UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ____ to ____

Commission file number: 000-55723

GUARDION HEALTH SCIENCES, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**15150 Avenue of Science, Suite 200 San Diego, California 92128 Telephone: 858-605-9055**	**47-4428421**
(State or other jurisdiction of incorporation or organization)	*(Address and telephone number of principal executive offices)*	*(I.R.S. Employer Identification No.)*

15150 Avenue of Science, Suite 200
San Diego, California 92128
Telephone: 858-605-9055
Telecopier: (858) 630-5543
(Address and telephone number of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	GHSI	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. [X] Yes [ ] No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). [X] Yes [ ] No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company”, and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). [ ] Yes [X] No

On June 28, 2019, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value (based on the closing per share sales price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was approximately $20.8 million.

As of March 27, 2020, there were 85,264,962 shares of the registrant’s common stock, par value $0.001 per share, issued and outstanding.

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2019 contains "forward-looking statements" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects, and other similar matters. These forward-looking statements are based on management's current expectations and assumptions about future events, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. These statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning.

Actual results could differ materially from those contained in forward-looking statements. Many factors could cause actual results to differ materially from those in forward-looking statements, including those matters discussed below, as well as those listed in Item 1A. Risk Factors.

Other unknown or unpredictable factors that could also adversely affect our business, financial condition and results of operations may arise from time to time. Given these risks and uncertainties, the forward-looking statements discussed in this report may not prove to be accurate. Accordingly, you should not place undue reliance on these forward-looking statements, which only reflect the views of the Company's management as of the date of this report. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results or expectations, except as required by law.

PART I

ITEM 1. BUSINESS

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "our company," "Guardion" the "Company" and the "Registrant" refer to Guardion Health Sciences, Inc. and its subsidiaries.

Overview

The Company is a specialty health sciences company (1) that has developed medical foods and medical devices in the ocular health space and (2) that is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers.

Medical Foods:

- **Lumega-Z®:** The Company formulates and distributes Lumega-Z®, which is designed to replenish and restore the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as adult dry macular degeneration ("AMD") and computer vision syndrome ("CVS"). The Company believes this risk may be modified by taking Lumega-Z to maintain a healthy macular protective pigment. Additionally, early research has shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's disease and dementia.

- **GlaucoCetin™ :** In November 2018, the Company launched its second medical food product, GlaucoCetin™. The Company believes GlaucoCetin™ is the first vision-specific medical food designed to support and protect the mitochondrial function of optic nerve cells and improve blood flow in the ophthalmic artery in patients with glaucoma. The parent compound of GlaucoCetinTM, called "GlaucoHealth," was designed by Robert Ritch, M.D., one of the Company's Medical Advisory Board members.

Medical Devices:

- **MapcatSF®:** The Company invented a proprietary technology, embodied in the Company's medical device, the MapcatSF®, that accurately measures the macular pigment optical density ("MPOD"). On November 8, 2016, the United States Patent and Trademark Office ("USPTO") issued patent number 9,486,136 for the MapcatSF invention. Using the MapcatSF to measure the MPOD allows one to monitor the increase in the density of the macular protective pigment after taking Lumega-Z. The MapcatSF device is a Class I medical device under the U.S. Food and Drug Administration ("FDA") classification scheme for medical devices, which the Company has determined does not require pre-market approval. The Company's focus is to deploy the MapcatSF in clinics accompanied by trained technicians to conduct the MPOD measurements and collaborate with the physicians treating their patients. The Company maintains ownership and possession of the MapcatSF when used in this fashion but will sell the device to physicians upon request.

- **VectorVision and CSV-1000:** In September 2017, the Company, through its wholly-owned subsidiary VectorVision Ocular Health, Inc., acquired substantially all of the assets and certain liabilities of VectorVision, Inc., a company that specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study ("ETDRS") visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing for use by eye doctors in clinical trials, for real-world vision evaluation, and industrial vision testing. The acquisition expands the Company's technical portfolio. The Company believes the acquisition of VectorVision, through which it added the CSV-1000 to its product portfolio, further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases. Although the CSV-1000 will continue to be sold, the Company plans to put a greater focus on sales and marketing efforts of the new CSV-2000.

- **CSV-2000:** In September 2019, the Company announced that it completed development of its new proprietary, digital CSV-2000 standardized contrast sensitivity testing device. The Company believes that the CSV-2000 is the only computer-generated vision testing instrument available that will provide the optical marketplace with the Company's proprietary, industry-standard contrast sensitivity test, along with a full suite of standard vision testing protocols. The proprietary standardization methodology incorporated into the CSV-2000 includes a patented technology known as AcQviz, embodied in its own device, that automatically and constantly measures and adjusts screen luminance to a fixed standard light level for vision testing. The Company began selling the new CSV-2000 and AcQviz devices at the end of the first quarter of 2020.

Nutraceuticals:

- **NutriGuard Acquisition:** In September 2019, the Company, through its wholly owned subsidiary NutriGuard Formulations, Inc., acquired NutriGuard Research, Inc. The Company intends to build a portfolio of nutraceutical products under the NutriGuard brand by developing new formulations and marketing its products to patients directly through direct to consumer ("DTC") channels and through recommendations by their physicians.

- **acuMMUNE**: The first new nutraceutical product under development is acuMMUNE, designed with the objective of supporting effective immune function. acuMMUNE has been specially formulated with ingredients that have been shown in studies to support interferon-mediated anti-viral mechanisms, which are important components of the body's immune response during viral infections.* The Company is currently in the process of arranging for the manufacture and packaging of acuMMUNE at contract facilities in the United States and expects that this product will be available for sale beginning in approximately April 2020. The Company anticipates that acuMMUNE will also be available for export to various international markets shortly thereafter.

  *This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

- In addition to NutriGuard's acuMMUNE product, a Malaysian company has contracted with NutriGuard to develop a proprietary formula to meet the demands of the Malaysian company's customers for an immune-supportive product. Each unit of the product will consist of two (2) bottles packaged together, one named Astramune-H and one named Astramune-V. The formula will be designed to provide both immuno-supportive and anti-inflammatory benefits to its users.

Transcranial Doppler Ultrasound Services:

- **TDSI:** In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). TDSI is dedicated to the pursuit of early predictors of eye diseases. The Company believes the ultrasound diagnosis of the vasculature of the brain is a valuable therapeutic intervention for practitioners and their patients, and the Company hopes that this business line will result in additional revenue streams generated from the testing and sale of Company products to appropriate customers. TDSI has established operations with selected clinics and is sending trained sonographers to conduct transcranial doppler ultrasound ("TCD") services on the physicians' patients at these initial facilities. The Company is working on expanding its client base by contacting and visiting new facilities to educate physicians on the benefits of the TCD service to facilitate scheduling additional facilities. The Company intends to target more fee-for-service practices that cater to cash paying patients.

Background

Medical Foods

Medical foods are not considered to be either dietary or nutritional supplements. The Company believes that there is an increasing level of acceptance of medical foods as a primary therapy by patients and healthcare providers to manage pain syndromes, sleep and cognitive disorders, obesity, hypertension, and viral infection. In clinical practice, medical foods are being prescribed as both a standalone therapy and as an adjunct therapy to low doses of commonly prescribed drugs. The Company believes that medical foods will continue to grow in importance over the coming years.

Lumega-Z® is a medical food product that has a patent-pending formula that is designed to replenish and restore the macular protective pigment simultaneously delivering critical and essential nutrients to the eye. Management believes, based on review of products on the market and knowledge of the industry, that Lumega-Z is the first liquid ocular health formula to be classified as a medical food (as defined in Section 5(b) of the "Orphan Drug Act"). However, the FDA has not monitored nor approved Lumega-Z as a medical food. Formulated by Dr. Sheldon Hendler in 2010, modifications were made over a two-year period to improve the taste and method of delivery. The current formulation has been delivered to patients and used in clinics since 2014.

Lumega-Z is must be administered under the supervision of a physician or professional healthcare provider. In order to reach the large, expanding AMD patient population, the Company primarily markets Lumega-Z to patients through ophthalmologists and optometrists.

The patients come from a combination of the three initial testing sites, healthcare provider sites where the MapcatSF® has been demonstrated, patients that have found Lumega-Z online and through other patient referrals, healthcare provider sites administering Lumega-Z to their patients without use of the MapcatSF, and MapcatSF devices recently placed in additional healthcare facilities. Patients take Lumega-Z under the supervision of their physician.

Nearly half of Americans have low MPOD, a risk factor for AMD. As the MapcatSF is specifically designed to measure the MPOD, the Company and the physicians that utilize the MapcatSF are able to observe changes in that macular protective pigment density in patients who are taking Lumega-Z. The Company encourages sites using the MapcatSF to provide the Company anonymized data on the MPOD readings. Anecdotal reports from physicians indicate improvements in their patients such as increased visual function, a noticeable halt in the progression of the patient's AMD, improvement in glare and contrast sensitivity, and stabilization and improvement of vision. No adverse effects of taking Lumega-Z have been reported by any of the physicians administering Lumega-Z to their patients.

Lumega-Z® has been used in Institutional Review Board ("IRB")-approved patient studies to examine its effectiveness. The study was conducted by research scientists at the Western University College of Optometry to evaluate the visual benefits of Lumega-Z in one group of patients as compared to a group of patients taking AREDS 2 soft gel supplements. Each patient has retinal drusen and was at risk of developing AMD. The results of the study were presented at the Association for Research in Vision and Ophthalmology ("ARVO") 2019 annual meeting and showed improvements in visual function ("CSF") in the group of patients taking Lumega-Z that were statistically significant. The patients taking AREDS 2 showed no statistical change. Data was also presented at ARVO on a separate study that showed patients with drusen and at risk of vision loss from macular degeneration who were treated with Lumega-Z for 6 months showed improvements in vision, as measured by contrast sensitivity. Similar patients treated with standard over-the-counter AREDS2 gel caps showed no change.

The number of patients regularly ordering Lumega-Z continues to increase as new healthcare providers have begun working with the Company, with a concurrent rise in patients set on an auto-ship program for delivery every four weeks. The Company's operations, to date, indicate that each MapcatSF® deployed in a clinic can generate an average of 75 new customers for its Lumega-Z product over a period of approximately 90 days when a MapcatSF is deployed in a small, low volume clinic. The Company has determined that the value of the MapcatSF is through this utilization. The Company intends to continue to deploy the MapcatSF in this fashion, with a focus of assigning the MapcatSF to clinics to build and maintain relationships with the clinics rather than selling the MapcatSF devices.

The National Academics of Sciences, Engineering, and Medicine projects that "every four minutes, one American will experience partial or complete loss of sight." According to The Lancet, AMD cases in the US are projected to pass 18 million in 2017, and 20 million by 2022.

AMD is the third leading cause of blindness in the world. More than 10 million people in the United States suffer from various forms of this incurable disease, according to the American Macular Degeneration Foundation. As the population ages, that number is expected to triple by 2025. Cataract patients are operated on earlier and younger. After surgery, the long-term damage from oxidative stress & high energy light exposure to the retina becomes more important to address. Protecting the retina after surgery maintains better visual outcomes for the long term.

The Company believes that there is an increasing level of acceptance of medical foods as a primary therapy by patients and healthcare providers to manage pain syndromes, sleep and cognitive disorders, obesity, hypertension, and viral infection. In clinical practice, medical foods are being prescribed as both a standalone therapy and as an adjunct therapy to low doses of commonly prescribed drugs. From a regulatory standpoint, the FDA took steps in 1988 to encourage the development of medical foods by regulating this product category under the Orphan Drug Act. The term "medical food" as defined in Section 5(b) of the Orphan Drug Act is a "food which is formulated to be consumed or administered internally (by mouth) under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." This definition was incorporated by reference into the Nutrition Labeling and Education Act of 1990.

These regulatory changes have reduced the costs and time associated with bringing medical foods to market. Until 1972, medical foods were categorized as drugs and then until 1988 as "foods for special dietary purposes." The field of candidates for development into medical foods is expanding due to continuing advances in the understanding of the science of nutrition and disease, coupled with advances in food technology thereby increasing the number of products that can be formulated and commercialized.

The Company distributes its medical food products through E-commerce in an online store that is operated at www.guardionhealth.com. Information about VectorVision products can be found at www.vectorvision.com. Information about NutriGuard Formulations products can be found at www.nutriguard.com.

The Company believes that the science of nutrition was long overlooked and underdeveloped. The Company believes that the sick and elderly have special nutritional needs that cannot be met by traditional adult di%ts. Medical nut2tion has emerged as a large and attractive segment in the food industry today. A number of diseases are associated with metabolic imbalances, and patients in treatment for such diseases have specific nutritional requirements.

Medical foods consist of food-based ingredients that are part of the normal human diet and are Generally Recognized as Safe ("GRAS") under FDA standards. Medical foods must make claims for which there is scientific evidence that nutrient deficiencies cannot be corrected by normal diet. All ingredients must be designated GRAS and used in therapeutic concentrations to address the particular nutritional needs of the patient. Medical foods are taken under the supervision of a physician or professional healthcare provider who monitors and adjusts the food 'dosage.' In addition, under FDA guidelines and congressionally approved laws, medical foods do not require FDA prea0proval but undergo continuous FDA monitoring and approval of label claims. Even though pre-market FDA approval is not required for a medical food, the official requirements and responsibilities for the manufacturer, in terms of safety, are greater than for dietary supplements, including solid scientific support for the formula as a whole. For these reasons, medical foods have greater guarantees of efficacy. In contradistinction, dietary supplements, such as vitamins, minerals and botanicals, do not require FDA preapproval, cannot make disease claims, are intended for normal people without disease and cannot claim that they prevent, mitigate or treat a given disease. Dietary supplements do not require physician supervision and can be administered to a person that can self-administer the supplement without supervision.

Based on the advice of intellectual property counsel and regulatory affairs consultants, the Company believes that Lumega-Z and GlaucoCetin are properly categorized as medical foods. While the Company believes it is unlikely the FDA would conclude otherwise, if the FDA determines Lumega-Z or GlaucoCetin should not be defined as a medical food, the Company would need to relabel and rebrand that product. The Company believes there would be minimal impact on its operations and financial condition if it were required to change labeling and packaging back to that of a dietary supplement. While reclassification and the subsequent relabeling and rebranding would be an added cost to operations, it would not change the use or effectiveness of Lumega-Z or GlaucoCetin, although there is a chance that certain physicians may choose not to recommend Lumega-Z or GlaucoCetin to their patients or that certain consumers may choose not to buy Lumega-Z or GlaucoCetin if they are not classified as medical foods.

Medical Devices - Testing Industry Overview

The Company believes that consistent, repeatable and accurate results for visual acuity testing are of paramount importance for effective eye health care and for accurately establishing and enforcing the vision performance criteria for certain professions. Variance in test lighting is a major cause of inconsistency in vision testing results. Standards for testing luminance, have been in place for more than three decades. However, recently, vision testing has evolved from the use of projection systems and charts to the use of digital displays. The Company believes that the variance in luminance provided by digital displays is large, and clinicians are now obtaining highly inconsistent results from practice to practice. Conservatively, the Company believes more than 250,000 eye care examination rooms are in use in the United States today.

The variability described above has caused the FDA and other agencies to require standardized test lighting for vision tests. Because VectorVision specializes in the standardization of vision tests, VectorVision is the only company that offers fully standardized vision testing products that ensure consistent, repeatable and highly accurate results. The CSV-1000 device offers auto-calibrated tests to ensure the correct testing luminance and contrast levels for consistent, highly accurate and repeatable results, which is why the VectorVision instruments ca. detect and quantify su"tle ch!nges in vision. Consistency, repeatability and accuracy are also why the VectorVision CSV-1000 instrument is used worldwide by eye doctors in more than 60 countries to accomplish contrast sensitivity testing. The Company's research has revealed there are no competing products that offer auto-calibration of ambient illumination. Competitive devices do not allow for variations in ambient light levels, resulting in variability of test results due to the environment in which the testing is performed. The CSV-1000 uses self-calibrated test lighting. The self-calibrated test lighting is proprietary. The self-calibrated test lighting technology is a proprietary and patented technology known as AcQviz, which tests the faces of the CSV-1000 and CSV-2000 and automatically and constantly measures and adjusts screen luminance to a fixed standard light level for vision testing. The test faces of the CSV-1000 are proprietary and their intellectual property is protected under copyright and trade secret law. CSV-1000 is currently sold worldwide, and the Company expects this global distribution to continue. There is a training requirement in incorporating the CSV-1000 and the CSV-2000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy.

Nutraceutical Industry Overview

A dietary supplement is a defined in the Dietary Supplement Health and Education Act, enacted in 1994 ("DSHEA"), as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins, minerals, amino acids, herbs or other botanicals; a concentrate, metabolite, constituent, extract or combination of the ingredients listed above. Dietary supplements are intended to be taken orally and are labeled on the front panel as being a dietary supplement.

DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires the product to be labeled as a "dietary supplement." The terms "dietary supplement" and "nutraceutical" are often used interchangeably.

Under DSHEA, a company is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. Dietary supplements do not need approval from FDA before they are marketed, although "new dietary ingredients" do require premarket review by FDA. This allows companies to bring products to market in less time and with less cost than is required for drug approval from the FDA.

Competitive Advantage and Strategy

Medical Foods

There are no research-validated pharmaceutical solutions for slowing the progression of adult dry macular degeneration ("AMD"). As a result, it is necessary for physicians to recommend Age-Related Eye Disease Study ("AREDS")-based supplements to AREDS-based AMD patients. However, more than 90% of all AREDS-based nutritional products currently on the market are in tablet, capsule and gel capsule form. As previously discussed, tablets, capsules and gel capsules have a low efficiency of absorption.

Lumega-Z is a medical food designed to enhance the bioavailability of "difficult to absorb" ingredients like carotenoids. In contrast to other formulations, Lumega-Z is a liquid formulated using a proprietary molecular micronization process ("MMP") to maximize efficiency of absorption and to minimize compatibility issues. The MMP is a proprietary homogenization process whereby the particle size of the ingredients is reduced to facilitate more efficient absorption into the body. In clinical studies, Lumega-Z has been shown to deliver nearly four times times more carotenoid into the bloodstream compared to standard supplements (See Richard Bone, Pinakin G Davey, David Evans. *Serum, macular pigment and visual function response to commercially available supplements: IOVS (Investigative Ophthalmology and Vision Science)* ARVO).

Medical Devices

The MapcatSF has been installed in several teaching and ocular research facilities, such as the Illinois College of Optometry ("ICO"), the New York Eye and Ear Infirmary, and the Rosenberg School of Optometry at the University of the Immaculate Word. The Company's focus is to deploy the MapcatSF in clinics accompanied by trained technicians to conduct the MPOD measurements and collaborate with the physicians treating their patients.

VectorVision specializes in the standardization of vision tests, specifically, contrast sensitivity, glare testing and early treatment diabetic retinopathy study, or ETDRS, acuity. The variability in test lighting has caused the FDA and other agencies to require standardized test lighting for vision tests. Contrast sensitivity testing measures how people see in the real world. A depleted macular pigment greatly affects contrast sensitivity. Research suggests that contrast sensitivity is a better measure than standard acuity tests for real-world vision applications such as military pilots and highway driving. The Company believes that VectorVision is the only company that offers fully standardized vision testing products that ensure consistent, repeatable and highly accurate results. These qualities are why the VectorVision instruments can detect and quantify subtle changes in vision, and why the VectorVision CSV-1000 instrument is used worldwide by eye doctors in more than 60 countries to accomplish contrast sensitivity testing. On July 10, 2018, the USPTO issued US Patent No. 10,016,128, titled Method and Apparatus for Visual Acuity Testing. This patent describes an invention pertaining to automatic light calibration of the display screens used for vision testing. The Company owns this patent, and its VectorVision CSV-1000 device embodies this invention. On July 17, 2018, the USPTO issued US Patent No. 10,022,045, also titled Method and Apparatus for Visual Acuity Testing, which describes a methodology to continuously calibrate display monitors to automatically hold display luminance constant for vision testing. This second patent also covers a methodology to compensate for other testing factors, such as room illumination and when patients view the vision test through a mirror, which is a common practice in eye doctors' offices worldwide. The Company also owns this patent. The Company's new AcQviz device embodies this invention, which is now used in conjunction with the VectorVision CSV-1000 device.

The Company believes the CSV-1000 is the current standard of care for clinical practice. The Company recently announced it is preparing to launch the new CSV-2000, which is an enhanced, electronic version of the CSV-1000. There is a training requirement in incorporating the CSV-1000 and CSV-2000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy.

The CSV-1000 and CSV-2000 use self-calibrated test lighting. The self-calibrated test lighting technology is a proprietary and patented technology known as AcQviz, which tests the faces of the CSV-1000 and CSV-2000 and automatically and constantly measures and adjusts screen luminance to a fixed standard light level for vision testing. Although the CSV-1000 will continue to be sold, the Company plans to put a greater focus on sales and marketing efforts of the new CSV-2000 in the first quarter of 2020. There can be no assurances that the marketing efforts will be successful and sales of the CSV-2000 will be comparable or exceed sales of the CSV-1000.

Nutraceuticals

The Company intends to build a portfolio of nutraceutical products under the NutriGuard brand by developing new condition-specific formulations and marketing the NutriGuard products to patients directly through direct to consumer ("DTC") channels and make the NutriGuard products available to patients through recommendations by their physicians.

NutriGuard intends to formulate high quality scientifically credible nutraceuticals with a goal to become a globally respected and physician-preferred nutraceuticals brand. The Company believes its nutraceuticals can play an important role in optimizing, preserving and restoring health.

Growth Strategy

The Company believes that marketing its products is critical in ensuring its success. The Company has several marketing initiatives and will implement them according to the success and product feedback that the Company and products create. The Company will also consider acquiring other companies, product lines and intellectual property that may be complementary or supplementary as part of its future efforts to expand the business, which acquisitions could be for cash, stock or a combination thereof.

Sales Force

The Company has made a number of recent changes to its sales force and sales efforts. The Company now has new sales leadership with extensive industry experience. The Company currently has a sales force of account managers who are trained healthcare providers including NDs and physician assistants. The last of the new sales staff was put in place mid-March 2020.

While the Company has been developing the NutriGuard website, the Company is currently promoting the NutriGuard line.

International Expansion Strategy

Retinal diseases that include macular degeneration, glaucoma and diabetic retinopathy are not exclusive to the United States. The Company believes there is great interest internationally to find non-pharmacologic treatments for these diseases. The largest market opportunity is China where some of these diseases are at substantial levels. The Company intends to explore opportunities and channels to enter this expansive market. The Company is also looking to expand the NutriGuard line to international markets.

Ocular Care

Based on management's knowledge of the industry, the Company believes that Lumega-Z is the only medical food in the ocular health space. The most analogous products on the market are dietary supplements. While the medical food category is well established and growing for certain diseases or disorders (for example, inborn errors of metabolism, metabolic syndrome, gastrointestinal disorders, and neurological disorders), there are currently no medical foods other than Lumega-Z specifically addressing ocular health. Thus, with regard to the ocular health market no such data is available regarding medical foods. The most comparable industry is dietary supplements. In an attempt to illustrate the market potential for Lumega-Z, the Company has examined ocular health products in the dietary supplement market as the closest appropriate data set available. The use of dietary supplements to enhance health and well-being is a longstanding and increasing trend. According to industry sources, up to 52% of adults in the United States have reported taking nutritional supplements. Worldwide sales of supplements surpassed $132 billion in 2016. Supplementation has recently generated much interest among health professionals in a relatively new area, the prevention and slowing of the AMD epidemic.

U.S. Statistics

- According to Ocular Surgery News, there are 4 million cataract surgeries in the United States each year.
- According to the BrightFocus Foundation, more than three million Americans are living with glaucoma, 2.7 million whom are aged 40 and older.
- According the American Glaucoma Society, over 27 million people are affected with glaucoma in the U.S. alone.
- According to the American Society of Retina Specialists an estimated 15 million Americans had AMD as of 2016.
- According to Am Fam Physician, one in three people in the U.S. over age 65 will develop AMD or some vision-reducing eye disease.
- MarketScope indicates that US ophthalmology practices are comprised of approximately 18,000 individual optometrists, approximately 10,000 individual ophthalmologists, and approximately 7,000, 5,000, and 2,000 optometrist groups, ophthalmologist groups, and retail establishments, respectively.

Worldwide Statistics

- According to Bekryl Market Analysts, the "Global Medical Foods Market" was valued at $11.1 billion in 2018 and will exceed $17.5 billion by 2028. North America was expected to account for 33% of global sales in 2018.
- According to the International Council of Ophthalmology, AMD is the third leading cause of blindness throughout the world, exceeded only by cataracts and glaucoma.
- BrightFocus Foundation has indicated that globally, 60.5 million people had glaucoma in 2010. Due to the aging of the world's population, BrightFocus Foundation has indicated that this number may increase to almost 80 million by 2020.
- According to Transparency Market Research, the global glaucoma therapeutics market was valued at over $5.9 billion in 2017 and is projected to expand at a compound annual growth rate of 2.9% from 2018 to 2026.
- According to South China Morning Post, 22 million AMD patients are Chinese patients which account for approximately 18% of global Glaucoma patients.
- BrightFocus Foundation has indicated that globally, AMD is expected to reach 196 million people worldwide by 2020 and increase to 288 million by 2040.
- BrightFocus Foundation estimates the global cost of visual impairment due to AMD is $343 billion, including $255 billion in direct health care costs, and estimates the direct health care costs of visual impairment due to AMD in the U.S., Canada and Cuba to be approximately $98 million.
- BrightFocus Foundation estimates the global cost of vision loss due to all causes to be nearly $3 trillion for the 733 million people living with low vision and blindness worldwide. BrightFocus Foundation also estimates the direct costs for vision loss due to all causes was $512.8 billion in North America alone, with indirect costs of $179 billion.

- GlobalData indicates that the potential global market of AMD is currently estimated at $5 billion and expected to reach $11.5 billion by 2026.
- According to Sohu, in China there are 36,342 Ophthalmologists and 3,950 Optometrists.
- According to Springer approximately 25 to 30 million people are affected worldwide by AMD.
- The prevalence of AMD appears to be lower and more variable in the developing nations as compared to more developed countries. Healthcare experts believe this will likely change for the worse with increasing life expectancy, changing lifestyles and increase in viewing computer monitors and other devices.

Due to an aging population, the AMD, Glaucoma and Cognitive Decline epidemics are global and growing, creating a significant market for the Company's products.

Marketing Lumega-Z to Practitioners

In order to reach the large, expanding AMD patient population, the Company will primarily market Lumega-Z to the patients through ophthalmologists and optometrists. In the U.S. alone, there are more than 18,515 ophthalmologists and over 34,000 optometrists currently practicing. There are over 213,000 ophthalmologists worldwide. This marketing reach will be achieved through a combination of collaboration with industry-specific publishers, peer-to-peer promotion using key opinion leader clinicians, organic and paid search engine optimization and marketing, and other content-driven & educational approaches.

The MapcatSF® has demonstrated itself to be an effective tool to promote Lumega-Z. The Company has determined that the value of the MapcatSF is through this utilization. The Company intends to continue to deploy the MapcatSF in this fashion, with a focus of assigning the MapcatSF to clinics to build and maintain relationships with the clinics and assist the physicians in making a determination to recommend Lumega-Z to their patients. The Company believes that continued deployment of MapcatSF devices in this fashion will build effective relationships with physicians and their clinics, expand the awareness of the Company's products and increase sales of Lumega-Z.

Marketing the CSV-1000 and CSV-2000 to Practitioners

Contrast sensitivity is currently one of the standard tests for clinical trials relating to ocular surgeries and treatments, and the CSV-1000 is considered the benchmark for these applications. In addition, there is an increasing need for functional vision assessment in everyday clinical practice, as a means of measuring the effect of disorders such as cataract and macular degeneration on the patient's functional vision, and the impact of treatment of these conditions on the patient's vision. The Company will concentrate its efforts on increasing the use of contrast sensitivity in everyday clinical practice, as a means of targeting the optometry and ophthalmology markets, which consists of over 34,000 and over 18,000 doctors, respectively, in the United States.

The Company expects to continue to sell the CSV-1000 for the foreseeable future. The CSV-2000 is not yet approved by the local organizations equivalent to the FDA in many countries, and this process can take up to one or more years. The CSV-1000 will continue to be sold exclusively in those countries during that time period. The first unit of the CSV-2000 was shipped in the first quarter of 2020.

Proprietary Technology and Intellectual Property

Patents

The Company currently owns and has exclusive rights to 4 U.S. patents and 2 U.S. patent applications and 5 foreign patents and 3 foreign patent applications covering its products and product candidates.

Trade Secrets

The MapcatSF® device employs a proprietary algorithm for correcting macular pigment optical density measurements with respect to lens density effects. More particularly, the proprietary algorithm adjusts the photopic luminosity function for the age equivalence of the subject's lens using a relationship disclosed by Sagawa and Takahashi (*J. Opt. Soc. Am. 18, 2659-2667*). The algorithm is embedded in an integrated circuit block designed in such a way as to make it difficult to reverse engineer.

VectorVision's CSV-1000 has proprietary testing charts that are not only copyright protected but can only be reproduced accurately by using special lithographs. These lithographs are kept secure, with very limited access, and are closely guarded trade secrets.

Trademarks

The Company utilizes trademarks on all current products and believes that having distinguishing marks is an important factor in marketing its products. The Company has six U.S. registered trademarks on the principal register at the USPTO. These marks are listed below. The Company has two foreign registered trademarks for its products and product candidates at this time and is evaluating whether additional foreign trademark protection is appropriate. U.S. trademark registrations are generally for fixed, but renewable, terms. The Company also has common law trademark rights for the use of its marks, including common law trademark rights to the NUTRIGUARD mark.

Copyrights

In addition to patent and trademark protection, VectorVision has three copyrights registered with the U.S. Copyright Office relating to the CSV-1000 and CSV-2000 medical devices. VectorVision also has common law copyright protection on the testing charts contained in the CSV-1000 and CSV-2000 medical devices, which includes Vision Testing Chart #1, Vision Testing Chart #2 and Vision Testing Chart #3.

Medical Foods, Medical Device and Nutraceuticals Manufacturing and Sources and Availability of Raw Materials

The Company outsources the manufacturing of its medical food products, nutraceutical product line and medical devices to contract manufacturers. The Company processes orders through purchase orders and invoices with each manufacturer. The Company believes that there are multiple alternative sources, suppliers and manufacturers available for its products in the event of a termination or a disagreement with any current vendor.

Government Regulation

Medical Food Statutory Definition and One FDA Regulation

Under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), products are regulated on the basis of their intended use. Their intended use is determined by the objective factors surrounding their use. Numerous categories and subcategories of products exist under the FDCA that could relate to the Company's products, such as food, food additive, dietary supplement, GRAS food component, new drug, GRAS and Effective ("GRAS/E") drug for over the counter use, and GRAS/E drug for use under the supervision of a physician. The categories overlap and products can fall within more than one category depending on their intended use.

The FDA has provided little guidance on the regulation of medical foods, as it is still a relatively new and evolving category of product under the FDCA.

The Company's medical food products are defined and regulated by the FDA. The term medical food is a "food which is formulated to be consumed or administered enterally, or by mouth, under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The FDA advises that it considers the statutory definition of medical foods to "narrowly" constrain the types of products that fit within the category of food (see May 2007 Guidance, and Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule). This is a Final Rule and binding regulation on nutrition labeling for conventional foods.

The only FDA regulation pertaining to medical foods exempts them from the nutrition labeling requirements that apply to conventional foods, but they are subject to special labeling requirements, as noted in the following excerpt:

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(8) Medical foods as defined in section 5(b) of the Orphan Drug Act. A medical food is a food which is formulated to be consumed or administered enterally, or by mouth, under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if: (i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube; (ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; (iv) It is intended to be used under medical supervision; and (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

Unlike regulation for drugs and for dietary supplements, there is no overall regulatory scheme for medical foods, or even a pending proposed rule, meaning that no FDA rulemaking is in progress. However, a very detailed Advanced Notice of Proposed Rulemaking ("ANPR") entitled "Regulation of Medical Foods," was published in the Federal Register on Nov. 29, 1996 ("ANPR 1996"). This ANPR never progressed to a proposed rule, or through the Notice and Comment procedure, or to an eventual Final Rule (binding regulation). However, the ANPR, in conjunction with the May 2007 and August 2013 Draft Guidance still represents the FDA's position and policy on medical foods. This ANPR was in effect withdrawn, because on April 22, 2003, the FDA published a proposal to withdraw numerous long-pending proposed rules, including this ANPR. The FDA cited as its reasons for withdrawal, first, that the subjects are not a regulatory priority, and agency resources are limited; second, the proposed rules have become outdated due to advances in science or changes in the products or the industry regulated, or changes in legal or regulatory contexts; and, third, to eliminate uncertainty, so that the FDA or the private sector may resolve underlying issues in ways other than those in the proposals. In May 2007, the FDA issued its Guidance to Industry relating to medical foods ("2007 Guidance"), presumably because the medical foods sector was growing, but it did not engage in a formal rulemaking procedure, either because it did not have the resources and/or because the medical foods category is still lower priority than drugs and medical devices. A third draft guidance was issued in August 2013 further attempting to clarify the FDA's position on medical foods ("August 2013 Draft Guidance"). Although the guidance has not been formalized, the Company maintains compliance with this draft guidance.

Medical Food Regulatory Requirements

Overview: Medical foods are FDA-regulated, but there is no complete set or scheme of regulations. There is no pre-market approval, or even pre-market notification required. Rather, it is the responsibility of the manufacturer and marketer to test for safety and efficacy before marketing and selling. The developer of a medical food must adhere closely to the statutory definition, and to the descriptions of a medical food in the sole FDA regulation regarding exemption from nutrition labeling, and in the 2007 Guidance and the August 2013 Draft Guidance.

Threshold Issue: The manufacturer must demonstrate that the disease or condition to be targeted, scientifically and medically, is a disease with distinctive or unique nutritional requirements. The FDA has stated that this is a "narrow category," and that whether a product is valid for this category depends on the published medical science of the disease and its origins. The targeted disease or condition may be, or caused by, a metabolic imbalance or deficiency or the accelerated requirements for a certain nutrient caused by a disease state. The Company and its Scientific Advisory Board examine the distinctive nutritional requirements of a disease.

Formulation: A medical food may not be a single ingredient formula. Otherwise, that product would be a dietary supplement for a nutrient deficiency. A medical food formula must go beyond a mere modification of the diet. The formula must meet and satisfy the distinctive nutritional requirements, not merely ameliorate the symptoms. For example, Glucosamine or MSM, or an herb's "active" constituent may indeed help osteoarthritis. One must demonstrate that these nutrients are the distinctive nutritional requirements for osteoarthritis.

Safety: There is no particular or mandated FDA pre-market safety studies required of the formula as a whole. However, all ingredients must be either GRAS or approved food-additives. Since medical foods are typically taken with prescription drugs, the developer must assess whether any medical food/drug interactions pose a risk. Many ingredients have been determined by the FDA to be GRAS and are listed as such by regulation. Other ingredients may achieve self-affirmed GRAS status through a panel of experts on that particular substance that author a GRAS Report. The standard for an ingredient to achieve GRAS status requires not only technical demonstration of non-toxicity and safety, but also general recognition and agreement on that safety by experts in the field. All ingredients used in the Company's medical foods are either FDA-approved food additives or have GRAS status. The GRAS requirement for ingredients is arguably a higher safety standard than the risk/benefit analysis required for pharmaceuticals. Like any evolving area, especially where no premarket approval is required, the FDA reserves the right to raise questions about the qualification of products within any category as well as the labeling and manufacturing safety of those products.

Efficacy: No particular FDA pre-market efficacy studies are required by the FDA or by statute, similar to or comparable to Phase 2 & 3 trials for prescription drugs. However, a company must have data to demonstrate that the formula, when taken as directed, meets the distinctive nutritional requirements of the particular disease.

Manufacturing: There are no GMP regulations for medical foods in particular. Drug GMPs are not required, nor are the relatively new dietary supplement GMPs required; only food GMPs are required. The manufacture of the Company's medical foods is outsourced in its entirety. The Company engages state of the art facilities that manufacture only nutritional supplements and medical foods.

Labeling: As for all food labels, printing must be legible, and many required elements must be conspicuous, such as a statement of identity, which is the name of the food; the statement: "Must be administered under the supervision of a physician or professional healthcare provider;" the quantity; the ingredients listing; the name and address of the distributor among other requirements.

Marketing: A medical food is a food product, thus the FDA does not regulate advertisements and promotional activities according to the pharmaceutical statutes and regulations; there is no side effects disclaimer or fair balancing required, as in direct to consumer ("DTC") advertising of drugs on television. However, the FDA has a very broad definition of "labeling"; thus, all promotional materials, including websites, are under the authority, monitoring and enforcement of FDA. The Federal Trade Commission ("FTC") also has joint jurisdiction with the FDA over food products, per a 1983 Memorandum of Understanding. Thus, all advertising claims, both express and implied, must be true, accurate, well-substantiated, and not misleading.

Enforcement: Enforcement is post-market, mostly via annual FDA inspections of food facilities, including packaging, distribution facilities, and fulfillment houses, as well as the manufacturer. The FDA also gathers material at trade shows and conferences and examines websites. The FTC has joint jurisdiction, and performs sophisticated Internet searches, both randomly and at the request of the FDA or of a competitor.

Nutraceutical Regulation

The FDA regulates foods, food additives, drugs and cosmetics. Unlike pharmaceutical drugs and conventional foods, nutraceuticals are regulated as "dietary supplements" under the Dietary Supplement, Health and Education Act of 1994 ("DSHEA") as a separate regulatory category of food. Before the DSHEA, dietary supplements were subject to the same regulatory requirements as were other foods. DSHEA amended the FDCA to create a new regulatory framework for the safety and labeling of dietary supplements. Under DSHEA, a company is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. Dietary supplements do not need approval from FDA before they are marketed. Except in the case of a "new dietary ingredient," where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after marketing a product. In addition, there is a requirement for manufacturers to register pursuant to the Bioterrorism Act with FDA before producing or selling supplements. In June 2007, FDA published regulations for Current Good Manufacturing Practices ("cGMP") for those who manufacture, package, label or hold dietary supplement products. These regulations focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements.

Congress defined the term "dietary supplement" in DSHEA as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins, minerals, amino acids, herbs or other botanicals; a concentrate, metabolite, constituent, extract or combination of the ingredients listed above." A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites and can also be extracts or concentrates. Dietary supplements are produced in the form of tablets, capsules, softgels, gelcaps, liquids, or powders. Dietary supplements can also be in other forms, such as a nutrition bar, but if they are in another form, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Regardless of form, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires the product to be labeled as a "dietary supplement."

According to the FDA, a drug is an article intended to diagnose, cure, mitigate, treat or prevent disease. While nutraceuticals are not intended to cure or treat disease, both dietary supplements and drugs are intended to affect the structure or function of the body. Dietary supplements that contain structure/function claims on their labels must bear the disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. Moreover, dietary supplements are supposed to enhance the diet, not be used as a conventional food or as the sole item of a meal or diet, and not supposed to be taken alone as a substitute for any food or medicine.

The DSHEA requires that a manufacturer or distributor notify FDA if it intends to market a dietary supplement in the U.S. that contains a "new dietary ingredient." The manufacturer and distributor must demonstrate to FDA why the ingredient is reasonably expected to be safe for use in a dietary supplement, unless it has been recognized as a food substance and is present in the food supply. A new dietary ingredient is an ingredient marketed after October 15, 1994. There is no authoritative list of dietary ingredients that were marketed before October 15, 1994. Therefore, manufacturers and distributors are responsible for determining if a dietary ingredient is "new," and if it is not, for documenting that the dietary supplements its sells, containing the dietary ingredient, were marketed before October 15, 1994. The DSHEA states that the manufacturer is responsible for the safety evaluation of the product. If the dietary supplement contains a new ingredient, the manufacturer must inform FDA that the new ingredient "can reasonably be expected to be safe" within 75 days of going to market. This notice must provide information that supports the manufacturer's conclusion that the ingredient is safe. It is up to the FDA to prove that a dietary supplement is unsafe after it is marketed.

A dietary supplement is adulterated if, among other things, it or an ingredient in it presents a "significant or unreasonable risk of illness or injury" when used as directed or contains a new ingredient for which there is insufficient information to provide assurance that the ingredient does not present any significant or unreasonable risk of illness or injury. The DSHEA also has labeling requirements for dietary supplements including requiring information on the label such as: (1) name of each ingredient; (2) quantity of each ingredient; (3) total weight of all ingredients, if a blend; (4) identity of the plant part used; (5) the term "Dietary Supplement;" (6) nutritional labelling information (calories, fat, sodium, etc.).

Medical Device Regulatory Requirements

To fall within the purview of the FDA, a product must first meet the definition of a medical device, whereby it is then subject to regulation before and after it is marketed. Section 201(h) of the FDCA defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." If the product in question is not a medical device, then no regulation applies. If it is a medical device, then one must evaluate applicable regulation.

Since 1976, the FDA's paradigm has categorized medical devices in three distinct classes based on the potential health risks to the public – Class I, Class II, and Class III. Medical devices are assigned a classification based on the level of control needed in order to provide the FDA reasonable assurance of the product's safety and effectiveness. If a device represents a very low risk of injury, it is considered Class I and does not require any premarket approval. While most Class I devices are exempt from premarket notification requirements and regulations for good manufacturing practices, there are some general controls that companies must conduct such as registering the company with the FDA, listing the device, paying an annual registration fee and tracking device activity.

Devices that present an intermediate level of risk of injury to people are considered Class II. The FDA's perspective is that for Class II devices "general controls alone are insufficient to assure safety and effectiveness." In addition to general controls, Class II devices also require special controls such as specified content on labels, adherence to performance standards and surveillance of the product in the marketplace. Some medical devices are also subject to a "Premarket Notification" under Section 510(k) of the FDCA. Most Class I and some Class II devices are exempt from the 510(k) Premarket Notification requirement. If a Class II device is subject to the 510(k) requirement, the manufacturer must file a premarket notification with the FDA to demonstrate that the device is "substantially similar" to another Class II device already on the market. Establishing substantial similarity provides the FDA reasonable assurance that the device is safe and effective.

High risk devices are Class III. These are devices that either sustain human life or present an unreasonable risk of injury to humans. Because of the risks involved, the FDA does not believe that general or special controls are sufficient to assure safety and effectiveness. The FDA requires general controls and premarket approval ("PMA") for Class III devices.

The Company is registered with the FDA as a medical device manufacturer under registration number 3010367547. The MapcatSF is listed with the FDA as a Class I medical device. With the assistance of regulatory affairs consultants, the Company has determined the relevant predicate device for the MapcatSF is the MPS II, the applicable product code for the MapcatSF is HJW and the applicable Code of Federal Regulation is 886.1050. The FDA has determined that this particular predicate device, and related product code, is a Class I medical device. Based on this, the Company believes the MapcatSF is correctly classified as a Class I medical device, is a safe medical device with a very low potential risk of injury to a patient and does not require any premarket approval. As a Class I medical device, the MapcatSF is a safe medical device with a very low potential risk of injury to a patient. This device does not require any premarket approval.

VectorVision is registered with the FDA as a medical device manufacturer under registration number 1527853. The CSV-1000 and the ESV-3000 medical devices are listed with the FDA as Class I medical devices. The applicable product code for these devices is HOX and the applicable Code of Federal Regulation is 886.1150. As Class I medical devices, the CSV-1000 and the ESV-3000 are safe medical devices each with a very low potential risk of injury to a patient. These devices do not require any premarket approval.

Stark Law

Congress enacted significant prohibitions against physician self-referrals in the Omnibus Budget Reconciliation Act of 1993. This law and its supporting regulations, which have been amended and expanded substantially, are commonly referred to as the "Stark Law," and prohibit a physician from making any referral of a Stark Designated Health Service ("DHS") to an entity with which the physician has any kind of financial relationship, unless all of the requirements of a statutory or regulatory exception are met. Stark covered DHS include both outpatient prescription drugs and diagnostic testing that are reimbursable by Medicare or Medicaid. Many states have similar laws, some of which can apply to all payors and not just governmental payors. While the Company believes that its arrangements with its customers are in compliance with the federal and any state Stark Laws, the Stark Laws present different levels of risks as to the Company's two lines of business: (1) sale of the Company's medical food, Lumega-Z, and medical device, the MapcatSF; and (2) the Company's performance of TCD testing.

1. Medical Foods, and Medical Devices. These products are neither prescription drugs nor are they reimbursable under any federal program at present. The federal Stark Law is thus inapplicable. Further, the Company's believes that these products are also not covered under any potentially applicable state Stark Laws. The federal Stark Law, however, includes an exception for the provision of in-office ancillary services, including a physician's dispensing of outpatient prescription drugs, provided that the physician meets specified requirements. To the extent that the products might become reimbursable under a federal program, or otherwise become covered under the Stark Law, the Company believes that the physicians who use the Company's medical device, the MapcatSF, purchase the CSV-1000, CSV-2000 or ESV-3000, or recommend its medical foods, Lumega-Z and GlaucoCetin, to their patients are aware of these requirements. However, the Company does not monitor their compliance and has no assurance that the physicians are in material compliance with Stark II. If it were determined that the physicians who use the Company's medical device or prescribe medical foods purchased from the Company were not in compliance with Stark II, it could potentially have an adverse effect on the Company's business, financial condition and results of operations.

2. The TCD Testing Business. The TCD tests performed by the Company can be reimbursed by Medicare or Medicaid and otherwise constitute a Stark covered DHS, which include diagnostic testing. In conducting TCD tests, the Company will be providing the tests to the ordering physician, who will be paying TCD as a vendor to perform the test on behalf of the physician; and the physician will then be billing for the test to third party payers, including potentially Medicare and Medicaid. As a result, the tests will be considered to be an in-office ancillary service covered under Stark. The Stark Law, however, includes an exception for the provision of such in-office ancillary services, provided that the physician meets specified requirements. The Company believes that the physicians who engage the Company as a vendor to perform the TCD tests are aware of these requirements. However, the Company does not monitor the physicians' compliance and has no assurance that the physicians are in material compliance with the Stark Law. If it were determined that the physicians were not in compliance with Stark, such could potentially have an adverse effect on the Company's business, financial condition and results of operations.

Anti-Kickback Statute and HIPAA Criminal Laws

The federal anti-kickback statute (the "AKS") applies to Medicare, Medicaid and other state and federal programs. AKS prohibits the solicitation, offer, payment or receipt of remuneration in return for referrals or the purchase, or in return for recommending or arranging for the referral or purchase, of goods, including drugs, covered by the federal health care programs. At present, the Company does not participate in any federal programs and its products are not reimbursed by Medicare, Medicaid or any other state or federal program. The AKS is a criminal statute with criminal penalties, as well as potential civil and administrative penalties. The AKS, however, provides a number of statutory exceptions and regulatory "safe harbors" for particular types of transactions. Many states have similar fraud and abuse laws and their own anti-kickback laws, some of which can apply to all payors, and not just governmental payors. While the Company believes that it is in material compliance with both federal and state AKS laws, the AKS laws present different levels of risks as to the Company's two lines of business: (1) sale of the Company's medical food, Lumega-Z, and medical device, the MapcatSF; and (2) the Company's performance of TCD testing.

1. Medical Foods, and Medical Devices. At present, the Company's products are not reimbursable under any federal program. If, however, that changes in the future and it were determined that the Company was not in compliance with the AKS, the Company could be subject to liability, and its operations could be curtailed. Moreover, if the activities of its customers or other entity with which the Company has a business relationship were found to constitute a violation of the AKS and the Company, as a result of the provision of products or services to such customer or entity, were found to have knowingly participated in such activities, the Company could be subject to sanctions or liability under such laws, including civil and/or criminal penalties, as well as exclusion from government health programs. As a result of exclusion from government health programs, neither products nor services could be provided to any beneficiaries of any federal healthcare program.

2. The TCD Testing Business. The TCD tests performed by the Company can be reimbursed by Medicare or Medicaid. As a result, the federal AKS (and potentially any state anti-kickback law) will be implicated to the extent the financial relationships between the physician customers and the Company are (1) not set at a fair market value amount unrelated to the volume or value of TCD tests being ordered; or (2) were found to be a circumvention of the AKS through the creation of a suspect contractual joint venture. If the Company's arrangements with ordering physicians were found to constitute a violation of the federal AKS, or any applicable state anti-kickback law, we could be subject to sanctions or liability under such laws, including civil and/or criminal penalties, as well as exclusion from government health programs. As a result of exclusion from government health programs, neither products nor services could be provided to any beneficiaries of any federal healthcare program.

HIPAA Compliance and Privacy Protection

HIPAA established comprehensive federal protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": (1) health plans, (2) health care clearing houses, and (3) health care providers who conduct certain health care transactions electronically. Covered Entities must have in place administrative, physical and technical standards to guard against the misuse of individually identifiable health information. Additionally, some state laws impose privacy protections more stringent than HIPAA's. There are also international privacy laws, such as the European Data Directive, that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact the Company's business in the future.

HITECH Act

The Health Information Technology for Economic and Clinical Health ("HITECH") Act promotes the adoption and meaningful use of health information technology. The HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA rules.

Physician Sunshine Act

Health Care Reform Law provision, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for drug and device manufacturers with regard to payments or other transfers of value made to certain practitioners (including physicians, dentists and teaching hospitals), and for such manufacturers and for group purchasing organizations, with regard to certain ownership interests held by physicians in the reporting entity. The Centers for Medicine and Medicaid Services ("CMS") publishes information from these reports on a publicly available website, including amounts transferred and physician, dentist and teaching hospital identities.

Under the Physician Payment Sunshine Act applicable organizations are required to collect and report detailed information regarding certain financial relationships they have with physicians, dentists and teaching hospitals. The Physician Payment Sunshine Act preempts similar state reporting laws, although some companies may also be required to report under certain state transparency laws that address circumstances not covered by the Physician Payment Sunshine Act, and some of these state laws, as well as the federal law, are ambiguous. Because the Company's medical devices are Class I, not subject to premarket approval, and not reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program the Company believes it is not currently subject to the Physician Payment Sunshine Act requirements. As the Company pursues commercialization of the MapcatSF® and considers introducing new products, these requirements will be reevaluated to determine their applicability to the Company's activities.

The Federal False Claims Act

The Federal False Claims Act provides for the imposition of extensive financial penalties (including treble damages and fines of over $22,000 for every false claim) if a provider submits false claims to any governmental health program either knowingly or in reckless disregard or in deliberate ignorance of the truth or falsity of the claims at issue. Liability under the False Claims Act can arise from patterns of deficient documentation, coding and billing, as well as for billing for services that are deemed not to have been medically necessary for the treatment of the patient. Many states have their own False Claims Acts as well. The Company will be billing governmental health care programs for the TCD testing, and the False Claims Act is thus potentially applicable to the Company's operations. The Company is putting in place a fraud and abuse compliance program that is designed to ensure that the Company's documentation, coding and billing for TCD tests are accurate and compliant. Any patterns of uncorrected deficiencies in documenting, coding and billing for TCD tests, however, may result in fines and other liabilities, which may adversely affect the Company's results of operations.

State Regulatory Requirements

Each state has its own regulations concerning physician dispensing, restrictions on the Corporate Practice of Medicine ("CPOM"), anti-kickback and false claim regulations. In addition, each state has a board of pharmacy that regulates the sale and distribution of drugs and other therapeutic agents. Some states require that a physician obtain a license to dispense prescription products. When considering the commencement of business in a new state, the Company consults with healthcare counsel regarding the expansion of operations and utilizes local counsel when necessary.

Many states prohibit or otherwise regulate under CPOM rules the extent to which non-licensed personnel may be involved in the practice of medicine or otherwise employ licensed personnel. Related state rules further limit the extent to which fees for professional services may be shared or "split" between parties. Under the TCD Testing line of business, such rules in some states my impact the Company's relationship with the radiologists who will be reading and interpreting the results of the TCD tests, and thereby providing the "professional component" of such tests. The Company is structuring its financial and billing relationships with such radiologists to be in compliance with applicable state rules. Failure to comply with state CPOM and fee splitting rules, however, may result in fines and other liabilities, which may adversely affect the Company's results of operations.

Other United States Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws. In addition, the Company may be subject to federal and state laws requiring the disclosure of financial arrangements with health care professionals.

Foreign Regulatory Requirements

The Company may eventually be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacturing, product registration and approval, and sales. Whether or not FDA approval has been obtained, generally the Company must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in those countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Corporate History

Guardion Health Sciences, Inc. was formed under the name P4L Health Sciences, LLC in December 2009 in California as a limited liability company. The Company changed its name to Guardion Health Sciences, LLC in December 2009. In June 2015, the Company converted into a Delaware "C" corporation.

On January 30, 2019, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-two (1:2) reverse stock split (the "Reverse Stock Split") of its common stock without any change to its par value. Proportional adjustments for the Reverse Stock Split were made to the Company's outstanding common stock, stock options, and warrants as if the split occurred at the beginning of the earliest period presented in this Annual Report.

Employees

As of March 27, 2020, the Company, including its subsidiaries, had a total of 22 employees, including 21 full-time employees and one part-time employee.

Advisory Boards

The Company's research and development efforts are shaped by a Science Advisory Board with advice from a Medical Advisory Board consisting of practicing physicians. Both teams are committed to revealing and validating the connections between health and nutrition and then developing products based on these findings. Their joint goal is the integration of a medical model incorporating nutritional therapy into clinical practice.

Science Advisory Board

The Company's Science Advisory Board is a product development and research team of esteemed experts in the fields of biochemistry, biophysics, and clinical nutrition. In addition to developing products based on scientific studies in the public domain, members of the Science Advisory Board conduct and publish their own evidence. Their expertise and the evidence they develop guide the formulation of all of the Company's products. As an elite team of scientists and researchers, members of the Science Advisory Board contribute a high level of experience and judgment to the field of retinal health and nutrition. The Science Advisory Board currently consists of:

- **Richard A. Bone, BSc, PhD, FARVO**
  Dr. Bone is an experimental biophysicist and professor in the department of physics at Florida International University in Miami. Bone was just awarded The Presidential Award for achievement in macular pigment research and dedicated service to the carotenoid field.

- **John T. Landrum, BS, MS, PhD, FARVO**
  Dr. Landrum is a research scientist and professor of Chemistry and Biochemistry at Florida International University (FIU). Dr. Landrum was just appointed president of the International Carotenoid Society for the next 3 years.

- **William E. Sponsel, M.D., M.B., Ch.B., F.R.A.N.Z.C.O., F.A.C.S.**
  Dr. Sponsel established the Glaucoma Research and Diagnostic Laboratory at Indiana University in 1991, and was later recruited to the University of Texas Health Science Center at San Antonio in 1994, where he became Professor and Director of Clinical Research. He is presently Professor of Vision Sciences at UIW and Adjunct Professor of Biomedical Engineering at UTSA in San Antonio, Texas.

- **Robert J. Donati, PhD.**
  Dr. Donati has a PhD in Anatomy and Cell Biology with a minor in Neuroscience from the University of Illinois at Chicago (UIC). He joined the faculty at the Illinois College of Optometry (ICO) in 2004 and has been an Associate Professor for the past 5 years. He is currently the Chair of the ICO Institutional Review Board.

- **Mark F. McCarty**
  Mr. McCarty is a nutritionist and a researcher who obtained his undergraduate education in biochemistry at the University of California San Diego, Revelle College. He has published over three hundred articles on a wide range of biomedical topics in the peer-reviewed medical literature. He has been awarded seven U.S. patents for a variety of applied nutritional measures. McCarty co-founded NutriGuard Research and previously worked as the research director for Nutrition 21. Mr. McCarty also serves as the Director of Research of NutriGuard Formulations, Inc.

- **In memoriam of:**
  Sheldon Saul Hendler, M.D., Ph.D., FACP, FACN, FAIC – (1936-2012)
  Dr. Hendler was the principal author and editor of the PDR for Nutritional Supplements. Dr. Hendler passed away suddenly in November 2012. He was the founding head of the Company's Science Advisory Board. Dr. Hendler supervised and completed the formulas for Lumega-Z for the Company in 2011.

Medical Advisory Board

The Company's Medical Advisory Board is composed of clinicians who are active medical practitioners. Members of the Medical Advisory Board consult with the Scientific Advisory Board on the current standards of care in relevant medical practices. Members of the Medical Advisory Board objectively advise on trends, needs, and issues of concern within their specialties. Their input helps shape the direction of the Company's research and product development efforts. The Medical Advisory Board currently consists of:

- **Robert Ritch, M.D.**
  Dr. Ritch holds the Shelley and Steven Einhorn Distinguished Chair in Ophthalmology and is Surgeon Director Emeritus and Chief of Glaucoma Services at the New York Eye & Ear Infirmary, New York City and Professor of Ophthalmology at The New York Medical College, Valhalla, New York.

- **John A. Hovanesian, M.D., FACS**
  Dr. Hovanesian is faculty member at the UCLA Jules Stein Eye Institute, a board-certified ophthalmologist, and an internationally recognized leader in the field of corneal, cataract, refractive, and laser surgery. He is the chairman of the American Academy of Ophthalmology's online cataract surgery education committee and an editorial board member for five other eye journals.

- **Richard Rosen, M.D.**
  Dr. Rosen is a vitreoretinal surgeon and consultant at the New York Eye and Ear Infirmary where he serves as Vice Chairman and Director of Ophthalmology Research, as well as Surgeon Director and Chief of Retinal Services. Dr. Rosen is Professor of Ophthalmology at the Icahn School of Medicine at Mount Sinai and Visiting Professor in Applied Optics at the University of Kent in Canterbury, UK.

- **William Trattler, M.D.**
  Dr. Trattler received the "Outstanding Young Ophthalmologist Leadership Award" from the Florida Society of Ophthalmology (FSO) and was elected President of the Miami Ophthalmology Society for 2006. In March 2006, Dr. Trattler was selected as one of the top 50 opinion leaders in Ophthalmology, as voted by his peers in a National survey.

- **James A. Davies, M.D.**
  Dr. Davies is a Fellow of the American College of Surgeons, the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery. He serves on the Medical Advisory Board of Bausch + Lomb Surgical, Inc., and is a consultant for Glaukos, Inc., Optovue, Inc., and Guardion Health Sciences. He also serves as an advisor to the Charity Vision Foundation.

- **P. Dee Stephenson, M.D.**
  Dr. Stephenson is a Board Certified Ophthalmic Surgeon with extensive expertise in micro-incisional cataract surgery and implantation of premium intra-ocular lenses, as well as custom femto cataract techniques. Dr. Stephenson has been recognized by numerous institutions for her expertise. She is also the current president (2015-2017) of the American College of Eye Surgeons (ACES).

- **Bridgitte Shen Lee, O.D.**
  Dr. Lee is the cofounder of Vision Optique. She also founded iTravelCE in 2010 and serves as a consultant and a speaker for various optical industry companies to introduce eye care professionals in the U.S. and Asia to the latest innovations. She served on the Houston Miller Theatre Advisory Board, and she currently serves on the Houston Ballet Foundation Board of Trustees.

- **Joseph S. Andrews, M.D.**
  Dr. Andrews is a member of the Private Internal Medicine Center (PIMC) at Scripps Clinic Torrey Pines, San Diego and has diplomate board certification from the American Board of Internal Medicine. He is currently a clinical mentor at St. Vincent de Paul Clinic. In 2009, he was listed among San Diego's Top Doctors by San Diego magazine.

- **John E. Wanebo, M.D., FACS**
  Dr. Wanebo is the Director of Neurotrauma at the Scottsdale Healthcare System. Additionally, he serves as a staff neurosurgeon and Director of the Moyamoya Center at Barrow Neurological Institute, St. Joseph's Medical Center, in Phoenix, where he is also an assistant professor within the Division of Neurological Surgery. He is board certified by the American Board of Neurological Surgery.

ITEM 1A. RISK FACTORS

Investing in the Company's common stock involves a high degree of risk. Prospective investors should carefully consider the risks described below, together with all of the other information included or referred to in this Form 10-K, before purchasing shares of the Company's common stock. There are numerous and varied risks that may prevent the Company from achieving its goals. If any of these risks actually occurs, the business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of the Company's common stock could decline and investors in the Company's common stock could lose all or part of their investment.

Risks Related to the Company's Business

As the Company has incurred recurring losses and negative cash flows since our inception, there is no assurance that the Company will be able to continue as a going concern absent additional financing, which the Company may not be able to obtain on favorable terms or at all.

The Company has incurred net losses since inception in 2009 and cannot be certain if or when the Company will produce sufficient revenue from operations to support costs. The Company had a net loss of $10,878,308 for the year ended December 31, 2019 and a net loss of $7,767,407 for the year ended December 31, 2018. The Company had an accumulated deficit of $45,511,671 as of December 31, 2019. The Company expects to continue to incur net losses and negative operating cash flows in the near-term.

The Company will continue to incur significant expenses for commercialization activities related to its medical foods Lumega-Z® and Glauco-Cetin™, its nutraceuticals product line, the MapcatSF® medical device and the CSV-1000 and CSV-2000 medical devices, and with respect to efforts to build its infrastructure and expand its operations.

Even if profitability is achieved in the future, the Company may not be able to sustain profitability on a consistent basis. The Company expects to continue to incur substantial losses and negative cash flow from operations for the foreseeable future. The Company's financial statements included in this Annual Report have been prepared assuming that the Company will continue as a going concern. The Company's auditors have made reference to the substantial doubt as to our ability to continue as a going concern in their audit report on its audited financial statements for the year ended December 31, 2019. Because the Company has been issued an opinion by its auditors that substantial doubt exists as to whether the Company can continue as a going concern, it may be more difficult for the Company to attract investors. The Company's future is dependent upon its ability to obtain financing and upon future profitable operations.

The Company does not have any credit facilities as a source of present or future funds, and there can be no assurance that the Company will be able to raise sufficient additional capital on acceptable terms, or at all. The Company may seek additional capital through a combination of private and public equity offerings and debt financings. If the Company raises additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting the ability to take specific actions, such as incurring additional debt, would increase expenses and require that Company assets secure such debt. Moreover, any debt the Company incurs must be repaid regardless of our operating results.

The Company's ability to obtain additional financing in the future will be subject to a number of factors, including market conditions, operating performance and investor sentiment. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may have to significantly delay, scale back or discontinue our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on its business, stock price and relationships with third parties, at least until additional funding is obtained. If the Company does not have sufficient funds to continue operations, the Company could be required to seek other alternatives that would likely result in our stockholders losing some or all of their investment.

The Company's future success is largely dependent on the successful commercialization of Lumega-Z® and GlaucoCetin™ medical foods, its line of nutraceuticals, the MapcatSF® medical device, and the CSV-1000 and CSV-2000 medical devices.

The future success of the Company's business is largely dependent upon the successful commercialization of its medical foods, nutraceuticals and medical devices. If the Company is unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, it may be unable to successfully commercialize its products. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues the Company may be able to generate from sales. If this occurs, it will have an adverse impact on operations and the Company's ability to fund future development and commercialization efforts.

The Company may fail to realize all of the anticipated benefits of the VectorVision acquisition and NutriGuard Acquisition or those benefits may take longer to realize than expected. The Company may also encounter significant difficulties in integrating VectorVision and NutriGuard into the existing business and VectorVision and NutriGuard may underperform relative to the Company's expectations.

The Company may not fully realize the anticipated benefits of the VectorVision acquisition and NutriGuard Acquisition. The Company has integrated the business of VectorVision and begun to integrate NutriGuard with its legacy businesses, and the Company may continue to devote significant management attention and resources to operate and grow these businesses. The failure to realize the anticipated benefits of the VectorVision acquisition and the NutriGuard Acquisition could cause an interruption of, or a loss of momentum in, the Company's operations and could adversely affect its business, financial condition and results of operations. In addition, continued operation of VectorVision and NutriGuard may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customers and other business relationships, and diversion of management's attention. Additional challenges may include, among other things, difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects and the impact of potential liabilities the Company may be assuming from VectorVision or NutriGuard.

During the fourth quarter of 2019, the Company conducted its annual impairment analysis, considering multiple qualitative observations and indicators, including our customer relationships, the regulatory environment as it impacts medical devices, market penetration expectations and barriers, and our anticipated competitive environment. In addition, we assessed the operating results of our VectorVision reporting unit against the quantitative assumptions we used when determining the initial fair values associated with the 2017 business combination. Accordingly, the Company has recorded a goodwill impairment charge of $1,563,520 and has accelerated the remaining amortization expense of $191,468 on its identifiable intangible assets as of December 31, 2019.

The Company has limited experience in developing medical foods, medical devices and nutraceuticals and it may be unable to commercialize some of the products and services it develops or acquires.

Development and commercialization of medical foods and medical devices involves a lengthy and complex process. The Company has limited experience in developing products and has only two commercialized medical food products on the market, Lumega-Z and GlaucoCetin. In addition, no one has ever developed or commercialized a medical device like the MapcatSF. The Company cannot assure you that it is possible to further develop or successfully commercialize the MapcatSF or that it will be successful in doing so. The Company is preparing to launch the CSV-2000, but there is no assurance the introduction of the instrument will be successful. Furthermore, there is no guarantee that the NutriGuard nutraceuticals will be marketable or that the Company will achieve commercial success with the product line.

Even if the Company develops or acquires products for commercial use, these products may not be accepted by the medical and pharmaceutical marketplaces or be capable of being offered at prices that will enable the Company to become profitable. The Company cannot assure you that its products will be approved by regulatory authorities, if required, or ultimately prove to be useful for commercial markets, meet applicable regulatory standards, or be successfully marketed.

The Company's ongoing investment in new businesses and new products, services, and technologies is inherently risky, and could disrupt its current operations.

The Company has invested and expects to continue to invest in new businesses, products, services, and technologies. The expansion into the transcranial doppler testing business is a reflection of its ongoing efforts to innovate and provide useful products and services. Such endeavors involve significant risks and uncertainties, including insufficient revenues from such investments to offset any new liabilities assumed and expenses associated with these new investments, inadequate return of capital on the Company's investments, distraction of management from current operations, and unidentified issues not discovered in its due diligence of such strategies and offerings that could cause the Company to fail to realize the anticipated benefits of such investments and incur unanticipated liabilities. Because these new ventures are inherently risky, no assurance can be given that such strategies and offerings will be successful and will not adversely affect the Company's reputation, financial condition, and operating results.

The Company and its suppliers and manufacturers are subject to a number of existing laws, regulations and industry initiatives and the regulatory environment of the healthcare industry is continuing to change. If it is determined that the Company or its suppliers or manufacturers are not in compliance with the laws and regulations to which they are respectively subject, the Company's business, financial condition and results of operations may be adversely affected.

As a participant in the healthcare industry, the Company's operations and relationships, and those of the Company's customers, are regulated by a number of federal, state, local, and foreign governmental entities, and the Company's products must be capable of being used by its customers in a manner that complies with those laws and regulations. For example, from the FDA's perspective, a drug cures, treats, or mitigates the effects or symptoms of a specific disease. A medical food manages a specific disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. While the Company believes Lumega-Z and GlaucoCetin are medical foods, if the FDA determines Lumega-Z or GlaucoCetin to be a drug, the Company and the product would be subject to considerable additional FDA regulation. Similarly, the Company believes the MapcatSF is correctly classified as a Class I medical device, which does not require any premarket approval. The Company also believes the CSV-2000 is a Class I medical device. If, however, the FDA were to determine that the MapcatSF or CSV-2000 is a Class II medical device, the Company and the particular product or products would be subject to considerable additional regulatory requirements.

The NutriGuard line of products are nutraceuticals and are regulated as dietary supplements under the Dietary Supplement, Health and Education Act of 1994 ("DSHEA"). Although dietary supplements are considered a separate regulatory category of food from consumer food products and medical foods, the FDA requires facilities that manufacture nutraceuticals to comply with regulations for current good manufacturing practices ("cGMP"). The Company does not manufacture any of the medical foods or nutraceuticals internally. The Company relies on contract manufacturers to manufacture the products. The FDA cGMP regulations largely are applicable to the site where the product is manufactured. Thus, the Company depends on the contract manufacturers to maintain cGMP compliance.

In addition, the Company cannot anticipate how changes in regulations or determinations by regulatory agencies may evolve. Thus, application of many foreign, state and federal regulations to the Company's business operations is uncertain. Further, there are federal and state fraud and abuse laws, including anti-kickback laws and limitations on physician referrals and laws related to off-label promotion of prescription drugs that may or may not be directly or indirectly applicable to the Company's operations and relationships or the business practices of its customers. It is possible that a review of its business practices or those of its customers by courts or regulatory authorities could result in a determination that may adversely affect the Company. In addition, the healthcare regulatory environment may change in a way that restricts existing operations or growth. The healthcare industry is expected to continue to undergo significant changes for the foreseeable future, which could have an adverse effect on the Company's business, financial condition and results of operations. The Company cannot predict the effect of possible future legislation and regulation.

The Company may be subject to fines, penalties, injunctions and other sanctions if it is deemed to be promoting the use of its products as a drug.

The Company's business and future growth depend on the development, use and ultimate sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, the Company is prohibited from promoting its products for treatment of a condition or disease. This means that the Company may not make claims about the usefulness or effectiveness or expected outcome of use of its products for any particular condition or disease and may not proactively discuss or provide information on the use of its products, except as allowed by the FDA.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for use as a drug in violation of applicable law. The Company also faces the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that the Company discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations are typically expensive, disruptive, burdensome and generate negative publicity. If its promotional activities are found to be in violation of applicable law or if the Company agrees to a settlement in connection with an enforcement action, the Company would likely face significant fines and penalties and would likely be required to substantially change its sales, promotion and educational activities. In addition, were any enforcement actions against the Company or its senior officers to arise, the Company could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

The Company's products may cause undesirable side effects or have other properties that could delay or prevent any required regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

If the Company's products, including Lumega-Z, GlaucoCetin or the NutriGuard line of products, are associated with undesirable side effects or have characteristics that are unexpected, the Company may need to abandon its development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any serious adverse or undesirable side effects identified during the development of its products, could interrupt, delay or halt commercialization and/or could result in the additional regulatory requirements by the FDA or other regulatory authorities, and in turn prevent the Company from commercializing its product candidates and generating revenues from their sale.

A key part of the Company's business strategy is to establish collaborative relationships to commercialize and develop its product candidates. The Company may not succeed in establishing and maintaining collaborative relationships, which may significantly limit its ability to develop and commercialize its products successfully, if at all.

A key part of the Company's business strategy is to establish collaborative relationships to commercialize and fund development of its product candidates. The Company is currently a party to several collaborative relationships.

While the Company believes that these collaborative relationships help further validate our products, these relationships are not material to the Company because none of these relationships is exclusive, there are many potential collaborative partners available, and the Company and each collaborator is free to enter into other collaborative relationships as needed.

The Company may not be able to negotiate collaborations on acceptable terms, if at all, and if it does enter into collaborations, these collaborations may not be successful. The Company's current and future success depends in part on its ability to enter into successful collaboration arrangements. If the Company is unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, the Company may have to delay or discontinue further development of one or more of its product candidates, undertake development and commercialization activities at its own expense or find alternative sources of capital. Consequently, if it is unable to enter into, maintain or extend successful collaborations, the Company's business may be harmed.

The Company's long-term success may depend upon the successful development and commercialization of products other than its current products.

The Company's long-term viability and growth may depend upon the successful development and commercialization of products other than its current line of products. Product development and commercialization is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Product development is a complex and time-consuming process. If the Company fails to adequately manage the research, development, execution and regulatory aspects of new product development it may fail to launch new products altogether.

We could be negatively impacted by the recent outbreak of coronavirus (COVID-19).

In light of the uncertain and rapidly evolving situation relating to the spread of the coronavirus (COVID-19), this public health concern could pose a risk to our customers, our employees, our vendors and the communities in which we operate, which could negatively impact our business. Additionally, the State of California issued a Statewide Executive Order on March 19, 2020, which could impact our operations materially in the short term. The extent to which the coronavirus (COVID-19) may impact our business will depend on future developments, which are highly uncertain and cannot be predicted at this time. We could experience customer or widespread shutdowns to prevent spread of the virus, employee impacts from illness, school closures and other community response measures, all of which could negatively impact our business. We intend to continue to monitor the situation and may adjust our current policies and practices as more information and guidance become available.

Government agencies may establish usage guidelines that directly apply to the Company's products or proposed products or change legislation or regulations to which the Company is subject.

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of the Company's products and products that the Company may develop. In addition, there can be no assurance that government regulations applicable to the Company's products or proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of its products for a period of time or permanently. The FDA's policies may change and additional government regulations may be enacted that could modify, prevent, delay or change the regulatory approval required of the Company's products. The Company cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or in other countries.

Patent litigation is common in the pharmaceutical and biopharmaceutical industries. Any litigation or claim against the Company may cause it to incur substantial costs and could place a significant strain on its financial resources, divert the attention of management from its business and harm the Company's reputation.

While the Company is not a pharmaceutical or a biopharmaceutical company, as a health sciences company, the Company's medical foods or its medical devices may come into competition with products in the medical foods and related industries, such as pharmaceuticals, biologics or dietary supplements. There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. The Company expects it will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain its competitive position. The Company may find it necessary to initiate claims to defend its intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of the Company's products or know-how or require the Company to license such patents and pay significant fees or royalties to produce its products. In addition, future patents may issue to third parties which the Company's technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which the Company is unaware that may later result in issued patents that the Company's products may infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, and could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, the Company may be required to pay substantial damages, including treble damages and attorney's fees to the party claiming infringement if the Company were to be found to have willfully infringed a third party's patent. The Company may also have to develop non-infringing technology, stop selling any products it develops, cease using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. The Company's failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm its business. Modification of any products the Company develops or development of new products thereafter could require the Company to become subject to other requirements of the FDA and other regulatory bodies, which could be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent the Company from selling any products it develops, which could harm its business.

The Company's competitors may develop products similar to the Company's medical foods, medical devices and nutraceuticals, and the Company may therefore need to modify or alter its business strategy, which may delay the achievement of its goals.

Competitors may develop products with similar characteristics to our products. Such similar products marketed by larger competitors could hinder the Company's efforts to penetrate the market.

Many large competitors have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may develop products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in manufacturing, sales and marketing.

As a result, the Company may be forced to modify or alter its business and regulatory strategy and sales and marketing plans, as a response to changes in the market, competition and technology limitations, among others. Such modifications may pose additional delays in achieving the Company's goals.

If the Company is unable to develop its own sales, marketing and distribution capabilities, or if it is not successful in contracting with third parties for these services on favorable terms, or at all, revenues from product sales could be limited.

The Company currently has a sales force consisting of a sales manager and four salespeople. To commercialize our products successfully, we have to develop more robust capabilities internally or collaborate with third parties that can perform these services for us. In the process of commercializing our products, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations capable of successfully launching new products and generating sufficient product revenues. In addition, establishing such operations takes time and involves significant expense.

If the Company decides to enter into co-promotion or other licensing arrangements with third parties, we may be unable to identify acceptable partners because the number of potential partners is limited and because of competition from others for similar alliances with potential partners. Even if we are able to identify one or more acceptable partners, we may not be able to enter into any partnering arrangements on favorable terms, or at all. If we enter into any partnering arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

In addition, any revenues the Company receives would depend upon our partners' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, and change of strategic focus, further business combinations or other factors outside of our control. Depending upon the terms of our agreements, the remedies we have against an under-performing partner may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement partner on acceptable terms, or at all.

Product liability lawsuits against the Company could divert its resources and could cause it to incur substantial liabilities and to limit commercialization of Company products.

We face a risk of product liability exposure related to the use of our products, including Lumega-Z, GlaucoCetin and the NutriGuard product line of nutraceuticals. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- loss of revenue; and
- reduced time and attention of our management to pursue our business strategy.

Our insurance policies may not fully cover liabilities that we may incur in the event of a product liability lawsuit. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

The Company may be unsuccessful in expanding its product distribution outside the United States.

To the extent we begin to offer our products outside the United States, we expect that we may be dependent on third-party distribution relationships. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations. If distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, our ability to realize long-term international revenue growth would be materially adversely affected.

Additionally, our products may require regulatory clearances and approvals from jurisdictions outside the United States. We expect that we will be subject to and required to comply with local regulatory requirements before selling our products in those jurisdictions. We are not certain that we will be able to obtain these clearances or approvals or compliance requirements on a timely basis, or at all.

Manufacturing risks and inefficiencies may adversely affect the Company's ability to produce products.

We engage third parties to manufacture our products in sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements. In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products we require. If we are unable to obtain from one or more of our vendors the needed materials or components that meet our specifications on commercially reasonable terms, or at all, we may not be able to meet the demand for our products. While we have not arranged for alternate suppliers, and it may be difficult to find alternate suppliers in a timely manner and on terms acceptable to us, we believe that there are multiple alternative sources, suppliers and manufacturers available for our products and devices in the event of a termination or a disagreement with any current vendor. Additionally, our supply chain may be jeopardized for a period of time due to the COVID-19 outbreak.

Security breaches and other disruptions could compromise the Company's information and expose it to liability, which would cause its business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers and business partners, including personally identifiable information of our customers, some of which is stored on our network and some of which is stored with our third-party E-commerce vendor. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to operator error, malfeasance or other disruptions. Any such breach could compromise our network and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, which could adversely affect our business.

The Company's products and facility and the facilities of its manufacturers are subject to federal laws and regulations and certain requirements in the State of California. Failure to comply with any law or regulation could result in penalties and restrictions on the Company's manufacturers' ability to manufacture and the Company's ability to distribute products. If any such action were to be imposed, it could have a material adverse effect on the Company's business and results of operations.

Although medical foods do not require pre-market approval by the FDA, manufacturers of medical foods must be registered with the FDA under a provision promulgated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"*).* Manufacturers of medical foods are subject to periodic inspection by the FDA. The manufacture of our medical foods is outsourced in its entirety to three third-party manufacturers. We are evaluating additional manufacturers for selection as second source or back-up providers. Our medical foods have not been reviewed by the FDA. There is no certainty that the FDA will favorably review our medical food products or our manufacturers' facilities. If the outcome of an inspection is negative or if we or our manufacturers fail to comply with any law or regulation, we could be subject to penalties and restrictions on our manufacturers' ability to manufacture and distribute products. Any such action may result in a material adverse effect on our business and results of operations. For a more complete discussion of the laws and regulations to which we are subject, see the section of this annual report titled "Business - Government Regulation."

The Company's billings and revenues are derived from a limited number of customers and the loss of any one or more of them may have an immediate adverse effect on its financial results.

In the years ended December 31, 2019 and 2018, the Company's billings were derived from a limited number of individual customers and distributors. During the year ended December 31, 2019, the Medical Devices segment had one customer who accounted for approximately 22% of the Company's sales; and during the year ended December 31, 2018, the Medical Devices segment had one customer who accounted for approximately 47% of the Company's sales. No other customer accounted for more than 10% of sales in either year. Customers may stop purchasing our products with little or no warning. Loss of customers may have an immediate adverse effect on our financial results.

If the Company is forced to reduce its prices, its business, financial condition and results of operations may suffer.

The Company may be subject to pricing pressures with respect to its future sales arising from various sources, including practices of health insurance companies, healthcare providers and competition in the marketplace. If the Company's pricing experiences significant downward pressure, our business could be less profitable, and our results of operations may be adversely affected. In addition, because cash from sales funds our working capital requirements, reduced profitability could require us to raise additional capital to support our operations.

If the Company is unable to successfully introduce new products or fails to keep pace with medical advances and developments, its business, financial condition and results of operations may be adversely affected.

The successful implementation of our business model depends on our ability to adapt to evolving technologies and industry standards and introduce new products and services. We cannot assure you that we will be able to introduce new products on schedule, or at all, or that such products will achieve market acceptance. Moreover, competitors may develop competitive products that could adversely affect our results of operations. A failure by us to introduce planned products or other new products or to introduce these products on schedule may have an adverse effect on our business, financial condition and results of operations.

In addition, introduction of a new product that has similar or advances features over a current product may reduce interest and sales in the current product. There is no assurance that a new product will achieve the same or greater sales levels of a current product or that sales of a new product will replace or exceed the sales of a current product.

If we cannot adapt to changing technologies, our products and services may become obsolete, and our business could suffer. Because the healthcare industry is characterized by rapid technological change, we may be unable to anticipate changes in our current and potential customers' requirements that could make our existing technology obsolete. Our success will depend, in part, on our ability to continue to enhance our existing products, develop new technology that addresses the needs of our prospective customers, license leading technologies and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of our proprietary technology entails significant technical and business risks. We may not be successful in using new technologies effectively or adapting our proprietary technology to evolving customer requirements or emerging industry standards, and, as a result, our business may suffer.

If customers do not accept the Company's products or delay in deciding whether to recommend the Company's products and services, its business, financial condition and results of operations may be adversely affected.

Our business model depends on our ability to sell our products. Acceptance of our products requires physicians to use our MapcatSF to measure the macular protective pigment in their patients' eyes, understand and appreciate the benefits of Lumega-Z and GlaucoCetin and nutraceuticals in order to recommend them to their patients, and to understand the benefits of visual acuity testing using the CSV-2000 device. We cannot assure you that physicians will integrate our products into their treatment plans or patient recommendations. Achieving market acceptance for our products and services will require substantial sales and marketing efforts and the expenditure of significant financial and other resources to create awareness and demand by participants in the healthcare industry. If we fail to achieve broad acceptance of our products by physicians, and other healthcare industry participants or if we fail to position our products as an ocular health remedy, our business, financial condition and results of operations may be adversely affected.

If the Company's principal suppliers fail or are unable to perform their contracts with the Company, it may be unable to meet its commitments to its customers. As a result, the Company's reputation and its relationships with its customers may be damaged and its business and results of operations may be adversely affected.

We currently purchase all our medical food ingredients and products from three vendors – one for carotenoids, one for Omega 3, and one for all other supplements. All of the ingredients for the nutraceutical products are sourced by the contract manufacturer that produces the NutriGuard products. These companies are subject to FDA regulation and they are responsible for compliance with current Good Manufacturing Practices ("cGMP" as defined by the FDA). Although our agreements provide that our suppliers will abide by the FDA manufacturing requirements, we cannot control their compliance. If they fail to comply with FDA manufacturing requirements, the FDA could prevent our vendors from manufacturing our ingredients and products. Although we believe that there are a number of other sources of supply of ingredients and manufacturers of medical food products, if these suppliers are unable to perform under our agreements, particularly at certain critical times, we may be unable to meet our commitments to our customers. Additionally, if our suppliers are impacted by the recent outbreak of coronavirus (COVID-19), we may be unable to meet our commitments to our customers. If this were to happen, our reputation as well as our relationships with our customers may suffer and our business and results of operations may be adversely affected. We are evaluating several additional manufacturers for selection as second source or back-up providers.

If the Company incurs costs exceeding its insurance coverage in lawsuits that are brought against it in the future, such incident may adversely affect the Company's business, financial condition and results of operations.

If we were to become a defendant in any lawsuits involving the manufacture and sale of our products and if our insurance coverage were inadequate to satisfy these liabilities, it would be expected to have an adverse effect on our business, financial condition and results of operations.

If the Company is deemed to infringe on the proprietary rights of third parties, it could incur unanticipated expense and be prevented from providing its products and services.

We could be subject to intellectual property infringement claims as the number of our competitors grows and if our products or the functionality of our products overlap with patents of our competitors. While we do not believe that we have infringed or are infringing on any proprietary rights of third parties, we cannot assure you that infringement claims will not be asserted against us or that those claims will be unsuccessful. We could incur substantial costs and diversion of management resources defending any infringement claims whether or not such claims are ultimately successful. Furthermore, a party making a claim against us could secure a judgment awarding substantial damages, as well as injunctive or other equitable relief that could effectively block our ability to provide products or services. In addition, we cannot assure you that licenses for any intellectual property of third parties that might be required for our products or services will be available on commercially reasonable terms, or at all.

The Company's business depends on its intellectual property rights, and if it is unable to protect them, its competitive position may suffer.

Our business plan is predicated on our proprietary technology. Accordingly, protecting our intellectual property rights is critical to our continued success and our ability to maintain our competitive position. Our goal is to protect our proprietary rights through a combination of patent, trademark, trade secret and copyright law, confidentiality agreements and technical measures. We generally enter into non-disclosure agreements with our employees and consultants and limit access to our trade secrets and technology. We cannot assure you that the steps we have taken will prevent misappropriation of our technology. Misappropriation of our intellectual property would have an adverse effect on our competitive position.

Our success, competitive position, and future revenues will depend, in part, on our ability to obtain and maintain patent protection for our products, methods, processes, and other technologies; to preserve our trade secrets; to obtain trademarks for our name, logo and products; to prevent third parties from infringing our proprietary rights; and to operate without infringing the proprietary rights of third parties. To counter infringement or unauthorized use by third parties, we may be required to file infringement claims, which can be expensive and time-consuming.

The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- Claims of issued patents, and the claims of any patents which may be issued in the future and be owned by or licensed to the Company may be challenged by third parties, resulting in patents being deemed invalid, unenforceable, or narrowed in scope, a third party may circumvent any such issued patents, or such issued patents may not provide any significant commercial protection against competing products;

- Our competitors, many of which have substantially greater resources than we do and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets; and

- The legal systems of some foreign countries do not encourage the aggressive enforcement of patents, and countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products. Thus, the Company's foreign patents may not be enforceable to the same extent as the counterpart U.S. patents.

In addition, the USPTO, and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or any of our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

The Company must attract and retain quality management and employees in order to manage its growth. Failure to do so may result in slower expansion.

In order to support the growth of our business and the additional obligations that come with being an exchange-listed company, we will need to expand our senior management team and attract and retain quality employees. There is no assurance that we will be capable of attracting and retaining quality executives and integrating those individuals into our management system. Without experienced and talented management and employees, the growth of our business may be adversely impacted.

The Company's ability to attract and retain qualified members of our board of directors may be impacted due to new state laws, including recently enacted gender quotas.

In September 2018, California enacted SB 826 requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by the end of 2019, at least one woman on its board, by the end of 2020, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors. Failure to achieve designated minimum levels in a timely manner exposes such companies to financial penalties and reputational harm. We cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender quotas as a result of the California law, which may expose us to penalties and/or reputational harm.

The Company may consider acquiring other companies or product lines in an effort to expand its business in exchange for cash and/or stock of the Company (or a combination thereof), which may not be successful or which may cause dilution to investors.

The Company will consider acquiring other companies or product lines that may be complementary or supplementary as part of our future efforts to expand the business, which acquisitions could be for cash, stock or a combination thereof. There is no guarantee that any such acquisition will be successful or that an acquired company's products, operations or corporate culture will mesh with our Company, integrate well, or that any economies of scale will be realized. In addition, any such transaction that involves the Company's stock would cause dilution to investors. In addition, any such transaction that involves cash would result in a reallocation of funds on hand that would be needed to support an acquired company or acquired product line.

In order to expand the Company's business into additional jurisdictions, it may need to comply with regulatory requirements specific to such states and there can be no assurance that it will be able to initially meet such requirements or that it will be able to maintain compliance on an on-going basis.

While we believe Lumega-Z® and Glauco-Cetin™ to be medical foods and not drugs, they are only available under the supervision of a physician. While not available in pharmacies, we are mindful that the act of physicians prescribing, particularly if conducted across state lines, could potentially be subject to certain pharmacy regulations. Each state has its own regulations concerning physician dispensing, restrictions on the corporate practice of medicine, anti-kickback and false claims. In addition, each state has a board of pharmacy that regulates the sale and distribution of drugs and other therapeutic agents. Some states require a physician to obtain a license to dispense prescription products. While we do not believe these pharmacy requirements are applicable, should a pharmacy board or medical board determine otherwise, there can be no assurance that we will be able to comply with the regulations of particular states into which we may expand or that we will be able to maintain compliance with the states in which we currently distribute our products. We currently have Lumega-Z customers in California, Massachusetts, Connecticut, New York, Pennsylvania, New Jersey, Georgia, North Carolina, South Carolina, Florida, Kentucky, Tennessee, Kansas, Indiana, Illinois, Minnesota, Oklahoma, Texas, New Mexico, Mississippi, Idaho, Utah, Nevada, Arizona, Washington, Hawaii and Alberta, Canada. Our inability to maintain compliance with the regulations of California and these other jurisdictions or expand our business into additional states may adversely affect our results of operations.

The Company is subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If it fails to comply with these laws, it could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the U.S. or be required to develop and implement costly compliance programs, which could adversely affect its business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future, particularly as we expand our sales and operations to foreign markets. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the U.S., we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the U.S., and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

We may not be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

The Company's Second Amended and Restated Bylaws designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of state law actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Article XI of our Second Amended and Restated Bylaws, or our Bylaws, dictates that the Delaware Court of Chancery is the sole and exclusive forum for certain state law based actions including certain derivative actions or proceedings brought on behalf of the Company; an action asserting a breach of fiduciary duty owed by an officer, a director, employee or to the shareholders of the Company; any claim arising under Delaware corporate law; and any action asserting a claim governed by the internal affairs doctrine.

This exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or other federal securities laws for which there is exclusive federal or concurrent federal and state jurisdiction.

This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our Bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

The Company has no experience in conducting transcranial doppler ultrasound studies or selling nutraceuticals.

The Company's ability to realize the anticipated benefits of the new Transcranial Doppler Solutions, Inc. business or NutriGuard line of products will depend on its ability to attract qualified personnel and to successfully launch, market and advance a new service in an area where the Company has limited experience, which may be a complex, costly and time-consuming process. The Company may be required to devote significant management attention and resources to develop these businesses. The initiation process may disrupt its business and, if implemented ineffectively, could restrict the realization of the full expected benefits of the new business service. The failure to meet the challenges involved in the initiation process and to realize the anticipated benefits of the new business could cause an interruption of, or a loss of momentum in, the Company's operations and could adversely affect its business, financial condition and results of operations.

Risks Related to the Company's Industry

Any failure to comply with all applicable federal and state privacy and security requirements for the protection of patient information may result in fines and other liabilities, which may adversely affect the Company's results of operations and reputation.

The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Title XIII of the American Recovery and Reinvestment Act of 2009 (the "HITECH Act"), and related regulations promulgated by the Secretary ("HIPAA Regulations") grant a number of rights to individuals as to their identifiable confidential medical information (called "Protected Health Information") and restrict the use and disclosure of Protected Health Information. Failure to comply with these confidentiality requirements may result in penalties and sanctions. In addition, certain state laws may impose independent obligations upon us with respect to patient-identifiable medical information. Moreover, various new laws relating to the acquisition, storage and transmission of patient medical information have been proposed at both the federal and state level. These laws (collectively, the "State and Federal Privacy and Security Laws") present different risks as to two lines of business of the Company: (1) our sale of medical foods, and (2) our performance of Trans Cranial Doppler ultrasound ("TCD") testing.

1. Medical Foods: Lumega-Z and GlaucoCetin. When a physician recommends one or more of the Company's medical foods to a patient, the Company typically receives an order from the customer, but does not usually receive medical information. As part of the operation of its business, it is possible, however, that during communication with customers or with physicians the Company might receive patient-identifiable medical information. To the extent the Company obtains access to Protected Health Information, it must ensure it complies with the State and Federal Privacy and Security Laws. Any failure to comply may result in fines and other liabilities, which may adversely affect its results of operations.

2. The TCD Testing Business. In the TCD Testing line-of-business, the Company will go into physicians' offices and, as a vendor to the physicians, perform TCD tests on patients, as ordered by and under the supervision of the patients' treating physicians. Radiologists will read and report on the results of the tests, and the results will be reported back to the ordering/treating physician. The treating physician who orders the tests bill for the TCD tests to third party payors. During this process, the Company directly interacts with patients and has access to, processes and transmits Protected Health Information. As a result, the State and Federal Privacy and Security Laws will fully apply to the TCD testing business. As required by federal law, the Company has been putting into place a HIPAA compliance program, including providing training to staff, instituting appropriate Business Associate Agreements, implementing required policies and procedures, and conducting regular risk assessments. Any failure to comply with the requirements of the State and Federal Privacy and Security Laws – or any loss of Protected Health Information, whether inadvertent or not – may result in fines and other liabilities, which may adversely affect the Company's results of operations.

Any failure to comply with all applicable federal and state physician self-referral law (the "Stark Law") may result in fines and other liabilities, which may adversely affect the Company's results of operations and reputation.

Congress enacted significant prohibitions against physician self-referrals in the Omnibus Budget Reconciliation Act of 1993. This law and its supporting regulations, which have been amended and expanded substantially, are commonly referred to as the "Stark Law," and prohibit a physician from making any referral of a Stark Designated Health Service ("DHS") to an entity with which the physician has any kind of financial relationship, unless all of the requirements of a statutory or regulatory exception are met. Stark covered DHS include both outpatient prescription drugs and diagnostic testing that are reimbursable by Medicare or Medicaid. Many states have similar laws, some of which can apply to all payors and not just governmental payors. While the Company believes that its arrangements with its customers are in compliance with the federal and any state Stark Laws, the Stark Laws present different levels of risks as to three of the Company's lines of business: (1) sale of the Company's medical foods, (2) sale of the Company's medical devices; and (3) the Company's performance of TCD testing.

1. Medical Foods and Medical Devices. These products are neither prescription drugs nor are they reimbursable under any federal program at present. Therefore, the Company believes that the federal Stark Law is not applicable. Further, the Company's believes that these products are also not covered under any potentially applicable state Stark Laws. The federal Stark Law, however, includes an exception for the provision of in-office ancillary services, including a physician's dispensing of outpatient prescription drugs, provided that the physician meets specified requirements. To the extent that the products might become reimbursable under a federal program, or otherwise become covered under the Stark Law, the Company believes that the physicians who use the Company's medical devices or recommend its medical foods to their patients are aware of these requirements. However, the Company does not monitor their compliance and has no assurance that the physicians are in material compliance with the Stark Law. If it were determined that the physicians who use the Company's medical device or prescribe medical foods purchased from the Company were not in compliance with Stark II, it could potentially have an adverse effect on the Company's business, financial condition and results of operations.

2. The TCD Testing Business. The TCD tests performed by the Company can be reimbursed by Medicare or Medicaid and otherwise constitute a Stark covered DHS, which include diagnostic testing. In conducting TCD tests, the Company will be providing the tests to the ordering physician, who will be paying TCD as a vendor to perform the test on behalf of the physician; and the physician will then be billing for the test to third party payers, including potentially Medicare and Medicaid. As a result, the tests will be considered to be an in-office ancillary service covered under Stark. The Stark Law, however, includes an exception for the provision of such in-office ancillary services, provided that the physician meets specified requirements. The Company believes that the physicians who engage the Company as a vendor to perform the TCD tests are aware of these requirements. However, the Company does not monitor the physicians' compliance and has no assurance that the physicians are in material compliance with the Stark Law. If it were determined that the physicians were not in compliance with Stark, such could potentially have an adverse effect on the Company's business, financial condition and results of operations.

The Company believe its current structure of its relationships with the ordering physicians to be in compliance with all of the requirements of applicable Stark Law exceptions. Any failure to comply the requirements of the Stark Law, however, may result in fines and other liabilities, which may adversely affect the Company's results of operations, and the future operations of the TCD business could be adversely affected.

Any failure to comply with all applicable federal and state anti-kickback laws may result in fines and other liabilities, which may adversely affect the Company's results of operations and reputation.

The federal anti-kickback statute (the "AKS") applies to Medicare, Medicaid and other state and federal programs. AKS prohibits the solicitation, offer, payment or receipt of remuneration in return for referrals or the purchase, or in return for recommending or arranging for the referral or purchase, of goods, including drugs, covered by the federal health care programs. At present, the Company does not participate in any federal programs and its products are not reimbursed by Medicare, Medicaid or any other state or federal program. The AKS is a criminal statute with criminal penalties, as well as potential civil and administrative penalties. The AKS, however, provides a number of statutory exceptions and regulatory "safe harbors" for particular types of transactions. Many states have similar fraud and abuse laws and their own anti-kickback laws, some of which can apply to all payors, and not just governmental payors. While the Company believes that it is in material compliance with both federal and state AKS laws, the AKS laws present different levels of risks as to three of the Company's lines of business: (1) sale of the Company's medical foods, (2) sale of the Company's medical devices, and (2) the Company's performance of TCD testing.

1. Medical Foods and Medical Devices. At present, the Company's products are not reimbursable under any federal program. If, however, that changes in the future and it were determined that the Company was not in compliance with the AKS, the Company could be subject to liability, and its operations could be curtailed, which could have a material adverse effect on the Company's business, financial condition and results of operations. Moreover, if the activities of its customers or other entity with which the Company has a business relationship were found to constitute a violation of the AKS and the Company, as a result of the provision of products or services to such customer or entity, were found to have knowingly participated in such activities, the Company could be subject to sanctions or liability under such laws, including civil and/or criminal penalties, as well as exclusion from government health programs. As a result of exclusion from government health programs, neither products nor services could be provided to any beneficiaries of any federal healthcare program.

2. The TCD Testing Business. The TCD tests performed by the Company can be reimbursed by Medicare or Medicaid. As a result, the federal AKS (and potentially any applicable state anti-kickback law) will be implicated to the extent the financial relationships between the physician customers and the Company are (1) not set at a fair market value amount unrelated to the volume or value of TCD tests being ordered; or (2) were found to be a circumvention of the AKS through the creation of a suspect contractual joint venture. If the Company's arrangements with ordering physicians were found to constitute a violation of the federal AKS, or any applicable state anti-kickback law, we could be subject to sanctions or liability under such laws, including civil and/or criminal penalties, as well as exclusion from government health programs. As a result of exclusion from government health programs, neither products nor services could be provided to any beneficiaries of any federal healthcare program.

As to the nutraceuticals line of business, any failure to comply with applicable federal and state laws, rules and regulations, including the DSHEA, may result in fines and other liabilities, which may adversely affect the Company's results of operations and reputation.

Unlike pharmaceutical drugs and conventional foods, nutraceuticals are regulated as "dietary supplements" under the Dietary Supplement, Health and Education Act of 1994 ("DSHEA") as a separate regulatory category of food. According to the FDA, a drug is an article intended to diagnose, cure, mitigate, treat or prevent disease. While nutraceuticals are not intended to cure or treat disease, both dietary supplements and drugs are intended to affect the structure or function of the body. Dietary supplements that contain structure/function claims on their labels must bear the disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. Moreover, dietary supplements are supposed to enhance the diet, not be used as a conventional food or as the sole item of a meal or diet, and not supposed to be taken alone as a substitute for any food or medicine.

As to the TCD Testing line of business, any failure to comply with applicable federal and state documentation, coding and billing laws, rules and regulations, including the federal False Claims or similar state laws, may result in fines and other liabilities, which may adversely affect the Company's results of operations and reputation.

The Federal False Claims Act provides for the imposition of extensive financial penalties (including treble damages and fines of over $22,000 for every false claim) if a provider submits false claims to any governmental health program either knowingly or in reckless disregard or in deliberate ignorance of the truth or falsity of the claims at issue. Liability under the False Claims Act can arise from patterns of deficient documentation, coding and billing, as well as for billing for services that are deemed not to have been medically necessary for the treatment of the patient. Many states have their own False Claims Acts as well. The Company intends to bill governmental health care programs for the TCD testing, and the False Claims Act is thus potentially applicable to the Company's operations. Here, the Company will not be billing for the performance of the tests to governmental health care plans; the treating and ordering physician will. As a result, any patterns of uncorrected deficiencies in coding and billing for TCD tests by the physician could result in fines or other liabilities imposed on the physician. The imposition of such fines and penalties or an investigation into any alleged deficiencies by the physician could adversely affect the Company's business, financial condition and results of operations.

Any failure to comply with all state laws relating to the Corporate Practice of Medicine or fee splitting may result in fines and other liabilities, which may adversely affect the Company's business, financial condition and results of operations and reputation.

Many states prohibit or otherwise regulate under Corporate Practice of Medicine ("CPOM") rules the extent to which non-licensed personnel may be involved in the practice of medicine or otherwise employ licensed personnel. Related state rules further limit the extent to which fees for professional services may be shared or "split" between parties. Under the TCD Testing line of business, such rules in some states my impact the Company's relationship with the radiologists who will be reading and interpreting the results of the TCD tests, and thereby providing the "professional component" of such tests. In order to avoid such a potential impact, the Company is structuring its financial and billing relationships with such radiologists to be in compliance with applicable state rules by providing that the Company will not be billing for the "professional component," which will be billed instead either by the treating and ordering physician or the radiologists themselves. Failure to comply with state CPOM and fee splitting rules, however, may result in fines and other liabilities, which may adversely affect the Company's business, financial condition and results of operations.

Increased government involvement in healthcare could adversely affect the Company's business.

U.S. healthcare system reform under the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Patient Protection and Affordable Care Act of 2010 and other initiatives at both the federal and state level, could increase government involvement in healthcare, lower reimbursement rates and otherwise change the business environment of our customers and the other entities with which we have a business relationship. While no federal price controls are included in the Medicare Prescription Drug, Improvement and Modernization Act, any legislation that reduces physician incentives to dispense medications in their offices could adversely affect physician acceptance of our products. We cannot predict whether or when future healthcare reform initiatives at the federal or state level or other initiatives affecting our business will be proposed, enacted or implemented or what impact those initiatives may have on our business, financial condition or results of operations. Our customers and the other entities with which we have a business relationship could react to these initiatives and the uncertainty surrounding these proposals by curtailing or deferring investments, including those for our products. Additionally, government regulation could alter the clinical workflow of physicians, hospitals and other healthcare participants, thereby limiting the utility of our products and services to existing and potential customers and curtailing broad acceptance of our products and services. Additionally, new safe harbors to the federal Anti-Kickback Statute and corresponding exceptions to such law may alter the competitive landscape.

Risks Related to The Company's Common Stock

The Company is an "emerging growth company" and it has elected to comply with certain reduced reporting and disclosure requirements which could make its common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an emerging growth company, we have elected to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which we refer to as the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. As a result of these reduced reporting and disclosure requirements our financial statements may not be comparable to SEC registrants not classified as emerging growth companies. We may be an emerging growth company for up to five years following the first sale our equity securities in a public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million before that time or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would immediately cease to be an emerging growth company. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other SEC registrants that are not emerging growth companies.

Investors may find our common stock less attractive as a result of our election to utilize these exemptions, which could result in a less active trading market for our common stock and/or the market price of our common stock may be more volatile.

The Company does not intend to pay cash dividends to its stockholders, so you may not receive any return on your investment in the Company prior to selling your interest in the Company.

We have never paid any dividends to our common stockholders and do not foresee doing so as a public company. We currently intend to retain any future earnings for funding growth and, therefore, do not expect to pay any cash dividends in the foreseeable future. If we determine that we will pay cash dividends to the holders of our common stock, we cannot assure that such cash dividends will be paid on a timely basis. The success of your investment in the Company will likely depend entirely upon any future appreciation. As a result, you will not receive any return on your investment prior to selling your shares in our Company and, for the other reasons discussed in this "Risk Factors" section, you may not receive any return on your investment even when you sell your shares in our Company.

The Company will require additional capital in the future to support its operations, and this capital has not always been readily available.

We will likely require additional debt or equity financing to fund our operations, including, but not limited to, working capital. Our limited operating history makes it difficult to evaluate our current business model and future prospects. Accordingly, investors should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, as we have, in fact, encountered. Potential investors should carefully consider the risks and uncertainties that a new company with a limited operating history and with limited funds, will face. In particular, while we do not have current plans to re-prioritize our business plan, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, which may or may not be sound;
- maintain our anticipated management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we raise additional funds through further issuances of equity or convertible debt securities, our existing shareholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our existing capital stock. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities. In addition, we may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to support our current operations and to respond to business challenges would be significantly limited. If we cannot access the capital necessary to support our business, we would be forced to curtail our business activities or even shut down operations. If we cannot execute any one of the foregoing or similar matters relating to our business, the business may fail, in which case you would lose the entire amount of your investment in the Company.

The obligations associated with being a public company require significant resources and management attention, which may divert from the Company's business operations.

We are subject to the reporting requirements of the Exchange Act, and the Sarbanes-Oxley Act. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition, proxy statement, and other information. The Sarbanes-Oxley Act requires, among other things, that we establish and maintain effective internal controls and procedures for financial reporting. Our Chief Executive Officer and Chief Accounting Officer need to certify that our disclosure controls and procedures are effective in ensuring that material information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. We will need to hire additional financial personnel in order to develop and implement appropriate internal controls and reporting procedures. As a result, we will incur significant legal, accounting and other expenses. Furthermore, the need to establish the corporate infrastructure demanded of a public company may divert management's attention from implementing our growth strategy, which could prevent us from improving our business, results of operations and financial condition. We have made, and will continue to make, changes to our internal controls and procedures for financial reporting and accounting systems to meet our reporting obligations as a public company. However, the measures we take may not be sufficient to satisfy our obligations as a public company. In addition, we cannot predict or estimate the amount of additional costs we may incur in order to comply with these requirements. We anticipate that these costs will materially increase our selling, general and administrative expenses.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies. If we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, then we may not be able to obtain the independent account certifications required by that act, which may preclude us from keeping our filings with the SEC current, and interfere with the ability of investors to trade our securities and our shares to be quoted or our ability to list our shares on any national securities exchange.

We have identified a material weakness in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for the year ended December 31, 2019, we concluded that there was material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. We have identified a material weakness in our internal controls resulting from:

Segregation of Duties – The Company did not maintain effective policies to ensure adequate segregation of duties within its accounting processes. Specifically, due to the size of the Company and the smaller nature of department teams, opportunities are limited to segregate duties, resulting in one individual having almost complete responsibility for the processing of certain financial information.

While we have designed and implemented, or expect to implement, measures that we believe address or will address this control weakness, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, and designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight. We plan to remediate the identified material weakness through the redistribution of job responsibilities, by hiring additional senior accounting staff, and through the design and implementation of additional internal controls in order to promote adequate segregation of duties. We expect to complete the remediation by the end of 2020. We expect to incur additional costs to remediate this weakness, primarily personnel costs. We may not be successful in implementing these changes or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Further, we will not be able to fully assess whether the steps we are taking will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

The Company's failure to meet the continued listing requirements of Nasdaq could result in a delisting of its common stock.

On September 20, 2019, the Company received a notice from Nasdaq notifying the Company that the closing bid price of our common stock had been below $1.00 per share for 30 consecutive business days and that we no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market. The notice provided an initial compliance period of 180 calendar days, or until March 18, 2020, to regain compliance with the minimum bid price requirement.

On March 19, 2020, the Company received a written notification from Nasdaq that the Company has been granted an additional 180 calendar days, or until September 14, 2020, to regain compliance with the minimum bid price requirement.

If at any time before September 14, 2020, the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the Rule. If compliance with the minimum bid price requirement cannot be demonstrated by September 14, 2020, Nasdaq will provide written notification that the Company's common stock will be delisted. At that time, the Company may appeal Nasdaq's determination to a Hearings Panel.

If we fail to satisfy the continued listing requirements of the Nasdaq Capital Market, including the minimum bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. A delisting would adversely affect the liquidity, trading volume and likely the price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations.

The Company's stock price may be volatile, and you may not be able to resell your shares at or above the purchase price.

The market price of our common stock is volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- our ability to execute our business plan;
- changes in our industry;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- additions or departures of key personnel;
- sales of our common stock;
- operating results that fall below expectations;
- regulatory developments;
- economic and other external factors;

- period-to-period fluctuations in our financial results;
- the public's response to press releases or other public announcements by us or third parties, including filings with the SEC;
- changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- the development and sustainability of an active trading market for our common stock; and
- any future sales of our common stock by our officers, directors and significant stockholders.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

The Company's address is 15150 Avenue of Science, Suite 200, San Diego, California 92128. The Company's corporate offices are rented under a five-year lease for approximately 9,605 square feet of space at a current rental of $12,336 per month. We believe these facilities will be adequate for our needs during the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

The Company's common stock is listed on The NASDAQ Capital Market under the symbol "GHSI." As of March 18, 2020, there were approximately 117 record holders of the Company's common stock.

Dividend Policy

The Company has not declared nor paid any cash dividend on its common stock, and it currently intends to retain future earnings, if any, to finance the expansion of its business, and the Company does not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on its common stock will be made by its board of directors, in its discretion, and will depend on the Company's financial condition, results of operations, capital requirements and other factors that its board of directors considers significant.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Presentation of Information

As used in this Annual Report, the terms "we," "us" "our" and the "Company" mean Guardion Health Sciences, Inc. and its subsidiaries unless the context requires otherwise. The following discussion and analysis should be read in conjunction with the Company's audited (and unaudited) financial statements and the related notes thereto. All dollar amounts in this Annual Report refer to U.S. dollars unless otherwise indicated. Certain prior period amounts have been reclassified to conform to current period presentation.

Overview

Guardion Health Sciences, Inc. (the "Company" or "we") was formed in December 2009 in California as a limited liability company under the name P4L Health Sciences, LLC, and it subsequently changed its name to Guardion Health Sciences, LLC. On June 30, 2015, the Company converted from a California limited liability company to a Delaware corporation, changing its name to Guardion Health Sciences, Inc.

The Company is a specialty health sciences company (1) that has developed medical foods and medical devices in the ocular health space and (2) that is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers.

Recent Trends – Market Conditions

The COVID-19 pandemic has and will continue affecting economies and businesses around the world. The impacts of the pandemic could be material, but due to the evolving nature of this situation, we are not able at this time to estimate the impact on our financial or operational results. Among the factors that could impact our results are: effectiveness of COVID-19 mitigation measures, global economic conditions, consumer spending, work from home trends, supply chain sustainability and other factors. These factors could result in increased or decreased demand for our products and services and impact our ability to serve customers.

Recent Developments

Initial Public Offering

On April 9, 2019, the Company closed its initial public offering (the "IPO") of 1,250,000 shares of common stock, par value $0.001 per share, at an IPO price to the public of $4.00 per share resulting in net proceeds to the Company of $3,888,000 after all costs and expenses. The shares began trading on the NASDAQ Capital Market on April 5, 2019 under the symbol "GHSI."

Follow-On Public Offerings

On August 15, 2019, the Company completed a second public offering (the "August Offering") of (i) 12,000,000 shares of common stock, (ii) pre-funded warrants exercisable for 1,000,000 shares of common stock (the "Pre-Funded Warrants"), and (iii) warrants to purchase up to an aggregate of 13,000,000 shares of common stock (the "August Warrants"). The August Offering was conducted pursuant to an Underwriting Agreement, dated August 13, 2019 by and between the Company and Maxim Group LLC and WallachBeth Capital, LLC. On August 16, 2019, the Company sold an additional 1,950,000 August Warrants upon exercise of the underwriters' over-allotment option. The net proceeds to the Company from the August Offering, after deducting underwriting discounts and commissions and other estimated expenses were $4,944,340.

The public offering price was $0.44 per share of common stock and $0.01 per accompanying August Warrant. Each August Warrant represents the right to purchase one share of common stock at an exercise price of $0.585 per share. The August Warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) September 11, 2019 and (ii) the date on which the common stock traded an aggregate of more than 40,000,000 shares after the announcement of the pricing of the August Offering, and ending on the twelve (12) month anniversary thereof, each August Warrant may be exercised at the option of the holder on a cashless basis at a ratio of one August Warrant for one share of common stock, in whole or in part, if the weighted average price of the Common Stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the August Warrant. As of November 13, 2019, 1,000,000 August Pre-Funded Warrants have been exercised for proceeds of $10,000 and 14,723,800 August Warrants have been exercised on a cashless basis, and the Company has issued an aggregate of 15,723,800 shares of common stock upon such exercises.

On October 30, 2019, the Company completed a third public offering of 24,500,000 shares of its common stock (including 1,700,000 pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 24,500,000 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $0.342 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but will be issued separately and will be immediately separable upon issuance. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7.4 million.

The Series B warrants are exercisable at a price of $0.342 per share of common stock and will expire five years from the date on which the Series B warrants become initially exercisable. On December 6, 2019, pursuant to shareholder approval, the Company filed a Certificate of Amendment to amends its Certificate of Incorporation to increase its authorized shares of common stock to 250 million shares. Thus, the Company has a sufficient number of authorized shares of common stock to issue the shares of common stock issuable upon the exercise of the Series B warrants. As of March 20, 2020, 10,277,400 Series B warrants have been exercised for which the Company has received $3,514,870 for the purchase of these shares.

NutriGuard Acquisition

Effective September 20, 2019 (the "Effective Date"), the Company's newly-formed wholly-owned subsidiary, NutriGuard Formulations, Inc., a Delaware corporation ("Buyer"), entered into an asset purchase agreement (the "Asset Purchase Agreement") with NutriGuard Research, Inc., a California corporation ("NutriGuard"), and NutriGuard's sole shareholder, Mark McCarty (the "NutriGuard Acquisition").

Pursuant to the Asset Purchase Agreement, Buyer purchased from NutriGuard specified assets of the NutriGuard brand and business, primarily consisting of inventory, trademarks, copyrights and other intellectual property. In exchange, Buyer agreed to pay a royalty fee to NutriGuard subsequent to meeting certain financial performance metrics based on the operating results of the NutriGuard brand of products following the Effective Date. NutriGuard and Mr. McCarty also agreed, among other terms, to no longer use the "NutriGuard" name upon the Effective Date.

Going Concern and Liquidity

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of $10,878,308 and utilized cash in operating activities of $6,030,004 during the year ended December 31, 2019. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are issued.

The Company's independent registered public accounting firm has also included explanatory language in their opinion accompanying the Company's audited financial statements for the year ended December 31, 2019. The Company's financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern.

The Company will continue to incur significant expenses for commercialization activities related to its medical foods, the MapcatSF medical device, VectorVision diagnostic equipment, the TDSI business, the new NutriGuard line of nutraceuticals and with respect to efforts to continue to build the Company's infrastructure. Development and commercialization of medical foods and medical devices involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines.

The Company is seeking to raise additional debt and/or equity capital to fund future operations, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations.

Reverse Stock Split

On January 30, 2019, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended Certificate of Incorporation, as amended (the "Amendment"), with the Secretary of State of the State of Delaware to effectuate a one-for-two (1:2) reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value. The Amendment became effective on the filing date. The number of shares authorized for common and preferred stock were not affected by the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split as all fractional shares were "rounded up" to the next whole share. Proportional adjustments for the Reverse Stock Split were made to all share and per share amounts as if the split occurred at the beginning of the earliest period presented.

Board Actions

In October 2019, our board of directors approved an amendment to increase the number of authorized common stock from 90,000,000 to 250,000,000 shares. In addition, the board approved an amendment to our certificate of incorporation, as amended, to combine the outstanding shares of our common stock into a lesser number of outstanding shares (a "Reverse Stock Split").

The board of directors determined that an increase in authorized common shares is in the best interests of the Company and believes that the availability of additional authorized shares of common stock is required for several reasons, including enabling investors to exercise the Series B warrants issued pursuant to our October 30 public offering as well as the flexibility to issue common stock for a variety of general corporate purposes as the board of directors may determine to be desirable, including future financings, investment opportunities, acquisitions, or other distributions.

Recent Accounting Pronouncements

See Note 2 to the financial statements for Management's discussion of recent accounting pronouncements.

Concentration of Risk

Cash balances are maintained at large, well-established financial institutions. At times, cash balances may exceed federally insured limits. Insurance coverage limits are $250,000 per depositor at each financial institution. The Company has never experienced any losses related to these balances.

Critical Accounting Policies and Estimates

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of its financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The Company's financial statements included herein include all adjustments, consisting of only normal recurring adjustments, necessary to present fairly the Company's financial position, results of operations and cash flows.

The following critical accounting policies affect the more significant judgments and estimates used in the preparation of the Company's financial statements.

Identifiable Intangible Assets and Goodwill

In connection with the VectorVision transaction in 2017, the Company identified and allocated estimated fair values to intangible assets including customer relationships, technology, tradenames, and competition. Our goodwill represents the excess of the purchase consideration over the fair value of the net tangible and identifiable intangible assets acquired during our VectorVision acquisition.

The Company utilized the services of an independent third-party valuation firm to assist it in identifying intangible assets and in estimating their fair values. The useful lives for its intangible assets other than goodwill were estimated based on Management's consideration of various factors, including assumptions that market participants might use about sales expectations as well as potential effects of obsolescence, competition, technological progress and the regulatory environment. The following table summarizes the acquired identifiable intangible assets:

	Estimated Fair Value	Estimated Useful Life in Years
Customer relationships	$ 430,700	3
Technology	161,100	3
Trade name	65,600	5
Non-compete covenant	17,000	4
	$ 674,400	

The useful lives for the intangible assets were estimated based on Management's consideration of various factors, including assumptions that market participants might use about sales expectations as well as potential effects of obsolescence, competition, technological progress and the regulatory environment. Because the future pattern in which the economic benefits of these intangible assets may not be reliably determined, amortization expense has been calculated on a straight-line basis through September 30, 2019.

In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, the Company's goodwill and other intangible assets are subject to periodic impairment testing. The Company reviews intangible assets for impairment when circumstances indicate that their carrying values may not be recoverable. If the carrying value of an asset group is not recoverable, the Company recognizes an impairment loss for the excess carrying value over the fair value in its consolidated statements of operations.

During 2018 and through September 30, 2019, the Company was not aware of the existence of any indicators of impairment such that the carrying amount of its identifiable intangible assets or goodwill were more likely than not to exceed their fair values. The Company evaluates goodwill for impairment on an annual basis or whenever events and changes in circumstances suggest that the carrying amount may not be recoverable.

During the fourth quarter of 2019, the Company conducted its annual impairment analysis, considering multiple qualitative observations and indicators, including our customer relationships, the regulatory environment as it impacts medical devices, market penetration expectations and barriers, and our anticipated competitive environment. In addition, we assessed the operating results of our VectorVision reporting unit against the quantitative assumptions we used when determining the initial fair values associated with the 2017 business combination.

The Company believes strongly in the future growth and success of the VectorVision business. However, development of the CSV-2000 has taken longer than expected due to software engineering and other factors. Although we believe we will enjoy a dominant market share over time, there is subjectivity of predicting the amount and timing of that value. Recent changes in the regulatory environment may cost us more than anticipated to begin marketing the new device in Europe. Accounting treatment for intangible assets and goodwill requires thoughtful, objective judgment and evidence-based facts in order to support a fair value assertion. After objectively assessing the qualitative and quantitative factors above, Management concluded that it is more likely than not that the fair value for accounting purposes of the VectorVision intangible assets and goodwill is less than their carrying amount.

Due to the highly subjective and forward-looking nature of many of the indicators of impairment that might affect our business as well as the recent results of operations of the reporting unit, Management has concluded that as of December 31, 2019 it is no longer possible to determine a reasonable and objectively supportable fair value for the goodwill and identifiable intangible assets associated with the VectorVision acquisition. Accordingly, the Company recorded a goodwill impairment charge of $1,563,520 as of December 31, 2019.

Stock-Based Compensation

The Company periodically issues stock-based compensation to officers, directors, contractors and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, consultants, contractors, and employees, which include grants of employee stock options, are recognized in the financial statements based on their fair values. Stock option grants, which are generally time vested, will be measured at the grant date fair value and charged to operations on a straight-line basis over the vesting period. The fair value of stock options is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the expected life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date and the estimated volatility of the common stock over the term of the equity award.

In prior periods, the Company accounted for stock option and warrant grants issued and vesting to non-employees in accordance with the authoritative guidance of the FASB whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. On January 1, 2019, the Company adopted Accounting Standards Update (ASU) 2018-07 which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Non-employee stock-based compensation charges generally are amortized over the vesting period using a graded vesting basis. In certain circumstances where there are no future performance requirements by the non-employee, grants are immediately vested and the total stock-based compensation charge is recorded in the period of the measurement date. The adoption of ASU 2018-07 had no cumulative effect on previously reported amounts.

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading market for its common stock, estimated volatility is based on the average historical volatilities of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date. The Company has never declared or paid dividends on its common stock and has no plans to do so for the foreseeable future.

The fair value of common stock was determined based on management's judgment. Due to the availability of historical data from the Company's preferred stock sales in 2018, Management used a valuation of $1.15 for accounting purposes during the first six months of 2018. Management used a valuation $4.00 for the first quarter of 2019. Management considered business and market factors affecting the Company during these periods, including capital raising efforts, its proprietary technology, and other factors. Based on this evaluation, management believes that its valuations are appropriate for accounting purposes during these periods. Closing prices of our common stock ranging from $0.54 to $3.30 were used in fair value calculations during 2019 subsequent to the completion of our IPO.

The Company recognizes the fair value of stock-based compensation within its statements of operations with classification depending on the nature of the services rendered.

Income Taxes

The Company currently accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of December 31, 2019, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company determines that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

Plan of Operations

General Overview

Based on the availability of sufficient funding, the Company intends to increase its commercialization activities and:

- expand the Company's domestic sales and marketing efforts;
- explore sales and marketing opportunities in foreign markets such as Asia and Europe;
- increase production of Lumega-Z® and GlaucoCetin™ to support the additional sales resulting from the deployment of additional MapcatSF units and increased marketing and promotional activity;
- increase the existing NutriGuard customer base through NutriGuard Formulations, Inc. and build on its product platform, including launch of the new acuMMUNE product under development, by making NutriGuard products available to customers directly through direct-to-consumer (DTC) channels and through recommendations by their physicians.

Results of Operations

Through December 31, 2019, the Company has primarily been engaged in product development, commercialization, and raising capital. The Company has incurred and will continue to incur significant expenditures for the development of its products and intellectual property, which includes medical foods and medical devices for the treatment of various eye diseases and nutraceuticals. The Company had limited revenue during the years ended December 31, 2019 and 2018.

Comparison of Years Ended December 31, 2019 and 2018

	Years Ended December 31,			
	2019	2018	Change	
Revenue	$ 902,937	$ 942,153	$ (39,216)	(4)%
Cost of goods sold	341,315	398,179	(56,864)	(14)%
Gross Profit	561,622	543,974	17,648	3%
Operating Expenses:				
Research and development	194,311	231,847	(37,536)	(16)%
Sales and marketing	1,874,901	1,520,862	354,039	23%
General and administrative	7,425,827	4,934,986	2,490,841	50%
Goodwill impairment	1,563,520	-	1,563,520	100%
Total Operating Expenses	11,058,559	6,687,695	4,370,864	65%
Loss from Operations	(10,496,937)	(6,143,721)	(4,353,216)	71%
Other (income) Expense:				
Interest expense	258,365	2,289	256,076	11187%
Finance cost upon issuance of warrants	415,955	-	415,955	100%
Change in fair value of derivative warrants	(292,949)	-	(292,949)	(100)%
Costs associated with extension of warrant expiration dates	-	1,621,397	(1,621,397)	(100)%
Net Loss	$ (10,878,308)	$ (7,767,407)	$ (3,110,901)	40%

Revenue

For the year ended December 31, 2019, revenue from product sales was $902,937 compared to $942,153 for the year ended December 31, 2018, resulting in a decrease of $39,216 or 4%. The decrease is primarily due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. Although the CSV-1000 will continue to be sold, the Company plans to put a greater focus on sales and marketing efforts of the new CSV-2000. The Company commenced sales of the next generation CSV-2000 device in February 2020. For the year ended December 31, 2019, revenue from medical foods was $444,657 compared to $332,795 for the year ended December 31, 2018, resulting in an increase of $111,862 or 34%.

Cost of Goods Sold

For the year ended December 31, 2019, cost of goods sold was $341,315 compared to $398,179 for the year ended December 31, 2018, resulting in a decrease of $56,864 or 14%. The decrease reflects the VectorVision product transition noted above.

Gross Profit

For the year ended December 31, 2019, gross profit was $561,622 compared to $543,974 for the year ended December 31, 2018, resulting in an increase of $17,648 or 3% due to pricing and product mix changes. Gross profit represented 62% of revenues for the year ended December 31, 2019, versus 58% of revenue for the year ended December 31, 2018.

Research and Development

For the year ended December 31, 2019, research and development costs were $194,311 compared to $231,847 for the year ended December 31, 2018, resulting in a decrease of $37,536 or 16%. The decrease was due to reduced engineering development costs associated with the Company's MapcatSF medical device during 2019 partially offset by engineering costs associated with the Company's CSV-2000 product.

Sales and Marketing

For the year ended December 31, 2019, sales and marketing expenses were $1,874,901 compared to $1,520,862 for the year ended December 31, 2018. The increase in sales and marketing expenses of $354,039 or 23% compared to the prior period was primarily due to a non-cash amortization impairment charge of approximately $191,000 recorded pursuant to our identifiable intangible assets. In addition, we incurred increases in trade show costs of approximately $173,000 and increases in labor, professional services, and website development of approximately $166,000. The increases were partially offset by the cancellation of a third-party contract sales agreement in the second quarter of 2018.

General and Administrative

For the year ended December 31, 2019, general and administrative expenses were $7,425,827 compared to $4,934,986 for the year ended December 31, 2018. The increase of $2,490,841 or 50% compared to the prior period was primarily due to an increase in non-cash stock compensation costs during the current period of approximately $1,123,000. Consulting, professional services, and investor relations costs increased approximately $701,000 in the current period, legal fees increased approximately $260,000, corporate insurance costs rose approximately $260,000, and travel costs increased approximately $111,000.

Goodwill Impairment

Due to the highly subjective and forward-looking nature of many of the indicators of impairment that might affect the VectorVision business and the fair values associated with goodwill, the Company recorded a goodwill impairment charge of $1,563,520 as of December 31, 2019.

Interest Expense

For the year ended December 31, 2019, interest expense was $258,365 compared to $2,289 for the year ended December 31, 2018. The increase of $256,076 compared to the prior period was due primarily to the amortization of the debt discount associated with March 2019 convertible notes for $250,000 that were converted to equity in April of 2019. There were no such costs for the comparable period in 2018.

Finance Cost Upon Issuance of Warrants

Finance costs for the year ended December 31, 2019 of $415,955 include the following: (a) In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019. The fair value of the warrants at the closing of the IPO was determined to be $436,034, of which $250,000 was recorded as a valuation discount, and $186,034 was recorded as a finance cost; and (b) On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants at the date of issuance was determined to be $229,921 and was recorded as a finance cost. There were no such costs for the comparable period in 2018.

Change in Fair Value of Derivative Warrants

The change in fair value of the derivative warrant liability was a decrease of $292,949 for the year ended December 31, 2019 and includes the following: (a) In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019 with a fair value of $436,034. Upon completion of the IPO on April 9, 2019, the exercise price and the number of warrants were fixed and the warrants were no longer accounted for as liabilities. As such the fair value of the warrant liability of $359,683 was reclassified to equity and the remaining liability of $76,351 was recorded as a change in fair value of derivative liabilities in the Statements of Operations; and (b) On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants will be remeasured at each reporting period, with the change in the fair value recognized in earnings in the accompanying Statements of Operations. The fair value of the warrants at the date of issuance was determined to be $229,921 and was recorded as a finance cost. As of December 31, 2019, the fair value of the warrant liability was determined to be $13,323 and the Company recorded a change in fair value of derivative warrants of $216,598 in the Statements of Operations. There were no such costs for the comparable period in 2018.

Costs Associated with Extension of Warrant Expiration Dates

During April, May and September of 2018, the Company and certain stockholders who held warrants to purchase shares of common stock of the Company that were scheduled to expire at various dates in 2018 and early 2019 extended the termination dates of such warrants. The Company recognized expense of $1,621,397 relating to the extension of the exercise period of the warrants using a Black-Scholes option-pricing model to estimate fair value.

Net Loss

For the year ended December 31, 2019, the Company incurred a net loss of $10,878,308, compared to a net loss of $7,767,407 for the year ended December 31, 2018. The increase in net loss of $3,110,901 or 40% compared to the prior year period was primarily due to a non-cash goodwill impairment charge of approximately $1,564,000 as well as an increase in non-cash stock compensation costs of approximately $1,123,000. In addition, expenses for corporate insurance, investor relations, labor, legal and professional fees, and travel have increased versus the prior period but were offset by the elimination of costs associated with engagement of a third-party contract sales organization in 2018 as well as non-cash costs associated with the extension of warrant expiration dates in 2018.

Segment Information

The following tables set forth our results of operations by segment (results allocated to Corporate consist of the TDSI and NGFI operations):

	For the Year Ended December 31, 2019			
	Corporate	**Medical Foods**	**Medical Devices**	**Total**
Revenue	$ 24,270	$ 444,657	$ 434,010	$ 902,937
Cost of goods sold	7,288	155,212	178,815	341,315
Gross profit	16,982	289,445	255,195	561,622
Stock compensation expense	-	2,717,731	-	2,717,731
Goodwill impairment charge	-	-	1,563,520	1,563,520
Operating expenses	360,257	5,308,508	1,108,543	6,777,308
Loss from operations	**$ (343,275)**	**$ (7,736,794)**	**$ (2,416,868)**	**$ (10,496,937)**

	For the Year Ended December 31, 2018			
	Corporate	**Medical Foods**	**Medical Devices**	**Total**
Revenue	$ -	$ 332,795	$ 609,358	$ 942,153
Cost of goods sold	-	161,023	237,156	398,179
Gross profit	-	171,772	372,202	543,974
Stock compensation expense	-	1,595,037	-	1,595,037
Operating expenses	72,797	4,355,674	664,187	5,092,658
Loss from operations	**$ (72,797)**	**$ (5,778,939)**	**$ (291,985)**	**$ (6,143,721)**

Revenue

For the year ended December 31, 2019, revenue from our Medical Foods segment was $444,657 compared to $332,795 for the year ended December 31, 2018, resulting in an increase of $111,862 or 34%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the year ended December 31, 2019, revenue from our Medical Devices segment was $434,010 compared to $609,358 for the year ended December 31, 2018, resulting in a decrease of $175,348 or 29%. The decrease was due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. The Company began sales of the next generation CSV-2000 device at the end of the first quarter of 2020. The first unit of the CSV-2000 was shipped in the first quarter of 2020. The Company also earned $24,270 from a combination of diagnostic imaging services revenue from its TDSI business and nutraceutical product sales from its NGFI business during the year ended December 31, 2019, as shown in the Other category above.

Cost of Goods Sold

For the year ended December 31, 2019, cost of goods sold from our Medical Foods segment was $155,212 compared to $161,023 for the year ended December 31, 2018, resulting in a decrease of $5,811 or 4% due to pricing and product mix changes. For the year ended December 31, 2019, cost of goods sold from our Medical Devices segment was $178,815 compared to $237,156 for the year ended December 31, 2018, resulting in a decrease of $58,341 or 25%. The decrease reflects the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device.

Gross Profit

For the year ended December 31, 2019, gross profit from the Medical Foods segment was $289,445 compared to $171,772 for the year ended December 31, 2018, resulting in an increase of $117,673 or 69%. The increase reflects an increased customer base for Lumega-Z. For the year ended December 31, 2019, gross profit from the Medical Devices segment was $255,195 compared to $372,202 for the year ended December 31, 2018, resulting in a decrease of $117,007 or 31%. The decrease is due to the transition of sales efforts away from our VectorVision CSV-1000 device. Gross profit overall represented 62% of revenues for the year ended December 31, 2019, versus 58% of revenue for the year ended December 31, 2018.

Stock Compensation Expense

For the year ended December 31, 2019, non-cash stock compensation expense Medical Foods segment was $2,717,731 compared to $1,595,037 for the year ended December 31, 2018, resulting in an increase of $1,122,694 or 70% due primarily to a stock option granted to the Company's Chairman and CEO to purchase 1,250,000 shares of common stock on April 9, 2019.

Goodwill Impairment Charge

Due to the highly subjective and forward-looking nature of many of the indicators of impairment that might affect the VectorVision business and the fair values associated with goodwill, the Company recorded a goodwill impairment charge of $1,563,520 as of December 31, 2019.

Liquidity and Capital Resources

Since its formation in 2009, the Company has devoted substantial effort and capital resources to the development and commercialization activities related to its product candidates. As a result of these and other activities, the Company utilized cash in operating activities of $6,030,004 during the year ended December 31, 2019. The Company had working capital of $11,457,484 at December 31, 2019. As of December 31, 2019, the Company had cash in the amount of $11,115,502 and no available borrowings. The Company's financing has historically come primarily from the issuance of convertible notes, promissory notes and from the sale of common and preferred stock.

The financial statements have been prepared assuming the Company will continue as a going concern. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are issued.

The Company's independent registered public accounting firm has also included explanatory language in their opinion accompanying the Company's audited financial statements for the year ended December 31, 2019. The Company's financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern.

The Company will continue to incur significant expenses for continued commercialization activities related to its medical foods, medical devices and its nutraceuticals product line. Development and commercialization of medical foods, medical devices and nutraceuticals involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. On April 9, 2019, the Company completed the IPO, resulting in net cash proceeds of $3,888,000 to the Company. On August 15, 2019, the Company consummated an underwritten public offering resulting in net proceeds to the Company of $4,944,340. On October 30, 2019, the Company consummated an underwritten public offering resulting in net proceeds to the Company of $7,392,467.

The Company received total gross proceeds of $3,514,870 during the period from February 28, 2020 through March 20, 2020 from the exercise of 10,277,400 warrants issued in the Company's October 2019 follow-on offering.

The Company will continue to seek to raise additional debt and/or equity capital to fund future operations as necessary, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations.

Management believes that the Company has adequate funding to pursue its planned business initiatives and operations through at least December 31, 2020.

Sources and Uses of Cash

The following table sets forth the Company's major sources and uses of cash for each of the following periods:

	Year Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (6,030,004)	$ (4,173,831)
Net cash used in investing activities	(171,076)	(310,243)
Net cash provided by financing activities	16,645,634	419,792
Net increase (decrease) in cash	$ 10,444,554	$ (4,064,282)

Operating Activities

Net cash used in operating activities was $6,030,004 during the year ended December 31, 2019, versus $4,173,831 used during the comparable prior year period. Cash in both periods was used for used for engineering, corporate insurance, investor relations, labor, legal and professional fees, travel and other operating costs.

Investing Activities

Net cash used in investing activities was $171,076 for the year ended December 31, 2019 and $310,243 for the year ended December 30, 2018. In June 2019, we purchased medical imaging equipment for use in our TDSI business. In January 2018, we acquired the rights to a trademark portfolio for $50,000. In addition, we purchased a trade show booth in February 2018 and have invested in MapcatSF equipment and internal-use software development.

Financing Activities

Net cash provided by financing activities was $16,645,634 for the year ended December 31, 2019 was due primarily to the completion of our IPO, which resulted in net proceeds of $3,888,000, our follow-on offering in August which resulted in net proceeds of $4,944,340, and our follow-on offering in October which resulted in net proceeds of $7,392,467. In addition, in March 2019, the Company issued $350,000 in promissory and convertible promissory notes and received cash of $154,375 from the exercise of warrants. These proceeds were partially offset by payment of $100,000 to settle a promissory note. Net cash provided by financing activities was $419,792 for the year ended December 31, 2018 was due primarily to the sale of common stock, partially offset by deferred costs relating to our IPO, reduction in related party obligations, and payoff of a line of credit balance that had been assumed during our 2017 VectorVision acquisition.

Off-Balance Sheet Arrangements

At December 31, 2019 and December 31, 2018, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found beginning on page F-1 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our Chief Executive Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and directors, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control Over Financial Reporting. The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)). Our internal control over financial reporting is a process, under the supervision of our Chief Executive Officer and Chief Accounting Officer, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. These internal controls over financial reporting processes include policies and procedures that:

a. Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

b. Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

c. Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework 2013. Based on this evaluation, our Chief Executive Officer and our Chief Accounting Officer determined, based upon the existence of the material weakness described below, that we did not maintain effective internal control over financial reporting as of December 31, 2019.

Segregation of Duties – The Company did not maintain effective policies to ensure adequate segregation of duties within its accounting processes. Specifically, due to the size of the Company and the smaller nature of department teams, opportunities are limited to segregate duties, resulting in one individual having almost complete responsibility for the processing of certain financial information.

While we have designed and implemented, or expect to implement, measures that we believe address or will address this control weakness, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, and designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight. We plan to remediate the identified material weakness through the redistribution of job responsibilities, by hiring additional senior accounting staff, and through the design and implementation of additional internal controls in order to promote adequate segregation of duties. We expect to complete the remediation by the end of 2020. We expect to incur additional costs to remediate this weakness, primarily personnel costs.

We may not be successful in implementing these changes or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Further, we will not be able to fully assess whether the steps we are taking will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting.

Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

(c) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during or subsequent to the Company's last fiscal quarter of the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Set forth below is certain information regarding the Company's current executive officers and directors based on information furnished to the Company by each executive officer and director. Each of the directors listed below was elected to the Board of Directors to serve until the Company's next annual meeting of stockholders or until his or her successor is elected and qualified.

Name	Age	Position
Michael Favish	71	President, Chief Executive Officer and Chairman of the Board of Directors
Robert Weingarten	67	Director, Lead Director
Mark Goldstone	56	Director
David W. Evans	63	Director, Chief Science Officer
Donald A. Gagliano	67	Director
Kelly Anderson	52	Director
John Townsend	59	Controller, Chief Accounting Officer
Vincent J. Roth	52	General Counsel and Corporate Secretary

Management Team

Michael Favish has been Chief Executive Officer, President and Chairman of the Board since the Company's formation in 2009. He has more than 30 years' experience in founding, developing and managing private and public companies, all of which the Company believes contribute to his qualifications as a director. He is an acknowledged and respected leader and innovator with hands-on experience in strategic marketing, brand building and product development. Mr. Favish founded Fotoball USA, Inc. ("Fotoball"), a pioneer in retail licensed products and marketing, in 1984. In 1994, Mr. Favish transformed Fotoball into a publicly held company with 200 employees and was listed on the Nasdaq Stock Market. After growing revenues from $7 million in 1994 to $50 million in 2003, Fotoball was acquired in January 2004 by an industry leading NYSE company. The Company believes that Mr. Favish's experience in an entrepreneurial environment such as Fotoball is particularly suitable for the Company because it was a small, developing and entrepreneurial company introducing products of a kind that did not currently exist. Mr. Favish's team building skills from his track record at Fotoball, are also applicable as the Company is still building its departments and leadership team. Mr. Favish developed familiarity with the capital markets and obligations of a public reporting company through his experience at Fotoball which is also pertinent to the Company as it engages in fund raising efforts and pursues its endeavor to become a public reporting company. These experiences collectively make Mr. Favish suitable to serve the Company as Chief Executive Officer and a director.

Robert N. Weingarten has been a Director of the Company effective June 30, 2015 and Lead Director on the Board of Directors since January 2017. He is an experienced business consultant and advisor with an ongoing consulting practice. Since 1979, he has provided financial consulting and advisory services and served on boards of directors of numerous public companies in various stages of development, operation or reorganization, which the Company believes qualifies him to serve on the Board of Directors. Mr. Weingarten was the CFO of Alltemp, Inc, from July 10, 2017 through June 28, 2018. Alltemp, Inc. was an SEC full reporting company until it filed a Form 15 on April 16, 2018. Mr. Weingarten was the Non-Executive Chairman of New Dawn Mining Corp. ("New Dawn") from August 31, 2005 through September 30, 2010, and was named the Executive Chairman of New Dawn in October 2010. New Dawn has ceased to be publicly traded and reporting company. On April 29, 2013, Mr. Weingarten was appointed to the Board of Directors of RespireRx Pharmaceuticals Inc., formerly known as Cortex Pharmaceuticals, Inc. ("RespireRx"), and was named Vice President and Chief Financial Officer of RespireRx. He resigned from those positions on February 17, 2017. Mr. Weingarten received a B.A. Degree in Accounting from the University of Washington in 1974, and an M.B.A. Degree in Finance from the University of Southern California in 1975. Mr. Weingarten is a Certified Public Accountant (inactive) in the State of California. Mr. Weingarten has considerable accounting and finance acumen, particularly with regard to public reporting requirements. He also has considerable experience in the pharmaceutical industry, which has many similar regulatory requirements supplement as the medical foods and medical device markets in which the Company operates. These skills and experiences make Mr. Weingarten particularly suitable to serve as a director and offer guidance to the Company.

Mark Goldstone has been a Director since June 2015. Mr. Goldstone has over 25 years of experience in the healthcare industry, encompassing operations, commercialization and consulting. He has executed numerous M&A, financing and strategic partnership transactions, for a broad array of middle market and emerging growth companies in technology, life sciences and healthcare services, which qualifies him to serve on the Board of Directors. From 2007 to 2013, Mr. Goldstone was the global President of DDB Worldwide Communications Group Inc.'s healthcare business, where he was responsible for a global communications business spanning 40+ offices in over 36 markets. The business covered advertising, digital, integrated communications, healthcare professional promotion, branding, naming, design, market shaping, medical education and scientific communications. Mr. Goldstone has previously held senior positions at Publicis Healthcare Communications Group where he was responsible for the global Sanofi-Aventis business and at Interbrand where he was CEO of its global Healthcare business.

Mr. Goldstone moved from the United Kingdom to New York with Havas Group, where from 1996 to 2003 he held senior positions at Robert A. Becker, Euro RSCG and Jordan McGrath Case & Partners, Euro RSCG and ultimately at Euro RSCG Worldwide Headquarters, where he helped devise and build their global healthcare business – Euro RSCG Life Worldwide (Now Havas Life). Mr. Goldstone holds a BSc (Hons) in Pharmacy. He is a board member of the prestigious Galien Foundation and a board member of G3 Global Genomics Group. He is a member of the Royal Pharmaceutical Society of Great Britain and is a past Co-Chairman of New York Corporate Development for the American Diabetes Association. Mr. Goldstone's breadth of experience in sales, marketing and strategic transactions in the healthcare industry is particularly useful to the Company as it develops its business, commercializes products and builds its marketing channels. The Company believes that these experiences make Mr. Goldstone particularly suitable to serve as a director and guide the Company in the complexities of the life science and healthcare services industries.

Donald A. Gagliano has served as a Director since the Company's initial public offering on April 9, 2019. Dr. Gagliano has been a member of our Scientific Advisory Board since June 2015. Since October 2018, Dr. Gagliano has been the principal of GMIC LLC, which provides healthcare consultation services primarily for health systems engineering and ophthalmology subject matter expertise. Dr. Gagliano does not currently hold any directorships and has not held any directorships within the past five years. From April 2013 to October 2013, Dr. Gagliano was the Vice President for Global Medical Affairs for Bausch+Lomb, Inc. From 2016 to present, Dr. Gagliano has served as the President of the Prevention of Blindness Society. From November 2008 to March 2013, Dr. Gagliano served as the Assistant Secretary of Defense for Health Affairs as the first Executive Director of the Joint Department of Defense (DoD) and Department of Veterans Affairs (VA) Vision Center of Excellence (VCE). In 1975, Dr. Gagliano graduated from the US Military Academy at WestPoint with a degree in Engineering. In 1981, he received a Bachelor of Science in medicine from Chicago Medical School and in 1998 he received his Master of Healthcare Administration from Penn State University. Dr. Gagliano's breadth of experience in the healthcare industry is particularly useful to the Company as it develops its business, commercializes products and builds its marketing channels. The Company believes that these experiences make Dr. Gagliano particularly suitable to serve as a director and guide the Company in the complexities of the life science and healthcare services industries.

David W. Evans has been a Director since September 2017 and Chief Science Officer. Dr. Evans is the founder of VectorVision, was appointed to the Company's Board of Directors on September 29, 2017, the closing of the VectorVision acquisition, and thereafter was engaged as a consultant to serve as the Company's Chief Science Officer. Dr. Evans is recognized as the leading expert in clinical contrast sensitivity and glare testing. He has provided his testing expertise and data analysis capability to a wide range of leading ophthalmic companies. Dr. Evans has published more than 30 scientific articles and 3 book chapters in the areas of refractive surgery, glaucoma, ocular blood flow and visual function, and is the inventor of 5 patents related to vision testing devices. Dr. Evans received his Bachelor of Science degree in Human Factors Engineering from the United States Air Force Academy, a Master of Science degree and Masters in Business Administration from Wright State University in Dayton, Ohio, and a Ph.D. in Ocular Physiology from Indiana University. The Company believes that these experiences make Dr. Evans particularly suitable to serve as a director and guide the Company in the complexities of the life science and healthcare services industries.

Kelly Anderson has been a Director since December 2019. Ms. Anderson is an experienced and strategic Board Member and Chief Financial Officer. With strong organizational achievements in a diverse group of industries, she has executed successful initial public offerings, follow-on offerings, mergers and acquisitions; creating value for investors and liquidity for ownership and management. Ms. Anderson has extensive finance, management and operating experience across industries, including: Internet, Subscription, Services, Clean Technology, Manufacturing and Financial Services companies. As a Board Member, Ms. Anderson has chaired the audit committee and has been a member on the compensation committee and nomination committee. Ms. Anderson brings her financial as well as industry knowledge to her board positions. As a strategic member of the executive team, she takes responsibility for reporting performance,

trends and business issues that affect the execution of company goals. These roles require working closely with the CEO, the Board of Directors and senior management to present and communicate company-wide achievements and provide ideas on how to seize new opportunities and mitigate shortfalls.

Ms. Anderson has been a Board member for Tomi Environmental Services (TOMZ) since 2016, and is its Audit Committee Chair, and a member of its Compensation Committee. She is currently working on a capital market strategy for Concierge Technologies (CNCG) for uplisting and expects to be its audit committee chair upon completion. She also serves on the Accounting Advisory Committee for California State University, Fullerton. She is also a Board Member and on the Awards Committee for the Association for Corporate Growth. Ms. Anderson has a Bachelor of Arts, Accounting Concentration, from California State University, Fullerton and is a California CPA. Her license is currently inactive.

John Townsend has served as Controller since July 2016 and Chief Accounting Officer since March 2017. He has over 20 years of public and private company experience in industries including biotechnology, medical devices, and high-tech electronics manufacturing. Before joining the Company, Mr. Townsend worked at Cosmederm Biosciences, Inc., a specialty pharmaceutical company in 2016. From 2005 until 2015, he worked at Cytori Therapeutics, Inc., a stem cell therapy company. From 1996 to 2005, he worked at several high-tech companies, and he started his career at Deloitte (formerly Deloitte and Touche) after graduating from San Diego State University in 1993. Mr. Townsend is a Certified Public Accountant in the state of California.

Vincent J. Roth has served as General Counsel and Corporate Secretary since April 2015. He is an experienced corporate attorney with over 20 years of experience serving as the General Counsel to public and private companies in the high-tech, healthcare, medical device, nutraceutical, and biotechnology industries. Mr. Roth has worked as the General Counsel and Corporate Secretary for NucleusHealth, LLC, a medical device and teleradiology company since 2009. Mr. Roth worked as a partner at InnovaCounsel, LLP providing general counsel services to clients from 2009 to 2018. In addition to managing legal affairs, Mr. Roth is very familiar with operating in highly regulated industries. Mr. Roth completed a Master of Laws in Intellectual Property at the University of San Diego where he graduated with honors. He also received a Master of Laws in Business and Corporate Law from the University of San Diego with honors, a Juris Doctor and an MBA from Temple University, a Master of Liberal Arts in Sociology from the University of Pennsylvania and a BBA in Marketing and Human Resources from Temple University.

Director or Officer Involvement in Certain Legal Proceedings

The Company's directors and executive officers were not involved in any legal proceedings described in Item 401(f) of Regulation S-K in the past ten years.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Director Independence

The listing rules of NASDAQ Capital Market require that independent directors must comprise a majority of a listed company's board of directors. In addition, the rules of the NASDAQ Capital Market require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the NASDAQ Capital Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

The Company's Board of Directors has undertaken a review of the independence of the Company's directors and director nominees and considered whether any director has a material relationship with it that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, the Board of Directors has determined that each of Messrs. Weingarten, Goldstone, Gagliano and Anderson, representing four (4) of the Company's six (6) directors, are "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of the NASDAQ Capital Market. In making these determinations, the Board of Directors considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances the Board of Directors deemed relevant in determining their independence, including the beneficial ownership of the Company's capital stock by each non-employee director, and any transactions involving them described in the section captioned "—Certain Relationships and Related Transactions and Director Independence."

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in the ownership of our common stock and other equity securities. Such persons are required to furnish us copies of all Section 16(a) filings. Based solely upon a review of the copies of the forms furnished to us, we believe that our officers, directors and holders of more than 10% of our common stock complied with all applicable filing requirements, with the exception of David Evans and Donald Gagliano each failing to file one Form 4 on a timely basis.

Code of Business Conduct and Ethics

The Company's board of directors adopted a code of business conduct and ethics applicable to its employees, directors and officers, in accordance with applicable U.S. federal securities laws and the corporate governance rules of the Nasdaq Capital Market. The code of business conduct and ethics is publicly available on the Company's website. Any substantive amendments or waivers of the code of business conduct and ethics or code of ethics for senior financial officers may be made only by the Company's board of directors and will be promptly disclosed as required by applicable U.S. federal securities laws and the corporate governance rules of the Nasdaq Capital Market.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the total compensation paid or accrued during the fiscal years ended December 31, 2019 and 2018 to (i) our Chief Executive Officer, and (ii) our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2019 and were serving as executive officers as of such date (we refer to these individuals as the "Named Executive Officers").

Executive	Year	Salary	Bonus	Stock Awards	All Other Compensation	Total
Michael Favish (1)	2019	$ 300,000	$ -	$4,122,750	$ -	$4,422,750
	2018	$ 275,000	$ -	$ -	$ -	$ 275,000
John Townsend (2)	2019	$ 185,000	$ 25,000	$ -	$ -	$ 210,000
	2018	$ 165,000	$ 3,000	$ -	$ -	$ 168,000
Vincent J. Roth (3)	2019	$ 161,000	$ -	$ -	$ -	$ 161,000
	2018	$ 156,000	$ -	$ -	$ -	$ 156,000

(1) Michael Favish has been the Company's CEO since inception. Mr. Favish received 2,750,000 units of membership interest at inception of the Company on December 1, 2009 when the Company was a California limited liability company, such units became 2,750,000 shares of common stock when the Company incorporated as a Delaware corporation on June 30, 2015. Mr. Favish was awarded a stock grant on December 31, 2016 for services rendered for 25,000 shares of the Company's common stock valued at $0.18 per share. Mr. Favish was awarded a stock option grant on April 9, 2019 for 1,250,000 shares of the Company's common stock at an exercise price of $4.40 per share (110% of the IPO price per common share) pursuant to his employment agreement.

(2) John Townsend has served as Controller since July 2016 and Chief Accounting Officer since March 2017. Mr. Townsend was awarded a stock grant on December 31, 2016 for services rendered for 2,500 shares of the Company's common stock valued at $0.18 per share. Mr. Townsend received a stock grant in August 2017 for services rendered for 50,000 shares of the Company's common stock valued at $0.18 per share.

(3) Vincent J. Roth has served as General Counsel and Corporate Secretary since April 2015. On December 31, 2016, Mr. Roth was awarded a stock grant for services rendered for 7,500 shares of the Company's common stock valued at $0.18 per share.

Employment Agreements

On December 21, 2018, the Company entered into an Employment Agreement (the "Agreement") with Michael Favish, its President and Chief Executive Officer, and Chairman of the Board, which agreement became effective as of January 1, 2019. Pursuant to the Agreement, Mr. Favish will serve in such positions for a term of three (3) years, and following the expiration of such three (3) year term, Mr. Favish's employment shall be on an "at-will" basis, and such post-term employment will be subject to termination by either party at any time, with or without cause or prior notice.

Pursuant to the terms of the Agreement, Mr. Favish is entitled to receive an annual base salary of $300,000 in 2019, $325,000 in 2020 and $350,000 in 2021. Mr. Favish shall be eligible for an annual bonus as follows: (i) the initial annual bonus target will be 100% of Mr. Favish's salary for the applicable calendar year, and (ii) the actual bonus amount awarded will be based 50% on the achievement of Company financial and other performance metrics as determined by the Board and 50% as determined by the Board, in its sole discretion.

Additionally, the Company granted Mr. Favish a non-qualified stock option (the "Option") to purchase 1,250,000 shares of common stock upon the completion of the Public Offering (the "Grant Date"). The Option term shall be five years from the Grant Date and the Option shall have a purchase price per common share equal to 110% of the final offering price per share of common stock in the Public Offering. The Option shall vest ratably over three years commencing one twelfth on the first calendar quarter end date following the Grant Date), and one twelfth at the end of each calendar quarter thereafter until fully vested.

Mr. Favish shall devote his full business time and attention to the performance of his duties and will be eligible to participate in benefit programs offered by the Company to similarly situated employees, which may include a paid time off program and medical benefits.

If Mr. Favish's employment is terminated as a result of Mr. Favish's death or permanent disability, Mr. Favish will be entitled to receive (i) any unpaid salary through the date of termination and any accrued vacation in accordance with Company policy; (ii) reimbursement for any unreimbursed expenses incurred through the date of termination; (iii) any bonus payments due and payable; and (iv) as and when due thereunder, all other payments, benefits or fringe benefits to which Mr. Favish may be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant or the Agreement (collectively, the "Accrued Amounts").

If Mr. Favish's employment is terminated by the Company for Cause (as defined in the Agreement) or if Mr. Favish terminates the Agreement voluntarily without Good Reason (as defined in the Agreement), Mr. Favish will be entitled to receive the Accrued Amounts, and the unvested portion of the Option shall terminate. Mr. Favish shall have ninety (90) days to exercise the vested portion of the Option in such circumstances.

If Mr. Favish's employment is terminated by the Company without Cause or if Mr. Favish terminates his employment for Good Reason, the Company shall pay Mr. Favish the Accrued Amounts (and the unvested portion of the Option shall continue in full force and effect under its terms) and, additionally, subject to (x) Mr. Favish's immediate return to the Company of all Company property, and (y) Mr. Favish's execution and non-revocation of a waiver and release (the "Release"), the Company shall pay as a lump sum the prorated bonus that would have been paid for the year of termination and any bonus for the year preceding termination, to the extent unpaid, and in addition Mr. Favish will be entitled to (i) a severance payment equal to his then current annual salary payable over a period of one (1) year and (ii) the potential reimbursement of certain COBRA expenses.

Finally, if Mr. Favish's employment is terminated pursuant to a Change in Control Termination (as defined in the Agreement), the Company shall pay Mr. Favish the Accrued Amounts and, additionally, subject to (x) Mr. Favish's immediate return to the Company of all Company property, and (y) Mr. Favish's execution and non-revocation of the Release, the Company shall pay as a lump sum the prorated bonus that would have been paid for the year of termination and any bonus for the year preceding termination, to the extent unpaid, and in addition he will be entitled to (i) a severance payment equal to two (2) times his then current annual salary payable in a lump sum in the event that Mr. Favish's termination occurs after the Change in Control or payable 50% in a lump sum if Mr. Favish's termination occurs prior to the date of the Change in Control and 50% payable over a one (1) year period, (ii) with respect to the Option and any other outstanding equity awards time vesting (but not performance vesting, if any), accelerated vesting as to 100% of the then-unvested shares subject to the Option and other equity awards effective on the date that the Release becomes irrevocable (and Mr. Favish shall have 360 days (or until the date the Option is set to expire per its original term) to exercise the Option) and (iii) the potential reimbursement of certain COBRA expenses.

Mr. Favish will be subject to non-solicitation restrictions for a period of one (1) year following any termination of his employment and various other customary restrictions.

Outstanding Equity Awards at Fiscal Year-End

Pursuant to the employment agreement entered into on December 21, 2018 between the Company and Michael Favish, the Company granted Mr. Favish a non-qualified stock option on April 4, 2019 to purchase 1,250,000 shares of common stock. The options have a strike price of $4.40 per share and vest ratably over three years. As of December 31, 2019, 312,500 option shares have vested. There were no other outstanding unexercised options, unvested stock, and/or equity incentive plan awards issued to our named executive officers as of December 31, 2019.

Director Compensation

The Company accrued or paid compensation to its directors for serving in such capacity, as show in the table below.

Director	Year	Stock Awards	Fees Earned or Paid in Cash	Total
Mark Goldstone	2019	$ -	$ -	$ -
	2018	$ -	$ -	$ -
Robert Weingarten (1)	2019	$ -	$ 60,000	$ 60,000
	2018	$ -	$ 60,000	$ 60,000
David W. Evans (2)	2019	$ -	$ -	$ -
	2018	$ -	$ -	$ -
Michael Favish	2019	$ -	$ -	$ -
	2018	$ -	$ -	$ -
Donald A. Gagliano	2019	$ -	$ -	$ -
	2018	$ -	$ -	$ -
Kelly Anderson	2019	$ -	$ -	$ -
	2018	$ -	$ -	$ -

(1) Mr. Weingarten earned $60,000 as compensation for services as Lead Director during 2018, of which $10,000 was paid in December 2018 and $50,000 was paid in 2019. Mr. Weingarten earned $60,000 as compensation for services as Lead Director during 2019, of which $45,000 was paid in 2019 and $15,000 was paid in 2020.

(2) Mr. Evans was appointed as a Director on September 29, 2017. The Company entered into a Consulting Agreement with Dr. Evans, dated as of September 29, 2017 (the "Consulting Agreement"), whereby Dr. Evans has been engaged to serve as a consultant to the Company to further the Company's planned development and commercialization of the Company's portfolio of products and technology. Dr. Evans was given the title of Chief Science Officer on April 1, 2018. The Consulting Agreement had an initial term of 3 years, with automatic one-year renewals unless earlier terminated. Pursuant to the Consulting Agreement and subsequent amendments, Dr. Evans earned monthly compensation of $10,000 in 2018 and through April 2019, and monthly compensation of $15,000 beginning in May 2019.

On December 5, 2019, the Board of Directors adopted a director compensation program for the Company's independent directors consisting of both cash and equity compensation, beginning in 2020. The program consists of the following compensation for directors:

Cash Compensation (payable quarterly)

- Board service - $20,000 per year
- Chairman of the Audit Committee – additional $10,000 per year
- Chairman of any other Standing Committee – additional $5,000 per year
- Member of the Audit Committee – additional $5,000 per year
- Member of any other Standing Committee – additional $2,500 per year

Equity Compensation

- Initial grant for new director – five year stock option to purchase 250,000 shares of Company common stock at the closing price of the Company's common stock on the grant date, vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, subject to continued service.

- Annual grant – five year stock option to purchase 100,000 shares of Company common stock granted on the earlier of the date of the Company's annual meeting of stockholders or the last business day of the month ending June 30, vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, subject to continued service.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding our common stock, beneficially owned as of March 20, 2020 by (i) each person known to us to beneficially own more than 5% of our common stock, (ii) each executive officer and director, and (iii) all officers and directors as a group. The following table is based on the Company having 85,259,962 shares of common stock issued and outstanding as of March 20, 2020. We calculated beneficial ownership according to Rule 13d-3 of the Securities Exchange Act of 1934, as amended as of that date. Shares of our common stock issuable upon exercise of options or warrants or conversion of notes that are exercisable or convertible within 60 days after March 20, 2020 are included as beneficially owned by the holder, but not deemed outstanding for computing the percentage of any other stockholder for Percentage of Common Stock Beneficially Owned. For each individual and group included in the table below, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the 85,259,962 shares of common stock outstanding at March 20, 2020, plus the number of shares of common stock that such person or group had the right to acquire on or within 60 days after March 20, 2020. Beneficial ownership generally includes voting and dispositive power with respect to securities. Unless otherwise indicated below, the persons and entities named in the table have sole voting and sole dispositive power with respect to all shares beneficially owned. Unless otherwise indicated, the address for each person listed is: c/o Guardion Health Sciences, Inc., 15150 Avenue of Science, Suite 200, San Diego, CA 92128.

Name of Beneficial Owner and Title of Officers and Directors	Shares of Common Stock Beneficially Owned	Percentage
Michael Favish, Chief Executive Officer, President and Director [(a)]	3,535,134	4.13%
Robert N. Weingarten, Director	652,500	*%
Mark Goldstone, Director	525,300	*%
Donald A. Gagliano, Director	136,500	*%
David Evans, Director and Chief Science Officer[(b)]	1,542,500	1.81%
Kelly Anderson, Director	250,000	*%
John Townsend, Chief Accounting Officer and Controller	52,500	*%
Vincent J. Roth, General Counsel and Corporate Secretary	132,500	*%
All Officers and Directors as a Group (8 persons)	**6,826,934**	**7.99%**

* Less than 1%.

(a) Consists of 2,750,000 shares of common stock issued on December 1, 2009 for services provided; 25,000 shares issued on December 31, 2016 for services provided; 342,467 shares issued on December 31, 2016 in exchange for accrued compensation owed; 1,000 shares of common stock purchased April 10, 2019 in the Initial Public Offering, which shares were registered on the S-1 Registration Statement that the SEC declared effective on April 4, 2019; and 416,667 shares of common stock shares issuable upon the exercise of a common stock purchase option granted April 9, 2019 with a per share exercise price of $4.40 per share and a five-year term (the "Favish Option"). Excludes 833,333 unvested shares of common stock underlying the Favish Option. The Favish Option vests ratably on the last day of each calendar quarter following the date of grant over a period of three (3) years and is subject to Mr. Favish remaining employed with the Company on the applicable vesting dates.

(b) Consists of 1,371,000 shares of common stock issued on September 29, 2017 in connection with the 2017 acquisition of VectorVision, Inc., 6,500 shares of common stock purchased April 9, 2019 in the Initial Public Offering, which shares were registered on the S-1 Registration Statement that the SEC declared effective on April 4, 2019, 40,000 shares purchased in the August follow-on offering and 125,000 of the shares issued in exchange for the VectorVision, Inc. acquisition serve as security for VectorVision, Inc.'s indemnification obligations under the Asset Purchase Agreement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS AND DIRECTOR INDEPENDENCE

Except as set forth below, during the past three years, there have been no transactions, whether directly or indirectly, between the Company and any of its officers, directors or their family members.

During the twelve months ended December 31, 2019 and 2018, the Company incurred and paid $300,000 and $275,000, respectively, of salary expense to our Board Chairman and CEO, Mr. Michael Favish. In addition, compensation cost of $2,339,560 was recognized on amortization of stock option awards during the twelve months ended December 31, 2019. During the twelve months ended December 31, 2019 and 2018, the Company incurred and paid salaries of $114,000 and $103,000, respectively, to Karen Favish, spouse of Michael Favish. During the twelve months ended December 31, 2019 and 2018, the Company incurred and paid salaries of $55,000 and $33,000, respectively, to Kristine Townsend, spouse of Controller and Chief Accounting Officer John Townsend.

On September 29, 2017, the Company completed the acquisition of substantially all of the assets and liabilities of VectorVision Ohio in exchange for 1,525,000 shares of the Company's common stock, pursuant to the Asset Purchase and Reorganization Agreement ("Asset Purchase Agreement"), which was entered into on an arm's-length basis. David W. Evans, a Director of the Company, owned 28% of the issued and outstanding shares of VectorVision Ohio and his wife, Tamara Evans, owned 72% of the issued and outstanding shares of VectorVision Ohio. VectorVision Ocular Health, Inc is a wholly owned subsidiary of the Company formed by the Company in connection with the acquisition of assets from VectorVision Ohio. Dr. Evans was appointed as a director of the Company on September 29, 2017 pursuant to the Asset Purchase Agreement. The Company entered into a Consulting Agreement with Dr. Evans, dated as of September 29, 2017, whereby Dr. Evans has been engaged to serve as a consultant to the Company to further the Company's planned

development and commercialization of the Company's portfolio of products and technology. The Consulting Agreement has an initial term of 3 years, with automatic one-year renewals unless earlier terminated. Dr. Evans is entitled to compensation of $10,000 per month for the first six months of the term of the Consulting Agreement and $7,500 per month for the remainder of the term of the Consulting Agreement. Additionally, on the same date, the Company and Dr. Evans entered into an Intellectual Property Purchase Agreement wherin the Company agreed to pay to Dr. Evans a commercially reasonable royalty payments on sales of goods relating to vision acuity testing during the term of the agreement. The parties agreed to negotiate the amount and the terms and conditions of the royalty in good faith.

Due to and from related parties represents unreimbursed expenses and compensation incurred on behalf of, and amounts loaned to the Company by, Michael Favish, the Company's Chief Executive Officer, as well as other shareholders. The advances are unsecured, non-interest bearing and are due on demand. As of December 31, 2019 and 2018, there were no amounts due to related parties. As of December 31, 2017, the Company had $146,133 due to related parties.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Weinberg & Company, P.A. acted as the Company's independent registered public accounting firm for the years ended December 31, 2019 and 2018 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by the Company for audit and other services provided by Weinberg & Company, P.A. for the years ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	**2018**
Audit Fees [(a)]	$ 92,467	$ 100,990
Tax Fees [(b)]	31,818	26,740
Other Fees [(c)]	240,093	33,141
Total	$ 364,378	$ 160,871

(a) Audit fees represent fees for professional services provided in connection with the audit of the Company's annual financial statements and the review of its financial statements included in the Company's Quarterly Reports on Form 10-Q and services that are normally provided in connection with statutory or regulatory filings.

(b) Tax fees represent fees for professional services related to tax compliance, tax advice and tax planning.

(c) Other fees represent fees related to our filing of certain Registration Statements.

All audit related services, tax services and other services rendered by Weinberg & Company, P.A. were pre-approved by the Company's Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for the Company by its independent registered public accounting firm. Our independent registered public accounting firm and management are required to periodically report to the Board of Directors regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) list of documents filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Financial Statements on page F-1, where these documents are listed.

(2) Financial Statement Schedules

The financial statement schedules have been omitted because the required information is not applicable, or not present in amounts sufficient to require submission of the schedules, or because the information is included in the financial statements or notes thereto.

(3) Exhibits

(b) Exhibits:

A list of exhibits required to be filed as part of this Annual Report on Form 10-K is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein by reference.

Guardion Health Sciences, Inc.
Consolidated Financial Statements and Footnotes
Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Guardion Health Sciences, Inc.
San Diego, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Guardion Health Sciences, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1, the Company has experienced recurring losses and negative operating cash flows since inception. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the financial statements. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Weinberg & Company, P.A.

We have served as the Company's auditor since 2015.

Los Angeles, California
March 30, 2020

Guardion Health Sciences, Inc.

Consolidated Balance Sheets

	December 31,	
	2019	**2018**
Assets		
Current assets		
Cash	$ 11,115,502	$ 670,948
Accounts receivable	78,337	28,203
Inventories	310,941	357,997
Prepaid expenses	362,938	47,773
Total current assets	**11,867,718**	**1,104,921**
Deposits	11,751	11,751
Property and equipment, net	374,638	274,804
Right of use asset, net	572,714	-
Deferred offering costs	-	270,000
Intangible assets, net	50,000	456,104
Goodwill	-	1,563,520
Total assets	**$ 12,876,821**	**$ 3,681,100**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 129,132	$ 413,925
Accrued expenses and deferred rent	116,211	81,412
Derivative warrant liability	13,323	-
Lease liability - current	151,568	-
Total current liabilities	**410,234**	**495,337**
Lease liability – long term	434,747	-
Total liabilities	**844,981**	**495,337**
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 74,982,562 and 20,564,328 shares issued and outstanding at December 31, 2019 and December 31, 2018	74,983	20,564
Additional paid-in capital	57,468,528	37,798,562
Accumulated deficit	(45,511,671)	(34,633,363)
Total stockholders' equity	**12,031,840**	**3,185,763**
Total liabilities and stockholders' equity	**$ 12,876,821**	**$ 3,681,100**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Operations

	Years Ended December 31,	
	2019	**2018**
Revenue		
Medical foods	$ 444,657	$ 332,795
Medical Devices	434,010	609,358
Other	24,270	-
Total revenue	902,937	942,153
Cost of goods sold		
Medical foods	155,212	161,023
Medical Devices	178,815	237,156
Other	7,288	-
Total cost of goods sold	341,315	398,179
Gross profit	561,622	543,974
Operating expenses		
Research and development	194,311	231,847
Sales and marketing	1,874,901	1,520,862
General and administrative	7,425,827	4,934,986
Goodwill impairment	1,563,520	-
Total operating expenses	11,058,559	6,687,695
Loss from operations	(10,496,937)	(6,143,721)
Other (income) expenses:		
Interest expense	258,365	2,289
Finance cost upon issuance of warrants	415,955	-
Change in fair value of derivative warrants	(292,949)	-
Costs associated with extension of warrant expiration dates	-	1,621,397
Total other (income) expenses	381,371	1,623,686
Net loss	**(10,878,308)**	**(7,767,407)**
Net loss per common share – basic and diluted	$ (0.30)	$ (0.38)
Weighted average common shares outstanding – basic and diluted	36,468,081	20,188,628

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	20,091,761	$ 20,092	$ 33,716,140	$ (26,865,956)	$ 6,870,276
Fair value of vested stock options	-	-	1,595,037	-	1,595,037
Issuance of common stock – warrant exercises	103,000	102	16,358	-	16,460
Sale of common stock	369,567	370	849,630	-	850,000
Warrants - extension of expiration dates	-	-	1,621,397	-	1,621,397
Net loss	-	-	-	(7,767,407)	(7,767,407)
Balance at December 31, 2018	20,564,328	20,564	37,798,562	(34,633,363)	3,185,763
Fair value of vested stock options – officer and director	-	-	2,339,560	-	2,339,560
Fair value of vested stock options	-	-	254,170	-	254,170
Reclass of warrant liability to equity	-	-	359,683	-	359,683
Sale of common stock	36,050,000	36,050	16,188,757	-	16,224,807
Issuance of common stock for services	54,387	55	123,947	-	124,002
Issuance of common stock – warrant exercises	18,204,809	18,205	153,170	-	171,375
Fair value of common stock – conversion of notes payable and related interest	109,038	109	250,679	-	250,788
Net loss	-	-	-	(10,878,308)	(10,878,308)
Balance at December 31, 2019	74,982,562	$ 74,983	$ 57,468,528	$ (45,511,671)	$ 12,031,840

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2019	**2018**
Operating Activities		
Net loss	$ (10,878,308)	$ (7,767,407)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	477,346	295,672
Amortization of debt discount	250,000	-
Accrued interest expense included in notes payable	788	-
Amortization of right of use asset	148,440	-
Stock-based compensation	378,172	1,595,037
Stock-based compensation – officer and director	2,339,560	-
Goodwill impairment charge	1,563,520	-
Non-cash financing costs – derivative liability	415,955	-
Change in fair value of warrants – derivative liability	(292,949)	-
Costs associated with extension of warrant expiration dates	-	1,621,397
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	(50,135)	44,568
Inventories	47,056	(203,267)
Deposits and prepaid expenses	(315,165)	68,111
Increase (decrease) in -		
Accounts payable and accrued expenses	(14,244)	102,689
Lease liability	(140,888)	-
Accrued and deferred rent costs	40,848	69,369
Net cash used in operating activities	(6,030,004)	(4,173,831)
Investing Activities		
Purchase of property and equipment	(171,076)	(260,243)
Purchase of intellectual property	-	(50,000)
Net cash used in investing activities	(171,076)	(310,243)
Financing Activities		
Proceeds from issuance of common stock	16,224,807	850,000
Proceeds from issuance of convertible notes	250,000	-
Proceeds from issuance of promissory note	100,000	-
Payments on promissory note	(100,548)	-
Proceeds from exercise of warrants	171,375	16,460
Payments on line of credit	-	(30,535)
Deferred financing costs of IPO	-	(270,000)
Decrease in due to related parties	-	(146,133)
Net cash provided by financing activities	16,645,634	419,792
Cash:		
Net increase (decrease)	10,444,554	(4,064,282)
Balance at beginning of period	670,948	4,735,230
Balance at end of period	$ 11,115,502	$ 670,948
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash financing activities:		
Fair value of warrant liability in connection with issuance of convertible notes	$ 436,034	$ -
Recording of lease asset and liability upon adoption of ASU 2016-02	$ 721,154	$ -
Reclass of warrant liability to equity	$ 359,683	$ -
Fair value of common stock issued upon conversion of convertible notes and accrued interest	$ 250,788	$ -
Reclass of deferred offering costs to equity	$ 270,000	$ -

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2019 and 2018

1. Organization and Business Operations

Organization and Business

Guardion Health Sciences, Inc. (the "Company") was formed in December 2009 as a California limited liability company under the name P4L Health Sciences, LLC. On June 30, 2015, the Company converted from a California limited liability company to a Delaware corporation, changing its name from Guardion Health Sciences, LLC to Guardion Health Sciences, Inc.

The Company is a specialty health sciences company (1) that has developed medical foods and medical devices in the ocular health space and (2) that is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers.

Medical Foods:

- **Lumega-Z®:** The Company formulates and distributes Lumega-Z®, which is designed to replenish and restore the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as adult dry macular degeneration ("AMD") and computer vision syndrome ("CVS"). The Company believes this risk may be modified by taking Lumega-Z to maintain a healthy macular protective pigment. Additionally, early research has shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's disease and dementia.

- **GlaucoCetin™ :** In November 2018, the Company launched its second medical food product, GlaucoCetin™. The Company believes GlaucoCetin™ is the first vision-specific medical food designed to support and protect the mitochondrial function of optic nerve cells and improve blood flow in the ophthalmic artery in patients with glaucoma. The parent compound of GlaucoCetin™, called "GlaucoHealth," was designed by Robert Ritch, M.D., one of the Company's Medical Advisory Board members.

Medical Devices:

- **MapcatSF®:** The Company invented a proprietary technology, embodied in the Company's medical device, the MapcatSF®, that accurately measures the macular pigment optical density ("MPOD"). On November 8, 2016, the United States Patent and Trademark Office ("USPTO") issued patent number 9,486,136 for the MapcatSF invention. Using the MapcatSF to measure the MPOD allows one to monitor the increase in the density of the macular protective pigment after taking Lumega-Z. The MapcatSF device is a Class I medical device under the U.S. Food and Drug Administration ("FDA") classification scheme for medical devices, which the Company has determined does not require pre-market approval. The Company's focus is to deploy the MapcatSF in clinics accompanied by trained technicians to conduct the MPOD measurements and collaborate with the physicians treating their patients. The Company maintains ownership and possession of the MapcatSF when used in this fashion but will sell the device to physicians upon request.

- **VectorVision and CSV-1000:** In September 2017, the Company, through its wholly-owned subsidiary VectorVision Ocular Health, Inc., acquired substantially all of the assets and certain liabilities of VectorVision, Inc., a company that specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study ("ETDRS") visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing for use by eye doctors in clinical trials, for real-world vision evaluation, and industrial vision testing. The acquisition expands the Company's technical portfolio. The Company believes the acquisition of VectorVision, through which it added the CSV-1000 to its product portfolio, further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases. Although the CSV-1000 will continue to be sold, the Company plans to put a greater focus on sales and marketing efforts of the new CSV-2000.

- **CSV-2000:** In September 2019, the Company announced that it completed development of its new proprietary, digital CSV-2000 standardized contrast sensitivity testing device. The Company believes that the CSV-2000 is the only computer-generated vision testing instrument available that will provide the optical marketplace with the Company's proprietary, industry-standard contrast sensitivity test, along with a full suite of standard vision testing protocols. The proprietary standardization methodology incorporated into the CSV-2000 includes a patented technology known as AcQviz, embodied in its own device, that automatically and constantly measures and adjusts screen luminance to a fixed standard light level for vision testing. The Company started selling the new CSV-2000 and AcQviz devices at the end of the first quarter of 2020.

Nutraceuticals:

- **NutriGuard Acquisition:** In September 2019, the Company, through its wholly owned subsidiary NutriGuard Formulations, Inc., acquired NutriGuard Research, Inc. The Company intends to build a portfolio of nutraceutical products under the NutriGuard brand by developing new formulations and marketing its products to patients directly through direct to consumer ("DTC") channels and through recommendations by their physicians.
- **acuMMUNE**: The first new nutraceutical product under development is acuMMUNE, designed with the objective of supporting effective immune function. acuMMUNE has been specially formulated with ingredients that have been shown in studies to support interferon-mediated anti-viral mechanisms, which are important components of the body's immune response during viral infections.* The Company is currently in the process of arranging for the manufacture and packaging of acuMMUNE at contract facilities in the United States and expects that this product will be available for sale beginning in approximately April 2020. The Company anticipates that acuMMUNE will also be available for export to various international markets shortly thereafter.

  *This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.
- In addition to NutriGuard's acuMMUNE product, a Malaysian company has contracted with NutriGuard to develop a proprietary formula to meet the demands of the Malaysian company's customers for an immune-supportive product. Each unit of the product will consist of two (2) bottles packaged together, one named Astramune-H and one named Astramune-V. The formula will be designed to provide both immuno-supportive and anti-inflammatory benefits to its users.

Transcranial Doppler Ultrasound Services:

- **TDSI:** In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). TDSI is dedicated to the pursuit of early predictors of eye diseases. The Company believes the ultrasound diagnosis of the vasculature of the brain is a valuable therapeutic intervention for practitioners and their patients, and the Company hopes that this business line will result in additional revenue streams generated from the testing and sale of Company products to appropriate customers. TDSI has established operations with selected clinics and is sending trained sonographers to conduct transcranial doppler ultrasound ("TCD") services on the physicians' patients at these initial facilities. The Company is working on expanding its client base by contacting and visiting new facilities to educate physicians on the benefits of the TCD service to facilitate scheduling additional facilities. The Company intends to target more fee-for-service practices that cater to cash paying patients.

The Company has been primarily engaged in research and development, product commercialization and capital raising activities.

Going Concern and Liquidity

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of $10,878,308 and utilized cash in operating activities of $6,030,004 during the year ended December 31, 2019. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are issued.

The Company's independent registered public accounting firm has also included explanatory language in their opinion accompanying the Company's audited financial statements for the year ended December 31, 2019. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern.

The Company will continue to incur significant expenses for commercialization activities related to its medical foods, the MapcatSF medical device, VectorVision diagnostic equipment, the TDSI business, the new NutriGuard line of nutraceuticals and with respect to efforts to continue to build the Company's infrastructure. Development and commercialization of medical foods and medical devices involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines.

The Company is seeking to raise additional debt and/or equity capital to fund future operations, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations.

NASDAQ Notice

On September 20, 2019, the Company received a notification letter from the Nasdaq Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock was below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Nasdaq letter has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, the Company has been provided an initial period of 180 calendar days, or until March 18, 2020 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the closing bid price of the Company's common stock is at least $1.00 for a minimum of 10 consecutive business days, the Staff will provide the Company written confirmation of compliance with the Minimum Bid Price Requirement and the matter will be closed. If the Company does not regain compliance by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify for such additional compliance period, the Company would have to meet the continued listing requirements of the NASDAQ Capital Market, except for the Minimum Bid Price Requirement, and the Company would need to provide written notice of its intention to cure the deficiency during the additional compliance period. If the Company is not eligible for the additional compliance period or it appears to the Staff that the Company will not be able to cure the deficiency or if the Staff exercises its discretion to not provide such additional compliance period, the Staff will provide written notice to the Company that its common stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearing Panel.

Reverse Stock Split

On January 30, 2019, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended Certificate of Incorporation, as amended (the "Amendment"), with the Secretary of State of the State of Delaware to effectuate a one-for-two (1:2) reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value. The Amendment became effective on the filing date. The number of shares authorized for common and preferred stock were not affected by the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split as all fractional shares were "rounded up" to the next whole share. Proportional adjustments for the Reverse Stock Split were made to all share and per share amounts as if the split occurred at the beginning of the earliest period presented.

2. Summary of Significant Accounting Policies

Use of Estimates

Our financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of our financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates. Significant estimates include those related to assumptions used in valuing assets acquired in business acquisitions, impairment testing of goodwill and other long-term assets, accruals for potential liabilities, valuing equity instruments issued during the period, and realization of deferred tax assets. Actual results could differ from those estimates.

Certain prior period amounts have been reclassified to conform to current period presentation. Such amounts consist of operating segment disclosures, whereby revenue and cost of goods sold have been broken out on the Consolidated Statements of Operations to conform with the Company's two reportable business segments as of December 31, 2019.

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as noted below. Disclosure as to transfers into and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded, non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The Company believes the carrying amount of its financial instruments (consisting of cash, accounts receivable, and accounts payable and accrued liabilities) approximates fair value due to the short-term nature of such instruments.

Concentration of Credit Risk and Other Risks and Uncertainties

Cash balances are maintained at large, well-established financial institutions. At times, cash balances may exceed federally insured limits. Insurance coverage limits are $250,000 per depositor at each financial institution. The Company has never experienced any losses related to these balances.

During the year ended December 31, 2019, the Medical Devices segment had one customer who accounted for approximately 22% of the Company's sales; and during the year ended December 31, 2018, the Medical Devices segment had one customer who accounted for approximately 47% of the Company's sales. No other customer accounted for more than 10% of sales in either year.

Accounts Receivable

The Company evaluates the collectability of its trade accounts receivable based on multiple factors. In circumstances where the Company becomes aware of a specific customer's inability to meet its financial obligations to the Company, a specific reserve for bad debts is estimated and recorded, which reduces the recognized receivable to the estimated amount the Company believes will ultimately be collected. In addition to specific customer identification of potential bad debts, bad debt charges are recorded based on the Company's historical losses and an overall assessment of past due trade accounts receivable outstanding.

The allowance for doubtful accounts and returns is established through a provision reducing the carrying value of receivables. At December 31, 2019 and 2018, no allowance for doubtful accounts and returns was considered necessary.

Inventories

The Company's inventories are stated at the lower of weighted-average cost or net realizable value. The cost of finished goods and raw materials is determined on a first-in, first-out basis. The Company evaluates its inventories for obsolescence and recoverability at each reporting period.

Property and Equipment

Property and equipment are initially recorded at their historical cost. Depreciation is computed using the straight-line method over the estimated useful lives of the depreciable assets (ranging from three to seven years). Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the remaining lease term.

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value. As of December 31, 2019 and 2018, the Company was not aware of the existence of any indicators of impairment at such dates.

Identifiable Intangible Assets and Goodwill

In connection with the VectorVision transaction in 2017, the Company identified and allocated estimated fair values to intangible assets including customer relationships, technology, tradenames, and competition. Our goodwill represents the excess of the purchase consideration over the fair value of the net tangible and identifiable intangible assets acquired during our VectorVision acquisition.

The Company utilized the services of an independent third-party valuation firm to assist it in identifying intangible assets and in estimating their fair values. The useful lives for its intangible assets other than goodwill were estimated based on Management's consideration of various factors, including assumptions that market participants might use about sales expectations as well as potential effects of obsolescence, competition, technological progress and the regulatory environment. Because the future pattern in which the economic benefits of these intangible assets may not be reliably determined, amortization expense has been calculated on a straight-line basis through September 30, 2019.

In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, the Company's goodwill and other intangible assets are subject to periodic impairment testing. The Company reviews intangible assets for impairment when circumstances indicate that their carrying values may not be recoverable. If the carrying value of an asset group is not recoverable, the Company recognizes an impairment loss for the excess carrying value over the fair value in its consolidated statements of operations.

During 2018 and through September 30, 2019, the Company was not aware of the existence of any indicators of impairment such that the carrying amount of its identifiable intangible assets or goodwill were more likely than not to exceed their fair values. The Company evaluates goodwill for impairment on an annual basis or whenever events and changes in circumstances suggest that the carrying amount may not be recoverable.

During the fourth quarter of 2019, the Company conducted its annual impairment analysis, considering multiple qualitative observations and indicators, including our customer relationships, the regulatory environment as it impacts medical devices, market penetration expectations and barriers, and our anticipated competitive environment. In addition, we assessed the operating results of our VectorVision reporting unit against the quantitative assumptions we used when determining the initial fair values associated with the 2017 business combination.

The Company believes strongly in the future growth and success of the VectorVision business. However, development of the CSV-2000 has taken longer than expected due to software engineering and other factors. Although we believe we will enjoy a dominant market share over time, there is subjectivity of predicting the amount and timing of that value. Recent changes in the regulatory environment may cost us more than anticipated to begin marketing the new device in Europe. Accounting treatment for intangible assets and goodwill requires thoughtful, objective judgment and evidence-based facts in order to support a fair value assertion. After objectively assessing the qualitative and quantitative factors above, Management concluded that it is more likely than not that the fair value for accounting purposes of the VectorVision intangible assets and goodwill is less than their carrying amount.

Due to the highly subjective and forward-looking nature of many of the indicators of impairment that might affect our business as well as the recent results of operations of the reporting unit, Management has concluded that as of December 31, 2019 it is no longer possible to determine a reasonable and objectively supportable fair value for the goodwill and identifiable intangible assets associated with the VectorVision acquisition. Accordingly, the Company recorded a goodwill impairment charge of $1,563,520 as of December 31, 2019.

Deferred Offering Costs

Deferred offering costs consist principally of legal, accounting, and underwriters' fees incurred related to equity financings. These deferred offering costs are charged against the gross proceeds received during the appropriate period. During the period ended June 30, 2019, $270,000 of offering costs deferred at December 31, 2018 were offset to paid in capital upon completion of our April 2019 offering. As of December 31, 2019, there were no comparable deferred offering costs.

Revenue Recognition

The Company's revenue is comprised of sales of medical foods and dietary supplements to consumers through a direct sales/credit card process. In addition, the Company sells medical device equipment and supplies to customers both in the U.S. and internationally.

The Company recognizes revenue in accordance with ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09" or "Topic 606") and all related amendments. The standard provides authoritative guidance clarifying the principles for recognizing revenue and developing a common revenue standard for U.S. generally accepted accounting principles. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which the entity expects to be entitled in the exchange for those goods or services.

Under the guidance, revenue is recognized when control of promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The Company reviews its sales transactions to identify contractual rights, performance obligations, and transaction prices, including the allocation of prices to separate performance obligations, if applicable. Revenue and costs of sales are recognized once products are delivered to the customer's control and performance obligations are satisfied.

All products sold by the Company are distinct individual products and consist of medical foods, supplemental formulas, medical devices and related supplies. The products are offered for sale as finished goods only, and there are no performance obligations required post-shipment for customers to derive the expected value from them. Contracts with customers contain no incentives or discounts that could cause revenue to be allocated or adjusted over time.

Control of products sold transfers to customers upon shipment from the Company's facilities, and the Company's performance obligations are satisfied at that time. Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Payment for sales of Lumega-Z is generally made by approved credit cards. Payments for medical device sales are generally made by check, credit card, or wire transfer. Historically the Company has not experienced any significant payment delays from customers.

The Company provides a 30-day right of return to its retail Lumega-Z customers. A right of return does not represent a separate performance obligation, but because customers are allowed to return products, the consideration to which the Company expects to be entitled is variable. Upon evaluation of historical Lumega-Z and VectorVision product returns, the Company determined that less than one percent of products is returned, and therefore believes it is probable that such returns will not cause a significant reversal of revenue in the future. Due to the insignificant amount of historical returns as well as the standalone nature of the Company's products and assessment of performance obligations and transaction pricing for the Company's sales contracts, the Company does not currently maintain a contract asset or liability balance at this time. The Company assesses its contracts and the reasonableness of its conclusions on a quarterly basis.

The following table presents the Company's revenues disaggregated by segment:

	Year Ended December 31,	
	2019	**2018**
Medical Foods	$ 444,657	$ 332,795
Medical Devices	434,010	609,358
Other	24,270	-
	$ 902,937	$ 942,153

All of the Company's Medical Foods revenues are derived from individual retail customers in North America. Medical Devices revenues are derived from a worldwide customer base consisting of both retail customers and distributors. International customers contributed approximately 93% and 94% of Medical Devices revenues for the years ended December 31, 2019 and 2018, respectively. Distributors contributed approximately 62% and 80% of Medical Devices revenues for the years ended December 31, 2019 and 2018, respectively.

Research and Development Costs

Research and development costs consist primarily of fees paid to consultants and outside service providers, patent fees and costs, and other expenses relating to the acquisition, design, development and testing of the Company's medical foods and related products. Research and development expenditures, which include stock compensation expense, are expensed as incurred and totaled $194,311 and $231,847 for the years ended December 31, 2019 and 2018, respectively.

Advertising Costs

Advertising costs are expensed as incurred and are included sales and marketing expense. Advertising costs aggregated $19,645 and $30,773 for the years ended December 31, 2019 and 2018, respectively.

Patent Costs

The Company is the owner of three issued domestic patents, three pending domestic patent applications, one issued foreign patent in Europe, one issued foreign patent in Hong Kong, and three foreign patent applications in Canada, Europe and Hong Kong. Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, patent costs, including patent-related legal fees, filing fees and internally generated costs, are expensed as incurred. During the years ended December 31, 2019 and 2018, patent costs were $137,183 and $93,149, respectively, and are included in general and administrative costs in the statements of operations.

Stock-Based Compensation

The Company periodically issues stock-based compensation to officers, directors, contractors and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, and employees, which include grants of employee stock options, are recognized in the financial statements based on their fair values in accordance with Topic 718. Stock option grants, which are generally time vested, will be measured at the grant date fair value and charged to operations on a straight-line basis over the vesting period. The fair value of stock options is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the expected life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date and the estimated volatility of the common stock over the term of the equity award.

In periods prior to January 1, 2019, the Company accounted for stock option and warrant grants issued and vesting to non-employees in accordance with the authoritative guidance of the FASB whereby the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. On January 1, 2019, the Company adopted Accounting Standards Update (ASU) 2018-07 which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company recognizes the fair value of stock-based compensation within its statements of operations with classification depending on the nature of the services rendered. The adoption of the new standard had no cumulative effect on previously reported amounts.

Income Taxes

The Company currently accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company determines that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of December 31, 2019 and 2018 and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of December 31, 2019, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

On December 22, 2017, the President of the United States signed and enacted into law H.R. 1 (the "Tax Reform Law"). The Tax Reform Law, effective for tax years beginning on or after January 1, 2018, except for certain provisions, resulted in significant changes to existing United States tax law, including various provisions that will impact the Company.

The Tax Reform Law reduces the federal corporate tax rate from 35% to 21% effective January 1, 2018. The Company will continue to analyze the provisions of the Tax Reform Law to assess the impact to the Company's consolidated financial statements.

Net Loss per Share

The Company's computation of basic and diluted net loss per common share is measured as net loss divided by the weighted average common shares outstanding during the respective periods, excluding unvested restricted common stock. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Potential common shares such as from unexercised warrants and options that have an anti-dilutive effect are excluded from the calculation of diluted net loss per share. The Company's basic and diluted net loss per share is the same for all periods presented because all shares issuable upon exercise of warrants and conversion of convertible debt outstanding are anti-dilutive as they decrease loss per share.

The following table sets forth the number of shares excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive:

	December 31,	
	2019	**2018**
Warrants	28,802,738	1,265,674
Options	2,962,500	1,362,500
	31,765,238	2,628,174

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments ("ASC 326"). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. As small business filer, the standard will be effective for us for interim and annual reporting periods beginning after December 15, 2022. The Company is currently assessing the impact of adopting this standard on the Company's financial statements and related disclosures.

The Company's management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

3. Acquisition of NutriGuard

Effective September 20, 2019 (the "Effective Date"), the Company's newly-formed wholly-owned subsidiary, NutriGuard Formulations, Inc., a Delaware corporation, completed an asset purchase agreement (the "Asset Purchase Agreement") with NutriGuard Research, Inc., a California corporation ("NutriGuard"), and NutriGuard's sole shareholder, Mark McCarty.

Pursuant to the Asset Purchase Agreement, the Company purchased specified assets of the NutriGuard brand and business, consisting primarily of inventory, trademarks, copyrights and other intellectual property. In exchange, the Company agreed to pay a 3% royalty, payable quarterly, to NutriGuard based on the operating results of the NutriGuard branded products in future periods, after $500,000 in gross revenues have been achieved by the Company. The Company is unable at this time to reasonably estimate the timing or amount of future revenue streams that would generate royalty payments, as the Company will need to develop new product formulations and implement a new marketing and distribution infrastructure, which will require the investment of a significant amount of capital over an extended period of time. Accordingly, any royalty payments in the future will be charged directly to operations when incurred.

In addition, on the Effective date, the Company and Mr. McCarty entered into a consulting agreement (as described below), and Mr. McCarty and NutriGuard agreed, among other terms, to no longer use the "NutriGuard" name. Mr. McCarty also entered into a non-competition covenant for a period of 5 years.

As the Company did not pay any cash or non-cash consideration, nor did it assume any liabilities, in conjunction with this acquisition, the Company did not recognize any tangible or intangible assets at closing. All costs related to this transaction, consisting primarily of legal fees, were charged to operations as incurred. Although NutriGuard has conducted limited operations with nominal revenues during the past few years, the Company has determined that the NutriGuard acquisition qualifies as the acquisition of a business under Accounting Standards Codification ("ASC") 805: Business Combinations ("ASC 805"). However, the recent historical operations of NutriGuard did not meet any of the three-element significance level tests (investment, assets and pre-tax income) with regard to the accounting standards requiring acquisition company financial statements and related pro forma financial information, and the Company has therefore concluded that the acquisition of NutriGuard was not significant. The value of the NutriGuard business consists primarily of intangible assets for which no accounting value will be attributed in the Company's financial statements. The Company intends to utilize these intangible assets to build a nutraceutical brand and product portfolio based on updated and reformulated compounds, which will require the investment of a significant amount of capital over an extended period of time.

The following preliminary unaudited pro forma financial information gives effect to the Company's acquisition of NutriGuard as if the acquisition had occurred on January 1, 2018 and had been included in the Company's consolidated statements of operations during the years ended December 31, 2019 and 2018:

	Years Ended December 31,	
	2019	2018
Pro forma net revenues	$ 963,167	$ 1,032,207
Pro forma net loss attributable to common shareholders	$ (10,913,833)	$ (7,920,263)
Pro forma net loss per share	$ (0.30)	$ (0.39)

Mr. McCarty's consulting agreement with the Company provides that Mr. McCarty will serve as, the Director of Research of the Company for a period of 3 years at a rate of $7,500 per month for 12 months and $5,000 per month thereafter. It is intended that Mr. McCarty will assist the Company, among other tasks, in developing new formulations for distribution under the NutriGuard brand, as well as identifying production sources for such compounds and developing distribution networks for such products.

Pursuant to the consulting agreement, the Company granted Mr. McCarty stock options to purchase 100,000 shares of the Company's common stock with a grant date fair value of $54,004 and an exercise price of $0.54 per share, which was the closing market price of the Company's common stock on the Effective Date. The stock options were granted under the terms of the Company's 2018 Equity Incentive Plan, and the options vest as follows: 25% on the Effective Date, 25% on the first anniversary following the Effective Date, 25% on the second anniversary following the Effective Date, and 25% on the third anniversary following the Effective Date.

4. Segment Reporting

The Company determined its reporting units in accordance with ASC 280, "Segment Reporting" ("ASC 280"). The Company historically has reported its operating results as a single reportable segment described as the business of developing and commercializing a variety of products that support the detection, intervention and monitoring of a range of eye diseases. The Company's chief executive officer, who is the Chief Operating Decision Maker ("CODM"), has historically reviewed financial information on an aggregated basis for purposes of allocating resources and evaluating financial performance.

In September 2017, the Company, through its wholly-owned subsidiary VectorVision Ocular Health, Inc., acquired substantially all of the assets and certain liabilities of VectorVision, Inc., a company that specialized in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study visual acuity testing. In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). The Company has established TDSI operations with selected clinics and is focusing on expanding its client base. In September 2019, the Company's newly-formed wholly-owned subsidiary, NutriGuard Formulations, Inc. ("NGFI"), completed an asset purchase agreement with NutriGuard Research, Inc., and NutriGuard's sole shareholder, Mark McCarty. The Company intends to utilize the NGFI subsidiary to build a nutraceutical brand and product portfolio based on updated and reformulated compounds.

The addition of potential new products or services as the Company grows requires management to periodically reevaluate its reporting structure. As sales of our medical foods as well as sales of VectorVision products grow, there is an increased need for the CODM to evaluate revenue and gross profit on a product line or group basis for purposes of resource allocation. As of December 31, 2019, the TDSI and NGFI subsidiaries do not meet the required quantitative criteria to be considered a reportable operating segment. Additionally, these subsidiaries do not share similar economic characteristics or a majority of the aggregation criteria set forth in ASC 280, and therefore are included in the category "Corporate" below. The TDSI and NGFI businesses earned $17,200 and $7,070 of service revenue, respectively, and incurred approximately $284,935 and $75,322 of operating costs, respectively, during the year ended December 31, 2019. As of December 31, 2019, based on anticipated growth and the expanding diversity of product and service offerings by the Company, management has concluded that results should be reported in two segments: Medical Foods and Medical Devices. The following tables set forth our results of operations by segment (results allocated to Corporate consist of the TDSI and NGFI operations):

	For the Year Ended December 31, 2019			
	Corporate	Medical Foods	Medical Devices	Total
Revenue	$ 24,270	$ 444,657	$ 434,010	$ 902,937
Cost of goods sold	7,288	155,212	178,815	341,315
Gross profit	16,982	289,445	255,195	561,622
Goodwill impairment charge	-	-	1,563,520	1,563,520
Operating expenses	360,257	8,026,239	1,108,543	9,495,039
Loss from operations	**$ (343,275)**	**$ (7,736,794)**	**$ (2,416,868)**	**$ (10,496,937)**

	For the Year Ended December 31, 2018			
	Corporate	Medical Foods	Medical Devices	Total
Revenue	$ -	$ 332,795	$ 609,358	$ 942,153
Cost of goods sold	-	161,023	237,156	398,179
Gross profit	-	171,772	372,202	543,974
Operating expenses	72,797	5,950,711	664,187	6,687,695
Loss from operations	**$ (72,797)**	**$ (5,778,939)**	**$ (291,985)**	**$ (6,143,721)**

The following tables set forth our total assets by segment. Intersegment balances and transactions have been removed:

	As of December 31, 2019			
	Corporate	Medical Foods	Medical Devices	Total
Current assets				
Cash	$ 11,115,502	$ -	$ -	$ 11,115,502
Inventories	5,003	126,708	179,230	310,941
Other	7,399	219,223	214,653	441,275
Total current assets	**11,127,904**	**345,931**	**393,883**	**11,867,718**
Right of use asset	-	509,464	63,250	572,714
Property and equipment, net	-	219,056	155,582	374,638
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	**$ 11,127,904**	**$ 1,136,202**	**$ 612,715**	**$ 12,876,821**

	As of December 31, 2018			
	Corporate	Medical Foods	Medical Devices	Total
Current assets				
Cash	$ 670,948	$ -	$ -	$ 670,948
Inventories	-	235,957	122,040	357,957
Other	-	44,110	31,866	75,976
Total current assets	**670,948**	**280,067**	**153,906**	**1,104,921**
Property and equipment, net	-	99,178	175,626	274,804
Deferred offering	-	270,000	-	270,000
Intangible assets, net	-	50,000	406,104	456,104
Goodwill	-	-	1,563,520	1,563,520
Other	-	11,751	-	11,751
Total assets	**$ 670,948**	**$ 710,996**	**$ 2,299,156**	**$ 3,681,100**

5. Inventories

Inventories consisted of the following:

	December 31,	
	2019	2018
Raw materials	$ 246,875	$ 282,574
Finished goods	64,066	75,423
	$ 310,941	$ 357,997

6. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2019	2018
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	394,427	249,447
Furniture and fixtures	185,799	163,186
Computer equipment	68,460	64,976
Office equipment	8,193	8,193
	755,236	584,159
Less accumulated depreciation and amortization	(380,598)	(309,355)
	$ 374,638	$ 274,804

For the years ended December 31, 2019 and 2018, depreciation and amortization expense was $71,242 and $81,035, respectively, of which $33,004 and $34,524 was included in research and development expense, $15,641 and $10,898 was included in sales and marketing expense, and $22,597 and $35,613 was included in general and administrative expense, respectively.

7. Intangible Assets

The Company's intangible assets consisted of the following:

	Estimated Useful Life in Years	December 31,	
		2019	2018
Customer relationships	3	$ 430,700	$ 430,700
Technology	3	161,100	161,100
Trade Names	5	65,600	65,600
Noncompetition	4	17,000	17,000
		674,400	674,400
Less accumulated depreciation and amortization		(674,400)	(268,296)
		$ -	**$ 406,104**

The Company's amortization expense on its finite-lived intangible assets was $406,104 and $214,637 for the years ended December 31, 2019 and 2018, respectively.

Due to the highly subjective and forward-looking nature of many of the indicators of impairment that might affect our VectorVision business, the Company has accelerated the remaining amortization of $191,467 on its identifiable intangible assets as of December 31, 2019.

	December 31,	
	2019	2018
Trademark	$ 50,000	$ 50,000

On January 26, 2018, the Company acquired the rights to the trademark GLAUCO-HEALTH as well as the name "International Eye Wellness Institute" (together, the "IP Assets") from an unrelated third party. The purchase included all rights, title, and interest in and to the IP Assets, including (a) the right to register and use the IP Assets; (b) all goodwill associated with the IP Assets; (c) all income, royalties, and damages hereafter due or payable with respect to the IP Assets; (d) all rights to sue for past, present, and future infringements or misappropriations of the IP Assets; and I and all other intellectual property rights owned or claimed by the seller or embodied in the IP Assets. In exchange for these rights, the Company paid the seller $50,000 in cash.

The Company determined that the acquired intangible asset met the definition of a defensive intangible asset under ASC 350. The Company accounted for the $50,000 payment as an acquired intangible asset as of the closing of the agreement. As the Company can renew the underlying rights to the IP Assets indefinitely at nominal cost, the assets have been classified as a non-amortizable intangible asset on the Company's balance sheet. The Company evaluates the status of the assets for impairment annually or more frequently if warranted. Based on management's measurement, there were no indications of impairment at December 31, 2019.

8. Promissory Notes

Promissory Note

On March 12, 2019, the Company issued a promissory note with principal in the amount of $100,000, simple interest of 10% annually, and with a maturity date of June 10, 2019. On April 11, 2019, the Company repaid the promissory note for a total of $100,548 including accrued interest.

Convertible Notes and Related Warrants

On March 15, 2019, the Company issued a convertible note with principal in the amount of $100,000, simple interest of 5% annually, and with a maturity date of September 30, 2019. In addition, on March 20, 2019, the Company issued a convertible note with principal in the amount of $150,000, simple interest of 5% annually, and with a maturity date of September 30, 2019. The convertible notes (principal and accrued interest) were mandatorily convertible upon the consummation of the IPO. Concurrent with the issuance of the notes, the Company issued warrants to both note holders equal to the number of shares of common stock that the holders receive in connection with the converted notes. The per share exercise price of the warrants was set at 125% of the conversion price of the notes, defined in the note agreements, as the lower of (a) 75% of the price per share of common stock of the IPO or (b) $2.30. The Company issued 109,038 warrants based upon the completion of the IPO in April 2019

Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as a derivative liability upon issuance. The aggregate fair value of the warrants was calculated as $436,034 based on a probability effected Black-Scholes option pricing model with a stock price of $4.00, volatility of 138%, and risk-free rates ranging from 2.34% - 2.39%. The Company recognized a debt discount of $250,000 equal to the face amount of the convertible notes and recorded a financing cost of $186,034 equal to the difference between the fair value of the warrants and the debt discount. See Note 11 for further discussion of the derivative liability.

The convertible notes and accrued interest with an aggregate balance of $250,788 were mandatorily converted into 109,038 shares of common stock based on a conversion price of $2.30 per share upon the consummation of the IPO in April 2019 and the valuation discount of $250,000 was recognized as interest cost.

9. Lease Liabilities

In October 2012, the Company entered into a lease agreement for 9,605 square feet of office and warehouse space commencing March 1, 2013. Upon entering into the agreement, the Company paid a deposit of $47,449, of which $36,979 represented prepaid rent. As of December 31, 2019, $11,751 remained on deposit under the lease agreement. The lease ("Lease 1") was renewed for an additional five years in 2018. As of December 31, 2019, remaining lease payments under the amended lease agreement averaged $13,000 per month through July 2023.

In connection with the VectorVision acquisition on September 29, 2017, the Company assumed a lease agreement for 5,000 square feet of office and warehouse space which commenced on October 1, 2017. The lease ("Lease 2") was renewed for an additional 65 months. As of December 31, 2019, remaining lease payments averaged $1,852 per month through February 2023.

In accounting for the leases on January 1, 2019, the Company adopted ASU 2016-02 - Leases, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. The Company classified the leases as operating leases and determined that the fair value of Lease 1 at the inception of the lease was $639,520 using a discount rate of 3.9% and the fair value of Lease 2 at the inception of the lease was $81,634 using a discount rate of 3.9%. During the year ended December 31, 2019, the Company made combined payments on both leases of $166,770 towards the lease liabilities. As of December 31, 2019, the lease liability for Lease 1 was $520,284, and the lease liability for Lease 2 was $66,031. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. Combined rent expense for both leases for the years ended December 31, 2019 and 2018 was $174,323 and $85,084, respectively. During the year ended December 31, 2019, the Company reflected amortization of right of use asset of $148,440 related to the leases, resulting in a net asset balance of $572,714 as of December 31, 2019.

10. Contingencies

The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. In the opinion of management of the Company, adequate provision has been made in the Company's financial statements at December 31, 2019 with respect to such matters.

11. Stockholders' Equity

Common Stock

On April 9, 2019, the Company closed its initial public offering (the "IPO") and issued 1,250,000 shares of its common stock at a public offering price of $4.00 per share for total gross proceeds of $5.0 million pursuant to an underwriting agreement by and between the Company, WallachBeth Capital, LLC, and WestPark Capital, Inc., acting as the representatives. On April 9, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the underwriters and affiliates in connection with the IPO. The Company accounted for these warrants as a derivative liability in the financial statements upon issuance because they were associated with a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. Net proceeds to the Company were $3,888,000 after deducting underwriting discounts, commissions, and other offering expenses. See Warrant Liability discussion below for additional details.

On August 15, 2019, the Company closed a second public offering consisting of (i) 12,000,000 shares of common stock, par value $0.001 per share, of the Company, (ii) pre-funded warrants exercisable for 1,000,000 shares of common stock, and (iii) warrants to purchase up to an aggregate of 13,000,000 shares of common stock pursuant to an underwriting agreement by and between the Company, Maxim Group LLC, and WallachBeth Capital LLC, acting as the representatives. On August 16, 2019, the Company sold an additional 1,950,000 Warrants upon exercise of the underwriters' over-allotment option. The public offering price was $0.44 per share of common stock, $0.43 per pre-funded warrant and $0.01 per accompanying warrant. On August 15, 2019, the Company issued 1,040,000 warrants with an exercise price of $0.50 per share to the underwriters in connection with the offering. Net proceeds to the Company were $4,944,340 after deducting underwriting discounts, commissions, and other offering expenses. See Warrants discussion below for additional details.

On October 30, 2019, the Company completed an underwritten public offering of 22,800,000 shares of its common stock plus 1,700,000 pre-funded warrants to purchase common stock in lieu thereof and Series B warrants to purchase up to 24,500,000 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $0.342 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but issued separately and were immediately separable upon issuance. Warrants to purchase 840,000 shares of common stock upon the exercise of the underwriters' over-allotment option and warrants to purchase 1,960,000 shares of common stock were issued to the underwriters as representatives of the public offering. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7,400,000. See Warrants discussion below for additional details.

Other Issuances

During the year ended December 31, 2019, the Company issued 54,387 fully vested shares of common stock for services rendered and recognized $124,002 in stock compensation expense related to these shares.

Warrants

A summary of the Company's warrant activity is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
December 31, 2017	**1,491,836**	**$ 0.89**	**1.16**
Granted	-	-	-
Forfeitures	-	-	-
Expirations	(158,162)	0.17	-
Exercised	(103,000)	0.01	-
December 31, 2018	**1,265,674**	**0.71**	**0.29**
Granted	46,161,538	0.42	4.81
Forfeitures	-	-	-
Expirations	(279,424)	(1.83)	-
Exercised	(18,345,050)	(0.50)	-
December 31, 2019, all exercisable	**28,802,738**	**$ 0.38**	**4.91**

The exercise prices of warrants outstanding and exercisable as of December 31, 2019 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
25,340,000	$ 0.34
1,960,000	0.44
1,040,000	0.50
226,200	0.59
65,000	1.50
109,038	2.88
62,500	5.00
28,802,738	

During the year ended December 31, 2019, the Company granted a total of 46,161,538 warrants consisting of: (a) 62,500 warrants associated with our IPO financing in April 2019 (see Warrant Liability discussion below), (b) 109,038 warrants in connection with the conversion of certain notes (c) 16,990,000 warrants associated with our August public offering, and (d) 29,000,000 warrants associated with our October public offering.

The August and October pre-funded warrants were sold to purchasers whose purchase of shares of common stock in the offerings would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the Company's outstanding common stock immediately following the consummation of the offerings, in lieu of shares of common stock. Each pre-funded warrant represents the right to purchase one share of common stock at an exercise price of $0.01 per share.

The August public offering price was $0.44 per share of common stock and $0.01 per accompanying warrant. Each warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $0.585 per share. The warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) 30 days from the effective date of the Registration Statement and (ii) the date on which the Common Stock trades an aggregate of more than 40,000,000 shares after the announcement of the pricing of the offering, and ending on the twelve month anniversary thereof, each warrant may be exercised at the option of the holder on a cashless basis at a ratio of one warrant for one share of common stock, in whole or in part, if the weighted average price of the common stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the warrant.

The October public offering price was $0.332 per share of common stock and $0.01 per accompanying warrant. Each warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $0.342 per share.

During the year ended December 31, 2019, investors exercised a total of 18,345,050 warrants for 18,204,809 shares of common stock, consisting of (I) 15,356,300 warrants exercised on a cashless basis for 15,216,059 net common shares, and (II) 2,988,750 warrants exercised for a total of $171,375 in proceeds to the Company (2,700,000 of these warrants were exercisable for $0.01 per share, and 288,750 were exercisable for $0.50 per share).

During the year ended December 31, 2019, 279,424 warrants expired unexercised.

As of December 31, 2019, the Company had an aggregate of 28,802,738 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $0.38, a weighted average remaining life of 4.91 years. The aggregate intrinsic value of warrants outstanding as of December 31, 2019 was $0.

Warrant Liability

In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at the issuance date. The fair value of the warrants will be remeasured at each reporting period, with the change in the fair value recognized in earnings in the accompanying statements of operations. The Company estimated that the issuance of 109,038 warrants with an exercise price of $2.88 per share would correspond to the number of shares of common stock that the holders would receive in connection with the completion of the IPO. The fair value of the warrants at issuance was determined to be $436,034, of which $250,000 was recorded as a valuation discount and $186,034 was recorded as a finance cost. Upon completion of the IPO, the exercise price and the number of warrants were fixed and the warrants are no longer accounted for as liabilities. The fair value of the warrants at the closing of the IPO was determined to be $359,683 using a Black-Scholes model with a weighted average remaining life of 4.94 years and a stock valuation of $3.30 per share, and such amount was reclassified to equity. During the year ended December 31, 2019, the Company recognized a change in warrant liability of $76,351 that was recorded in the accompanying statements of operations.

On April 9, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants is remeasured at each reporting period, and the change in the fair value is recognized in earnings in the accompanying Statements of Operations. The fair value of the warrants at the date of issuance was determined to be $229,921 and was recorded as a finance cost. As of December 31, 2019, the fair value of the warrants was determined to be $13,323 and the change in fair value of $216,598 was recognized in the accompanying statements of operations.

The fair value of the warrant liability was determined at the following issuance and reporting dates using the Black-Scholes-Merton option pricing model and the following assumptions:

	Convertible Noteholders Upon Issuance	Underwriter Upon Issuance	Warrant Liability As of December 31, 2019
Stock price	$ 4.00	$ 3.68	$ 0.22
Risk free interest rate	2.34 – 2.39%	2.29%	1.62%
Expected volatility	138%	137%	145%
Expected life in years	5.00	5.00	4.26
Expected dividend yield	0%	0%	0%
Number of warrants	109,038	62,500	62,500
Fair value of warrants	$ 436,034	$ 229,921	$ 13,323

Stock Options

A summary of the Company's stock option activity is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
December 31, 2017	**1,062,500**	**$ 2.19**	**5.14**
Granted	300,000	0.55	1.49
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2018	**1,362,500**	**2.26**	**3.78**
Granted	1,600,000	3.51	4.38
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2019, outstanding	**2,962,500**	**$ 2.94**	**3.64**
December 31, 2019, exercisable	**1,825,000**	**$ 2.47**	**3.19**

The exercise prices of options outstanding and exercisable as of December 31, 2019 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
250,000	125,000	$ 0.25
100,000	25,000	0.54
625,000	625,000	2.00
62,500	62,500	2.30
675,000	675,000	2.50
1,250,000	312,500	4.40
2,962,500	**1,825,000**	

On April 9, 2019, the Company granted options to purchase 1,250,000 shares of common stock to the Company's Chairman and CEO with a grant date fair value of $4,122,750 and an exercise price per share of $4.40. The options vest on a quarterly basis over three years. On September 20, 2019, the Company granted options to purchase 100,000 shares of common stock to a consultant with a grant date fair value of $54,004 and at a price per share of $0.54. 25,000 of the options vested immediately and the remainder vest on an annual basis over three years. On December 30, 2019, the Company granted options to purchase 250,000 shares of common stock to a director with a grant date fair value of $61,510 and an exercise price per share of $0.25. 125,000 options vested upon the date of grant, and the remaining 125,000 vest on a quarterly basis over four quarters.

The Company accounts for share-based payments in accordance with ASC 718 wherein grants are measured at the grant date fair value and charged to operations over the vesting periods. During the year ended December 31, 2019, $2,593,730 of compensation expense was recognized relating the amortization of these awards.

During the year ended December 31, 2019, option awards were valued based upon the Black-Scholes option-pricing model, with stock prices ranging from $0.25 to $4.00 per share, volatility ranging from 115% to 145%, and an average risk-free rate ranging from 1.63% to 2.46%.

As of December 31, 2019, the Company had an aggregate of 1,137,500 remaining unvested options outstanding, with a total estimated fair value of $1,839,635, weighted average exercise price of $3.69, and weighted average remaining life of 4.36 years. The aggregate intrinsic value of options outstanding as of December 31, 2019 was $0.

12. Related Party Transactions

During the twelve months ended December 31, 2019 and 2018, the Company incurred and paid $300,000 and $275,000, respectively, of salary expense to our Board Chairman and CEO, Mr. Michael Favish. In addition, compensation cost of $2,339,560 was recognized on amortization of stock option awards during the twelve months ended December 31, 2019. During the twelve months ended December 31, 2019 and 2018, the Company incurred and paid salaries of $114,000 and $103,000, respectively, to Karen Favish, spouse of Michael Favish. During the twelve months ended December 31, 2019 and 2018, the Company incurred and paid salaries of $55,000 and $33,000, respectively, to Kristine Townsend, spouse of Controller and Chief Accounting Officer John Townsend.

On December 21, 2018, the Company entered into an Employment Agreement (the "Agreement") with Michael Favish, which agreement became effective as of January 1, 2019. Pursuant to the Agreement, Mr. Favish will serve in such positions for a term of three (3) years, and following the expiration of such three (3) year term, Mr. Favish's employment shall be on an "at-will" basis, and such post-term employment will be subject to termination by either party at any time, with or without cause or prior notice.

Pursuant to the terms of the Agreement, Mr. Favish is entitled to receive an annual base salary of $300,000 in 2019, $325,000 in 2020 and $350,000 in 2021. Mr. Favish shall be eligible for an annual bonus as follows: (i) the initial annual bonus target will be 100% of Mr. Favish's salary for the applicable calendar year, and (ii) the actual bonus amount awarded will be based 50% on the achievement of Company financial and other performance metrics as determined by the Board and 50% as determined by the Board, in its sole discretion.

Additionally, the Company granted Mr. Favish a non-qualified stock option (the "Option") to purchase 1,250,000 shares of common stock upon the completion of the Public Offering (the "Grant Date"). The Option term shall be five years from the Grant Date and the Option shall have a purchase price per common share equal to 110% of the final offering price per share of common stock in the Public Offering. The Option shall vest ratably over three years commencing one twelfth on the first calendar quarter end date following the Grant Date), and one twelfth at the end of each calendar quarter thereafter until fully vested.

13. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 are summarized below.

	December 31,	
	2019	2018
Net operating loss carryforwards	$ 3,961,000	$ 2,689,000
Stock-based compensation	1,479,000	942,000
Amortization of intangibles	83,000	19,000
Accrued expenses	12,000	—
Research and development credit	(7,000)	—
Depreciation	(43,000)	(1,000)
Total deferred tax assets	5,485,000	3,649,000
Valuation allowance	(5,485,000)	(3,649,000)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2019, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

No federal tax provision has been provided for the years ended December 31, 2019 and 2018, due to the losses incurred during the periods. Reconciled below is the difference between the income tax rate computed by applying the U.S. federal statutory rate and the effective tax rates for the years ended December 31, 2019 and 2018:

	Years Ended December 31,	
	2019	2018
U. S. federal statutory tax rate	(21.0)%	(21.0)%
State, net of federal benefit	1.7%	5.0%
Non-deductible goodwill impairment charge	3.0%	—%
	(16.3)%	(16.0)%
Change in valuation allowance	16.3%	16.0%
Effective tax rate	0.0%	0.0%

At December 31, 2018, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $16,053,000 which, if not utilized earlier, will begin to expire in 2035. Under Internal Revenue Code Sections 382 and 383, management expects that the Company's ability to use its net operating loss carryforwards will be limited in future periods.

14. Subsequent Events

From January 1, 2020 through March 27, 2020, the Company received total gross proceeds of $3,516,581 from the exercise of 10,282,400 warrants issued in the Company's October 2019 follow-on offering.

On March 19, 2020, the Company received a written notification from Nasdaq that the Company has been granted an additional 180 calendar days, or until September 14, 2020, to regain compliance with the minimum bid price requirement.

On February 5, 2020, the Board of Directors granted a stock option from the Company's 2018 Equity Incentive Plan to a recently hired sales manager to purchase 250,000 shares of common stock of the Company with an exercise price of $0.27 per share. Such options vest ratably quarterly from the employee's date of hire. Such option has a term of 10 years provided the employee remains a service provider.

On February 5, 2020, the Board of Directors granted four stock options from the Company's 2018 Equity Incentive Plan, one to each of four recently hired salespeople. Each grant is to purchase 10,000 shares of common stock of the Company with an exercise price of $0.27 per share. Each option vests 100% on the date that is six months after each employee's date of hire. Each option has a term of 10 years provided each such employee remains a service provider.

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Asset Purchase and Reorganization Agreement dated as of September 29, 2017 (filed on Form 8-K on October 5, 2017 and incorporated herein by reference)
3.1	Articles of Organization of P4L Health Sciences, LLC and restatement changing name to Guardion Health Sciences, LLC filed in California (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
3.2	Articles of Conversion; Delaware and California (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
3.3	Certificate of Incorporation in Delaware and amendment thereto (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
3.4	Certificate of Amendment to Certificate of Incorporation (filed on Form 8-K on February 1, 2019 and incorporated herein by reference)
3.5	Certificate of Amendment to Certificate of Incorporation filed and effective with the Delaware Secretary of State on December 6, 2019 (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on December 10, 2019)
3.6	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on October 22, 2019)
3.7	Second Amended and Restated Bylaws, effective October 22, 2019 (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on October 22, 2019)
4.1	Restricted Stock Purchase Agreement by and between Michael Favish Living Trust dated January 31, 2007 and Guardion Health Sciences, Inc. (filed on Form 8-K on January 5, 2017 and incorporated herein by reference)
4.2*	Description of Securities
10.1	Lease for 15150 Avenue of the Sciences, Suite 200, San Diego California and amendments thereto (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.2	Form of Indemnification Agreement (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.3	Intellectual Property Assignment Agreement with David W. Evans and VectorVision, Inc. dated as of September 29, 2017 (filed on Form 8-K on October 5, 2017 and incorporated herein by reference)
10.4	Consulting Agreement with David W. Evans dated as of September 29, 2017 (filed on Form 8-K on October 5, 2017 and incorporated herein by reference)
10.5	Guardion Health Sciences, Inc. 2018 Equity Incentive Plan (filed with the Definitive Proxy Statement on Schedule 14A on October 22, 2018 and incorporated herein by reference)
10.6	Employment Agreement between Guardon Health Sciences, Inc. and Michael Favish (filed on Form 8-K on December 27, 2018 and incorporated herein by reference)
10.7	Form of Warrant (incorporated by reference to Exhibit 10.3 to the Company's current report on Form 8-K, filed with the SEC on March 21, 2019)
10.8	Warrant Agreement, including form of Warrant, made as of August 15, 2019, between the Company and VStock Transfer LLC (incorporated by reference to Exhibit 10.3 to the Company's current report on Form 8-K, filed with the SEC on August 19, 2019)
10.9	Asset Purchase Agreement, effective September 20, 2019 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed with the SEC on September 24, 2019)
10.10	Warrant Agreement, including form of Series B Warrant, made as of October 30, 2019, between the Company and VStock (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed with the SEC on October 31, 2019)
21.1*	List of Subsidiaries
23.1*	Consent of Weinberg & Company
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Accounting and Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Principal Executive Officer and the Principal Accounting and Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Guardion Health Sciences, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2018 and 2017, (ii) Statements of Operations for the years ended December 31, 2018 and 2017, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2018 and 2017, (iv) Statements of Cash Flows for the years ended December 31, 2018 and 2017, and (v) Notes to Financial Statements.

* filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 30th day of March 2020.

GUARDION HEALTH SCIENCES, INC.

By: */s/ Michael Favish*
Name: Michael Favish
Title: Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of GUARDION HEALTH SCIENCES, INC., hereby severally constitute and appoint Michael Favish and Vincent J. Roth, and each of them (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution, for us in any and all capacities, to sign any amendments to this Form 10-K, and to file the same, with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael Favish Michael Favish	CEO, President and Chairman of the Board (Principal Executive Officer)	March 30, 2020
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Financial and Principal Accounting Officer)	March 30, 2020
/s/ Robert N. Weingarten Robert N. Weingarten	Director	March 30, 2020
/s/ Mark Goldstone Mark Goldstone	Director	March 30, 2020
/s/ David W. Evans David W. Evans	Director	March 30, 2020
/s/ Donald A. Gagliano Donald A. Gagliano	Director	March 30, 2020
/s/ Kelly Anderson Kelly Anderson	Director	March 30, 2020

EXHIBIT 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 27, 2020, Guardion Health Sciences, Inc. ("the Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")—our common stock, par value $0.001 per share ("Common Stock").

Description of Common Stock

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the "Certificate of Incorporation") and our Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part. We encourage you to read our Certificate of Incorporation, Bylaws, and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Capital Shares

Our authorized capital shares consist of 250,000,000 shares of Common Stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). As of March 27, 2020, there were 85,264,962 shares of Common Stock issued and outstanding. There were no shares of Preferred Stock issued or outstanding as of March 27, 2020.

Voting Rights

Holders of Common Stock are entitled to one vote per share on all matters voted on by the stockholders, including the election of directors. Our Certificate of Incorporation and Bylaws do not provide for cumulative voting in the election of directors.

Dividend Rights

Holders of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Board of Directors ("Board") in its discretion out of funds legally available for the payment of dividends subject to the prior rights of holders of Preferred Stock and any contractual restrictions we have against the payment of dividends on Common Stock.

Liquidation Rights

In the event of our liquidation, the holders of our Common Stock will be entitled to share ratably in any distribution of our assets after payment of all debts and other liabilities and the preferences payable to holders of shares of Preferred Stock then outstanding, if any.

Applicable Anti-Takeover Provisions

Set forth below is a summary of the provisions of the Certificate of Incorporation and the Bylaws that could have the effect of delaying or preventing a change in control of the Company. The following description is only a summary and it is qualified by refence to the Certificate of Incorporation, the Bylaws and relevant provisions of the Delaware General Corporation Law ("DGCL").

Ability of Stockholders to Call Special Meetings

Our Certificate of Incorporation and Bylaws provide that stockholders can only call a special meeting if stockholders holding over 50% of all issued and outstanding shares of the Corporation entitled to vote at a meeting do so.

Advance Notice Requirements

Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of stockholders. These procedures provide that notice of such stockholder proposals must be timely given in writing to the Secretary of the Company prior to the meeting at which the action is to be taken. The notice must contain certain information specified in our Bylaws.

Blank Check Preferred Stock

Our Certificate of Incorporation provides for 10,000,000 authorized shares of "blank check" preferred stock, the terms of which may be determined by our board of directors without obtaining stockholder approval. Undesignated or "blank check" preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a tender offer, proxy contest, merger or otherwise, and to thereby protect the continuity of our management.

Exclusive Forum Provision

In accordance with an exclusive forum provision set forth in the Bylaws, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (d) any action asserting a claim governed by the internal affairs doctrine.

Listing

The Common Stock is traded on NASDAQ Global Market under the trading symbol "GHSI".

Transfer Agent

The Company's transfer agent is VStock Transfer, LLC.

EXHIBIT 21.1

LIST OF SUBSIDIARIES

Name	State or Other Jurisdiction of Incorporation
VectorVision Ocular Health, Inc.	Delaware
Transcranial Doppler Solutions, Inc.	Delaware
NutriGuard Formulations, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-1 (No. 333-232544, No. 333-234322 and No. 333-233067) and Form S-8 (No. 333-231603) of our report dated March 30, 2020, with respect to the financial statements of Guardion Health Sciences, Inc. of December 31, 2019 and 2018 and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Weinberg & Company, P.A.
Weinberg & Company, P.A.
Los Angeles, California
March 30, 2020

EXHIBIT 31.1

CERTIFICATION

I, Michael Favish, certify that:

1. I have reviewed this annual report on Form 10-K of Guardion Health Sciences, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

/s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, John Townsend, certify that:

1. I have reviewed this annual report on Form 10-K of Guardion Health Sciences, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

/s/ John Townsend

John Townsend
Controller and Chief Accounting Officer
(Principal Financial and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATIONS PURSUANT TO
18 U.S.C. SECTION 1350,
AS ENACTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Guardion Health Sciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Michael Favish, Chief Executive Officer of the Company, and John Townsend, Controller of the Company, certify, pursuant to 18 U.S.C. § 1350, as enacted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 30, 2020

/s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

March 30, 2020

/s/ John Townsend

John Townsend
Controller and Chief Accounting Officer
(Principal Financial and Principal Accounting Officer)