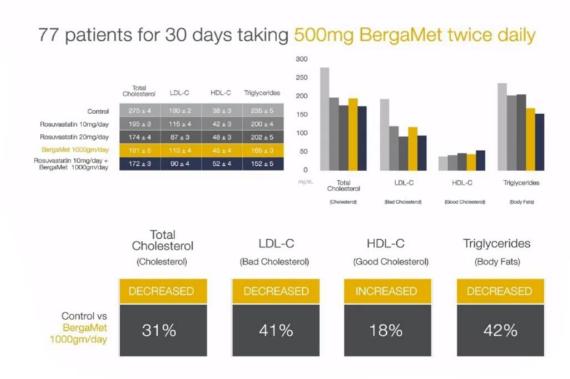
neodesmin, rhoifolin, and poncirin. These flavonoids are clinically proven to help maintaining healthy cholesterol and promoting healthy weight management. Recent studies showed that the Bergamot Polyphenolic Fraction (BPF®) represents a viable alternative to statins in patients who are intolerant to these drugs or in subjects who discontinue the treatment due to side effects. It has been proved that BPF® counteracts oxidative stress and suppresses inflammation in endothelial cells, thus inhibits plaque formation, and improvs arterial responsiveness.

https://www.head-natural.com/company/products/bpf/

#### Study Summations

The results below reflect the the impact of BPF both as a "monotherapy", and in turn in combination with a common pharmaceutical statin drug. To summarize *this study*, BPF performed better on its own than a low dose (10mg/day) of the statin, and BPF in conjunction with the low dose statin performed better overall than the moderate dose (20mg/day) of the same statin. Recognize, we are not suggesting this or any of the other trials referenced in this report are equivalent to typical FDA approval type trials. That said, on the face, we think the data are compelling. Specifically, we think BPF could help patients reduce overall statin use, and/or augment patients who are taking escalating doses of statins but are experiencing minimal marginal benefit.

# **BPF & Statins - Dose Response**



https://pubmed.ncbi.nlm.nih.gov/24239156/

The next illustration reflects results from BPF only trial that also included data regarding BPF's impact on glucose levels, which would of course be topical to diabetes:

# Metabolic Syndrome and NAFLD



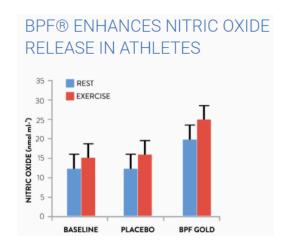


https://www.lipidjournal.com/article/S1933-2874(15)00186-5/fulltext

To reiterate, the Company has a bergamot-based product for athletes or otherwise active people. This study addresses BPF's impact on nitric oxide, heart rate and recovery. We would add, as we noted from one of the studies referenced above, the general role of nitric oxide is gathering additional clinical attention.

# BPF and Young Adult Sports Study

- Subjects: 30 Healthy Male Cyclists, Ages 23-33 Years
- Protocol: Placebo versus BPF (650 mg Twice a Day), 30 Days
- Increase (73%) in Nitric Oxide at Exercise
- Increase (16%) in VO2 Max (Maximum Oxygen Update)
- Reduction (14%) in Maximum Heart Rate
- Decrease (25%) in Reactive Hyperemia Index (Blood Vessel Function)



https://www.heighpubs.org/jsmt/jsmt-aid1027.php

#### > Products

To briefly summarize the above, the Company sources its bergamot from the leader in bergamot-based formularies, and they have exclusive North American distribution rights to a high concentration version of the product referred to as "BPF Gold". We believe that provides the Company a leg up in terms of other potential bergamot competitors, especially given that studies suggest that higher doses of bergamot work better than lower doses (We submit, to our knowledge, studies have NOT been performed to delineate those thresholds).

Keeping in mind that BPF is a supplement not a drug, to our knowledge no bergamot-based formulary has ever been subjected to specific FDA (pharmaceutical) studies/protocols. We recognize that for some, that would be reason enough not to believe in the efficacy of BPF, but we submit, there have been studies that in our view support the efficacy viewpoint. We would reiterate, according to surveys, nearly 80% of adult U.S. population takes a supplement of one form or another, none of which have been "subjected to specific FDA (pharmaceutical) studies/protocols".

The above said, while the Company has marketed some BPF based formularies in the past, they recently commenced new branding/packaging and product protocols and today, they sell 5 BPF based products/formularies. Here is a brief overview from the Company of each. We anticipate they will have additional products going forward as well. For additional product information visit: <a href="https://bergametna.com/collections/products">https://bergametna.com/collections/products</a>



#### • Ultimate Brain Nutrients

Ultimate Brain Nutrients ("UBN") is a science-based company that develops unique, plant-based superior health technology neuro-products that improve brain health, including memory, cognition, focus and neuro-energy. UBN's KETONOMICS® proprietary formulations – targeting brain activity, focus, headache and

cognitive behavior — provide multiple intellectual property license opportunities for monetizing the company's portfolio.

- Opportunities include multiple beverage formats, individual products, proprietary mixtures and other food platforms.
- *UBN has five unique formulation patents one issued and four pending targeting brain activity, focus, headache and cognitive behavior.*
- UBN's all-natural, sugar-free and caffeine-free proprietary formulations are the result of 20 years of scientific research and are positioned to provide consumer neuro-products that are natural brain solutions. UBN has filed for approval to the U.S. Food and Drug Administration (FDA) to make a Qualified Health Claim for its migraine formulation, tapping into consumer demands for healthy beverages that contribute to brain health, overall well-being and performance.
- Over 50 million Americans consume unhealthy energy shots and drinks each day, while the neuro/energy market generates over \$10 billion per year in revenue. Within this growing market, UBN is advancing its position to meet rising consumer demand for healthy, science-based options. The company's KETONOMICS® proprietary formulations have been proven to naturally elevate brain energy and function, including memory, cognition and focus.
- UBN's KETONOMICS® supplementation has also been studied in sports physiology, with specific regard to its potential benefits for competitive performance and endurance.

Much like with BPF in the Company's BergaMet NA line, UBN also has a (proprietary) formulary that will likely be common to the entire UBN product line. **Recognize**, **building a suite of products around a science-based proprietary or at least exclusive formulary is the approach here**. That said, the proprietary/common thread to the UBN "brain" line is a plant based medium-chain triglyceride ("MCT") the Company has spent that past five years developing its proprietary F4T<sup>TM</sup>. That development has included a proprietary processing and extraction protocol that they believe has led them to a highly efficacious F4T<sup>TM</sup>MCT product. They have branded and refer to that that formulary/asset as "KETONOMICS®".

MCTs or more commonly MCT oils are not new and they have been used in various supplements for several years. Moreover, there have been many studies highlighting the *potential* efficacy of MCTs for a variety of morbidities. For instance, HealthLine.com lists the *following "7 science-backed benefits you can get from adding MCT oil to your diet":* 

- 1. Promotes Weight Loss in Several Important Ways
- 2. Instant Source of Energy That Can Also Be Used to Fuel Your Brain
- 3. May Reduce Lactate Buildup in Athletes and Help Use Fat for Energy
- 4. Could Help Manage Epilepsy, Alzheimer's Disease and Autism
- 5. Contains Powerful Fatty Acids That Fight Yeast and Bacterial Growth
- 6. May Reduce Risk Factors for Heart Disease, Such as Weight and Cholesterol Heart disease is a growing problem.
- 7. May Help Control Blood Sugar Levels and Support Diabetes Management

As we alluded to above, from our perspective surviving in the nutraceutical space requires some differentiation via one or more comparative advantages. Beyond creative marketing, having a proprietary product is certainly one of those advantages and having some amount of clinical/scientific support is another. To that point, we would reiterate that UBN has spent the past five years or so developing their proprietary MCT and they have also spent considerable resources trying to protect that intellectual property. As a result, UBN has five unique

formulation patents that (collectively) target brain activity, focus, headache and cognitive behavior." Below is a short overview of the status/focus of each of these assets:

#### • PATENT #1 (Issued)

Relates to migraine headaches, particularly focusing on preventing, arresting, or reducing the frequency and severity of migraines with natural compositions.

#### • PATENT #2 (Pending)

Methods of reducing the frequency of migraine onset, migraine symptoms, and augmenting the effects of pharmaceutical and non-pharmaceutical interventions.

## • PATENT #3 (Pending)

Provides a formulation that relates to enhancement of metabolic energy pathways to improve attention, cognition, memory, analytical and executive functions of the human brain.

## • PATENT #4 (Pending)

Modulating metabolic pathways to benefit human performance, endurance and cardiometabolic health while improving cognition and executive brain function and enhancing women's health.

#### • PATENT #5 (Pending)

Secondary formulation and related method of manufacture for migraine headaches, more particularly to preventing, arresting, or reducing the frequency and severity.

Recall, earlier in this report we discussed the Company's efforts in seeking a Qualified Health Claim with the FDA. The Company's efforts in that regard are focused on its intellectual property related to the treatment/mitigation of migraine headaches. To that end, the Company is currently enrolling a study to help establish the efficacy of their proprietary formulation(s) for the treatment of migraines. We would add, there are currently few (practical) pharmaceutical treatments available for migraine sufferers, and for some of those people the condition is debilitating. The Company believes (and we tend to agree) that an *effective* proprietary nutraceutical for the treatment of migraines would be valuable. In addition, receiving a Qualified Health Claim exemption would likely be a significant catalyst for the Company. We do not know the likelihood of that event or the timing of the decision, although as we understand it, they *have* "passed" a couple of necessary milestones to that end. At the same time,



we are inclined to believe that positive results from the currently enrolling study could enhance the likelihood of that exemption.

The Company is just preparing the launch of their first UBN product called Fuel4Thought from the Company's collateral:

This pleasant tasting beverage was developed by leading medical and food scientists in the fields of clinical nutrition, metabolic science and food innovation. Through their extensive iterative research and development path, more than 90 versions were created and four released to the general market over a five-year test marketing program. This resulted in a strong intellectual property portfolio and an ingredient content that provides the highest potency ketone generating sources of the active medium chain triglycerides (MCT) available. F4T<sup>TM</sup> MCT's are not stored in the body as fat and ketones are a preferred "fuel" used to naturally power the brain and alleviate adverse decreases in glucose metabolism. In diverse studies, F4T has been shown to be effective at improving brain functionality by providing an increase in energy and brain

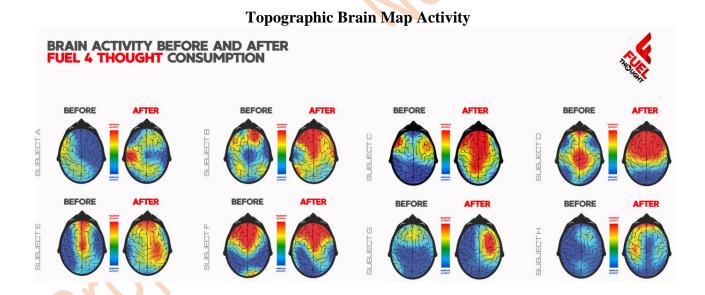
activation with resultant effects on focus, concentration, memory, clarity and enhancing centers for efficient learning.

...Further, ketone supplementation is emerging into the mainstream of sports physiology, for its documented benefits in competitive performance and endurance. With significant interest in ketones already established as well in the area of dietary supplements, there is a large and growing market for additional ketone supplementation for those already utilizing or considering ketogenic diets and regimens. Unlike many other products in the marketplace, F4T can point to its well documented and independently supported scientific basis for its action. Most recently, a 25-patient F4T exercise physiology and brain imaging study has been selected for poster presentation at the 2020 Annual Meeting of the American College of Sports Medicine.

As the above narrative notes, the Company has conducted a small investigational study to help establish the potential efficacy of their F4T<sup>TM</sup> MCT. The study's goal was to determine the MCT's potential impact on the improvement of EEG brain functions as well as in select sports vision measures. That study is available here:

https://ubnutrients.com/wp-content/uploads/2020/08/HE-F4T-ACSM-2020-poster-2.pdf

The following is a series of topographic brain maps measuring brain activity before and after Fuel4Thought consumption:



Our view of this is like that of the Company's BPF data. That is, recognizing that these studies perhaps lack some of the rigor of standard FDA pharmaceutical trials, we nonetheless find them compelling. We are eager to see the results of the migraine trial they are currently enrolling.

Looking ahead, we expect the Company to roll out three or four brain formularies through perhaps the first half of 2021. The first of these, Fuel4Thought is aimed at the "energy shot" and high caffeine energy drinks market, which typically targets teenagers and young adults, (18 to 34 years old). As we alluded to, we suspect the second product will be a migraine product and future products will likely be aimed at seniors and/or other improved memory and cognition markets.

#### Sales Channels and Marketing Strategy

In our experience, for small/nascent nutraceutical companies we think the critical path to success often involves having propriety products backed with some reasonable science. On the other hand, we have seen companies in the space with those attributes still struggle to sell product until they ultimately found the optimal sales channel for their product(s). While a quality product is in our view paramount to drive customer adoption and certainly customer retention, nothing sells itself, and as a result, marketing matters and finding the right sales channel(s) is part of that equation.

As we said, although certainly not unheard of, it is difficult for smaller players to access mass retailers, and that may be true of many natural and specialty retailers as well. As a result, many small nutraceutical companies either end up trying to deploy some sort of network/multilevel marketing approach, or perhaps a direct-to-consumer strategy that may include a variety of advertising and marketing pathways including radio, television and/or other E-Commerce approaches and platforms. Amazon.com for instance, has become a viable and growing platform for many small companies to shop their wares, and nutraceuticals are not an exception to that.

To that end, Healthy Extracts has developed a multi-pronged sales channel approach that they believe will result in broad consumer exposure. That approach includes the following channels.

#### Wholesale.

HE has an arrangement with a private company called XYMOGEN (https://www.xymogen.com/). HE sells XYMOGEN bulk BPF, which XYMOGEN then includes in some of its own formularies. XYMOGEN sells exclusively into the practitioner channel, and they have been doing so for "over a quarter century". As we understand it, XYMOGEN is a \$100 million revenue business so this could be a significant piece of business for HE. We also think there may be additional wholesale opportunities going forward, which could include KETONOMICS®.



#### Direct and Partner Practitioner Sales.

As demonstrated through their arrangement with XYMOGEN, we think the Company's strengths in terms of science-based success may provide additional opportunities in the practitioner space with *their own* labels/brands. Those could include white label opportunities as well.

#### **Affiliate & Distributor Sales.**

This approach has a bit of the network marketing twist, without the multilevel piece. This essentially, provides an opportunity for distributors to earn a commission or fee for sales, and that might include customers who refer others.

#### Online Sales.

We believe most of the Company's sales to date have been via their website and/or through online retail platforms largely Amazon. Our sense is that this channel will likely command the lion's share of the busines (although that may not necessarily be the case). Part of that notion is related to some of our prior narrative regarding the impact that E-Commerce is having on nutraceutical sales.

#### **Customer Retention**

It may go without saying, but consumer product Company's need to spend as much time/resources insuring they hang onto exiting customers as they do trying to find new ones. Again, in our view, in HE's case much of that may ultimately be a function of the quality of their products vis-à-vis their science. That is, we assume most customers who buy one of the bergamot products will have lowering their cholesterol in mind, and we suspect most will try to determine whether or not the product is actually working by having their cholesterol

tested before and after they use it. If they get good results, we assume they will keep using it, so again retention in that case may be a function of the product's quality. That may be true for some of the KETONOMICS® products as well. A person suffering from migraines retention will be driven by how well the product mitigates their migraines. We view those sorts of objective outcomes as positives (assuming they work as expected) but not all nutraceuticals have that luxury. For instance, we believe the Company's Clinical Immune product could prove particularly topical because of the pandemic as it addresses both general immune enhancement as well as some of the specific comorbidities associated with poor Covid19 patient outcomes. However, customers can measure their respective cholesterol levels and they can gauge the severity of their headache, but they may not be able to know whether the formulary is actually helping their immune system. To that end, beyond relying on what they believe will be the objective efficacy of at least some of their products, HE has also established things like a customer rewards system as well as the aforementioned referral program, to make their customer retention efforts stickier.

## **Operating Overview**

While the Company does have some limited operating history largely from the BergaMetNA side of the business, we generally view them as at the front end of commercialization, especially in terms of their new branding and the addition of UBN. As such we do not have a great deal of historic data to reference or otherwise back test our assumptions against, so the modeling at this point is precarious.

In speaking with management, we do have a sense of their anticipated metrics (margins, overhead etc.) and they have provided some guidance with respect to anticipated revenues for the next few quarters as well. We have constructed our models with that general guidance in mind and in the context of other comparable industry metrics we have seen, but frankly, we do not expect anyone's initial guidance to necessarily prove largely accurate due to the nascent and unpredictable nature of the business at this point in its evolution. Lack of operating visibility is one of the risks in the story. Obviously, we expect that predictability to improve as commercialization rolls out and we are better able to assess the success and breadth of the products and sales channels.

We would add, we have modeled some further dilution based on what we think will be added capital to accelerate/support growth.

## **Management Overview**

#### Jay Decker, Founder

- 4 exits, total proceeds exceeding \$4 billion
- Petroleum engineer

#### Kevin "Duke" Pitts, Director, President and Chief Operating Officer

- Started and built from the ground up two multi-million-dollar businesses, one of which grew into a Top 100 retailers in the U.S.
- Unique management skills led to the development of successful teams for 35 years
- Pioneered direct marketing for a Fortune 200 company, creating a 20% increase in targeted incremental sales
- Founded Einstein's Hemp, which developed and brought to market one of the only odorless and tasteless water-soluble CBD products in the world

- Developed and implemented digital/guerrilla marketing strategies for public and private companies focused on long-term brand position and acquisition efforts
- Specialized in customer relationship management (CRM) tools for creating the best customer experiences
- Worked in publicly traded industries for 10 years, overseeing up to \$20 million in annual marketing budget

#### Dr. Gerald Haase, Chief Medical Adviser

- Clinical professor of surgery at the University of Colorado, School of Medicine
- Actively involved in medical research and clinical trials for 35 years
- Received U-10 grant funding from the National Institutes of Health cooperative group clinical trials program, as well as U.S. Congressional funding for Cooperative Research and Development Agreements with the Department of Defense and NASA
- Was chairman of the Department of Pediatric Surgery at Children's Hospital Colorado; consultant surgeon to the Department of the Army; vice-chairman of the Children's Cancer Group, a cooperative research consortium of the National Cancer Institute; on the National Board of Directors of the American Cancer Society; a senior member of the Commission on Cancer of the American College of Surgeons; and a member of the editorial board of The Annals of Surgical Oncology
- Has published 180 scientific papers and is the inventor or co-inventor of 12 issued U.S. patents for micronutrient and phytonutrient therapy, with five pending patents

# William "Bill" Bossung, Director, Chief Financial Officer

- 35 years experience in corporate finance, insurance and accounting
- underwritings, private placements, PIPE financing
- Involved in 30+ companies transitioning from private to public companies

#### Bill Croyle, Director, Private Investor and Accomplished Senior Executive

- More than 40 years of success in the IT, energy, manufacturing, telecommunications, venture capital and finance industries
- Broad expertise includes negotiating mergers and acquisitions, as well as service and delivery contracts
- Formerly was a founder, owner or executive of EnTX Group; Impact Legacy Partners; FB Oilfield Special Tools; and Western Energy Advisors

#### **Risks and Caveats**

Healthy Extracts is a very small fish in a very large pond. While we have tried to delineate some advantages that we think may help them differentiate their products from other competitors, the nutraceutical industry is fiercely competitive and as such forging a successful niche is not an easy task. Further, their efforts will likely require effective direct to consumer marketing endeavors, which are often expensive. As a small and generally undercapitalized company, constrained marketing resources may also constrain their marketing success. To that end, they recently completed a small equity raise. We think it is likely (although not certain) that they may seek to raise additional equity capital in the future, which would result in the dilution of exiting shares.

As some of the industry research we have come across suggests, the nutraceutical industry can be "faddish by nature". We think that is a prescient observation. For instance, we noted above that we think the Company's Clinical Immune product is topical to the current pandemic. However, while many experts suggest that Covid19 will remain problematic for some time to come, the public's perception around the value of immune boosting supplements could certainly wane if/when the treatment of the virus becomes less acute. Further, as we covered above, the relatively benign regulatory scrutiny around supplements essentially provides low barriers of entry for the industry. That posture almost ensures new competitive elements constantly entering the market. From that perspective, even being in the middle of the next fad may not guarantee success, as competitors (both established and new) can likely develop some sort of competitive offerings to address those trends as well.

We believe the "relatively benign regulatory scrutiny" of nutraceuticals is a net plus for the industry. However, there is no guarantee that the industry will continue to enjoy that environment. The specter of more government oversight and regulation is an ongoing risk to the industry and we do not expect that to go away any time soon. Clearly, as in most industries, greater government oversight could prove particularly onerous for smaller participants.

While the Company has an exclusive long-term supply agreement with their Italian manufacturer, in our view, their reliance on that single manufacturer provides measurable risk. Any adverse event to the business of that supplier will likely have a direct and negative effect on HE. Moreover, The Company also relies on a variety of other third-party suppliers and manufactures. Any missteps from any one of those suppliers in terms of quality control and/or product safety would negatively impact Healthy Extracts.

Currently, the Company relies on a small handful of people to run and at least initially grow the business. That posture carries obvious risks with respect to the performance of those individuals. Further, as we noted, roughly 2/3rds of the Company is owned by a single shareholder, who by virtue of that ownership maintains de facto control of the Company.

We noted earlier that the Company is currently seeking a Qualified Health Claim from the FDA regarding their migraine formulary. These are generally difficult to obtain, and while thy have managed to successfully move through the process to this point, those efforts may fail. We do not know what the expectations are around that, but a decision of that nature could negatively impact the stock. Frankly, we do not view a negative response from the FDA as decidedly negative, nor do with view it as final. That is, if that is the outcome, and they continue to gather positive data from their migraine trial, we could see them revisiting that claim armed with new data. Further, they can certainly be successful even without the benefits that claim designation might provide. That said, the designation could provide a marked catalyst for the Company, so logically, its rejection would on the face be negative.

We generally view the nutraceutical industry as discretionary. As a result, we would expect slowing economic activity to have a negative impact on the industry.

The Company's stock is thinly traded, which generally leads to volatile share prices and illiquidity. That may remain the case into the foreseeable future.

These are just some of the more obvious risks we see in the Company. There are likely others we have overlooked as well as others that may arise in the future.

## Valuation, Summary and Conclusion

We are microcap generalists and as such over the years, we have covered several dozen companies in a variety of industries. That said, we *have had* some experience covering a few nutraceutical and/or functional food

companies, so we feel like we have a bit of practical exposure with respect to the elements that contribute to success and failure in the space. As we covered above, we believe solid science is one of those elements, and proprietary formulations is another. We think Healthy Extracts can demonstrate both of those attributes, and in fact, they have two formularies that fit that mold. The plan is to leverage each of those assets by creating multiple products around/including these proprietary formularies as their primary ingredient. Further, we think they have a good jump on that strategy, as today they have 5 separate bergamot-based products, with 5 different formularies, each aimed at specific niches. Further, by the time most read this, they will have rolled out their first UBN/brain product, and we expect to see others through calendar 2021. Moreover, one of those products will likely be a migraine formulation, for which they have filed 3 patents (one issued and two pending). In addition, they are seeking a Qualified Health Claim from the FDA regarding their migraine formula and they are also currently enrolling a clinical study with that formulation as well. We have no insight into the chances of gaining acceptance for that claim, but we do think success in that regard would be a major milestone for the Company. We also think that clinical success in the current study will be constructive as well and may ultimately support the Qualified Health Claim. Succinctly, we think their migraine product(s), has the potential to be a game changer for the Company.

From our perspective, for a small Company that has just recently put all these pieces together, they have an impressive number of things in motion on multiple fronts. As we noted, they have 6 products in the marketplace and others in the que, and they have established a handful of sales channels that they are also selling product through *right now*. As our model indicates, we anticipate sequentially improving revenue results into the foreseeable future. While we think their near-term momentum (again on multiple fronts) has been impressive, we also think it is important to recognize that while these two assets have just recently been put together, they have, at least on the science side, been developing separately for some time now. Keep in mind, as we noted above, Founder Jay Decker and others have been collectively developing these businesses for years and we think he has spent something approaching \$9 million doing that. That is not insignificant and perhaps speaks to the breadth of the science behind the products. By the way, just as a point of reference, that number suggests the Mr. Decker owns his portion of the Company at a price of roughly \$.05 per share, which is relatively close to the current price of the shares.

Much of the Company's product development is aimed at specific demographics and/or morbidities. For instance, as we have illustrated, they have a bergamot product geared towards women and another towards athletes and/or active people, while they have also tried to isolate specific morbidities, like high cholesterol and immune deficiency. To that end, above we noted some industry narrative that suggested that the industry can be "faddish", so focusing on established demographics with tailored formularies makes sense to us. However, it is hard not to recognize the good timing of their Clinical Immune product. Given some of the recent surveys we included above, we suspect the product will get some attention. As they say "sometimes it is better to be lucky (or "faddish") than good". We will see if that plays out in this instance, but again we have modeled some success there, especially since the product addresses a handful of the morbidities associated with poor Covid19 outcomes (cardiovascular disease, diabetes, immunity etc.).

We submit, Healthy Extracts is in the early innings and they are competing in a crowded field with some of the world's largest companies. On the other hand, there are many instances of nascent enterprises in the space becoming quite successful, and several of those ended up being acquired by some of those same large competitors. We are confident that trend will continue in the industry. We believe the space remains conducive to small companies that can deliver the right mix of proprietary, science-back products and effective marketing and we think HE may have found that formula. Obviously, the results of next few quarters will illuminate the accuracy of that view. We are initiating coverage of Healthy Extracts with an allocation of 4 and an initial 12-24 month price target of \$.17 per share. We will revisit each as/when visibility improves.

# **Projected Operating Model**

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#### **Rating System Overview:**

There are no letters in the rating system (Buy, Sell Hold), only numbers. The numbers range from 1 to 10, with 1 representing 1 "investment unit" (for my performance purposes, 1 "investment unit" equals \$250) and 10 representing 10 investment units or \$2,500. Obviously, a rating of 10 would suggest that I favor the stock (at respective/current levels) more than a stock with a rating of 1. As a guideline, here is a suggestion on how to use the allocation system.

Our belief at Trickle is that the best way to participate in the micro-cap/small cap space is by employing a diversified strategy. In simple terms, that means you are generally best off owning a number of issues rather than just two or three. To that point, our goal is to have at least 20 companies under coverage at any point in time, so let's use that as a guideline. Hypothetically, if you think you would like to commit \$25,000 to buying micro-cap stocks, that would assume an investment of \$1000 per stock (using the diversification approach we just mentioned, and the 20-stock coverage list we suggested and leaving some room to add to positions around allocation upgrades. We generally start initial coverage stocks with an allocation of 4. Thus, at \$1000 invested per stock and a typical starting allocation of 4, your "investment unit" would be the same \$250 we used in the example above. Thus, if we initiate a stock at a 4, you might consider putting \$1000 into the position (\$250 \* 4). If we later raise the allocation to 6, you might consider adding two additional units or \$500 to the position. If we then reduce the allocation from 6 to 4 you might consider selling whatever number of shares you purchased with 2 of the original 4 investment units. Again, this is just a suggestion as to how you might be able to use the allocation system to manage your portfolio.

For those attached to more traditional rating systems (Buy, Sell, Hold) we would submit the following guidelines.

A Trickle rating of 1 thru 3 would best correspond to a "Speculative Buy" although we would caution that a rating in that range should not assume that the stock is necessarily riskier than a stock with a higher rating. It may carry a lower rating because the stock is trading closer to a price target we are unwilling to raise at that point. This by the way applies to all of our ratings.

A Trickle rating of 4 thru 6 might best (although not perfectly) correspond to a standard "Buy" rating.

A Trickle rating of 7 thru 10 would best correspond to a "Strong Buy" however, ratings at the higher end of that range would indicate something that we deem as quite extraordinary..... an "Extreme Buy" if you will. You will not see a lot of these.