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, 2018

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 EXCHANGE ACT:
None

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE EXCHANGE ACT:
Common Stock, $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. ☐ Yes ☒ No

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. ☒ 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 such files). ☒ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒

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	☒	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 ☒ No

Registrants' common stock is not yet publicly traded.

As of February 8, 2019, there were issued and outstanding 20,564,328 shares of the registrant's common stock, $0.001 par value. 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.

DOCUMENTS INCORPORATED BY REFERENCE: None.

TABLE OF CONTENTS

Introductory Comment

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.

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (the “Annual Report”) contains forward-looking statements. These statements relate to future events or future predictions, including events or predictions relating to the Company’s future financial performance, and are based on current expectations, estimates, forecasts and projections about the Company, its future performance, its beliefs and management’s assumptions. They are generally identifiable by use of the words “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “feel,” “confident,” “estimate,” “intend,” “predict,” “forecast,” “project,” “potential” or “continue” or the negative of such terms or other variations on these words or comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks described under “Risk Factors” that may cause the Company’s or its industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In addition to the risks described in Risk Factors, important factors to consider and evaluate in such forward-looking statements include: (i) general economic conditions and changes in the external competitive market factors which might impact the Company’s results of operations; (ii) unanticipated working capital or other cash requirements including those created by the failure of the Company to adequately anticipate the costs associated with acquisitions and other critical activities; (iii) changes in the Company’s corporate strategy or an inability to execute its strategy due to unanticipated changes; and (iv) the failure of the Company to complete any transaction described herein on the terms currently contemplated. In light of these risks and uncertainties, many of which are described in greater detail elsewhere in this Risk Factors discussion, there can be no assurance that the forward-looking statements contained in this Annual Report will in fact transpire.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements. The Company will update or revise the forward-looking statements to the extent required by applicable law.

PART I

ITEM 1. BUSINESS

Overview

The Company is a specialty health sciences company formed to develop, formulate and distribute condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that replenishes and restores the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as age-related macular degeneration ("AMD"), computer vision syndrome ("CVS") and diabetic retinopathy. The Company believes this risk may be modified by taking Lumega-Z to maintain a healthy macular protective pigment. Additional research has also shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's disease and dementia.

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, adding the CSV-1000 and ESV-3000 to its product portfolio, further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases. The Company has had limited commercial operations to date. Until recently with the acquisition of VectorVision and development of the Company's sales force, the Company has primarily been engaged in research, development, commercialization, and capital raising.

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 is a non-mydriatic, non-invasive device that accurately measures the MPOD, the lens optical density and lens equivalent age, thereby creating an evidence-based protocol that is shared with the patient. A non-mydriatic device is one that does not require dilation of the pupil for it to function. The MapcatSF is the first medical device using a patented "single fixation" process and "automatic lens density correction" that produces accurate serialized data.

For the past three years, the clinical prototypes of the MapcatSF have been tested on patients, allowing for frequent modifications of the device's algorithms and retesting for accuracy, as well as to provide the inclusion of additional features not previously found in the initial prototype. The alpha prototype, which is the pre-commercial production version, was unveiled for the first time in July 2013 in Cambridge, United Kingdom, to researchers and scientists from around the world. The MapcatSF is manufactured and assembled in Irvine, California, and will be distributed from the Company's national headquarters in San Diego. The marketing of the device will be implemented through continuing education presentations conducted by key opinion leaders in the industry. 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.

Lumega-Z is a medical food product that has a patent-pending formula that replenishes and restores 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.

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 treat 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 regulated medical food and therefore 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.

Over 1,900 patients have been treated with Lumega-Z since the Company began selling the formulation in October 2011. 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. Lumega-Z is typically ingested by the patient on a daily basis. Patients are typically between 50 and 80 years old. Patients are mixed ethnically and socioeconomically. Patients typically have insurance, whether private insurance or Medicare. Physicians have determined that the patient is experiencing or is at a high risk of developing retinal disease and decide based on their medical determination that the patient is a candidate for Lumega-Z.

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.

The number of patients regularly ordering Lumega-Z has increased 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. Automatic shipment has an added benefit in that it aids physicians because it increases patient compliance in using Lumega-Z on a regular basis. 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. A larger, higher volume clinic is expected to generate a larger number of patients in a shorter period of time. All of the Company's medical food revenue is derived from a limited number of individual customers.

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. GHS is targeting this unattended market opportunity. Congress, the Food and Drug Administration, the Center for Medicare & Medicaid Services and private insurance companies are focusing increased efforts on pharmacovigilance (the branch of the pharmaceutical industry which assesses and monitors the safety of drugs either in the development pipeline or which have already been approved for marketing) to measure and reduce these adverse health consequences.

The Company believes that there is an increasing level of acceptance of medical foods as a primary therapy by patients and healthcare providers to treat 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.

Medical Foods Products Industry Overview

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 diets. Medical nutrition 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. Some examples are ocular health, pain syndromes, insomnia, cognitive disorders, IBS, and heart disease. Many older Americans have or will develop chronic diseases that are amenable to the dietary management benefits of medical foods. Medical foods help address these diseases and conditions in a drug-free way with food-based ingredients yet are still considered a medical product that should be taken under supervision by a physician. The term “medical foods” does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for patients who are seriously ill or who require the product as a major treatment modality according to FDA regulations.

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 disease claims for which there is scientific evidence that nutrient deficiencies cannot be corrected by normal diet. Medical foods are intended for a vulnerable population suffering from a particular chronic disease and therefor have special, extra-rigorous guarantees of safety. 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 preapproval 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 is properly categorized as a medical food. While the Company believes it is unlikely the FDA would conclude otherwise, if the FDA determines Lumega-Z 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, although there is a chance that certain physicians may choose not to recommend Lumega-Z to their patients or that certain consumers may choose not to buy Lumega-Z if it is not classified as a medical food.

Vision 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 and ESV-3000 devices offer 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 can detect and quantify subtle changes 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. For the same reasons, the Company believes that the ESV-3000 ETDRS testing device will become the worldwide standard for ETDRS visual acuity testing. The Company’s research has revealed no competing products that offers 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 and ESV-3000 use self-calibrated test lighting. The self-calibrated test lighting is proprietary, and the test faces of the CSV-1000 are proprietary and the intellectual property is protected under copyright and trade secret law. Both CSV-1000 and ESV-3000 are currently sold worldwide, and the Company expects this global distribution to continue. There is a training requirement in incorporating the CSV-1000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy.

Competitive Advantage and Strategy

There are no research-validated pharmaceutical solutions for slowing the progression of adult 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. For this reason, some doctors may hesitate to prescribe tablet, capsule and gel capsule form AREDS-based nutraceuticals despite the fact that these are currently the only options available to them.

The competitive landscape of supplements is crowded and confusing for physicians and patients looking to obtain an appropriate product for eye care. In October 2017, while searching walgreens.com for “AREDS,” the Company found 10 results, all of which are in tablet, capsule or gel capsule form. When searching the same website for “Eye Health Supplements” (a common search term for this category of product), the Company found 204 products, of which 196 (96%) are in tablet, capsule or gel capsule form. The same search term on cvs.com returned over 110 products. These supplement products all have varying ingredients, varying levels of similar ingredients, varying claims regarding their effects, and varying price points.

Lumega-Z is designed to address this concern. In contrast, Lumega-Z is a liquid formulated using a proprietary molecular micronization process (“MMP”) to maximize efficiency of absorption and safety and to minimize compatibility issues. The MMP is a proprietary homogenization process whereby the molecular structure of the ingredients is reduced in size to facilitate more efficient absorption in the body.

By combining the MapcatSF medical device, the newly acquired VectorVision standardized vision testing technology and Lumega-Z medical food, the Company has developed, based on Management’s knowledge of the industry, what it believes to be the only reliable three-pronged, evidence-based protocol for replenishing and restoring the macular protective pigment, increasing overall retinal health and measuring the related improvements in visual function. The MapcatSF is the first medical device to use a patented “single fixation” process and “automatic lens density correction” that produces accurate serialized data. Historically, a number of specialized densometers used by research groups within the medical community have been known to produce unreliable data; due in part to the fact that they are not Troxler-free. The Troxler effect is an optical illusion affecting visual perception where an unchanging stimulus away from a fixation point will fade away and disappear as one stares at a fixation point consistently. A device that is Troxler-free does not have this fading of images that otherwise would occur as a result of the Troxler effect. Being Troxler-free is thought to be an important function in being able to accurately complete the testing using these 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. While these collaborative relationships help further validate the MapcatSF and Lumega-Z, these relationships are not material to the Company because none of these relationships is exclusive. There are many potential collaborative partners available. The Company is free to enter into other collaborative relationships as needed. No sales of Lumega-Z are generated directly from Illinois College of Optometry because the MapcatSF is part of its teaching curriculum and not used for direct patient care. However, the other collaborative partners, as a result of using the MapcatSF on patients, periodically put patients on Lumega-Z if a physician determines it appropriate to do so. The majority of sales of Lumega-Z primarily come from clinicians outside of these collaborative relationships.

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 and ESV-3000 devices each embody 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, and its VectorVision CSV-1000 and ESV-3000 devices each embody this invention.

The Company believes the CSV-1000 is the standard of care for clinical practice. There is a training requirement in incorporating the CSV-1000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy.

Similarly, the Company believes that its ESV-3000 device will become the worldwide standard for ETDRS visual acuity testing. The CSV-1000 and ESV-3000 use self-calibrated test lighting. The self-calibrated test lighting is proprietary, and the test faces of the CSV-1000 are proprietary and protected intellectual property. Both CSV-1000 and ESV-3000 are currently sold worldwide, and the Company expects this global distribution to continue. The Company believes the acquisition of VectorVision, adding the CSV-1000 and ESV-3000 to its product portfolio, further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

An important part of the Company's competitive strategy lies in combining Lumega-Z with technology to demonstrate its effects. The Company's proprietary MapcatSF medical device measures MOPD, thereby showing changes in macular pigment density from the use of Lumega-Z. In addition, the VectorVision CSV-1000 provides a second opportunity to baseline the vision of patients, and monitor changes in vision performance over time while administering Lumega-Z. The VectorVision CSV-1000 is a highly accurate means of measuring and monitoring contrast sensitivity, a vision performance parameter that can be improved by increasing the level of macular pigment in the eye.

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.

Management believes that there is a significant unmet need in everyday clinical practice to provide a vision assessment protocol that improves upon the current standard of visual acuity. Contrast sensitivity with the VectorVision CSV-1000 is a highly sensitive and repeatable method of measuring vision performance and can be utilized to monitor the vision performance of patients undergoing treatment with Lumega-Z, as well as for the general patient population. The CSV-1000 is currently the worldwide standard for contrast sensitivity testing in clinical trials, and there is a growing understanding of the importance of contrast sensitivity in general clinical practice. The Company's intention is to penetrate the market by promotion of the CSV-1000 as the leading contrast sensitivity device available. The Company believes it can grow its business using the following sales and marketing strategies:

Sales and Marketing

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 effectively 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 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 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 South China Morning Post, 22 million AMD patients are Chinese patients which account for approximately 18% of global Glaucoma patients.
- 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.

Marketing the CSV-1000 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.

Sales Channel

Lumega-Z is a regulated medical food and therefore must be administered under the supervision of a physician or professional healthcare provider. Once the healthcare provider has determined that the patient requires Lumega-Z, they follow the following procedures:

- The Company provides all clinicians a DAC number (Doctor Authorization Code).
- Patients are given a customized recommendation from the clinician, including the DAC number; this enables patients to order Lumega-Z either online or by calling the 800 number.
- Patients are able to use their Health Care Flexible Spending Accounts ("FSA") or Health Savings Account ("HSA") dollars to pay for Lumega-Z.

The Company will support the clinicians by making available Online Ocular Nutrition courses to train their technicians.

Sales Force

The Company hired and trained a direct sales force in March 2018 consisting of a field-based team of account managers located in key geographical locations based on high population density areas with demographics that match the Company's target markets. Each account manager is responsible for a defined geographical area and is expected to travel extensively to support the needs of customers. The account managers are tasked with prospecting for new accounts, closing leads generated by the Company's marketing efforts, and generating revenue through account management activities including physician and staff training, and implementation of patient education resources. The account managers are expected to participate in national and regional trade shows and events, including supporting professional optometric and ophthalmological societies at a state level. Each account manager is assigned a quota that includes units of Lumega-Z sold, as well as sales of the MapcatSF, CSV-1000 and ESV-3000. Commissions are paid based on performance and achievement of quota.

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.

Transcranial Doppler Solutions

In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"), to further the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases. TDSI will be dedicated to the pursuit of early predictors resulting in, the Company believes valuable therapeutic intervention for practitioners and their patients, and additional revenues stream generated from the testing and sale of Company products to appropriate customers. TDSI will provide a service that makes TCD (as defined below) testing convenient by being in various medical facilities. A Transcranial Doppler ultrasound ("TCD") has been accepted as a safe, non-invasive, and lower-cost technique that uses a low-frequency transducer probe to assess intracerebral blood flow, within the brain and to the eyes. Studies have shown the ability of TCD to predict stroke risks as well as other potential cardiovascular events. TCD also plays an important role in detecting changes in the ophthalmic artery blood flow, which is important to help evaluate the course of common eye disorders. Blood velocities and intensities can be measured using TCD, which provides an effective way to determine more accurately the state of pathology in early stages of common eye disorders such as glaucoma and other eye diseases that cause visual field defects. Published medical resources indicate a strong relationship between ocular circulation and visual function in patients with glaucoma, diabetes, and macular disease, which are the three leading causes of acquired irreversible blindness throughout the world. A TCD is also highly repeatable, the results of which provide an effective tool for ophthalmologists to treat their patients. Through the monitoring of blood flow in the intracranial vessels, including the ophthalmic artery, the TCD results will in turn provide an evidence-based protocol for Guardion's medical foods, including the Company's soon to be released new GlaucoCetin™ product. The Company is currently setting up the operations of TDSI and hopes to launch its services in upcoming quarters.

Proprietary Technology and Intellectual Property

Patents

The Company currently owns and has exclusive rights to the following patent and pending patent applications:

DOMESTIC

Number	Title	Owner	Product	File Date
Patent 9,486,136	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**08/11/14**
Patent Application 15/346,010	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**11/08/16**
Patent Application 14/028,104	**EMULSION OF CAROTENOIDS AND OCULAR ANTIOXIDANTS**	**GHS**	**Lumega-Z®**	**09/16/13**
Patent 10,016,128	**METHOD AND APPARATUS FOR VISION ACUITY TESTING**	**VectorVision**	**CSV-1000 And ESV-3000**	**09/27/16**
Patent 10,022,045	**METHOD AND APPARATUS FOR VISION ACUITY TESTING**	**VectorVision**	**CSV-1000 and ESV-3000**	**02/28/17**

FOREIGN

Country / Number	Title	Owner	Product	File Date
CANADA Patent Application 2,864,154	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**08/08/14**
EUROPE Patent 2811892	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**09/09//14**
EUROPE Patent Application 18176935.7	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**06/11/18**
HONG KONG Patent Application 15105364.0	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**06/05/15**

The MapcatSF® patent, Patent 9,486,136, describes an apparatus for use in the measurement of the optical density of the macular protective pigment in the human eye, as well as an apparatus for the use in measuring the lens optical density of a human eye. The apparatus is particularly applicable to flicker photometers, which are used to measure the macular protective pigment in the human eye. The foreign counterpart patent applications describe the same invention.

Prior to the issuance of US Patent No. 9,486,136, the Company filed a continuation application, Patent Application 15/346,010, covering new embodiments around the MapcatSF® device. These new embodiments contain improvements related to the accuracy of intensity measurements made with the device, as well as updated features around photodiode detector calibrations.

The Lumega-Z® patent filing, Patent Application 14/028,104, describes a daily liquid supplement for ocular and body health containing at least one of the following: lutein, zeaxanthin, meso-zeaxanthin and astaxanthin for a human subject and for nutritionally supplementing macular pigments in the human eye. The micronized nutrients in a lipid-based emulsion described in the patent application are more efficiently absorbed into the bloodstream than conventional supplement formulations resulting in higher serum levels and increased macular protective pigment.

Patent 10,016,128 describes a methodology to calibrate display monitors to automatically hold display luminance constant for vision testing. The method includes a measurement device that is placed on the peripheral areas of the display monitor and feedback software to communicate with a computer and automatically control display luminance. Manual control of luminance based on the output of the measurement device is also included. This invention is embodied in the CSV-1000 and ESV-3000 devices.

Patent 10,022,045 describes a methodology to continuously calibrate display monitors to automatically hold display luminance constant for vision testing. The method includes a measurement device that is placed on the peripheral areas of the display monitor and feedback software to communicate with a computer and automatically control display luminance. Manual control of luminance based on the output of the measurement device is also included. Calibration of the luminance provided by mirrors, if patients view the display monitors through mirrors, is also embodied in the invention. This invention is also embodied in the CSV-1000 and ESV-3000 devices.

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 three U.S. registered trademarks on the principal register at the USPTO. These marks are listed below. The Company has not sought any foreign trademark protection for its products or product candidates at this time but is evaluating whether foreign trademark protection is appropriate. U.S. trademark registrations are generally for fixed, but renewable, terms.

The Company currently owns and has exclusive rights to the following registered trademarks:

Registration No.	Mark	Owner	Product
5,025,658	GUARDION	GHS	Guardion Health Sciences, Inc.
3,978,935	LUMEGA-Z	GHS	Lumega-Z
4,997,319	MAPCAT SF	GHS	MapcatSF
4,341,403	VECTORVISION	VectorVision	VectorVision
4,500,241	CSV-1000	VectorVision	CSV-1000
5,092,549	GLAUCO-HEALTH	GHS	Glauco-Health

Copyrights

In addition to patent and trademark protection, VectorVision relies on copyright protection and has common law copyright protection on the testing charts contained in the CSV-1000, which includes Vision Testing Chart #1, Vision Testing Chart #2 and Vision Testing Chart #3.

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

The Company outsources the manufacturing of its medical food products 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 and devices 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.

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.

VectorVision is registered with the FDA and the CSV-1000 and the ESV-3000 medical devices are listed with the FDA as Class I medical devices. 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.

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.

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 Food, Lumega-Z, and Medical Device, the MapcatSF. 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, or recommend its medical food, Lumega-Z, 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. Moreover, in conducting TCD tests, the Company will be using space provided by the ordering physician. As a result, the Stark Law fully applies to the TCD Testing Business, as the ordering physician has a financial relationship with the Company, through the Company's use of the physician's space (for which fair market value rent must be charged), and the physician is referring a DHS – the TCD tests – to the Company. In addition, the Company will be enrolling the ordering physicians in clinical research trials and compensating the physicians for their participation in the trials, thereby creating an additional Stark cognizable financial relationship between the parties.

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 Food, Lumega-Z, and Medical Device, the MapcatSF. 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 not set at a fair market value amount unrelated to the volume or value of TCD tests being ordered. 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 February 8, 2019, the Company had a total staff of thirteen, consisting of four officers and nine full-time employees. VectorVision had a staff of three, consisting of one officer, one full-time employee and one part-time employee, and Transcranial Doppler Solutions, Inc. had a staff of four, consisting of three officers and one full-time employee.

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 the Company cannot be certain if or when the Company will produce sufficient revenue from our operations to support our costs. The Company had a net loss of $7,767,407 for the year ended December 31, 2018 and a net loss of $5,305,169 for the year ended December 31, 2017 leading to an accumulated deficit of $34,633,363 and $26,865,956 as of December 31, 2018 and December 31, 2017, respectively. The Company has utilized cash in operating activities of $4,173,831 during the year ended December 31, 2018 and $3,403,696 during the year ended December 31, 2017, 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 lead product Lumega-Z, the MapcatSF medical device, the CSV-1000 and ESV-3000 devices, and with respect to efforts to build its infrastructure and expand its operations. The Company is contemplating a public offering of shares of its common stock and has applied to list its common stock on the Nasdaq Capital Market under the symbol "GHSI" (the "Public Offering"). The Company believes that the net proceeds from the Company's contemplated Public Offering, together with its existing cash and cash equivalents will allow it to fund its operating plan through at least the next twelve months. The Company has based these estimates, however, on assumptions that may prove to be wrong, and the Company could spend its available financial resources much faster than it currently expects and may need to raise additional funds sooner than it anticipates. There can be no assurances that the Company will complete the Public Offering.

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, 2018. 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 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, could increase expenses and require that assets secure such debt. Moreover, any debt the Company incur must be repaid regardless of our operating results.

The Company's ability to obtain additional financing will be subject to a number of factors, including market conditions, operating performance and investor sentiment. If the Company are 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®, the MapcatSF® medical device, the CSV-1000 and ESV-3000 testing devices, and the successful integration of VectorVision into the Company's business.

The future success of the Company's business is largely dependent upon the successful commercialization of its medical food, Lumega-Z, and its medical device, the MapcatSF and the VectorVision CSV-1000 and ESV-3000 testing devices. The Company is dedicating a substantial amount of its resources to advance Lumega-Z and certain resources to advance MapcatSF as aggressively as possible. If the Company encounters difficulties in the commercialization of Lumega-Z or the MapcatSF, the Company will not have the resources necessary to continue its business in its current form. 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. The Company believes it is creating an efficient commercial organization, taking advantage of outsourcing options where prudent to maximize the effectiveness of its commercial expenditures. However, it may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to be successful. 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 on sales of Lumega-Z or licensing fees or sales of the MapcatSF device or the CSV-1000 and ESV-3000 testing devices. If this occurs, it will have an adverse impact on operations and the Company's ability to fund any future development.

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

The Company's ability to realize the anticipated benefits of the VectorVision acquisition will depend, to a large extent, on its ability to integrate the business of VectorVision with its legacy business, which may be a complex, costly and time-consuming process. The Company may be required to devote significant management attention and resources to integrate the VectorVision business practices into its existing operations. The integration process may disrupt its business and, if implemented ineffectively, could restrict the realization of the full expected benefits of the acquisition. The failure to meet the challenges involved in the integration process and to realize the anticipated benefits of the VectorVision 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, the integration of VectorVision may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customers and other business relationships, and diversion of management's attention. Additional integration challenges may include, among other things:

- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects;
- difficulties in the integration of operations and systems;
- difficulties in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures;
- difficulties in the assimilation of employees;
- difficulties in managing the expanded operations of a larger and more complex company; and
- the impact of potential liabilities the Company may be assuming from VectorVision.

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

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 one commercialized medical food product on the market, Lumega-Z. 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. While the CSV-1000 and ESV-3000 visual acuity testing devices are commercialized, there is no guarantee that they will continue to be marketable or enjoy commercial success.

Even if the Company develops 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. Because of its business relationships with physicians and professional healthcare providers, and since its product, Lumega-Z is believed to be a medical food and the MapcatSF and the CSV-1000 and ESV-3000 are medical devices, a number of regulations are implicated. 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 is a medical food, if the FDA determines Lumega-Z to be a drug, the Company and the product would be subject to considerable additional FDA regulation. Similarly, while the Company believes the MapcatSF is a safe medical device, with a very low potential risk of injury to a patient, the Company believes the MapcatSF is correctly classified as a Class I medical device, which does not require any premarket approval. The CSV-1000 and ESV-3000 are currently classified with the FDA as Class I medical devices. If, however, the FDA were to determine that the MapcatSF, the CSV-1000 or ESV-3000 is a Class II medical device, the Company and the particular product or products would be subject to considerable additional regulatory requirements.

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.

Lumega-Z may not qualify as a medical food as defined by the FDA.

If the FDA makes a determination that Lumega-Z should not be defined as a medical food (and does not qualify as a drug), the Company would need to relabel and rebrand that product. 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. Although, management believes it is unlikely the FDA would make such a determination, there is a chance that certain physicians may choose not to recommend Lumega-Z to their patients or that certain consumers may choose not to buy Lumega-Z if it is not classified as a medical food. While there is no insurance coverage for Lumega-Z as a medical food, if insurance companies would otherwise pay for Lumega-Z because of it being a medical food, a determination by the FDA that Lumega-Z should not be defined as a medical food could limit or eliminate such potential insurance coverage which might adversely impact the sales of Lumega-Z.

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, 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. The Illinois College of Optometry, for example, has included the MapcatSF prototype in its curriculum to instruct students on how to measure the macular pigment. The New York Eye and Ear Infirmary is currently evaluating Lumega-Z on glaucoma patients. The Rosenberg School of Optometry at the University of the Immaculate Word is conducting research on patients with a MapcatSF prototype. Moreover, the Company's Science Advisory Board, each member of whom is displayed on the Company website, includes world renowned experts in macular carotenoids who are developing the peer review markets by conducting research and furthering the understanding of the relevance of the macular pigment in ocular health. The Company's Medical Advisors includes thought-leading clinicians in retina, glaucoma and the anterior segment of the eye, providing guidance on understanding the clinical applications of Lumega-Z and the MapcatSF and understanding the market opportunities and assisting in driving our strategic goals. However, there is no guarantee that the Company will be successful in negotiating similar collaborative relationships with regard to the CSV-1000 and ESV-3000.

While the Company believes that these collaborative relationships help further validate the MapcatSF and Lumega-Z, 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 is free to enter into other collaborative relationships as needed. No sales of Lumega-Z are generated directly from Illinois College of Optometry because the MapcatSF is part of its teaching curriculum, not used for direct patient care. However, the other collaborative partners, as a result of using the MapcatSF on patients, periodically put patients on Lumega-Z if a physician determines it appropriate to do so. The majority of sales of Lumega-Z primarily come from clinicians outside of these collaborative relationships.

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 Lumega-Z, the MapcatSF medical device and the CSV-1000 and ESV-3000 testing devices.

The Company's long-term viability and growth may depend upon the successful development and commercialization of products other than Lumega-Z and the MapcatSF. 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.

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 Lumega-Z, 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 Lumega-Z. Such similar products marketed by larger competitors could hinder the Company's efforts to penetrate the market. 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.

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

While the Company believes the MapcatSF is the only device available that can accurately measure the density of the macular pigment, competitors may develop products with similar characteristics to the Company's MapcatSF medical device. Such similar products marketed by larger competitors could hinder the Company's efforts to develop the market. 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.

The Company's competitors may develop products similar to the CSV-1000 and ESV-3000 devices, and the Company may therefore need to modify or alter its business strategy, which may delay the achievement of its goals.

While the Company believes that VectorVision is the only company that offers fully standardized vision testing products that ensure consistent, repeatable and highly accurate results, its competitors may introduce similar products that may compete with the CSV-1000 and ESV-3000 devices. These devices offer 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 can detect and quantify subtle changes in vision, and why the VectorVision CSV-1000 instrument is used by eye doctors in more than 60 countries to accomplish contrast sensitivity testing. For the same reasons, the Company believes that the ESV-3000 ETDRS testing device will become the worldwide standard for ETDRS visual acuity testing. The Company's research has revealed no competing products that offers 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 and ESV-3000 use self-calibrated test lighting. The self-calibrated test lighting is proprietary, and the test faces of the CSV-1000 are proprietary and the intellectual property is protected under copyright and trade secret law. Both CSV-1000 and ESV-3000 are currently sold worldwide, and the Company expects this global distribution to continue. There is a training requirement in incorporating the CSV-1000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy. Competitors currently exist, and while the Company believes its market penetration and intellectual property protection are barriers to entry, competitors may invent around the Company's intellectual property or otherwise overcome barriers to entry and introduce similar products to compete with either the CSV-1000 or ESV-3000.

The Company's failure to compete successfully could cause its revenue or market share to decline.

The market for our products and services is competitive and is characterized by rapidly evolving industry standards, technology and user needs and the frequent introduction of new products and services. Some of our competitors, which include major pharmaceutical companies with alternatives to our products, may be more established, benefit from greater name recognition and have substantially greater financial, technical and marketing resources than us. We compete on the basis of several factors, including distribution of products, reputation, scientific validity, reliability, client service, price, and industry expertise and experience. There can be no assurance that we will be able to compete successfully against current and future competitors or that the competitive pressures that we face will not materially adversely affect our business, financial condition and results of operations.

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 products could be limited.

The Company currently has limited sales, marketing and distribution capabilities. 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.

If the Company cannot compete successfully for market share against other companies, it may not achieve sufficient product revenues and its business will suffer.

The market for our products and product candidates is characterized by competition and technological advances. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete for market share against fully integrated medical food and medical device companies or other companies that develop products independently or collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater capital resources, larger research and development staffs and facilities, and greater financial resources than we do, as well as significantly greater experience in:

- developing medical foods and medical devices;
- conducting product testing and studies;
- complying with regulatory requirements;
- formulating and manufacturing products; and
- launching, marketing, distributing and selling products.

Our competitors may:

- develop and patent processes or products earlier than we will;
- develop and commercialize products that are less expensive or more efficient than our products;
- comply with regulatory requirements more rapidly than us; or
- improve upon existing technological approaches or develop new or different approaches that render our technology or products obsolete or uncompetitive.

If we are unable to compete successfully against current or future competitors, we may be unable to obtain market acceptance for any product candidates that we create, which could prevent us from generating revenues or achieving profitability and could cause the market price of our common stock to decline.

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. 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.

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 a third-party manufacturer. 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."

Prior to the acquisition of VectorVision, all of the Company's billings and revenues have been derived from the sale of a single product.

For the year ended December 31, 2018 as well as the year ended December 31, 2017, the Company derived a portion of its revenues from the sale of Lumega-Z®. While we continue to see an increasing demand for Lumega-Z from our customers, we cannot assure you that the demand will continue. A decline in sales of Lumega-Z to our customers may have an immediate adverse effect on our financial results. The Company expects to continue to realize revenues from sales of the CSV-1000 and ESV-3000 products, however, there is no assurance that such sales will continue at historical levels or that any of our products will otherwise continue to be commercially viable.

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, 2018 and 2017, the Company's billings were derived from a limited number of individual customers and distributors. 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.

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 in order to recommend it to their patients, and to understand the benefits of visual acuity testing using the CSV-1000 and ESV-3000 devices. 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. 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 such as when we add new physician clients that will require a large production of one or more products, 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.

The Company has four issued patents and five pending patent applications related to its products. There currently are no issued patents relating to Lumega-Z. 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's business depends in part on and will continue to depend in part on its ability to establish and maintain additional strategic collaborative relationships. Failure to establish and maintain these relationships could make it more difficult to expand the reach of the Company's products, which may have a material adverse effect on its business.

To be successful, we must continue to maintain our existing strategic relationships, such as our relationship with our vendors who manufacture our medical food products. We also must continue to establish additional strategic relationships with healthcare leaders. This is critical to our success because we believe that these relationships contribute towards our ability to extend the reach of our products and services to a larger number of physicians, professional healthcare providers and physician groups and to other participants in the healthcare industry; develop and deploy new products and services; and generate additional revenue and cash flows. Entering into strategic relationships is complicated because strategic partners may decide to compete with us in some or all of our markets. In addition, we may not be able to maintain or establish relationships with key participants in the healthcare industry if we conduct business with their competitors.

The Company must attract quality management 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. We plan to recruit additional personnel, including a Chief Financial Officer and a Chief Operating Officer in the near future. 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, the growth of our business may be adversely impacted.

Competition for qualified employees is intense. The Company may not be able to attract and retain the highly skilled employees needed to support its business. Without skilled employees, the quality of its product development and services could diminish and the growth of its business may be slowed, which could have a material adverse effect on the Company's business, financial condition and results of operations.

Our ability to provide high-quality products and services to our clients depends, in large part, upon our employees' experience and expertise. We must attract and retain highly qualified personnel with a deep understanding of the pharmaceutical and healthcare information technology industries. In addition, we will invest significant time and expense in training our employees, increasing their value to clients as well as to competitors who may seek to recruit them, which will increase the cost of replacing them. If we fail to retain our employees, the quality of our product development and services could diminish and the growth of our business may be slowed. This may have a material adverse effect on our business, financial condition and results of operations.

If the Company loses the services of its Chief Executive Officer and other key personnel, it may be unable to replace them, and the Company's business, financial condition and results of operations may be adversely affected.

Our success largely depends on the continued skills, experience, efforts and policies of our management team and other key personnel and our ability to continue to attract, motivate and retain highly qualified employees. In particular, the services of Michael Favish, our founder, President and Chief Executive Officer, and David Evans, director of the Company and a consultant to VectorVision, are integral to the execution of our business strategy. We believe that the loss of the services of Mr. Favish or Dr. Evans could adversely affect our business, financial condition and results of operations. We cannot assure you that Mr. Favish, Dr. Evans or our other executive officers will continue to provide services to the Company. We do not maintain key man insurance for any of our key personnel.

The Company's future success depends upon its ability to grow. If the Company is unable to manage its growth effectively, it may incur unexpected expenses and be unable to meet its customers' requirements.

We will need to expand our operations if we successfully achieve market acceptance for our products and services. We cannot be certain that our systems, procedures, controls and existing space will be adequate to support expansion of our operations. Our future operating results will depend on the ability of our officers and key employees to manage changing business conditions and to implement and improve our technical, administrative, financial control and reporting systems. We may not be able to expand and upgrade our systems and infrastructure to accommodate these increases or we may not have the qualified personnel to implement them. Difficulties in managing any future growth could have a significant negative impact on our business, financial condition and results of operations because we may incur unexpected expenses and be unable to meet our customers' requirements.

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 states, 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 our product, Lumega-Z®, to be a medical food and not a drug, it is only available under the supervision of a physician. While it is 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. 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 Bylaws have an exclusive forum for adjudication of disputes provision which limits the forum to the Delaware Court of Chancery for certain actions against the Company.

Article XI of our Bylaws dictates that the Delaware Court of Chancery is the sole and exclusive forum for certain actions including derivative action or proceeding 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 means a shareholder has a limited forum in which to bring one of the above causes of action, which can be inconvenient for the shareholder.

A Delaware corporation is allowed to mandate in its corporate governance documents a chosen forum for the resolution of state law based shareholder class actions, derivative suits and other intra-corporate disputes. The Company's management believes limiting state law based claims to Delaware will provide the most appropriate outcomes as the risk of another forum misapplying Delaware law is avoided. Delaware courts have a well-developed body of case law and limiting the forum will preclude costly and duplicative litigation and avoids the risk of inconsistent outcomes. It also means a shareholder's ability to bring a claim in a forum it believes is favorable to shareholders in disputes with directors, officers or other employees is limited and may discourage shareholders from bringing such claims. Additionally, Delaware Chancery Courts can typically resolve disputes on an accelerated schedule when compared to other forums.

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

The Company's ability to realize the anticipated benefits of the new Transcranial Doppler Solutions, Inc. business will depend on its ability to successfully launch and advance a new service in an area where the Company has no 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 the Transcranial Doppler Solutions, Inc. business. 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 the Company's two lines of business: (1) our sale of medical food, Lumega-Z; and (2) our performance of Trans Cranial Doppler ("TCD") testing.

1. Medical Food, Lumega-Z. When a physician recommends the Company's medical food, Lumega-Z, 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 performs TCD tests on patients, as ordered by the patients' treating physicians. The Company is establishing agreements with radiologists to read and report on the results of the tests. These results will be reported back to the ordering/treating physician. Finally, the Company will 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 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 Food, Lumega-Z, and Medical Device, the MapcatSF. 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 device, the MapcatSF, or recommend its medical food, Lumega-Z, 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. Moreover, in conducting TCD tests, the Company will be using space provided by the ordering physician. As a result, the Stark Law applies to the TCD Testing Business, as the ordering physician has a financial relationship with the Company, through the Company's use of the physician's space (for which fair market value rent must be charged), and the physician is referring a DHS – the TCD tests – to the Company. In addition, the Company will be enrolling the ordering physicians in clinical research trials and compensating the physicians for their participation in the trials, thereby creating an additional Stark cognizable financial relationship between the parties.

The Company believe its planned 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 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 Food, Lumega-Z, and Medical Device, the MapcatSF. 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 not set at a fair market value amount unrelated to the volume or value of TCD tests being ordered. 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 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. 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 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. 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 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 this Annual Report and 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 and two years of selected financial data in this Annual Report. 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. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

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's directors and executive officers beneficially own a significant number of shares of the Company's common stock. Their interests may conflict with our outside stockholders, who may be unable to influence management and exercise control over the business.

As of the date of this Annual Report, our executive officers and directors beneficially own approximately 29.8% of our shares of common stock. As a result, our executive officers and directors may be able to affect the election or defeat the election of our directors, amend or prevent amendment to our certificates of incorporation or bylaws, effect or prevent a merger, sale of assets or other corporate transaction, and control the outcome of any other matter submitted to the shareholders for vote. Accordingly, our outside stockholders may be unable to influence management and exercise control over our business.

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 requires additional capital to support its current operations, and this capital has not been readily available.

We require additional debt or equity financing to fund our current 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, 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 reporting, internal controls and other 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.

If the Company fails to establish and maintain an effective system of internal controls, it may not be able to report its financial results accurately or prevent fraud. Any inability to report and file its financial results accurately and timely could harm the Company's reputation and adversely impact the trading price of its common stock.

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. We plan to recruit additional personnel in order to achieve our financial reporting obligations. With each prospective acquisition, we will conduct whatever due diligence is necessary or prudent to assure us that the acquisition target can comply with the internal controls requirements of the Sarbanes-Oxley Act. Notwithstanding our diligence, certain internal controls deficiencies may not be detected. As a result, any internal control deficiencies may adversely affect our financial condition, results of operations and access to capital. We have not performed an in-depth analysis to determine if historical undiscovered failures of internal controls exist, and may in the future discover areas of our internal controls that need improvement

Risks Related to The Company's Securities

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

In the event that the Company's common stock becomes listed or traded, the market price of our common stock is likely to be highly 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.

There can be no assurance that there will be an active trading market for the Company's shares of common stock in the future.

If we complete our Public Offering and establish a public market for our securities, the market liquidity will be dependent on the perception of our operating business, among other things. We intend to take certain steps including utilizing investor awareness campaigns and firms, press releases, road shows and conferences to increase awareness of our business. Any steps that we might take to bring us to the awareness of investors may require that we compensate consultants with cash and/or stock. There can be no assurance that there will be any awareness generated or the results of any efforts will result in any impact on our trading volume. Consequently, investors may not be able to liquidate their investment or liquidate it at a price that reflects the value of the business, and trading may be at an inflated price relative to the performance of the Company due to, among other things, the availability of sellers of our shares.

The Company may be subject to penny stock regulations and restrictions and you may have difficulty selling shares of its common stock.

The Company's common stock will be subject to the provisions of Section 15(g) and Rule 15g-9 of the Exchange Act, commonly referred to as the "penny stock rules." Section 15(g) sets forth certain requirements for transactions in penny stock, and Rule 15g-9(d) incorporates the definition of "penny stock" that is found in Rule 3a51-1 of the Exchange Act. The SEC generally defines a penny stock to be any equity security that has a market price less than $5.00 per share, subject to certain exceptions. We will be subject to the SEC's "penny stock rules." The Company may fall within an exception to the "penny stock rules" described in Rule 3a51-1(g), which states that the stock of an issuer that has net tangible assets in excess of $2,000,000 is not considered a penny stock. There are no assurances that we will fall within this or other exceptions to the "penny stock rules."

In the event that our common stock is deemed to be penny stock, trading in the shares of our common stock will be subject to additional sales practice requirements on broker-dealers who sell penny stock to persons other than established customers and accredited investors. "Accredited investors" are persons with assets in excess of $1,000,000 (excluding the value of such person's primary residence) or annual income exceeding $200,000 or $300,000 together with their spouse. For transactions covered by these rules, broker-dealers must make a special suitability determination for the purchase of such security and must have the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt from the rules require the delivery, prior to the first transaction of a risk disclosure document, prepared by the SEC, relating to the penny stock market. A broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information for the penny stocks held in an account and information to the limited market in penny stocks. Consequently, these rules may restrict the ability of broker-dealer to trade and/or maintain a market in our common stock and may affect the ability of the Company's stockholders to sell their shares of common stock.

There can be no assurance that our shares of common stock will qualify for exemption from the penny stock rules. In any event, even if our common stock was exempt from the penny stock rules, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the SEC the authority to restrict any person from participating in a distribution of penny stock if the SEC finds that such a restriction would be in the public interest.

Public company compliance may make it more difficult to attract and retain officers and directors.

The Sarbanes Oxley Act and rules implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, these rules and regulations increase our compliance costs and make certain activities more time consuming and costly. As a public company, these rules and regulations may make it more difficult and expensive for us to maintain our director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors or as executive officers, and to maintain insurance at reasonable rates, or at all.

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. Our telephone number is 858-605-9055. 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 $12,816 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.

On or about July 26, 2017, the Company received a payment demand from a former consultant to the Company alleging that the consultant was owed approximately $192,000 for services rendered. The Company disputed the demand whereby the Company filed a lawsuit on January 29, 2018 against the consultant and its related entities in the United States District Court for the Southern District of California seeking declaratory relief regarding advisory fees and ownership interest in the Company. The parties settled the disputes in their entirety and the case was dismissed with prejudice on August 29, 2018.

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

There is currently no public market for shares of the Company's common stock. The Company has applied for listing of its common stock on the NASDAQ Capital Market in connection with the Public Offering, however, we cannot assure you that our application will be approved or be certain of the timing for commencement of trading.

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 formed to develop, formulate and distribute condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that replenishes and restores the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as age-related macular degeneration ("AMD"), computer vision syndrome ("CVS") and diabetic retinopathy. This risk may be modified by taking Lumega-Z to maintain a healthy macular protective pigment. Additional research has also shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's disease and dementia.

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, adding the CSV-1000 and ESV-3000 to its product portfolio, further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

The Company has had limited operations to date and has been primarily engaged in research and development, product commercialization and capital raising activities.

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 is a non-mydriatic, non-invasive device that accurately measures the MPOD, the lens optical density and lens equivalent age, thereby creating an evidence-based protocol that is shared with the patient. A non-mydriatic device is one that does not require dilation of the pupil for it to function. The MapcatSF is the first medical device using a patented "single fixation" process and "automatic lens density correction" that produces accurate serialized data.

Lumega-Z is a medical food product that has a patent-pending formula that replenishes and restores 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.

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 treat 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.

By combining the MapcatSF medical device, the newly acquired VectorVision standardized vision testing technology and Lumega-Z medical food, the Company has developed, based on Management's knowledge of the industry, what it believes to be the only reliable three-pronged, evidence-based protocol for replenishing and restoring the macular protective pigment, increasing overall retinal health and measuring the related improvements in visual function.

Recent Developments

Patents

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 and ESV-3000 devices each embody 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, and its VectorVision CSV-1000 and ESV-3000 devices each embody this invention.

These patents serve as the basis for developing follow-on products to the CSV-1000. Importantly, the recently issued patents the Company received for continuously calibrating the light source will be incorporated into the new CSV-2000. The CSV-2000, in which the proprietary standardized contrast sensitivity test patterns can be presented to the patient using a computer monitor as opposed to the current calibrated backlit system. There are currently no digital contrast sensitivity devices on the market that will automatically meet FDA specifications without additional manual calibration. The Company also anticipates commercializing these proprietary methodologies for use with other types of vision tests so that other tests can be properly calibrated to adhere to recognized government vision test lighting standards.

Prior to the issuance of US Patent No. 9,486,136, the Company filed a continuation application, Patent Application 15/346,010, covering new embodiments around the MapcatSF® device. These new embodiments contain improvements related to the accuracy of intensity measurements made with the device, as well as updated features around photodiode detector calibrations.

Transcranial Doppler Solutions

In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"), to further the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases. TDSI will be dedicated to the pursuit of early predictors resulting in, the Company believes valuable therapeutic intervention for practitioners and their patients, and additional revenues stream generated from the testing and sale of Company products to appropriate customers. TDSI will provide a service that makes TCD (as defined below) testing convenient by being in various medical facilities. A Transcranial Doppler ultrasound ("TCD") has been accepted as a safe, non-invasive, and lower-cost technique that uses a low-frequency transducer probe to assess intracerebral blood flow, within the brain and to the eyes. Studies have shown the ability of TCD to predict stroke risks as well as other potential cardiovascular events. New technology for TCD now allows measurement of blood vessels previously unavailable. TCD also plays an important role in detecting changes in the ophthalmic artery blood flow, which is important to help evaluate the course of common eye disorders. Blood velocities and intensities can be measured using TCD, which provides an effective way to determine more accurately the state of pathology in early stages of common eye disorders such as glaucoma and other eye diseases that cause visual field defects. Published medical resources indicate a strong relationship between ocular circulation and visual function in patients with glaucoma, diabetes, and macular disease, which are the three leading causes of acquired irreversible blindness throughout the world. A TCD is also highly repeatable, the results of which provide an effective tool for ophthalmologists to treat their patients. Through the monitoring of blood flow in the intracranial vessels, including the ophthalmic artery, the TCD results will in turn provide an evidence-based protocol for Guardion's medical foods, including the Company's soon to be released new GlaucoCetin™ product. The Company is currently setting up the operations of TDSI and hopes to launch its services in upcoming quarters.

GlaucoCetin™

The Company has developed a new medical food product, GlaucoCetin™, which the Company believes 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. GlaucoCetin™ combines a unique set of ingredients, specifically designed to stop or potentially reverse the underlying cause of optic nerve loss, and ultimately vision loss, in patients with glaucoma. During the glaucomatous disease process, the metabolism for the optic nerve cells start to fail because of dysfunctional mitochondria. Mitochondria is responsible for energy production in these cells. When mitochondria are unable to function, the nerve cells do not have enough energy to operate, and they eventually die, causing vision loss.

The precursor formula of GlaucoCetin™ (previously known as GlaucoHealth™) has been under development for many years and has been proven in clinical studies to reverse mitochondrial damage and may be neuroprotective in glaucoma patients. In an IRB-approved, IND registered study conducted at the New York Eye and Ear Infirmary and presented at the American Glaucoma Society 2018, GlaucoHealth™ reversed mitochondrial metabolic dysfunction as determined by the Retinal Metabolic Analyzer, which measures retinal flavoprotein activity, a direct measure of mitochondrial activity.

The Company's GlaucoCetin™ product was developed in collaboration with Dr. Robert Ritch, a world-renowned glaucoma specialist from Manhattan Eye and Ear Infirmary and Mount Sinai Medical Center in New York City. Dr. Ritch has also been a member of the Company's Medical Advisory Board for the past three years. The Company is preparing to launch GlaucoCetin™ in upcoming quarters.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of $7,767,407 and utilized cash in operating activities of $4,173,831 during the year ended December 31, 2018. 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, 2018. 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 Lumega-Z, the MapcatSF® medical device, and VectorVision products. 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 continuing to attempt 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 the Company's outstanding common stock, stock options, and warrants as if the split occurred at the beginning of the earliest period presented.

Recent Accounting Pronouncements

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

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.

Intangible Assets

In connection with the VectorVision transaction, the Company identified and allocated estimated fair values to intangible assets including goodwill and customer relationships.

In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, the Company determined whether these assets are expected to have indefinite (such as goodwill) or limited useful lives, and for those with limited lives, the Company established an amortization period and method of amortization. The Company's goodwill and other intangible assets are subject to periodic impairment testing.

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 is generally calculated on a straight-line basis.

The Company reviews all 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. As of December 31, 2018 and 2017, the Company was not aware of the existence of any indicators of impairment of its intangibles at such dates.

Goodwill

Goodwill represents the excess of the purchase consideration over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. 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. The Company conducts its annual impairment analysis in the beginning of the fourth quarter of each fiscal year. Impairment of goodwill is tested at the reporting unit level by comparing the reporting unit's carrying amount, including goodwill, to the fair value of the reporting unit. Estimations and assumptions regarding the number of reporting units, future performances, results of the Company's operations and comparability of its market capitalization and net book value will be used. If the carrying amount of the reporting unit exceeds its fair value, goodwill is considered impaired and an impairment loss is measured by the resulting amount. Because the Company has one reporting unit, the Company utilizes an entity-wide approach to assess goodwill for impairment. As of December 31, 2018 and 2017, the Company was not aware of the existence of any indicators of impairment of its goodwill at such dates.

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.

The Company accounts 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. 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 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. In order to assist management in calculating such fair value, the Company retained a third-party valuation firm in determining the value of the Company. The third-party valuation firm's input was utilized in determining the related per unit or share valuations of the Company's equity used during 2017. Management used a valuation of $1.76 per share for the six months ended June 30, 2017. Internal valuations are based on various inputs, including valuation reports prepared by third-party valuation firms and are impacted by the dilutive effect of the issuance of common shares as compensation during the periods. There are numerous acceptable ways to estimate company value, including using net tangible assets, a market-based approach, or discounted cash flows. The Company considered alternative methods and concluded that due to the lack of suitably comparable market data, the discounted cash flows method was the most appropriate. A discounted cash flows (i.e. free cash flows to equity) methodology was applied by the third-party valuation firm to assist management in their determination of the $1.76 used during 2017. This methodology used multiple years of balance sheet and income statement projections along with the following primary assumptions:

	Six Months Ended June 30, 2017
Discount rate	16%
Risk free rate	2.48%
Rate of return	16%
Sustainable growth rate	5%
Company survival probability	65%
Liquidation value	$ 0

Due to the availability of historical data from the Company's recent preferred stock sales, Management used valuations of $1.50 and $2.30 for accounting purposes during the third and fourth quarters of 2017, respectively. Management used valuations of $2.30 and $4.00 for the first half and second half of 2018, respectively. Management considered business and market factors affecting the Company during 2018, including capital raising efforts, its proprietary technology, and other factors. Based on this evaluation, management believes that its valuations are appropriate for accounting purposes at December 31, 2018 and 2017, respectively.

The Company recognizes stock compensation expense, on stock purchases at a price less than fair value, and for fully-vested stock issued to consultants and other service providers, for the excess of fair value of the stock over the price paid for the stock. 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 Company will issue new shares to satisfy stock option exercises.

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, 2018, 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:

- further the commercial production of the MapcatSF, starting with the manufacture of at least 15 new units for sale or lease;
- expand the Company's domestic sales and marketing efforts, which include revamping its web site and creating new promotional materials;
- explore sales and marketing opportunities in foreign markets such as Asia and Europe;
- increase production of Lumega-Z as is necessary to support the additional sales resulting from the deployment of additional MapcatSF units and increased marketing and promotional activity;
- commence certain FDA electrical safety testing of the MapcatSF;
- increase focus on intellectual property protection and strategy;
- expand the sales and marketing of the VectorVision product line;
- develop the TDSI business and operations; and
- explore opportunities and channels to enter the expansive market opportunity in China for non-pharmacologic treatments of macular degeneration, glaucoma and diabetic retinopathy.

The FDA and other regulatory bodies require electronic medical devices to comply with IEC 60601 standards. The International Electrical Commission ("IEC") established technical standards for the safety and effectiveness of medical electrical equipment. Adherence to these standards is required for commercialization of electrical medical equipment. As a medical device powered by electricity, the MapcatSF will need to undergo testing to demonstrate compliance with the IEC 60601 standards. This testing is typically conducted by a Nationally Recognized Testing Laboratory ("NRTL"), which is an independent laboratory recognized by the Occupational Safety and Health Administration ("OSHA") to test products to the specifications of applicable product safety standards. The Company is in discussions with its contract manufacturer of the MapcatSF to engage an NRTL at the appropriate juncture prior to commercialization of the MapcatSF. The relevant predicate device for the MapcatSF is the MPS II, the applicable Class I product code for the MapcatSF is HJW and the applicable Code of Federal Regulation is 886.1050. The FDA does not require test documents to be submitted to the FDA for a Class I medical device, but that the evidence of such testing be placed in a Design History file and be kept internally at the company or manufacturer and readily available should the FDA or other regulatory bodies request to review the testing documents. While the FDA does not require that a Class I medical device have formal validation, the Company expects to complete applicable IEC 60601-1 testing prior to commercialization because the Company believes in marketing a product that has evidence that it is safe and effective.

Results of Operations

In November 2017, the Company received gross proceeds of $5,000,001 pursuant to the issuance and sale of 2,173,914 shares of common stock. During 2018, the Company has deployed significant efforts and capital resources to focus on development and commercialization activities related to its medical foods, the MapcatSF® medical device, the VectorVision CSV-1000 and ESV-3000 medical devices, and its newly incorporated subsidiary, Transcranial Doppler Solutions, Inc., which was formed to provide Transcranial Doppler ultrasound services on patients at medical facilities to further the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

Substantial resources were devoted in 2018 to the redesign and improvement of the sales and marketing infrastructure. The Company now has dedicated sales personnel located in and responsible for key strategic sales territories in the United States. In conjunction with hiring sales staff, the Company procured equipment and supplies to support the sales staff and incurs travel expenses related to their sales activities. The Company developed an ecommerce platform and has upgraded and added new website access for products and information. The Company's first targeted marketing campaign for Lumega-Z began in the second quarter of 2018. The Company also dedicated resources to attend certain trade shows to increase the presence of the Company and VectorVision in pertinent industries. Engineering and product development efforts in 2018 have resulted in the first group of commercially available upgraded MapcatSF® devices. The acquisition and development of intellectual property has enabled both the improvement of existing products and the development of new ones. Specifically, the Company believes that VectorVision's CSV-2000, an upgraded, digital version of the CSV-1000 device, will contribute to the Company's revenue beginning in 2019. Additionally, the development of the GlaucoCetin™ medical food product has led to an expected product launch in upcoming quarters. Once fully operational, the Company believes that the Transcranial Doppler subsidiary will provide ultrasound services for the monitoring of blood flow in intracranial vessels, which results the Company hopes will in turn provide an evidence-based protocol for the new GlaucoCetin™ medical food product.

Through December 31, 2018, the Company had limited operations and 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 both medical foods and medical diagnostic equipment for the treatment of various eye diseases. The Company had limited revenue during the years ended December 31, 2018 and 2017. In the fourth quarter of 2017, the Company began recognizing product revenue from the sale of VectorVision products in addition to sales of its proprietary product, Lumega-Z.

Comparison of Years Ended December 31, 2018 and 2017

	Year Ended December 31,			
	2018	2017	Change	
Revenue	$ 942,153	$ 437,349	$ 504,804	115%
Cost of goods sold	398,179	175,470	222,709	127%
Gross Profit	543,974	261,879	282,095	108%
Operating Expenses:				
Research and development	231,847	259,463	(27,616)	(11)%
Sales and marketing	1,520,862	599,926	920,936	154%
General and administrative	4,934,986	4,683,932	251,054	5%
Total Operating Expenses	6,687,695	5,543,321	1,144,374	21%
Loss from Operations	(6,143,721)	(5,281,442)	(862,279)	16%
Other Expense:				
Interest expense	2,289	23,727	(21,438)	(90)%
Warrants - extension of expiration dates	1,621,397	-	1,621,397	100%
Net Loss	$ (7,767,407)	$ (5,305,169)	$ (2,462,238)	46%

Revenue

For the year ended December 31, 2018, revenue from product sales was $942,153 compared to $437,349 for the year ended December 31, 2017, resulting in an increase of $504,804 or 115%. The increase reflects both an increased customer base for Lumega-Z as the Company expands into new clinics and increased sales of VectorVision products.

Cost of Goods Sold

For the year ended December 31, 2018, cost of goods sold was $398,179 compared to $175,470 for the year ended December 31, 2017, resulting in an increase of $222,709 or 127%. The increase reflects the additional sales recorded in 2018.

Gross Profit

For the year ended December 31, 2018, gross profit was $543,974 compared to $261,879 for the year ended December 31, 2017, resulting in an increase of $282,095 or 108%. The increase is primarily due to the sales of VectorVision products, which did not begin until the fourth quarter of 2017. Gross profit represented 58% of revenues the year ended December 31, 2018, versus 60% of revenue for the year ended December 31, 2017. The decrease in gross profit in 2018 was due to pricing and product mix changes in 2018.

Research and Development

For the year ended December 31, 2018, research and development costs were $231,847 compared to $259,463 for the year ended December 31, 2017, resulting in a decrease of $27,616 or 11%. The decrease was due to reduced engineering development costs associated with the Company's MapcatSF® medical device during 2018.

Sales and Marketing

For the year ended December 31, 2018, sales and marketing expenses were $1,520,862 compared to $599,926 for the year ended December 31, 2017. The increase in sales and marketing expenses of $920,936 or 154% compared to the prior period was primarily due to costs associated with engagement of a third-party contract sales organization, increased amortization expense, and increased costs associated with trade shows and marketing.

General and Administrative

For the year ended December 31, 2018, general and administrative expenses were $4,934,986 compared to $4,683,932 for the year ended December 31, 2017. The increase of $251,054 or 5% compared to the prior period was primarily due to increased labor costs related to new employees, benefits expenses, and the inclusion of the VectorVision employees in our consolidated financials. Legal and professional services costs also increased during the period.

Interest Expense

For the year ended December 31, 2018, interest expense was $2,289 compared to $23,727 for the year ended December 31, 2017. The decrease of $21,438, or 90%, was due to the repayment or conversion of promissory notes and convertible debt that had been outstanding during 2017.

Warrants – Extension of 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, 2018, the Company incurred a net loss of $7,767,407, compared to a net loss of $5,305,169 for the year ended December 31, 2017. The increase in net loss of $2,462,238 or 46% compared to the prior year period was due to the non-cash expense related to amortization expense and the extension of warrant expiration dates, as well as to the increased costs associated with the sales team, professional services, marketing and promotional activities, trade show visibility, and the internal labor force. Expenses were offset in part by increased revenue and gross profit.

Segment Information

As of December 31, 2018, Management reports its operating results in two operating segments: Medical Foods, and Vision Testing Diagnostics. As of December 31, 2018, the TDSI subsidiary does not yet earn revenues or meet the required criteria to be considered a reportable operating segment.

i. *Medical Foods* – Our Medical Foods segment develops, formulates and distributes condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that replenishes and restores the macular protective pigment. We have also invented a proprietary technology, embodied in a medical device, the MapcatSF,® that accurately measures the macular pigment optical density ("MPOD"). 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 Company has also developed a new medical food product, GlaucoCetin™, which the Company believes 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. GlaucoCetin™ combines a unique set of ingredients, specifically designed to stop or potentially reverse the underlying cause of optic nerve loss, and ultimately vision loss, in patients with glaucoma.

ii. *Vision Testing Diagnostics* – Our Vision Testing Diagnostics segment, under the brand name VectorVision, 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 following tables set forth our results of operations by segment (expenses allocated to Corporate consist of non-cash stock compensation expense, depreciation and amortization, and corporate legal fees):

	For the Year Ended December 31, 2018			
	Corporate	Medical Foods	Vision Testing Diagnostics	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	2,707,924	3,566,835	412,936	6,687,695
Loss from operations	**$ (2,707,924)**	**$ (3,395,063)**	**$ (40,734)**	**$ (6,143,721)**

	For the Year Ended December 31, 2017			
	Corporate	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 245,217	$ 192,132	$ 437,349
Cost of goods sold	-	110,993	64,477	175,470
Gross profit	-	134,224	127,655	261,879
Operating expenses	2,865,513	2,595,776	82,032	5,543,321
Loss from operations	**$ (2,865,513)**	**$ (2,461,552)**	**$ 45,623**	**$ (5,281,442)**

For the year ended December 31, 2018, revenue from our Medical Foods segment was $332,795 compared to $245,217 for the year ended December 31, 2017, resulting in an increase of $87,577 or 36%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the year ended December 31, 2018, revenue from our Vision Testing Diagnostics segment was $609,358 compared to $192,132 for the year ended December 31, 2017, resulting in an increase of $417,227 or 217%. The increase is due to both the timing of our acquisition of VectorVision in September of 2017 and increased distributor sales in 2018. As of December 31, 2018, the Company had a sales backlog of approximately $105,000 in VectorVision products that are expected to be delivered during the first quarter of 2019.

Cost of Goods Sold

For the year ended December 31, 2018, cost of goods sold from our Medical Foods segment was $161,023 compared to $110,993 for the year ended December 31, 2017, resulting in an increase of $50,030 or 45%. For the year ended December 31, 2018, cost of goods sold from our Vision Testing Diagnostics segment was $237,156 compared to $64,477 for the year ended December 31, 2017, resulting in an increase of $172,679 or 268%. The increase for both segments reflects the additional sales recorded in 2018. Additionally, cost of sales for the Vision Testing Diagnostics segment reflects twelve months of activity in 2018, versus only three months in 2017.

Gross Profit

For the year ended December 31, 2018, gross profit from the Medical Foods segment was $171,772 compared to $134,224 for the year ended December 31, 2017, resulting in an increase of $37,548 or 28%. For the year ended December 31, 2018, gross profit from the Vision Testing Diagnostics segment was $372,202 compared to $127,655 for the year ended December 31, 2017, resulting in an increase of $244,547 or 192%. The increase is due to the additional sales recorded for both segments in the current year as well as the timing of the VectorVision acquisition from September 2017. Gross profit overall represented 58% of revenues the year ended December 31, 2018, versus 60% of revenue for the year ended December 31, 2017. The modest decrease in gross profit in 2018 was due to pricing and product mix changes in 2018.

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 lead product Lumega-Z and its MapcatSF medical device. As a result of these and other activities, the Company utilized cash in operating activities of $4,173,831 during the year ended December 31, 2018. The Company had positive working capital of $609,584 at December 31, 2018 due primarily to the sale of common stock in November and December 2018. As of December 31, 2018, the Company had cash in the amount of $670,948 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 stocks.

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, 2018. 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 Lumega-Z, the MapcatSF® medical device, VectorVision products, and the TDSI business. 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 continuing attempts to raise additional debt and/or equity capital to fund future operations, including via the Company's Public Offering, 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. The Company believes that the net proceeds from the Company's Public Offering, together with its existing cash and cash equivalents will allow it to fund its operating plan through at least the next twelve months. 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.

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:

	Years Ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (4,173,831)	$ (3,403,696)
Net cash used in investing activities	(310,243)	(32,385)
Net cash provided by financing activities	419,792	8,108,791
Net (decrease) increase in cash	$ (4,064,282)	$ 4,672,710

Operating Activities

Net cash used in operating activities was $4,173,831 during the year ended December 31, 2018, versus $3,403,696 used during the comparable prior year period. The increase in 2018 was due primarily to higher sales, marketing, professional services, and labor costs.

Investing Activities

Net cash used in investing activities was $310,243 for the year ended December 31, 2018 and $32,385 for the year ended December 31, 2017. 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 MapCat equipment and internal-use software development.

Financing Activities

Net cash provided by financing activities was $419,792 for the year ended December 31, 2018 was due to the sale in November and December of $850,000 in common stock and the exercise of warrants for proceeds of $16,460. These proceeds were partially offset by the payoff of a $30,535 line of credit balance that had been assumed from the VectorVision transaction as well as payment of $146,133 due to related parties. Net cash provided by financing activities was $8,108,791 for the year ended December 31, 2017, consisting of $5,000,001 in proceeds from the issuance of common stock, $3,105,000 in proceeds from the issuance of preferred stock, and proceeds of $100,000 from the issuance of a note payable. Partially offsetting proceeds received were $150,860 of payments on notes payable and $54,650 of payments due to related parties.

Off-Balance Sheet Arrangements

At December 31, 2018 and 2017, 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 concluded that our internal control over financial reporting was effective as of December 31, 2018.

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 and director nominees based on information furnished to the Company by each executive officer, director and director nominee. 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. The director nominee will be appointed to the Board of Directors only upon the completion of the Company's Public Offering. All directors hold office for one-year terms until the election and qualification of their successors. The following table sets forth information regarding the members of the Board of Directors and the Company's executive officers:

Name	Age	Position
Michael Favish	70	President, Chief Executive Officer and Chairman of the Board of Directors
Robert Weingarten	66	Director
Mark Goldstone	56	Director
David W. Evans	62	Director
Donald A. Gagliano	66	Director Nominee
John Townsend	57	Controller, Chief Accounting Officer
Vincent J. Roth	51	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 appointed as a director of Staffing 360, Inc. on February 25, 2014 and resigned this position on April 20, 2014. 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. On July 8, 2010, Mr. Weingarten was appointed to the Board of Directors of Central African Gold Limited (formerly known as Central African Gold Plc and listed on the Alternative Investment Market of the London Stock Exchange at that time). Central African Gold Limited was an indirect, wholly-owned subsidiary of New Dawn. Both New Dawn and Central African Gold Limited have ceased to be publicly traded and reporting companies in their respective jurisdictions. 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. 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 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 will serve as a Director upon completion of the Company's Public Offering. 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.

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. 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 18 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 for the last 10 years. Mr. Roth worked as a partner at InnovaCounsel, LLP providing general counsel services to clients from 2006 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.

Directors and Officers Liability Insurance

The Company has directors' and officers' liability insurance insuring its directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures the Company against losses, which it may incur in indemnifying its officers and directors. In addition, officers and directors also have indemnification rights under applicable laws, and the Company's certificate of incorporation and bylaws.

Committees of the Board of Directors

Currently, our Board of Directors acts as our audit, nominating, corporate governance and compensation committees. The Board of Directors has not yet adopted charters relative to its audit committee, compensation committee and nominating committee. Until such time as we add more members to the Board, the entire Board will determine all matters and no committees have been formed. We intend to appoint persons to the Board of Directors and committees of the Board of Directors as required to meet the corporate governance requirements of a national securities exchange, although we are not required to comply with these requirements until we are listed on a national securities exchange. We intend to appoint directors in the future so that we have a majority of our directors who will be independent directors, and of which at least one director will qualify as an "audit committee financial expert," prior to a listing on a national securities exchange.

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, 2018 and 2017 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, 2018 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)	2018	$ 275,000	$ -	$ -	$ -	$ 275,000
	2017	$ 250,000	$ -	$ -	$ -	$ 250,000
John Townsend (2)	2018	$ 165,000	$ 3,000	$ -	$ -	$ 168,000
	2017	$ 144,000	$ 10,000	$ 9,000	$ -	$ 163,000
Vincent J. Roth (3)	2018	$ 156,000	$ -	$ -	$ -	$ 156,000
	2017	$ 156,000	$ 10,000	$ -	$ -	$ 166,000

(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. The Company accrued a salary of $250,000 for Mr. Favish in fiscal year 2017 and $275,000 in fiscal year 2018. 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 engaged with a formal employment agreement in 2018.

(2) John Townsend began as the Company's Controller July 1, 2016 with annual compensation of $144,000. 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. Mr. Townsend was engaged with a formal employment agreement in 2018.

(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 is 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 shall grant 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 March 31, 2019 (if the Public Offering has closed prior to such date, or otherwise 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.

2018 Equity Incentive Plan

Our stockholders adopted the Guardion Health Sciences 2018 Equity Incentive Plan, or the 2018 Plan, on November 20, 2018. The purpose of the Plan is to attract and retain key personnel and to provide a means for directors, officers, managers, employees, consultants and advisors to acquire and maintain an interest in the Company, which interest may be measured by reference to the value of its common stock. The material terms of the 2018 Plan are summarized below.

Shares Available; Certain Limitations. The maximum number of shares of common stock reserved and available for issuance under the 2018 Plan is 1,500,000.

New shares reserved for issuance under the 2018 Plan may be authorized but unissued shares or shares that will have been or may be reacquired by the Company in the open market, in private transactions or otherwise. If any shares subject to an award are forfeited, cancelled, exchanged or surrendered or if an award terminates or expires without a distribution of shares to the participant, the shares of common stock with respect to such award will, to the extent of any such forfeiture, cancellation, exchange, surrender, withholding, termination or expiration, again be available for awards under the 2018 Plan except that any shares of common stock surrendered or withheld as payment of either the exercise price of an award and/or withholding taxes in respect of an award will not again be available for awards under the Plan.

2018 Plan Term. The 2018 Plan will terminate on November 20, 2028 (although awards granted before that time will remain outstanding in accordance with their terms).

Types of Awards. The 2018 Plan provides for the issuance of options, share appreciation rights ("SARs"), restricted shares, restricted stock units ("RSUs"), other share-based awards and cash awards to our officers, employees, directors, independent contractors and consultants.

Shares of common stock subject to an award under the 2018 Plan that remain unissued upon the cancellation or termination of the award will again become available for grant under the 2018 Plan. However, shares of common stock that are surrendered by a participant or withheld as payment of the exercise price in connection with any award under the 2018 Plan, as well as any shares of common stock exchanged by a participant or withheld to satisfy tax withholding obligations related to any award, will not be available for subsequent awards under the 2018 Plan. If an award is denominated in shares, but settled in cash, the number of shares of common stock previously subject to the award will again be available for grants under the 2018 Plan. If an award can only be settled in cash, it will not be counted against the total number of shares of common stock available for grant under the 2018 Plan. However, upon the exercise of any award granted in tandem with any other awards, such related awards will be cancelled as to the number of shares as to which the award is exercised and such number of shares will no longer be available for grant under the 2018 Plan.

Administration. The 2018 Plan will be administered by our board of directors, or if our board of directors does not administer the 2018 Plan, a committee of our board of directors that complies with the applicable requirements of Section 16 of the Exchange Act and any other applicable legal or stock exchange listing requirements (each of our board of directors or such committee, the "plan administrator"). The plan administrator may interpret the 2018 Plan and may prescribe, amend and rescind rules and make all other determinations necessary or desirable for the administration of the 2018 Plan, provided that, subject to the equitable adjustment provisions described below, the plan administrator will not have the authority to reprice or cancel and re-grant any award at a lower exercise, base or purchase price or cancel any award with an exercise, base or purchase price in exchange for cash, property or other awards without first obtaining the approval of our stockholders.

The 2018 Plan permits the plan administrator to select the eligible recipients who will receive awards, to determine the terms and conditions of those awards, including but not limited to the exercise price or other purchase price of an award, the number of shares of common stock or cash or other property subject to an award, the term of an award and the vesting schedule applicable to an award, and to amend the terms and conditions of outstanding awards.

Restricted Shares and RSUs. Restricted shares and RSUs may be granted under the 2018 Plan. The plan administrator will determine the purchase price, vesting schedule and performance goals, if any, applicable to the grant of restricted shares. Unless otherwise determined by the plan administrator, if the restrictions, performance goals or other conditions determined by the plan administrator are not satisfied, the restricted shares and RSUs will be forfeited. Subject to the provisions of the 2018 Plan and the applicable individual award agreement, the plan administrator has the sole discretion to provide for the lapse of restrictions in installments or the acceleration or waiver of restrictions (in whole or part) under certain circumstances, including the attainment of certain performance goals, a participant's termination of employment or service or a participant's death or disability. The rights of restricted share and RSU holders upon a termination of employment or service will be set forth in individual award agreements.

Unless the applicable award agreement provides otherwise, participants with restricted shares will generally have all of the rights of a stockholder during the restricted period, including the right to receive dividends declared with respect to such shares; provided, however, that dividends declared during the restricted period with respect to an award will only become payable if (and to the extent) that the underlying restricted shares vest. During the restricted period, participants with RSUs will generally not have any rights of a stockholder, but will be credited with dividend equivalent rights, unless the applicable individual award agreement provides otherwise.

Options. We may issue non-qualified stock options and "incentive stock options" ("ISOs") (within the meaning of Section 422 of the Code) under the 2018 Plan. The terms and conditions of any options granted to a participant will be set forth in an award agreement and, subject to the provisions in the 2018 Plan, will be determined by the plan administrator. The exercise price of any option granted under our 2018 Plan must be at least equal to the fair market value of our common stock on the date the option is granted (110% of fair market value in the case of ISOs granted to ten percent stockholders). The maximum term of an option granted under our 2018 Plan is ten years. The amount of incentive stock options that become exercisable for the first time in a particular year cannot exceed a value of $100,000 per participant, determined using the fair market value of the shares on the date of grant.

Subject to our 2018 Plan, the plan administrator will determine the vesting and other terms and conditions of options granted under our 2018 Plan and the plan administrator will have the authority to accelerate the vesting of any option in its sole discretion. Treatment of an option upon termination of employment of a participant will be provided for by the plan administrator in the applicable award agreement.

Share Appreciation Rights. SARs may be granted under the 2018 Plan either alone or in conjunction with all or part of any option granted under the 2018 Plan. A free-standing SAR granted under the 2018 Plan entitles its holder to receive, at the time of exercise, an amount per share up to the excess of the fair market value (at the date of exercise) of a share of common stock over the exercise price of the free-standing SAR multiplied by the number of shares in respect of which the SAR is being exercised. An SAR granted in conjunction with all or part of an option under the 2018 Plan entitles its holder to receive, at the time of exercise of the SAR and surrender of the related option, an amount per share up to the excess of the fair market value (at the date of exercise) of a share of common stock over the exercise price of the related option multiplied by the number of shares in respect of which the SAR is being exercised. Each SAR will be granted with an exercise price that is not less than 100% of the fair market value of the related shares of common stock on the date of grant. Treatment of a SAR upon termination of employment of a participant will be provided for by the plan administrator in the applicable award agreement. The maximum term of all SARs granted under the 2018 Plan will be determined by the plan administrator but may not exceed ten years. The plan administrator may determine to settle the exercise of an SAR in shares of common stock, cash, or any combination thereof.

Each free-standing SAR will vest and become exercisable (including in the event of the SAR holder's termination of employment or service) at such time and subject to such terms and conditions as determined by the plan administrator in the applicable individual free-standing SAR agreement. SARs granted in conjunction with all or part of an option will be exercisable at such times and subject to all of the terms and conditions applicable to the related option.

Other Share-Based Awards. Other share-based awards, valued in whole or in part by reference to, or otherwise based on, shares of common stock (including dividend equivalents) may be granted under the 2018 Plan. The plan administrator will determine the terms and conditions of such other share-based awards, including the number of shares of common stock to be granted pursuant to such other share-based awards, the manner in which such other share-based awards will be settled (e.g., in shares of common stock, cash or other property), and the conditions to the vesting and payment of such other share-based awards (including the achievement of performance goals). The rights of participants granted other share-based awards upon the termination of employment with or service to us will be set forth in the award agreement. Any dividend or dividend-equivalent award issued under the 2018 Plan will be subject to the same restrictions and conditions as apply to the underlying award.

Cash Awards. Bonuses that are payable solely in cash may also be granted under the 2018 Plan and may be granted contingent upon the achievement of performance goals. The rights of participants granted cash awards upon the termination of employment with or service to us will be set forth in the applicable award agreement.

Equitable Adjustments. In the event of a merger, amalgamation, consolidation, reclassification, recapitalization, spin-off, spin-out, repurchase, reorganization, special or extraordinary dividend or other extraordinary distribution (whether in the form of common shares, cash or other property), combination, exchange of shares, or other change in corporate structure affecting our common stock, an equitable substitution or proportionate adjustment shall be made in (i) the aggregate number and kind of securities reserved for issuance under the 2018 Plan, (ii) the kind and number of securities subject to, and the exercise price of, any outstanding options and SARs granted under the 2018 Plan, (iii) the kind, number and purchase price of shares of common stock, or the amount of cash or amount or type of property, subject to outstanding restricted shares, RSUs and other share-based awards granted under the 2018 Plan and (iv) the terms and conditions of any outstanding awards (including any applicable performance targets). Equitable substitutions or adjustments other than those listed above may also be made as determined by the plan administrator. In addition, the plan administrator may terminate all outstanding awards for the payment of cash or in-kind consideration having an aggregate fair market value equal to the excess of the fair market value of the shares of common stock, cash or other property covered by such awards over the aggregate exercise price, if any, of such awards, but if the exercise price of any outstanding award is equal to or greater than the fair market value of the shares of common stock, cash or other property covered by such award, our board of directors may cancel the award without the payment of any consideration to the participant. With respect to awards subject to foreign laws, adjustments will be made in compliance with applicable requirements. Except to the extent determined by the plan administrator, adjustments to incentive stock options will be made only to the extent not constituting a "modification" within the meaning of Section 424(h)(3) of the Code.

Change in Control and Qualifying Termination. Unless otherwise determined by the plan administrator and evidenced in an award agreement, in the event that (i) a "change in control" (as defined below) occurs and (ii) a participant's employment or service is terminated by us or any of our successors or affiliates without cause or by the participant for good reason (if applicable) within 12 months following the change in control, then (a) any unvested or unexercisable portion of any award carrying a right to exercise will become fully vested and exercisable, and (b) the restrictions, deferral limitations, payment conditions and forfeiture conditions applicable to any award will lapse and such unvested awards will be deemed fully vested and any performance conditions imposed with respect to such awards will be deemed to be fully achieved at target performance levels.

Definition of Change in Control. For purposes of the 2018 Plan, a "change in control" will mean, in summary, the first to occur of the following events: (i) a person or entity becomes the beneficial owner of more than 50% of our voting power; (ii) an unapproved change in the majority membership of our board of directors; (iii) a merger or consolidation of us or any of our subsidiaries, other than (A) a merger or consolidation that results in our voting securities continuing to represent 50% or more of the combined voting power of the surviving entity or its parent and our board of directors immediately prior to the merger or consolidation continuing to represent at least a majority of the board of directors of the surviving entity or its parent or (B) a merger or consolidation effected to implement a recapitalization in which no person is or becomes the owner of our voting securities representing more than 50% of our combined voting power; or (iv) stockholder approval of a plan of complete liquidation or dissolution of us or the consummation of an agreement for the sale or disposition of substantially all of our assets, other than a sale or disposition to an entity, more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of us immediately prior to such sale or a sale or disposition to an entity controlled by our board of directors. However, a change in control will not be deemed to have occurred as a result of any transaction or series of integrated transactions following which our stockholders, immediately prior thereto, hold immediately afterward the same proportionate equity interests in the entity that owns all or substantially all of our assets.

Tax Withholding. Each participant will be required to make arrangements satisfactory to the plan administrator regarding payment of taxes up to the maximum statutory tax rates in the participant's applicable jurisdiction with respect to any award granted under the 2018 Plan, as determined by the Company. We have the right, to the extent permitted by applicable law, to deduct any such taxes from any payment of any kind otherwise due to the participant. With the approval of the plan administrator, the participant may satisfy the foregoing requirement by either electing to have us withhold from delivery of shares of common stock, cash or other property, as applicable, or by delivering already owned unrestricted shares of common stock, in each case, having a value not exceeding the applicable taxes to be withheld and applied to the tax obligations. We may also use any other method of obtaining the necessary payment or proceeds, as permitted by applicable law, to satisfy our withholding obligation with respect to any award.

Amendment and Termination of the 2018 Plan. The 2018 Plan provides our board of directors with authority to amend, alter or terminate the 2018 Plan, but no such action may impair the rights of any participant with respect to outstanding awards without the participant's consent. The plan administrator may amend an award, prospectively or retroactively, but no such amendment may materially impair the rights of any participant without the participant's consent. Stockholder approval of any such action will be obtained if required to comply with applicable law.

Clawback. If the Company is required to prepare a financial restatement due to the material non-compliance with any financial reporting requirement, then the plan administrator may require any Section 16 officer to repay or forfeit to the Company that part of the cash or equity incentive compensation received by that Section 16 officer during the preceding three years that the plan administrator determines was in excess of the amount that such Section 16 officer would have received had such cash or equity incentive compensation been calculated based on the financial results reported in the restated financial statement. The plan administrator may take into account any factors it deems reasonable in determining whether to seek recoupment of previously paid cash or equity incentive compensation and how much of such compensation to recoup from each Section 16 officer (which need not be the same amount or proportion for each Section 16 officer).

Indemnification. To the extent allowable pursuant to applicable law, each member of our board of directors and the plan administrator and any officer or other employee to whom authority to administer any component of the 2018 Plan is delegated shall be indemnified and held harmless by the Company from any loss or expense that may be reasonably incurred by such member in connection with any claim, action or proceeding in which he or she may be involved by reason of any action or failure to act pursuant to the 2018 Plan and against all amounts paid by him or her in satisfaction of judgment in such claim, action or proceeding against him or her, provided, however, that he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf.

Outstanding Equity Awards at Fiscal Year-End

There were no outstanding unexercised options, unvested stock, and/or equity incentive plan awards issued to our named executive officers as of December 31, 2018.

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	2018	$ -	$ -	$ -
	2017	$ -	$ -	$ -
Robert Weingarten (1)	2018	$ -	$ 60,000	$ 60,000
	2017	$ -	$ 60,000	$ 60,000
David W. Evans (2)	2018	$ -	$ -	$ -
	2017	$ -	$ -	$ -

(1) Mr. Weingarten was paid $60,000 in December 2017 as compensation for services as Lead Director provided to the Company during 2017. 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 will be paid in 2019.

(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 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.

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 February 8, 2019 (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 20,564,328 shares of common stock issued and outstanding as of February 8, 2019. 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 February 8, 2019 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 20,564,328 shares of common stock outstanding at February 8, 2019, plus the number of shares of common stock that such person or group had the right to acquire on or within 60 days after February 8, 2019. 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.

Name of Beneficial Owner and Title of Officers and Directors	Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Michael Favish, Chief Executive Officer, President and Director [a]	3,247,467	15.79%
Robert N. Weingarten, Director	650,000	3.16%
Mark Goldstone, Director	525,000	2.55%
Donald A. Gagliano, Director nominee	135,000	0.66%
David Evans, Director [b]	1,525,000	7.42%
John Townsend, Chief Accounting Officer and Controller	52,500	0.26%
Vincent J. Roth, General Counsel and Corporate Secretary	132,500	0.64%
All Officers, Directors, and Director Nominees as a Group (7 persons) [c]	6,267,467	30.48%
5% Shareholders:		
Leon Krajian [d]	1,858,121	8.81%
Digital Grid (Hong Kong) Technology Co., Limited [e]	2,173,914	10.57%
Christopher Scangas [f]	1,304,245	6.34%
Edward Grier	1,079,089	5.21%

(a) Includes 130,000 shares held by Mr. Favish's spouse.

(b) Includes 1,525,000 shares of common stock of the Company held in the name of VectorVision, Inc. issued on September 29, 2017 (the "Closing Date"). 125,000 of these shares serve as security for VectorVision, Inc.'s indemnification obligations (the "Holdback Shares") under the Asset Purchase Agreement, and the HoldBack Shares (or such portion thereof, if any, after any reduction to the HoldBack Shares in accordance with the terms of the Asset Purchase Agreement) shall be delivered to VectorVision, Inc. 26 months following the Closing Date. Dr. Evans owns 28% of the issued and outstanding shares of VectorVision, Inc. and his wife, Tamara Evans, owns 72% of the issued and outstanding shares of VectorVision, Inc. Mr. and Mrs. Evans exercise joint investment control and voting control over the shares of common stock of the Company held in the name VectorVision, Inc. Mrs. Evans business address at 4141 Jutland Drive, Suite 215, San Diego, CA 92117.

(c) Unless otherwise indicated, the business address of each individual is c/o Guardion Health Sciences, Inc., 15150 Avenue of Science, Suite 200, San Diego, California 92128.

(d) Includes 188,987 shares held in the name of Equity Trust Company Custodian FBO Leon S. Krajian IRA; 30,000 shares held in the name of The Leon S. Krajian Living Trust Dated December 18, 2017; 537,500 shares that may be purchased pursuant to exercisable warrants issued to Leon Krajian that are vested and expire at various dates between April 29, 2019 and December 31, 2019; and 1,101,634 shares of common stock owned by Mr. Krajian.

(e) Includes 652,174 shares held in the name of an affiliated company, Lianluo Smart Ltd. ("Lianluo"). Digital Grid (Hong Kong) Technology Co., Limited is a majority owner of Lianluo and is deemed to have voting control over the shares of common stock of the Company held by Lianluo. Mr. He Zhitao has voting and dispositive authority over these shares.

(f) Includes 1,037,877 shares held in the name of Cynthia Elaine Trust dated December 12, 2014; 69,375 shares held in the name of Cynthia Elaine Scangas Dated June 12 2002-IRA rollover, BNY Mellon Trustee; 181,993 shares held in the name of Jason Scangas, the son of Christopher Scangas, for whom Christopher Scangas holds Power of Attorney; and 15,000 shares that may be purchased pursuant to an exercisable warrant issued to Christopher Scangas that is vested and expires March 29, 2019.

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

On September 29, 2017, we completed the acquisition of substantially all of the assets and liabilities of VectorVision Ohio in exchange for 1,525,000 shares of our common stock, pursuant to the Asset Purchase Agreement, which was entered into on an arm's-length basis. David W. Evans, our Director, 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. Mr. Evans was appointed as a director of the Company on September 29, 2017 pursuant to the Asset Purchase Agreement. We 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. 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.

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, 2018 and 2017, the Company had $0 and $146,133, respectively, 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, 2018 and 2017 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, 2018 and 2017.

	Year Ended December 31,	
	2018	2017
Audit Fees [(a)]	$ 100,990	$ 129,834
Tax Fees [(b)]	26,740	2,960
Other Fees [(c)]	33,141	19,758
Total	$ 160,871	$ 152,552

(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 a Registration Statement on Form S-1.

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
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, 2018 and 2017, the related consolidated statements of operations, stockholders' equity (deficiency), 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, 2018 and 2017, 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 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.
Weinberg & Company, P.A.

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

Los Angeles, California
February 14, 2019

Guardion Health Sciences, Inc.

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash	$ 670,948	$ 4,735,230
Accounts receivable	28,203	72,771
Inventories	357,997	154,730
Prepaid expenses	47,773	117,164
Total current assets	**1,104,921**	**5,079,895**
Deposits	11,751	10,470
Property and equipment, net	274,804	95,597
Deferred offering	270,000	-
Intangible assets, net	456,104	620,741
Goodwill	1,563,520	1,563,520
Total assets	**$ 3,681,100**	**$ 7,370,223**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 413,925	$ 311,236
Accrued expenses and deferred rent	81,412	12,043
Line of credit	-	30,535
Due to related parties	-	146,133
Total current liabilities	**495,337**	**499,947**
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 and 0 shares issued and outstanding at December 31, 2018 and December 31, 2017		-
Common stock, $0.001 par value; 90,000,000 shares authorized; 20,564,328 and 20,091,761 shares issued and outstanding at December 31, 2018 and December 31, 2017	20,564	20,092
Additional paid-in capital	37,798,562	33,716,140
Accumulated deficit	(34,633,363)	(26,865,956)
Total stockholders' equity	**3,185,763**	**6,870,276**
Total liabilities and stockholders' equity	**$ 3,681,100**	**$ 7,370,223**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Operations

	Years Ended December 31,	
	2018	**2017**
Revenue		
Medical foods	$ 332,795	$ 245,217
Vision testing diagnostics	609,358	192,132
Total revenue	942,153	437,349
Cost of goods sold		
Medical foods	161,023	110,993
Vision testing diagnostics	237,156	64,477
Total cost of goods sold	398,179	175,470
Gross profit	543,974	261,879
Operating expenses		
Research and development	231,847	259,463
Sales and marketing	1,520,862	599,926
General and administrative	4,934,986	4,683,932
Total operating expenses	6,687,695	5,543,321
Loss from operations	(6,143,721)	(5,281,442)
Other expenses:		
Interest expense	2,289	23,727
Warrants – extension of expiration dates	1,621,397	-
Total other expenses	1,623,686	23,727
Net loss	(7,767,407)	(5,305,169)
Adjustments related to Series A and Series B convertible preferred stock:		
Accretion of deemed dividend	-	(601,952)
Dividend declared	-	(308,628)
Net loss attributable to common shareholders	**$ (7,767,407)**	**$ (6,215,749)**
Net loss per common share – basic and diluted	$ (0.38)	$ (0.45)
Weighted average common shares outstanding – basic and diluted	20,188,628	13,934,196

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Stockholders' Equity (Deficiency)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2016	1,705,154	1,705	-	$ -	12,341,998	$ 12,342	$ 20,290,586	$ (20,650,207)	$ (345,574)
Fair value of common stock issued for acquisition	-	-	-	-	1,525,000	1,525	2,285,975	-	2,287,500
Issuance of common stock for services	-	-	-	-	324,650	325	657,466	-	657,791
Sale of common stock	-	-	-	-	2,173,914	2,174	4,997,827	-	5,000,001
Issuance of preferred stock	-	-	3,105,000	3,105	-	-	3,101,895	-	3,105,000
Conversion of preferred stock	(1,705,154)	(1,705)	(3,105,000)	(3,105)	3,490,977	3,491	1,319	-	-
Fair value of vested stock options	-	-	-	-	-	-	1,457,527	-	1,457,527
Fair value of common stock issued upon conversion of notes payable and related interest	-	-	-	-	9,041	9	13,191	-	13,200
Accretion of beneficial conversion feature on preferred stock	-	-	-	-	-	-	601,952	(601,952)	-
Dividend on preferred stock	-	-	-	-	226,181	226	308,402	(308,628)	-
Net loss	-	-	-	-	-	-	-	(5,305,169)	(5,305,169)
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

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2018	**2017**
Operating Activities		
Net loss	$ (7,767,407)	$ (5,305,169)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	295,672	118,821
Accrued interest expense included in notes payable	-	(8,818)
Stock-based compensation	1,595,037	1,932,268
Stock-based compensation – related parties	-	183,051
Warrants – extension of expiration dates	1,621,397	-
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	44,568	(20,993)
Inventories	(203,267)	(17,439)
Deposits and prepaid expenses	68,111	(87,251)
Increase (decrease) in -		
Accounts payable and accrued expenses	102,689	(121,919)
Accrued and deferred rent costs	69,369	(76,247)
Net cash used in operating activities	(4,173,831)	(3,403,696)
Investing Activities		
Purchase of property and equipment	(260,243)	(37,280)
Purchase of intellectual property	(50,000)	-
Cash assumed upon acquisition	-	4,895
Net cash used in investing activities	(310,243)	(32,385)
Financing Activities		
Proceeds from issuance of promissory notes	-	100,000
Payments on promissory notes	-	(149,000)
Proceeds from issuance of preferred stock	-	3,105,000
Proceeds from issuance of common stock	850,000	5,000,001
Proceeds from exercise of warrants	16,460	-
Payments on line of credit	(30,535)	(1,860)
Deferred financing costs of IPO	(270,000)	-
(Decrease) increase in due to related parties	(146,133)	54,650
Net cash provided by financing activities	419,792	8,108,791
Cash:		
Net (decrease) increase	(4,064,282)	4,672,710
Balance at beginning of period	4,735,230	62,520
Balance at end of period	$ 670,948	$ 4,735,230
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$ -	$ 23,532
Income taxes	$ -	$ -
Non-cash financing activities:		
Issuance of common stock dividends on preferred stock	$ -	$ 308,628
Issuance of common stock upon conversion of notes payable and related interest	$ -	$ 13,562
Fair value of common shares issued for acquisition allocated to:		
Intangible assets	$ -	$ 674,400
Goodwill	$ -	$ 1,563,520
Other assets	$ -	$ 49,580

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018 and 2017

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 that develops, formulates and distributes condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that replenishes and restores the macular protective pigment.

The Company also developed a proprietary medical device called the MapcatSF® that accurately measures the macular pigment optical density.

On September 29, 2017, the Company completed its acquisition of 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 ETDRS visual acuity testing. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing.

In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). TDSI will be dedicated to the pursuit of early predictors resulting in, the Company believes, valuable therapeutic intervention for practitioners and their patients, and additional revenue streams generated from the testing and sale of Company products to appropriate customers. The Company is currently setting up the operations of TDSI and hopes to launch its services in upcoming quarters.

The Company has had limited operations to date and 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 has utilized cash in operating activities of $4,173,831 and $3,403,696 during the years ended December 31, 2018 and 2017, respectively, and had an accumulated deficit of $34,633,363 as of December 31, 2018. 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 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 lead product Lumega-Z, the MapcatSF medical device, and with respect to efforts 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 products other than Lumega-Z and the MapcatSF. The Company is continuing attempts 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 the Company's outstanding common stock, stock options, and warrants 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 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, 2018.

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. The fair value of the Company's line of credit approximates its carrying value given the interest rate of such line of credit.

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, 2018, the Vision Testing Diagnostics segment had one customer who accounted for approximately 47% of the Company's sales; and during the year ended December 31, 2017, the Vision Testing Diagnostics segment had one customer who accounted for approximately 30% 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, 2018 and 2017, 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 market. 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, 2018 and 2017, the Company was not aware of the existence of any indicators of impairment at such dates.

Intangible Assets

In connection with the VectorVision transaction, the Company identified and allocated estimated fair values to intangible assets including goodwill and customer relationships.

In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, the Company determined whether these assets are expected to have indefinite (such as goodwill) or limited useful lives, and for those with limited lives, the Company established an amortization period and method of amortization. Its goodwill and other intangible assets are subject to periodic impairment testing.

The Company utilized the services of an independent third-party valuation firm to assist in identifying intangible assets and in estimating their fair values. The useful lives for the Company's 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 is generally calculated on a straight-line basis.

Amortization expense for the identifiable intangible assets associated with the VectorVision acquisition is approximately $54,000 per quarter and is included with general and administrative expenses in the Company's Statements of Operations.

The Company reviews all 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. As of December 31, 2018 and 2017, the Company was not aware of the existence of any indicators of impairment of its intangibles at such dates.

Goodwill

Goodwill represents the excess of the purchase consideration over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. 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. The Company conducts its annual impairment analysis in the beginning of the fourth quarter of each fiscal year. Impairment of goodwill is tested at the reporting unit level by comparing the reporting unit's carrying amount, including goodwill, to the fair value of the reporting unit. Estimations and assumptions regarding the number of reporting units, future performances, results of the Company's operations and comparability of its market capitalization and net book value will be used. If the carrying amount of the reporting unit exceeds its fair value, goodwill is considered impaired and an impairment loss is measured by the resulting amount. Because the Company has one reporting unit, the Company utilizes an entity-wide approach to assess goodwill for impairment. As of December 31, 2018 and 2017, the Company was not aware of the existence of any indicators of impairment of its goodwill at such dates.

Deferred Offering Costs

Deferred offering costs consist principally of legal, accounting, and underwriters' fees incurred related to the planned underwritten public offering of the Company's Common Stock. These deferred offering costs will be charged against the gross proceeds received or will be charged to expense if the offering is not completed.

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.

Through December 31, 2017, the Company recognized revenue when risk of loss transferred to its customers and collection of the receivable was reasonably assured, which generally occurred when the product was shipped. A product is not shipped without an order from the customer and credit acceptance procedures performed. The Company allows for returns within 30 days of purchase, although for all periods presented, returns have been insignificant.

On January 1, 2018. the Company adopted ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09" or "Topic 606") and all related amendments and applied the concepts to all contracts using the full retrospective method. The new 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 new 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.

Due to the nature of the products sold by the Company, the adoption of the new standard has had no quantitative effect on the financial statements and the Company had no cumulative impact of adopting Topic 606 to record through accumulated deficit. However, the guidance requires additional disclosures to help readers of financial statements better understand the nature, amount, timing, and uncertainty of revenue that is recognized.

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,	
	2018	2017
Medical foods	$ 332,795	$ 245,217
Vision testing diagnostics	609,358	192,132
	$ 942,153	$ 437,349

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 $231,847 and $259,463 for the years ended December 31, 2018 and 2017, respectively.

Patent Costs

The Company is the owner of three issued domestic patents, two pending domestic patent applications, one issued foreign patent in Europe, 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, 2018 and 2017, patent costs were $93,149 and $30,789, 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, 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.

The Company accounts 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. 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 Company recognizes stock compensation expense, on stock purchases at a price less than fair value, and for fully-vested stock issued to consultants and other service providers, for the excess of fair value of the stock over the price paid for the stock. 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 Company will issue new shares to satisfy stock option exercises.

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, 2018 and 2017 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, 2018, 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, options, and shares associated with convertible debt outstanding 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,	
	2018	**2017**
Warrants	1,230,674	1,491,833
Options	1,362,500	1,062,500
	2,593,174	2,554,333

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. 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. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 has subsequently been amended and modified by ASU 2018-10 (codification improvements), 2018-11 (implementation improvements) and 2018-20 (scope revisions). ASU 2016-02 (including the subsequent amendments and modifications) is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company is evaluating the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation and disclosures and expects the most significant change will be the recognition of right-to-use assets and lease liabilities on its balance sheet for real estate operating lease commitments.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 is to be applied using a full or modified retrospective approach. The adoption of ASU 2017-11 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company will adopt the provisions of ASU 2018-07 in the quarter beginning January 1, 2019. The adoption of ASU 2018-07 is not expected to have a material impact on the Company's financial statement presentation or 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. 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 specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study ("ETDRS") visual acuity testing. In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). The Company is currently setting up the operations of TDSI and hopes to launch its services in upcoming quarters.

Although all of the Company's products and services target the early detection, intervention and monitoring of a range of eye diseases, 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 food 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, 2018, the TDSI subsidiary does not meet the required quantitative criteria to be considered a reportable operating segment. Additionally, TDSI does not share similar economic characteristics or a majority of the aggregation criteria set forth in ASC 280, and therefore is shown as "All other (TDSI)" below. As of December 31, 2018, 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 operating segments: Medical Foods, and Vision Testing Diagnostics. The following tables set forth our results of operations by segment (expenses allocated to Corporate consist of non-cash stock compensation expense, depreciation and amortization, and corporate legal fees):

	For the Year Ended December 31, 2018			
	Corporate	Medical Foods	Vision Testing Diagnostics	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	2,707,924	3,566,835	412,936	6,687,695
Loss from operations	**$ (2,707,924)**	**$ (3,395,063)**	**$ (40,734)**	**$ (6,143,721)**

	For the Year Ended December 31, 2017			
	Corporate	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 245,217	$ 192,132	$ 437,349
Cost of goods sold	-	110,993	64,477	175,470
Gross profit	-	134,224	127,655	261,879
Operating expenses	2,865,513	2,595,776	82,032	5,543,321
Loss from operations	**$ (2,865,513)**	**$ (2,461,552)**	**$ 45,623**	**$ (5,281,442)**

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

	As of December 31, 2018			
	Corporate	Medical Foods	Vision Testing Diagnostics	Total
Current assets				
Cash	$ -	$ 552,613	$ 118,335	$ 670,948
Inventories	-	235,957	122,040	357,957
Other	-	44,110	31,866	75,976
Total current assets	-	**832,680**	**272,241**	**1,104,921**
Property and equipment, net	-	264,178	10,626	274,804
Deferred offering	270,000	-	-	270,000
Intangible assets, net	456,104	-	-	456,104
Goodwill	1,563,520	-	-	1,563,520
Other	-	11,751	-	11,751
Total assets	**$ 2,289,624**	**$ 1,108,609**	**$ 282,867**	**$ 3,681,100**

	As of December 31, 2017			
	Corporate	Medical Foods	Vision Testing Diagnostics	Total
Current assets				
Cash	$ -	$ 4,709,512	$ 25,718	$ 4,735,230
Inventories	-	57,978	96,752	154,730
Other	-	119,640	70,295	189,935
Total current assets	-	**4,887,130**	**192,765**	**5,079,895**
Property and equipment, net	-	86,723	8,874	95,597
Deferred offering	-	-	-	-
Intangible assets, net	620,741	-	-	620,741
Goodwill	1,563,520	-	-	1,563,520
Other	-	10,470	-	10,470
Total assets	**$ 2,184,261**	**$ 4,984,323**	**$ 201,639**	**$ 7,370,223**

4. Inventories

Inventories consisted of the following:

	December 31,	
	2018	2017
Raw materials	$ 282,574	$ 133,354
Finished goods	75,423	21,376
	$ 357,997	$ 154,730

5. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2018	2017
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	249,447	150,603
Furniture and fixtures	163,186	50,300
Computer equipment	64,976	16,464
Office equipment	8,193	8,193
	584,159	323,917
Less accumulated depreciation and amortization	(309,355)	(228,320)
	$ 274,804	$ 95,597

For the years ended December 31, 2018 and 2017, depreciation and amortization expense was $81,035 and $65,161, respectively, of which $34,524 and $29,574 was included in research and development expense, $10,898 and $0 was included in sales and marketing expense, and $35,613and $35,587 was included in general and administrative expense, respectively.

6. Acquisition of VectorVision

On September 29, 2017, the Company, through a wholly-owned subsidiary, completed the acquisition of substantially all of the assets and liabilities of VectorVision, Inc., an Ohio corporation ("VectorVision"), in exchange for 1,525,000 shares of the Company's common stock, valued at $2,287,500, pursuant to the terms of an Asset Purchase and Reorganization Agreement dated September 29, 2017, which agreement was entered into on an arm's-length basis. The wholly-owned subsidiary that acquired the business is called VectorVision Ocular Health, Inc., a Delaware corporation, doing business as VectorVision. VectorVision's assets acquired by the Company pursuant to the agreement included, among others, accounts receivable, fixed assets, inventories, trademarks and copyrights. VectorVision's liabilities assumed by the Company included, among others, certain trade accounts payable to third parties and accrued liabilities, and amounts owed under an outstanding line of credit.

With respect to the 1,525,000 shares of common stock, 125,000 shares were held back as security for VectorVision's indemnification obligations to the Company and the remaining 1,400,000 shares were issued to VectorVision at the closing of the transaction. The shares represented approximately 11% of the Company's issued and outstanding common stock immediately following consummation of the agreement. The shares held back as security are included in our weighted average common shares outstanding for per-share calculations.

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. VectorVision specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS (Early Treatment Diabetic Retinopathy Study) visual acuity testing. VectorVision developed and commercialized its CSV-1000 medical device to conduct contrast sensitivity testing and it developed and commercialized its ESV-3000 medical device to conduct ETDRS visual acuity testing. The patented standardization system provides 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. The Company believes VectorVision's CSV-1000 device to be the standard of care for clinical trials. The acquisition of VectorVision expands the Company's technical portfolio and the Company believes it further establishes the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

The Company accounted for the acquisition pursuant to Accounting Standards Codification Topic 805, Business Combinations ("ASC 805"). Management identified and evaluated the fair values of the assets acquired, relying in part, on the work of an independent third party valuation firm engaged by the Company to provide input as to the fair value of the consideration paid (because there is no established trading market for the Company's Common Stock) and the assets acquired, including the valuation methodology most relevant to the transactions described herein, and to assist in the related calculations, analysis and allocations. Historical transactions, as well as the income, market and cost approaches to value were considered. Management ultimately determined that due to recent sales of the Company's preferred stock and consideration of current business and market factors, that the use of historical transactions, and a value of $1.50, would result in the most appropriate valuation for accounting purposes.

In accordance with ASC 805, the Company utilized the acquisition method of accounting, whereby the purchase consideration is allocated to specific tangible and intangible assets at their estimated fair values on the date of acquisition. The following table summarizes the allocation of preliminary fair values of the purchase consideration to the assets and liabilities assumed:

	Fair Values
Common stock consideration	$ 2,287,500
Liabilities assumed	108,722
Total purchase consideration	**2,396,222**
Cash	(4,895)
Accounts receivable	(50,105)
Inventory	(93,293)
Prepaid assets	(551)
Property and equipment	(9,458)
Intangible assets	(674,400)
Goodwill	**$ 1,563,520**

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the expected revenue and benefits of the combined company.

The Company has consolidated VectorVision's operations with the Company's statement of operations commencing October 1, 2017.

The following unaudited pro forma financial information gives effect to the Company's acquisition of VectorVision as if the acquisition had occurred on January 1, 2017 and had been included in the Company's consolidated statements of operations during the year ended December 31, 2017:

	December 31, 2017
Pro forma net revenues	$ 824,028
Pro forma operating expenses	$ 6,087,726
Pro forma net loss attributable to common shareholders	$ (6,500,590)
Pro forma net loss per share	$ (0.47)

7. Intangible Assets

The Company's finite-lived intangible assets consisted of the following:

	December 31,	
	2018	2017
Customer relationships	$ 430,700	$ 430,700
Technology	161,100	161,100
Trade Names	65,600	65,600
Noncompetition	17,000	17,000
	674,400	674,400
Less accumulated depreciation and amortization	(268,296)	(53,659)
	$ 406,104	**$ 620,741**

The Company's amortization expense on its finite-lived intangible assets was $214,637 and $53,659 for the years ended December 31, 2018 and 2017, respectively.

The Company estimates future amortization expense on its finite-lived intangible assets as of December 31, 2018 to be as follows:

For Years Ended December 31,	
2019	$ 214,637
2020	165,320
2021	16,307
2022	9,840
	$ 406,104

8. Acquisition of Intellectual Property

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.

ASC 350-30-20 defines a defensive intangible asset as an acquired intangible asset in a situation in which an entity does not intend to actively use the asset but intends to hold (lock up) the asset to prevent others from obtaining access to the asset. The Company determined that the acquired intangible asset met the definition of a defensive intangible asset. 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 at September 30, 2018. The Company will evaluate the status of the assets for impairment annually or more frequently if warranted.

On January 26, 2018 the Company entered into a consulting agreement with the principal of the seller to assist with the development of the IP Assets and other assets acquired by the Company in the transaction. In conjunction with the consulting agreement, the Company granted a stock option on January 26, 2018 to the consultant to purchase a total of 250,000 shares of the common stock of the Company (See Note 10).

9. Commitments and Contingencies

Operating Lease

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, 2018, $10,470 remained on deposit under the lease agreement. The lease agreement was renewed for an additional five years in 2018. As of December 31, 2018, remaining average monthly lease payments under the amended lease agreement were $12,816 through July 2023.

In connection with the acquisition of VectorVision on September 29, 2017, the Company assumed a lease agreement for 5,000 square feet of office and warehouse space commencing October 1, 2017. The lease was renewed for an additional 65 months. As of December 31, 2018, remaining average monthly lease payments are $1,825 through February 2023.

As of December 31, 2018 and 2017, the Company had accrued and deferred rent payable for its office and warehouse facilities under its lease agreements in the aggregate of $3,712.

The approximate future minimum lease payments under non-cancelable operating leases at December 31, 2018 are as follows:

Years ending December 31,

2019	$	166,770
2020		171,767
2021		176,933
2022		182,249
2023 and thereafter		98,417
	$	796,136

Rent expense was $192,624 and $157,751 for the years ended December 31, 2018 and 2017, respectively.

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, 2018 with respect to such matters, including the matter noted below.

On or about July 26, 2017, the Company received a payment demand from a former consultant to the Company alleging that the consultant was owed approximately $192,000 for services rendered. The Company disputed the demand whereby the Company filed a lawsuit on January 29, 2018 against the consultant and its related entities in the United States District Court for the Southern District of California seeking declaratory relief regarding advisory fees and ownership interest in the Company. The parties settled the disputes in their entirety and the case was dismissed with prejudice on August 29, 2018.

10. Stockholders' Equity (Deficit)

Preferred Stock

Series A

During 2016, the Company sold 1,170,000 shares of the Company's Series A Senior Convertible Preferred Stock (the "Series A Preferred Stock") to various investors. The purchase price of the Series A Preferred Stock was $1.00 per share, for an aggregate purchase price of $1,170,000. In addition, during 2016, the Company issued 535,154 shares of its Series A Preferred Stock with a fair value of $784,888 upon conversion of $535,149 of notes payable and accrued interest. The Series A Preferred Stock had a stated value of $1.00 per share and accrued an annual dividend at the rate of 8% of the stated value, calculated quarterly, paid in shares of common stock at the rate of $1.20 per share.

During the year ended December 31, 2017, the Company declared dividends of $122,328 on its Series A Preferred Stock which were satisfied in full through the issuance of an aggregate of 101,962 shares of common stock.

Series B

Beginning in March 2017 and through September 30, 2017, the Company sold 3,105,000 shares of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock") to various investors. The purchase price of the Series B Preferred Stock was $1.00 per share, for an aggregate purchase price of $3,105,000. The Series B Preferred Stock had a stated value of $1.00 per share and accrued an annual dividend at the rate of 6% of the stated value, calculated quarterly, paid in shares of common stock at the rate of $1.50 per share.

During the year ended December 31, 2017, the Company declared dividends of $186,300 on its Series B Preferred Stock which were satisfied in full through the issuance of an aggregate of 124,219 shares of common stock.

Preferred Stock Conversion Event

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 2,173,914 shares of common stock (see below). The completion of the private placement triggered, at the Company's election, the automatic conversion of the Series A Preferred Stock and the Series B Preferred Stock into shares of common stock. Accordingly, immediately following the completion of the private placement, the Company effected the conversion of all outstanding shares of Series A Preferred Stock and the Series B Preferred Stock into 3,490,977 shares of common stock effective November 3, 2017. On April 26, 2018, the Company filed a Certificate of Elimination with the Secretary of the State of Delaware, withdrawing the respective Certificates of Designation that established the right, privileges and preferences of the Series A Preferred Stock and Series B Preferred Stock, thereby making all 10,000,000 authorized shares of preferred stock available for issuance.

Common Stock

Sale of shares

During the period from November 26, 2018 through December 31, 2018, the Company completed the issuance and sale of an aggregate of 369,567 shares of common stock, par value $0.001 per share, at a purchase price of $2.30 per share. Total gross proceeds were $850,000. These shares were sold in a private placement to certain purchasers pursuant to Stock Purchase Agreements.

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 2,173,914 shares of common stock, par value $0.001 per share, at a purchase price of $2.30 per share. Total gross proceeds were $5,000,001. These shares were sold in a private placement to certain purchasers pursuant to a Stock Purchase Agreement dated as of November 3, 2017.

Shares issued with vesting requirements

The Company periodically issues shares of common stock that vest over time to service providers. As of December 31, 2016, there were 176,250 of previously issued shares of restricted common stock to service providers valued at $113,754 that had not yet vested.

During 2017, the Company issued an additional 81,250 shares of restricted common stock for services rendered. These shares were subject to vesting requirements over 6 months and subject to forfeiture if vesting conditions were not met. The aggregate fair value of the stock was $143,000 based on a valuation per share of $1.76 on the date of grant. During 2017, the Company recorded $256,754 expense related to the vested portion of restricted stock issued in 2017. As of December 31, 2017, all shares had vested.

Additional details of the Company’s restricted common stock are as follows:

	Number of Shares	Fair Value	Weighted Average Grant Date Fair Value Per Share
Non-vested, December 31, 2016	176,250	$ 113,754	$ 2.26
Issued	81,250	143,000	1.76
Vested	(257,500)	(256,754)	2.10
Forfeited	-	-	-
Non-vested, December 31, 2017	-	$ -	$ -

Other issuances

During 2017, the Company also issued 243,400 fully vested shares of common stock for services rendered. During the year ended December 31, 2017, the Company recognized $401,037 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, 2016	**1,461,836**	**$ 0.88**	**2.19**
Granted	30,000	0.03	0.04
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
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, all exercisable	**1,230,674**	**$ 0.71**	**0.29**

The exercise prices of warrants outstanding and exercisable as of December 31, 2018 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
876,250	$ 0.50
70,000	1.00
30,000	1.50
254,424	2.00
1,230,674	

In January 2018, an investor exercised warrants for 73,000 shares of common stock. The warrants were exercisable for $0.02 per share, and the Company received $1,460 in cash. The Company issued the shares and recorded the cash received as additional equity.

In December 2018, an investor exercised warrants for 30,000 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $15,000 in cash. The Company issued the shares and recorded the cash received as additional equity.

On April 30, 2018, The Company offered a one-month exercise period extension to stockholders who held warrants to purchase shares of common stock of the Company that were scheduled to expire on May 1, 2018. Pursuant to the terms of a Note and Warrant Purchase Agreement entered into by the Company and such holders, such warrants were issued upon the conversion of certain promissory notes into common stock on May 1, 2015. Four of the warrant holders did not extend their warrants, resulting in the expiration of 75,503 warrants on May 1, 2018. Six warrant holders extended the term of an aggregate of 201,543 warrants by one month to June 1, 2018. The exercise price of such warrants is $2.00 per share.

On May 31, 2018, the six warrant holders noted above were offered a further extension of the exercise period for their warrants. One holder did not extend, resulting in the expiration of 15,119 warrants on June 1, 2018. The Company and five warrant holders extended the term of an aggregate of 186,424 warrants. These warrants are now scheduled to expire on the earlier of (a) May 31, 2019 or (b) sixty days following the date on which the common stock of the Company becomes listed or approved for listing on a national securities exchange. The exercise price of such warrants remains unchanged at $2.00 per share, but cashless exercise provisions have been eliminated from such warrants.

On September 21, 2018, the Company extended the expiration date of warrants to purchase shares of common stock of the Company that were scheduled to expire at dates ranging from September 30, 2018 through January 25, 2019 held by two stockholders. Pursuant to the terms of a Promissory Note and Loan Agreements entered into by the Company and such holders, the warrants were originally issued as inducement to lend money to the Company. The warrant holders extended the expiration dates of an aggregate of 300,000 warrants. These warrants are now scheduled to expire on February 15, 2019. The exercise price of $0.50 per share and all other terms of the warrants remain unchanged.

Management applied the guidance in ASC 718 – Compensation-Stock Compensation which indicates that a modification to the terms of an award should be treated as an exchange of the original award for a new award with the resulting total compensation cost equal to the grant-date fair value of the original award plus the incremental value of the modification to the award. Under ASC 718, the calculation of the incremental value is based on the excess of the fair value of the new (modified) award based on current circumstances over the fair value of the original award measured immediately before its terms are modified based on current circumstances. The Company recognized expense of $1,621,397 during the year ended December 31, 2018 relating to the extension of the exercise periods of the warrants based upon a Black-Scholes option-pricing model using stock prices of $2.30 and $4.00, volatility of 118% and 119%, and average risk-free rates of 2.61 and 2.89. The expense is reflected as Warrants - extension of expiration dates in the Company's statements of operations.

As of December 31, 2018, the Company had an aggregate of 1,230,674 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $0.71, weighted average remaining life of 0.3 years and aggregate intrinsic value of $3,860,723, based upon a stock valuation of $4.00 per share. The intrinsic value is calculated as the difference between the market value of the underlying common stock and the exercise price of the warrants.

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, 2016	-	-	-
Granted	1,062,500	$ 2.19	5.14
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2017	**1,062,500**	**2.19**	**5.14**
Granted	300,000	0.55	0.55
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2018, outstanding	**1,362,500**	**$ 2.26**	**3.78**
December 31, 2018, exercisable	**1,262,500**	**$ 2.26**	**3.78**

The exercise prices of options outstanding and exercisable as of December 31, 2018 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
625,000	625,000	$ 2.00
62,500	62,500	2.30
675,000	575,000	2.50
1,362,500	**1,262,500**	

On September 30, 2017, the Company entered into a consulting agreement pursuant to which the Company granted a total of 625,000 common stock options. 325,000 of the options with a fair value of $486,070 vested immediately, and the remaining 300,000 options vested ratably over twelve months on a quarterly basis with compensation cost measured as the fair value at the end of each reporting period. The options are non-qualified, have an exercise price of $2.00 per share, and will expire 5 years from the grant date. As of December 31, 2017, the Company had recognized compensation cost of $658,383 relating to the vesting of 400,000 options. During the year ended December 31, 2018, the Company recognized stock compensation costs of $394,239 related to the vesting of 225,000 options based upon a graded vesting schedule. As of December 31, 2018, the 625,000 options were fully vested and exercisable.

On November 30, 2017, the Company granted a total of 62,500 common stock options to an employee. The options, with a fair value of $143,750 vested immediately and are fully exercisable. The options are non-qualified, have an exercise price of $2.30 per share, and will expire 10 years from the grant date.

On December 30, 2017, the Company entered into a consulting agreement pursuant to which the Company granted a total of 375,000 common stock options. 125,000 of the options with a fair value of $312,275 vested immediately, and the remaining 250,000 options vested ratably over six months on a quarterly basis with compensation cost measured as the fair value at the end of each reporting period, using a Black Scholes option-pricing model and a graded vesting schedule. The options are non-qualified, have an exercise price of $2.50 per share, and will expire 5 years from the grant date. During the year ended December 31, 2018, the Company recognized stock compensation costs of $413,877 related to the vesting of 250,000 options. As of December 31, 2018, the 375,000 options were fully vested and exercisable.

On January 26, 2018, the Company entered into an agreement with a consultant to develop products based on certain intellectual property owned by the Company (see Note 8). In conjunction with the consulting agreement, the Company granted a stock option to the consultant to purchase a total of 250,000 shares of the common stock of the Company. 125,000 shares of the option with a fair value of $287,500 vested immediately, 62,500 shares vested on December 31, 2018 and the remaining 62,500 shares vest on December 31, 2019 provided the consultant is still an active service provider. As of December 31, 2018, the 62,500 options that remain to vest were valued in total at $249,777 based upon a Black-Scholes option-pricing model. Compensation cost is measured as the fair value at the end of each reporting period and cost is amortized based upon a graded vesting schedule. The options are non-qualified, have an exercise price of $2.50 per share, and will expire 5 years from the grant date. During the year ended December 31, 2018, the Company recognized stock compensation costs of $656,735 related to the 250,000 options.

On July 25, 2018, the Company entered into an agreement with a consultant to develop products based on certain intellectual property owned by the Company. In conjunction with the consulting agreement, the Company granted a stock option to the consultant to purchase a total of 50,000 shares of the common stock of the Company. 12,500 shares of the option with a fair value of $44,994 vested immediately, while the remaining 37,500 shares vest on completion of certain performance conditions to the reasonable satisfaction of the Company. Specifically, 25,000 shares vest upon completion of design and construction of the AcQviz^{TM} device, and the remaining 12,500 shares vest upon integration of the AcQviz^{TM} send/receive functionality with vision testing software platform. As of December 31, 2018, the 37,500 options that remain to vest were valued in total at $149,939 based upon a Black-Scholes option-pricing model. As of December 31, 2018, the completion of all performance conditions was considered probable. Because completion of the performance conditions is considered probable, compensation cost is measured as the fair value at the end of each reporting period and cost is amortized based upon an accelerated attribution model using Management's estimates of anticipated timing for completion of the conditions. The options are non-qualified, have an exercise price of $2.50 per share, and will expire 5 years from the grant date. During the year ended December 31, 2018, the Company recognized stock compensation costs of $130,187 related to the 50,000 options.

As of December 31, 2018, options were valued based upon the Black-Scholes option-pricing model, with a stock price of $4.00, volatility of 115%, and an average risk-free rate of 2.46%.

During the years ended December 31, 2018 and 2017, we recognized aggregate stock-compensation expense of $1,595,037 and $2,115,319, respectively, based upon stock prices ranging from $1.76 to $4.00 per share, of which $1,595,037 and $2,094,334 was recorded in general and administrative expense, $0 and $20,357 was recorded in sales and marketing expense, and $0 and $628 was recorded in research and development expense, respectively.

As of December 31, 2018, the Company had an aggregate of 100,000 remaining unvested options outstanding, with a total estimated fair value of $399,716, weighted average exercise price of $2.50, and weighted average remaining life of 3.0 years. The Company remeasures unvested options for non-employees to fair value at the end of each reporting period. The aggregate intrinsic value of options outstanding as of December 31, 2018 was $2,368,750.

11. Related Party Transactions

On September 29, 2017, we completed the acquisition of substantially all of the assets and liabilities of VectorVision Ohio in exchange for 1,525,000 shares of our common stock, pursuant to the Asset Purchase Agreement, which was entered into on an arm's-length basis. David W. Evans, our Director, 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. Mr. Evans was appointed as a director of the Company on September 29, 2017 pursuant to the Asset Purchase Agreement. We 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. 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.

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, 2018 and 2017, the Company had $0 and $146,133, respectively, due to related parties.

During the twelve months ended December 31, 2018, the Company incurred and paid $275,000 of salary expense to our CEO, Michael Favish. During the twelve-month period ended December 31, 2017, the Company incurred salary expense of $250,000 and paid $170,000 in salary to Mr. Favish. Accrued amounts are included in general and administrative expenses.

12. 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, 2018 and 2017 are summarized below.

	December 31,	
	2018	2017
Net operating loss carryforwards	$ 2,689,000	$ 1,551,000
Stock-based compensation	942,000	504,000
Amortization of intangibles	19,000	—
Accrued compensation	—	17,000
Depreciation	(1,000)	5,000
Total deferred tax assets	3,649,000	2,077,000
Valuation allowance	(3,649,000)	(2,077,000)
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, 2018, 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, 2018 and 2017, 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, 2018 and 2017:

	Years Ended December 31,	
	2018	2017
U. S. federal statutory tax rate	(21.0)%	(35.0)%
Non-deductible stock-based compensation	—%	4.3%
Non-deductible fair value of warrant extensions	4.4%	—%
Expirations related to stock-based compensation	0.1%	—%
Adjustment to deferred tax asset	0.4%	68.5%
Change in valuation allowance	16.0%	(38.0)%
Other	0.1%	0.2%
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 $9,945,000 which, if not utilized earlier, will begin to expire in 2035. While the Company has not performed a formal analysis of the availability of its net operating loss carryforwards 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.

13. Subsequent Events

On January 30, 2019, Guardion Health Sciences, Inc. (the "Company") filed with the Secretary of State of Delaware an amendment to the Company's Certificate of Incorporation, (the "Charter Amendment") to affect a reverse stock split whereby every two (2) shares of the Company's common stock issued and outstanding immediately prior to filing the Charter Amendment (the "Old Common Stock") were automatically, without further action on the part of the Company or any holder of Old Common Stock, reclassified, combined, converted and changed into one (1) fully paid and nonassessable share of common stock, par value of $0.001 per share (the "New Common Stock"). Holders who otherwise would have been entitled to receive fractional share interests of New Common Stock upon the effectiveness of the reverse stock split received one (1) whole share of New Common Stock in lieu of any fractional share created as a result of the reverse stock split. The reverse stock split was approved by the Company's stockholders at the Company's Annual Meeting of Stockholders held on November 20, 2018.

On February 11, 2019, two investors exercised warrants for 312,500 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $31,250 in cash. The Company will issue the shares and record the cash received as additional equity.

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	Bylaws (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
4.1	November 30, 2015 Warrant Agreement (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
4.2	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)
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 Restricted Unit Purchase Agreement from Round 3 Funding in 2013 (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.3	Form of Bridge Loan from September 30, 2015 - January 25, 2016 (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.4	Form of Indemnification Agreement (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.5	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)
10.6	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)
10.7	Intellectual Property Purchase 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)
10.8	Stock Purchase Agreement dated as of November 3, 2017 (filed on Form 8-K on November 7, 2017 and incorporated herein by reference)
10.9	Form of November 2018 Stock Purchase Agreement (filed on Form 8-K on November 30, 2018 and incorporated herein by reference)
10.10	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)
10.11	Employment Agreement between Guardon Health Sciences, Inc. and Michael Favish (filed on Form 8-K on December 27, 2018 and incorporated herein by reference)
21.1*	List of Subsidiaries
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 14th day of February 2019.

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)	February 14, 2019
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Financial and Principal Accounting Officer)	February 14, 2019
/s/ Robert N. Weingarten Robert N. Weingarten	Director	February 14, 2019
/s/ Mark Goldstone Mark Goldstone	Director	February 14, 2019
/s/ David W. Evans David W. Evans	Director	February 14, 2019

Exhibit 21.1

LIST OF SUBSIDIARIES

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

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: February 14, 2019

/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: February 14, 2019

/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, 2018 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.

February 14, 2019 /s/ Michael Favish
Michael Favish
Chief Executive Officer
(Principal Executive Officer)

February 14, 2019 /s/ John Townsend
John Townsend
Controller and Chief Accounting Officer
(Principal Financial and Principal Accounting Officer)