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, 2017

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
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(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ 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
(Do not check if a smaller reporting company)		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 23, 2018, there were issued and outstanding 40,329,475 shares of the issuer’s common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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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 our future financial performance, and are based on current expectations, estimates, forecasts and projections about us, our future performance, our 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,” “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 and political 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; and (iii) changes in the Company’s corporate strategy or an inability to execute its strategy due to unanticipated changes. As a result of these risks and uncertainties, many of which are described in greater detail elsewhere in the “Risk Factors” section of this Annual Report, 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. 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 our technical portfolio and we believe it further establishes our 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, and has primarily been engaged in research, development, commercialization, and capital raising.

The Company invented a proprietary technology, embodied in 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.

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 our 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.

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 density in patients who are taking Lumega-Z. The Company encourages sites using the MapcatSF® to provide us 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 steadily 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 generates an average of 75 new customers for our 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.

AMD is the 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. 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.

Competitive Advantage

By combining the Company's MapcatSF medical device and Lumega-Z medical food, Management believes the Company has developed the only reliable two-pronged evidence-based protocol for replenishing and restoring the macular protective pigment and increasing overall retinal health. The MapcatSF is intended to be the first 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 relationships, 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. We believe 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 our VectorVision CSV-1000 instrument is used worldwide by eye doctors in more than 60 countries to accomplish contrast sensitivity testing. We believe the CSV-1000 is the standard of care for clinical trials. There is a training requirement in incorporating the CSV-1000 device into clinical practice, which we plan to provide as part of our commercialization strategy.

Similarly, we believe that our 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 we expect this global distribution to continue. We believe the acquisition of VectorVision, adding the CSV-1000 and ESV-3000 to our product portfolio, further establishes our position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

Medical Foods Products Industry Overview

The science of nutrition was long overlooked and underdeveloped and has now shown that the sick and elderly have special nutritional needs that cannot be met by traditional adult diets. Medical nutrition has emerged today as an attractive segment in the food industry.

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 Lumega-Z is properly categorized as a medical food. While the Company believes it is unlikely the FDA would conclude otherwise, if the FDA were to determine 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

We believe that repeatable, consistent results for visual acuity testing is 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. We believe that the variance in luminance provided by digital displays is large, and clinicians are now obtaining highly inconsistent results from practice to practice. Conservatively, we believe more than 250,000 eye care examination rooms are in use in the United States today.

VectorVision specializes in the standardization of vision tests, specifically, contrast sensitivity, glare testing and early treatment diabetic retinopathy study, or ETDRS, acuity. The variability described above has caused the FDA and other agencies to require standardized test lighting for 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, and 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 Strategy

Since there are no research-validated pharmaceutical solutions for slowing the progression of adult macular degeneration ("AMD"), 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. These supplement products all have varying ingredients, varying levels of similar ingredients, varying claims regarding their effects, and varying price points.

Lumega-Z addresses 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.

An important part of our competitive strategy lies in combining Lumega-Z with technology to demonstrate its effects. As well as our proprietary MapcatSF device, VectorVision 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 levels 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

- AMD is one of the leading causes of blindness in the developed world, responsible for 50% of blindness.
- The United States has an estimated 15 million AMD cases.
- One in three people in the U.S. will develop AMD or some vision-reducing eye disease by age 65.

Worldwide Statistics

- AMD is the third leading cause of blindness throughout the entire world, exceeded only by cataracts and glaucoma.
- Overall, 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.

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 US.

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 will follow the following procedures:

- The Company will provide all clinicians a DAC number (Doctor Authorization Code)
- Patients will be given a customized recommendation from the clinician, including the DAC number; this will enable them to order Lumega-Z either online or by calling the 800 number
- Patients will be able to take advantage of using their Health Care Flexible Spending Accounts ("HCFSA") 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.

Development of Sales Force

The Company is investing in a direct sales force comprised 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 will have responsibility for a pre-defined geographical area, and will be expected to travel extensively to support the needs of customers. The account managers will be 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 will also participate in national and regional trade shows and events, including supporting professional optometric and ophthalmological societies at a State level. Each account manager will be tasked with a quota that includes units of Lumega-Z sold, as well as sales of the MapcatSF, CSV-1000 and ESV-3000. Commissions will be paid based on performance and achievement of quota. Training of the direct sales force is expected to commence in March 2018.

International Expansion Strategy

Retinal diseases that include macular degeneration, glaucoma and diabetic retinopathy are not exclusive to the United States. We believe 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.

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 14/028,104	**EMULSION OF CAROTENOIDS AND OCULAR ANTIOXIDANTS**	**GHS**	**Lumega-Z®**	**09/16/13**
Patent Application 15277849	**METHOD AND APPARATUS FOR VISION ACUITY TESTING**	**VectorVision**	**CSV-1000 And ESV-3000**	**09/27/16**
Patent Application 15445586	**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 Application 13746669.4	**APPARATUS FOR USE IN THE MEASUREMENT OF MACULAR PIGMENT OPTICAL DENSITY AND/OR LENS OPTICAL DENSITY OF AN EYE**	**GHS**	**MapcatSF®**	**09/09//14**
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 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. On November 8, 2016, the United States Patent and Trademark Office ("USPTO") issued patent number 9,486,136 for the MapcatSF invention. The foreign counterpart patent applications describe the same invention.

The Lumega-Z® patent filing 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 Application 15277849 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.

Patent Application 15445586 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.

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. Healthy Solutions, LLC in Scottsdale, Arizona manufactures Lumega-Z for the Company. Device Labs in Irvine, California manufactures the MapcatSF for the Company.

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 our 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.

Our 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. We and our 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 II

Congress enacted significant prohibitions against physician self-referrals in the Omnibus Budget Reconciliation Act of 1993. This law commonly referred to as "Stark II," applies to physician dispensing of outpatient prescription drugs that are reimbursable by Medicare or Medicaid. Our product, Lumega-Z, is not a prescription drug, nor do we participate in Medicare, Medicaid or any other federal or state-funded reimbursement program. Stark II, 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 the requirements of the exception. We are mindful that if our Lumega-Z product becomes eligible for reimbursement from any such reimbursement program or if Lumega-Z were deemed to be a prescription drug, Stark laws could potentially become applicable with regard to Lumega-Z.

Anti-Kickback Statute and HIPAA Criminal Laws

While we do not yet participate in any federal or state-funded reimbursement programs, we are mindful that should we participate in such programs or should our customers receive reimbursement or subsidy from a federal or state healthcare program, certain laws may become applicable to us. The federal Anti-Kickback Statute makes it illegal for any person, including a pharmaceutical, biologic, or medical device company (or a party acting on its behalf), to knowingly and willfully solicit, offer, receive or pay any remuneration, directly or indirectly, in exchange for, or to induce, the referral of business, including the purchase, ordering or prescription of a particular item or service, or arranging for the purchase, ordering, or prescription of a particular item or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid. In 1996, under the Health Insurance Portability and Accountability Act ("HIPAA"), the Anti-Kickback Statute was expanded to be made applicable to most federal and state-funded health care programs.

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 our 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.

State Regulatory Requirements

Each state has its own regulations concerning physician dispensing, restrictions on the corporate practice of medicine, 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.

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, we may be subject to federal and state laws requiring the disclosure of financial arrangements with health care professionals.

Foreign Regulatory Requirements

While not yet applicable to us, we 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 we must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these 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.

Employees

As of December 31, 2017, the Company had a staff of nine, consisting of four officers, four full-time staff and one part-time staff person. In addition, VectorVision has a staff of four, consisting of two officers, one full-time employee and one part-time staff member.

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 could lose all or part of their investment.

Risks Related to the Company's Business

The Company's recurring operating losses have raised substantial doubt regarding its ability to continue as a going concern.

The Company has sustained recurring operating losses, which raises substantial doubt about its ability to continue as a going concern. The perception of the Company's ability to continue as a going concern may make it more difficult for it to obtain financing for the continuation of its operations and could result in the loss of confidence by investors, suppliers and employees. The Company's financial statements for all periods have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the Financial Statements, the continuation of the Company as a going concern is dependent upon the Company raising additional debt and/or equity financing to fund future operations and to provide additional working capital. The Company has completed multiple capital financing transactions during 2017, resulting in cash on hand of $4,735,230 at December 31, 2017.

As of December 31, 2017, management had concluded that there was substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements were issued, and the Company's independent registered public accounting firm also included explanatory going concern language in their report accompanying the Company's audited financial statements for the year ended December 31, 2017.

Although recent capital transactions have significantly improved our current cash position, we will continue to incur significant expenses for commercialization activities related to our lead product Lumega-Z, the MapcatSF medical device, the CSV-1000 and ESV-3000 devices, and with respect to efforts to build our infrastructure. If the Company is unable to raise additional capital, the Company will be forced to suspend or terminate operations and, in all likelihood, cause investors to lose their entire 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.

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

Our ability to realize the anticipated benefits of the VectorVision acquisition will depend, to a large extent, on our ability to integrate the business of VectorVision with our legacy business, which may be a complex, costly and time-consuming process. We may be required to devote significant management attention and resources to integrate the VectorVision business practices into our existing operations. The integration process may disrupt our 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, our operations and could adversely affect our 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 we may be assuming from VectorVision.

We have limited experience in developing medical foods and medical devices, and we may be unable to commercialize some of the products we develop.

Development and commercialization of medical foods and medical devices involves a lengthy and complex process. We have limited experience in developing products and have 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, and we cannot assure you that it is possible to further develop or successfully commercialize the MapcatSF or that we 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 we develop 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 us to become profitable. We cannot assure you that our 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.

We and our 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 we or our suppliers or manufacturers are not in compliance with the laws and regulations to which we are subject, our business, financial condition and results of operations may be adversely affected.

As a participant in the healthcare industry, our operations and relationships, and those of our customers, are regulated by a number of federal, state, local, and foreign governmental entities and our products must be capable of being used by our customers in a manner that complies with those laws and regulations. Because of our business relationships with physicians and professional healthcare providers, and since our 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 we believe Lumega-Z is a medical food, if the FDA was to determine Lumega-Z to be a drug, the Company and the product would be subject to considerable additional FDA regulation. Similarly, while we believe the MapcatSF is a safe medical device, with a very low potential risk of injury to a patient, we believe 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, we cannot anticipate how changes in regulations or determinations by regulatory agencies may evolve. Thus, application of many foreign, state and federal regulations to our 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 our operations and relationships or the business practices of our customers. It is possible that a review of our business practices or those of our customers by courts or regulatory authorities could result in a determination that may adversely affect us. In addition, the healthcare regulatory environment may change in a way that restricts our existing operations or our growth. The healthcare industry is expected to continue to undergo significant changes for the foreseeable future, which could have an adverse effect on our business, financial condition and results of operations. We cannot predict the effect of possible future legislation and regulation.

We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products as a drug.

Our 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, we are prohibited from promoting our products for treatment of a condition or disease. This means that we may not make claims about the usefulness or effectiveness or expected outcome of use of our products for any particular condition or disease and may not proactively discuss or provide information on the use of our 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. We also face the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that we have 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 our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we 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), we 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.

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

If our products, including Lumega-Z, are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon our 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 our 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 us from commercializing our product candidates and generating revenues from their sale.

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

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We are 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, our 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. Our 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. Furthermore, there is no guarantee that we will be successful in negotiating similar collaborative relationships with regard to the CSV-1000 and ESV-3000.

While we believe 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 relationships, 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.

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

Our 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.

Our 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, time-consuming and expensive process. If we fail to adequately manage the research, development, execution and regulatory aspects of new product development we may fail to launch new products altogether.

Government agencies may establish usage guidelines that directly apply to our products or proposed products or change legislation or regulations to which we are subject.

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of our products and products that we may develop. In addition, there can be no assurance that government regulations applicable to our products or proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our 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 our products. We 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 us may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.

While we are not a pharmaceutical or a biopharmaceutical company, as a health sciences company, our medical foods or our medical device 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. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We may find it necessary to initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties to produce our products. In addition, future patents may issue to third parties which our technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our 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, we may be required to pay substantial damages, including treble damages and attorney's fees to the party claiming infringement if we were to be found to have willfully infringed a third party's patent. We may also have to develop non-infringing technology, stop selling any products we develop, 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. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us 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 us from selling any products we develop, which could harm our business.

Our competitors may develop products similar to Lumega-Z, and we may therefore need to modify or alter our business strategy, which may delay the achievement of our goals.

Competitors may develop products with similar characteristics to Lumega-Z. Such similar products marketed by larger competitors could hinder our efforts to penetrate the market. As a result, we may be forced to modify or alter our 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 our goals.

Our competitors may develop products similar to the CSV-1000 and ESV-3000 devices, and we may therefore need to modify or alter our business strategy, which may delay the achievement of our goals.

While we believe 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.

If we are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, revenues from any products we develop could be limited.

We currently have 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 we decide 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 we receive 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 we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our 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 us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

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.

We may be unsuccessful in expanding our 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 our ability to produce products.

We engage third parties to manufacture our products in sufficient quantities and on a timely basis, while maintaining product quality and 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. 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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our 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.

Our products and facility and the facilities of our 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 our manufacturers' ability to manufacture and our ability to distribute products. If any such action were to be imposed, it could have a material adverse effect on our 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 report titled "*Description of 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, 2017 as well as the year ended December 31, 2016, the Company derived most 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. After September 30, 2017, the Company expects 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 our financial results.

In the years ended December 31, 2017 and 2016, the Company's billings were derived from a limited number of individual customers and distributors. The Company does not receive volume commitments from its customers. Customers may stop purchasing our products with little or no warning. After September 30, 2017, the Company's customer base has expanded due to sales of the CSV-1000 and ESV-3000 products. However, VectorVision also does not receive volume commitments from its customers. Customers may stop purchasing CSV-1000 or ESV-3000 products with little or no warning. Loss of customers may have an immediate adverse effect on our financial results.

If we are forced to reduce our prices, our business, financial condition and results of operations may suffer.

We may be subject to pricing pressures with respect to our future sales arising from various sources, including practices of health insurance companies, healthcare providers and competition in the marketplace. If our 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 we are unable to successfully introduce new products or fail to keep pace with medical advances and developments, our 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 our products, or delay in deciding whether to recommend our products and services, our 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 our principal suppliers fail or are unable to perform their contracts with us, we may be unable to meet our commitments to our customers. As a result, our reputation and our relationships with our customers may be damaged and our 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 we incur costs exceeding our insurance coverage in lawsuits that are brought against us in the future, it would be expected to adversely affect our 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 we are deemed to infringe on the proprietary rights of third parties, we could incur unanticipated expense and be prevented from providing our 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.

Our business depends on our intellectual property rights, and if we are unable to protect them, our 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 one issued patent and three pending patent applications related to its products. There currently are no issued patents relating to Lumega-Z and the CSV-1000 and EVS-3000 devices. 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. If we infringe the rights of third parties, we could be prevented from selling our products, forced to pay damages, and forced to incur substantial costs in defending litigation.

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.

- 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.

Our business depends in part on and will continue to depend in part on our ability to establish and maintain additional strategic collaborative relationships. Our failure to establish and maintain these relationships could make it more difficult to expand the reach of our products, which may have a material adverse effect on our 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.

We must attract quality management in order to manage our growth. Failure to do so may result in slower expansion.

In order to support the growth of our business, we will need to expand our senior management team. There is no assurance that we will be capable of attracting quality managers 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, and we may not be able to attract and retain the highly skilled employees we need to support our business. Without skilled employees, the quality of our product development and services could diminish and the growth of our business may be slowed, which could have a material adverse effect on our 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 we lose the services of our Chief Executive Officer and other key personnel, we may be unable to replace them, and our 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 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.

Our failure to compete successfully could cause our 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.

Our future success depends upon our ability to grow, and if we are unable to manage our growth effectively, we may incur unexpected expenses and be unable to meet our 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. 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.

We may consider acquiring other companies or product lines in an effort to expand our 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. In either event, 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 our business into additional states, we may need to comply with regulatory requirements specific to such states and there can be no assurance that we will be able to initially meet such requirements or that we 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.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we 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 our 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.

Our 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.

Risks Related to the Company's Industry

Any failure to comply with all applicable federal and state confidentiality requirements for the protection of patient information may result in fines and other liabilities, which may adversely affect our results of operations.

When a physician recommends our medical food, Lumega-Z, to a patient we typically receive an order from the customer, but we do not usually receive medical information. As part of the operation of our business, it is possible, however, that during communication with customers or with physicians we might receive patient-identifiable medical information. 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. Any failure to comply may result in fines and other liabilities, which may adversely affect our results of operations.

Congress enacted significant prohibitions against physician self-referrals in the Omnibus Budget Reconciliation Act of 1993. This law, commonly referred to as "Stark II," applies to physician dispensing of outpatient prescription drugs that are reimbursable by Medicare or Medicaid. Our products are neither prescription drugs nor are they reimbursable under any federal program at present. Stark II, 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. We believe that the physicians who use our medical device, the MapcatSF, or recommend our medical food, Lumega-Z, to their patients are aware of these requirements, but we do not monitor their compliance and have no assurance that the physicians are in material compliance with Stark II. If it were determined that the physicians who use our medical device or prescribe medical foods purchased from us were not in compliance with Stark II, it could potentially have an adverse effect on our business, financial condition and results of operations.

The federal anti-kickback statute applies to Medicare, Medicaid and other state and federal programs. At present, our products are not prescription drugs, nor are they reimbursable under any federal program. The federal anti-kickback statute 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 programs. The federal anti-kickback statute provides a number of statutory exceptions and regulatory "safe harbors" for particular types of transactions. We believe that our arrangements with our customers are in material compliance with the anti-kickback statute and relevant safe harbors. Many states have similar fraud and abuse laws, and we believe that we are in material compliance with those laws. At present, we do not participate in any federal programs and our products are not reimbursed by Medicare, Medicaid or any other state or federal program. If, however, that changes in the future and it were determined that we were not in compliance with the federal anti-kickback statute, we could be subject to liability, and our operations could be curtailed. Moreover, if the activities of our customers or other entity with which we have a business relationship were found to constitute a violation of the federal anti-kickback law and we, as a result of the provision of products or services to such customer or entity, were found to have knowingly participated in such activities, we could be subject to sanction 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.

Increased government involvement in healthcare could adversely affect our 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 Our Common Stock

We are an "emerging growth company" and we have elected to comply with certain reduced reporting and disclosure requirements which could make our 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 $1.0 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.

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

As of the date of this Annual Report, our executive officers and directors beneficially own approximately 30.4% 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.

We do not intend to pay cash dividends to our stockholders, so you will not receive any return on your investment in our 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.

We require additional capital to support our 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. As a publicly-owned reporting company, we expect that it may facilitate our ability to secure additional funds. 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 our business operations.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and The Sarbanes-Oxley Act of 2002 ("SOX"). 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. SOX 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 SOX 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 SOX, 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 we fail to establish and maintain an effective system of internal controls, we may not be able to report our financial results accurately or prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our 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. 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 SOX. 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 Our Securities

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

SOX 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.

Our 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 we become 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.

Our shares of common stock are not publicly traded and there can be no assurance that there will be an active market for our shares of common stock in the future.

Our shares of common stock are not currently publicly traded and timing for the commencement of trading is uncertain. There can be no assurance that there will be an active market for our shares of common stock in the future. If we are able to 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.

If an active market should develop, the price may be highly volatile. If there is a low price for our shares of common stock, many brokerage firms or clearing firms may not be willing to effect transactions in the securities or accept our shares for deposit in an account. Many lending institutions will not permit the use of low priced shares of common stock as collateral for any loans.

We are subject to penny stock regulations and restrictions and you may have difficulty selling shares of our common stock.

Our 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.

Since our common stock will be 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.

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 offices are rented under a six-year lease for approximately 9,605 square feet of space at a current rental of $10,181 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. In the opinion of management of the Company, adequate provision has been made in the Company's condensed financial statements at December 31, 2017 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 is owed approximately $192,000 for services rendered. The Company has disputed this demand and attempts to resolve this matter were unsuccessful. On January 29, 2018, the Company filed a lawsuit against the consultant and its related entities in the United States District Court for the Southern District of California (Case No. 18CV200-W-KSC) seeking declaratory relief regarding advisory fees and ownership interest in the Company. The Company cannot predict the outcome of this matter.

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 our shares of common stock. We intend to seek a listing of our common stock on a national securities exchange, however, we cannot assure you that our application will be approved or be certain of the timing for commencement of trading.

Dividend Policy

Guardion Health Sciences, Inc. has not declared nor paid any cash dividend on its common stock, and the Company currently intends to retain future earnings, if any, to finance the expansion of its business. The Company does not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on the Company's common stock will be made by the Board of Directors, in their discretion, and will depend on the Company's financial condition, results of operations, capital requirements, general business conditions and other factors that the 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 on Form 10-K, 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 our audited financial statements and the related notes that appear elsewhere in this report. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this Annual Report, and other factors that we may not know.

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 we subsequently changed our name to Guardion Health Sciences, LLC. On June 30, 2015, we converted from a California limited liability company to a Delaware corporation, changing our name to Guardion Health Sciences, Inc.

We are 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. Additional research has also shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's and dementia. We have had limited commercial operations to date, and have primarily been engaged in research, development, commercialization and capital raising.

We have also developed a proprietary medical device called the MapcatSF® that accurately measures the macular pigment optical density ("MPOD"). We invented our own proprietary patented technology embodied in the MapcatSF. On November 8, 2016, the 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 is designed to accurately measure 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 intended to be the first device using a patented "single fixation" process and "automatic lens density correction" that produces accurate serialized data.

Lumega-Z has a patent-pending formula that replenishes and restores the macular protective pigment simultaneously delivering critical and essential nutrients to the eye. Formulated by Dr. Sheldon Hendler in 2010, modifications were made over a two-year period to improve the taste and method of delivery. We believe 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. We believe that medical foods will continue to grow in importance over the coming years.

By combining our MapcatSF medical device and Lumega-Z medical food, we have developed, based on Management's knowledge of the industry, what we believe to be the only reliable two-pronged, evidence-based protocol for replenishing and restoring the macular protective pigment and increasing overall retinal health.

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 our technical portfolio and we believe it further establishes our position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

Recent Developments

Sale of Common Stock and Conversion of Preferred Stock into Common Stock

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 4,347,827 shares of common stock, par value $0.001 per share, at a purchase price of $1.15 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.

The completion of the private placement triggered, at the Company's election, the automatic conversion of the 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 preferred stock into 6,981,938 shares of common stock (excluding accrued but unpaid dividends) effective November 3, 2017. The Company issued 205,242 shares of common stock for the accrued but unpaid dividends from October 1, 2017 through November 3, 2017, representing the payment in full of all Preferred Stock dividend obligations.

Development of Sales Force

The Company is investing in a direct sales force comprised 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 will have responsibility for a pre-defined geographical area, and will be expected to travel extensively to support the needs of customers. The account managers will be 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 will also participate in national and regional trade shows and events, including supporting professional optometric and ophthalmological societies at a State level. Each account manager will be tasked with a quota that includes units of Lumega-Z sold, as well as sales of the MapcatSF, CSV-1000 and ESV-3000. Commissions will be paid based on performance and achievement of quota. Training of the direct sales force is expected to commence in March 2018.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern. The Company has utilized cash in operating activities of $3,403,696 and $1,653,574 during the years ended December 31, 2017 and 2016, respectively, and had a total accumulated deficit of $26,865,956 and $20,650,207 as of December 31, 2017 and 2016, respectively. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are issued.

The Company's auditors have also included explanatory language in their opinion that there is substantial doubt about the Company's ability to continue as a going concern. 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.

We will continue to incur significant expenses for commercialization activities related to our lead product Lumega-Z, the MapcatSF medical device, and with respect to efforts to build our infrastructure. Development and commercialization of medical foods and medical devices involves a lengthy and complex process. Additionally, our long-term viability and growth may depend upon the successful development and commercialization of products other than Lumega-Z and the MapcatSF. We are continuing attempts to raise additional debt and/or equity capital to fund future operations, but there can be no assurances that we will be able to secure such additional financing in the amounts necessary to fully fund our operating requirements on acceptable terms or at all. If we are unable to access sufficient capital resources on a timely basis, we may be forced to reduce or discontinue our technology and product development programs and curtail or cease operations.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB's Exposure Draft Update issued on April 29, 2015, and approved in July 2015, Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date, ASU 2014-09 is now effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The adoption of ASU 2014-09 is not expected to have any impact on our financial statement presentation or disclosures.

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 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation or disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (ASU 2016-09), Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. The adoption of ASU 2016-09 has not had any impact on the Company's financial statement presentation or disclosures.

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.

Concentration of Risk

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

Critical Accounting Policies and Estimates

Our financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of the 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. Our 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 consolidated financial statements.

Intangible Assets

In connection with our acquisition of VectorVision, Inc., we 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, we determined whether these assets are expected to have indefinite (such as goodwill) or limited useful lives, and for those with limited lives, we established an amortization period and method of amortization. Our goodwill and other intangible assets are subject to periodic impairment testing.

We utilized the services of an independent third party valuation firm to assist us in identifying intangible assets and in estimating their fair values. The useful lives for our 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.

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 consumers both in the U.S. and internationally. Revenue is recognized when the risk of loss transfers to our customers, and collection of the receivable is reasonably assured, which generally occurs when the product is 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. Product returns for the years ended December 31, 2017 and 2016 were insignificant.

Research and Development

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 $259,463 and $33,084 for the years ended December 31, 2017 and 2016, respectively.

Patent Costs

The Company is the owner of one issued domestic patent, three pending domestic patent applications, 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, 2017 and 2016, patent costs were $30,789 and $30,942, respectively, and are included in general and administrative costs in the statements of operations.

Convertible Notes Payable

When conventional convertible debt is issued with detachable warrants, the proceeds from issuance are allocated to the two instruments based on their relative fair values. This method is generally appropriate if debt is issued with any other freestanding instrument that is classified in equity.

When the convertible debt instrument includes both detachable instruments such as warrants, and a beneficial conversion option, the proceeds of issuance are allocated among the convertible instrument and the other detachable instruments based on their relative fair values as indicated above, and the amount allocated to the convertible instrument is further analyzed to determine if the embedded conversion option has intrinsic value. If the conversion features of conventional convertible debt provide for a rate of conversion that is below market value, then the conversion option has intrinsic value and this feature is characterized as a beneficial conversion feature ("BCF"). We calculate an effective conversion price based on the fair value allocated to the convertible instrument divided by the number of conversion shares based upon the conversion terms of the instrument. The resulting calculation or effective conversion price is used to measure the intrinsic value, if any, of the embedded conversion option. Stated differently, intrinsic value is calculated at the commitment date as the difference between the conversion price (effective or otherwise) and the fair value of the common stock or other securities into which the security is convertible, multiplied by the number of shares into which the security is convertible.

If the intrinsic value of the BCF is greater than the proceeds allocated to the convertible instrument, the amount of the discount assigned to the BCF is limited to the amount of the proceeds allocated to the convertible instrument. We record a BCF as a debt discount and in those circumstances, the convertible debt will be recorded net of the discount related to the BCF. The Company amortizes the discount to interest expense over the life of the debt using the effective interest rate method or the straight-line method, as an approximation of effective interest amortization.

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 and directors, and to 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 on a straight-line 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 or unit 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 or units over the price paid for the stock or units.

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, 2017, 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, we intend to increase our commercialization activities and:

- further the commercial production of our MapcatSF, starting with the manufacture of at least ten new units for sale or lease to our customers and for use in our internal clinics;
- expand our domestic sales and marketing efforts, which include revamping our web site and 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; and
- increase our focus on intellectual property protection and strategy;
- Expand the sales and marketing of our VectorVision product line.
- 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. We are in discussions with our 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, we expect to complete applicable IEC 60601-1 testing prior to commercialization as we believe in marketing a product that has evidence that it is safe and effective.

Results of Operations

Through December 31, 2017, we had limited operations and have primarily been engaged in research, development, commercialization and raising capital. We have incurred and will continue to incur significant expenditures for the development of our products and intellectual property, which includes research and development of both medical foods and medical diagnostic equipment for the treatment of various eye diseases. We had limited revenue during the years ended December 31, 2017 and 2016. Beginning in the fourth quarter of 2017, we recognized product revenue from the sale of VectorVision products in addition to sales of our proprietary product, Lumega-Z.

Comparison of Years Ended December 31, 2017 and 2016

	Year Ended December 31,		Change	
	2017	2016		
Revenue	$ 437,349	$ 141,029	$ 296,320	210%
Cost of goods sold	175,470	75,702	99,768	132%
Gross Profit	261,879	65,327	196,552	301%
Operating Expenses:				
Research and development	259,463	33,084	226,379	684%
Sales and marketing	599,926	389,111	210,815	54%
General and administrative	4,683,932	3,339,086	1,344,846	40%
Loss on settlement of promissory notes and accounts payable	-	249,739	(249,739)	(100)%
Total Operating Expenses	5,543,321	4,011,020	1,532,301	38%
Loss from Operations	(5,281,442)	(3,945,693)	(1,335,749)	34%
Other Expense:				
Interest expense	23,727	1,104,557	(1,080,830)	(98)%
Change in fair value of note	-	698,147	(698,147)	(100)%
Net Loss	$ (5,305,169)	$ (5,748,397)	$ 443,228	(8)%

Revenue

For the year ended December 31, 2017, revenue from product sales was $437,349 compared to $141,029 for the year ended December 31, 2016, reflecting an increase of $296,320 or 210%. The increase reflects both an increased customer base for Lumega-Z as we expand into new clinics and fourth quarter 2017 sales of VectorVision products. Approximately 44% of 2017 revenue was generated by sales of VectorVision products.

Cost of Goods Sold

For the year ended December 31, 2017, cost of goods sold was $175,470 compared to $75,702 for the year ended December 31, 2016, reflecting an increase of $99,768 or 132%. Cost of goods sold was 40% of revenue for the year ended December 31, 2017 compared to 54% of revenue for the year ended December 31, 2016. The increase in cost of sales is due to the rise in Lumega-Z customers as well as the inclusion in 2017 of VectorVision sales.

Research and Development

For the year ended December 31, 2017, research and development costs were $259,463 compared to $33,084 for the year ended December 31, 2016. The increase in research and development costs of $226,379 or 684% compared to the prior year was due primarily to development costs for our MapcatSF device.

Sales and Marketing

For the year ended December 31, 2017, sales and marketing expenses were $599,926 compared to $389,111 for the year ended December 31, 2016. The increase in sales and marketing expenses of $210,815 or 54% compared to the prior year was due primarily to an increase of approximately $178,000 in consulting, marketing and promotional costs.

General and Administrative

For the year ended December 31, 2017, general and administrative expenses were $4,683,932 compared to $3,339,086 for the year ended December 31, 2016. The increase in general and administrative expenses of $1,344,846 or 40% compared to the prior year was primarily due to a $645,000 increase in legal, professional, and travel costs as well as an increase in non-cash stock compensation of $282,000.

Loss on Settlement of Promissory Notes and Accounts Payable

In December 2016, the Company issued 535,154 shares of preferred stock valued at $784,888 upon the voluntary conversion of $535,149 of outstanding principal and interest. The Company recognized a loss on settlement of the promissory notes of $249,739.

Interest Expense

For the year ended December 31, 2017, interest expense was $23,727 compared to $1,104,557 for the year ended December 31, 2016. The decrease in interest expense of $1,080,830 or 98% compared to the prior year was due to the repayment or conversion of the majority of promissory notes and convertible debt that had been outstanding during 2016.

Change in Fair Value of Note

In May 2015, the Company issued a convertible note in the principal amount of $500,000, with interest at 5% per year, and a two-year maturity. This note was fully converted into 1,408,854 shares of common stock in December 2016. As a result of the conversion, a $698,147 change in fair value was recorded.

Net Loss

For the year ended December 31, 2017, the Company incurred a net loss of $5,305,169, compared to a net loss of $5,748,397 for the year ended December 31, 2016. The decrease in net loss of $443,228 or 8% compared to the prior year period was primarily due to the reduction of $1,080,830 in interest expense related to promissory notes and convertible debt that were repaid or converted in late 2016. This reduction was partially offset by increased legal, professional, and travel costs of $645,000 in the current year.

Liquidity and Capital Resources

Since our formation in 2009, we have devoted substantial effort and capital resources to the development and commercialization activities related to our lead product Lumega-Z and our MapcatSF medical device as well as to numerous corporate activities, including the acquisition of VectorVision. As a result of our activities we utilized cash in operating activities of $3,403,696 and $1,653,574 during the years ended December 31, 2017 and 2016, respectively. We had positive working capital of $4,579,948 at December 31, 2017 and negative working capital of $470,064 at December 31, 2016. As of December 31, 2017, we had cash in the amount of $4,735,230 and no available borrowings. Our financing has historically come from the issuance of convertible notes, promissory notes and from the sale of common and preferred stock and exercise of warrants. Some of our notes have remained outstanding beyond their stated maturity dates, resulting in additional interest charges due upon settlement.

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 consolidated financial statements are issued.

The Company’s auditors have also included explanatory language in their opinion that there is substantial doubt about the Company’s ability to continue as a going concern. 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.

We 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, our long-term viability and growth will 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 ultimately curtail or cease operations.

Sources and Uses of Cash

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

	Year Ended December 31,	
	2017	**2016**
Net cash used in operating activities	$ (3,403,696)	$ (1,653,574)
Net cash used in investing activities	(32,385)	(3,354)
Net cash provided by financing activities	8,108,791	1,705,598
Net increase in cash	$ 4,672,710	$ 48,670

Operating Activities

Net cash used in operating activities was $3,403,696 during the year ended December 31, 2017, versus $1,653,574 used during the year ended December 31, 2016. The increase in 2017 was due primarily to higher sales, marketing, travel, and legal costs, in addition to paydown of our accrued rent liability and the buildup of inventory stock.

Investing Activities

Net cash used in investing activities was $32,385 for the year ended December 31, 2017 and $3,354 for the year ended December 31, 2016, and consisted primarily of investments in property and equipment for both years.

Financing Activities

Net cash provided by financing activities was $8,108,791 for the year ended December 31, 2017. Financing activities for the 2017 period provided proceeds of $5,000,001 from the issuance of common stock, $3,105,000 in proceeds from the issuance of preferred stock, proceeds of $100,000 from the issuance of a note payable, payments of $150,860 on notes payable, and $54,650 in amounts due to related parties on a net basis.

Net cash provided by financing activities was $1,705,598 the year ended December 31, 2016. Financing activities for the 2016 period provided proceeds of $136,000 from the issuance of convertible notes payable, $360,000 in short-term loans partially offset by payments on those loans of $151,000, $1,145,000 in proceeds from the issuance of preferred stock, and $215,598 in amounts due to related parties on a net basis.

Principal Commitments

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2017:

		Payments Due by Year				
	Total	**2018**	**2019**	**2020**	**2021**	**2022**
Operating lease commitments	$ 184,262	$ 93,000	$ 20,898	$ 21,520	$ 22,174	$ 26,670

Off-Balance Sheet Arrangements

At December 31, 2017 and 2016, 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.

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, 2017.

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.

(b) 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 our current executive officers and directors based on information furnished to us by each executive officer and director. Each of the directors listed below was elected to our Board of Directors to serve until our next annual meeting of stockholders or until his or her successor is elected and qualified. 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 our Board of Directors and our executive officers:

Name	Age	Position
Michael Favish	69	President, Chief Executive Officer and Chairman of the Board of Directors
Robert Weingarten	65	Director
Mark Goldstone	54	Director
David W. Evans	61	Director
John Townsend	56	Controller, Chief Accounting Officer
Vincent J. Roth	50	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 we believe 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. We believe 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. 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 we believe qualifies him to serve on our Board of Directors. 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 our 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. We believe 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.

David W. Evans has been a Director since September 2017. Dr. Evans is the founder of VectorVision, and was appointed to the Company's Board of Directors on September 29, 2017, the closing of the VectorVision acquisition. 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. Dr. Evans also serves as a consultant to the Company to further the Company's planned development and commercialization of its portfolio of products.

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 17 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 (formerly StatRad, LLC), a medical device and teleradiology company for the last eight years. Mr. Roth has also worked as a partner at InnovaCounsel, LLP providing general counsel services to clients for the last eight years. 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

Our 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

We have directors' and officers' liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures us against losses, which we may incur in indemnifying our officers and directors. In addition, officers and directors also have indemnification rights under applicable laws, and our 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

The following table sets forth the total compensation paid or accrued during the fiscal years ended December 31, 2017 and 2016 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, 2017 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)	2017	$ 250,000	$ -	$ -	$ -	$ 250,000
	2016	$ 250,000	$ -	$ 4,500	$ -	$ 254,500
Gordon Bethwaite (2)	2017	$ 208,800	$ 15,000	$ -	$ -	$ 223,800
	2016	$ 208,800	$ -	$ 1,800	$ -	$ 210,600
John Townsend (3)	2017	$ 144,000	$ 10,000	$ 9,000	$ -	$ 163,000
	2016	$ 68,000	$ -	$ 450	$ -	$ 68,450

(1) Michael Favish has been the Company's CEO since inception. He does not have a written agreement with the Company. Mr. Favish received 5,500,000 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 5,500,000 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 2016 and $250,000 in fiscal year 2017. Mr. Favish was awarded a stock grant on December 31, 2016 for services rendered for 50,000 shares of the Company's common stock valued at $0.09 per share. Mr. Favish was engaged with a formal employment agreement in 2018.

(2) Gordon Bethwaite was awarded a stock grant on October 1, 2015 for 250,000 shares of the Company's common stock valued at $0.01 per share as an inducement to engage as the Company's Vice President of Sales and Marketing and to compensate Mr. Bethwaite for work to be performed. These shares reverse vest quarterly over the first year, with the first quarter vested on January 1, 2016. Mr. Bethwaite officially began his engagement as Vice President of Sales and Marketing on January 1, 2016 with an annualized compensation of $208,800. Mr. Bethwaite was awarded a stock grant on December 31, 2016 for services rendered for 20,000 shares of the Company's common stock valued at $0.09 per share. Mr. Bethwaite was engaged with a formal employment agreement in 2018. Mr. Bethwaite resigned from his position with the Company effective February 26, 2018.

(3) 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 5,000 shares of the Company's common stock valued at $0.09 per share. Mr. Townsend also received a stock grant in August 2017 for services rendered for 100,000 shares of the Company's common stock valued at $0.09 per share. Mr. Townsend was engaged with a formal employment agreement in 2018.

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, 2017.

Director Compensation

The Company awarded stock grants to its directors as compensation for serving in such capacity, as show in the table below.

Director	Year	Stock Awards
Mark Goldstone	2017	$ -
	2016	$ 4,500
Robert Weingarten	2017	$ -
	2016	$ 4,500
David W. Evans	2017	$ -
	2016	$ -

Mr. Goldstone and Mr. Weingarten have been Directors of the Company since June, 2015. Each Director was awarded a stock grant on December 31, 2016 for services rendered for 50,000 fully vested shares of the Company's common stock valued at $0.09 per share.

Mr. Evans was appointed as a director on September 29, 2017. 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 for the first six months of the term of the Consulting Agreement and $7,500 per month for the remainder of the term of the Consulting Agreement.

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 23, 2018 (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 40,329,475 shares of common stock issued and outstanding as of February 23, 2018. 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 23, 2018 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 40,329,475 shares of common stock outstanding at February 23, 2018, 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 23, 2018. 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)]	6,494,933	16.10%
Robert N. Weingarten, Director	1,300,000	3.22%
Mark Goldstone, Director	1,050,000	2.60%
David Evans, Director [(b)]	3,050,000	7.56%
John Townsend, Chief Accounting Officer and Controller	105,000	0.26%
Vincent J. Roth, General Counsel and Corporate Secretary	265,000	0.66%
All Officers and Directors as a Group (6 persons) [(c)]	12,264,933	30.41%
5% Shareholders:		
Leon Krajian [(d)]	3,668,458	8.85%
Digital Grid (Hong Kong) Technology Co., Limited [(e)]	4,347,827	10.78%
Christopher Scangas [(f)]	2,608,489	6.46%
Edward Grier	2,158,178	5.31%

(a) Includes 260,000 shares held by Mr. Favish's spouse.

(b) Includes 3,050,000 shares of common stock of the Company held in the name of VectorVision, Inc. issued on September 29, 2017 (the "Closing Date"). 250,000 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 231,974 shares held in the name of Equity Trust Company Custodian FBO Leon S. Krajian IRA; 146,000 shares that may be purchased pursuant to an exercisable warrant issued to Equity Trust Company Custodian FBO Leon S. Krajian IRA that is vested and expires May 1, 2018; 1,135,000 shares that may be purchased pursuant to exercisable warrants issued to Leon Krajian that are vested and expire at various dates between September 30, 2018 and December 31, 2019; and 518,092 shares of common stock owned by Mr. Krajian.

(e) Includes 1,304,348 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 2,075,753 shares held in the name of Cynthia Elaine Trust dated December 12, 2014; 138,750 shares held in the name of Cynthia Elaine Scangas Dated June 12 2002-IRA rollover, BNY Mellon Trustee; 363,986 shares held in the name of Jason Scangas, the son of Christopher Scangas, for whom Christopher Scangas holds Power of Attorney; and 30,000 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 3,050,000 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 for the first six months of the term of the Consulting Agreement and $7,500 per month for the remainder of the term of the Consulting Agreement.

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, 2017 and 2016, the Company had $146,133 and $91,483, respectively, due to related parties.

During the twelve months ended December 31, 2017, the Company incurred $250,000 of salary expense and paid $170,000 in salary to our CEO, Michael Favish. During the twelve-month period ended December 31, 2016, the Company incurred salary expense of $250,000 and paid $48,500 in salary to Mr. Favish. Accrued amounts are included in general and administrative expenses.

On April 10, 2017, the Company awarded a stock grant of 100,000 shares to John Townsend, our Controller and Chief Accounting Officer. These shares were fully vested upon issuance. The Company recorded $75,000 of stock-based compensation as a result of the award.

On December 31, 2016, the Company issued 684,933 shares of common stock, converted at $0.60 per share, to our CEO, Michael Favish, in settlement of $410,960 of previously accrued management and other fees earned by Mr. Favish from 2013 through 2016. The difference of $191,781 between the fair value of the shares issued and accrued fees was reflected as additional compensation in general and administrative expenses.

On December 31, 2016, the Company awarded stock grants to its management and directors as compensation for services rendered. This included 50,000 shares each to Michael Favish, our CEO, Mark Goldstone, a Director, and Robert Weingarten, a Director. 20,000 shares were awarded to Gordon Bethwaite, our former Vice President of Sales and Marketing, 15,000 shares were awarded to Vincent J. Roth, our General Counsel and Corporate Secretary and 5,000 shares were awarded to John Townsend, our Controller. All of these shares were fully vested on December 31, 2016. The Company recorded $162,800 of stock-based compensation as a result of these awards.

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, 2017 and 2016 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, 2017 and 2016.

	Year Ended December 31,	
	2017	**2016**
Audit Fees [(a)]	$ 129,834	$ 84,426
Tax Fees [(b)]	2,960	37,350
Other Fees [(c)]	19,758	19,073
Total	$ 152,552	$ 140,849

(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, 2017 and 2016, 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, 2017 and 2016, 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.

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, and 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.

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.

/s/ Weinberg & Company, P.A.

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

Los Angeles, California
February 27, 2018

Guardion Health Sciences, Inc.

Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash	$ 4,735,230	$ 62,520
Accounts receivable	72,771	1,673
Inventories	154,730	43,999
Current portion of deposits and prepaid expenses	117,164	29,363
Total current assets	**5,079,895**	**137,555**
Deposits and prepaid expenses, less current portion	10,470	10,470
Property and equipment, net	95,597	114,020
Intangible assets, net of accumulated amortization of $53,659	620,741	-
Goodwill	1,563,520	-
Total assets	**$ 7,370,223**	**$ 262,045**
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities		
Accounts payable and accrued liabilities	$ 311,236	$ 356,467
Accrued expenses and deferred lease costs	12,043	88,290
Line of credit	30,535	-
Due to related parties	146,133	91,483
Convertible notes payable	-	44,323
Promissory notes payable	-	10,251
Promissory notes payable related party	-	16,805
Total current liabilities	**499,947**	**607,619**
Commitments and contingencies		
Stockholders' Equity (Deficiency)		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 and 1,705,154 shares issued and outstanding at December 31, 2017 and December 31, 2016	-	1,705
Common stock, $0.001 par value; 90,000,000 shares authorized; 40,183,475 and 24,683,966 shares issued and outstanding at December 31, 2017 and December 31, 2016	40,183	24,684
Additional paid-in capital	33,696,049	20,278,244
Accumulated deficit	(26,865,956)	(20,650,207)
Total stockholders' equity (deficiency)	**6,870,276**	**(345,574)**
Total liabilities and stockholders' equity (deficiency)	**$ 7,370,223**	**$ 262,045**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Operations

	Years Ended December 31,	
	2017	**2016**
Revenue	$ 437,349	$ 141,029
Cost of goods sold	175,470	75,702
Gross profit	261,879	65,327
Operating expenses		
Research and development	259,463	33,084
Sales and marketing	599,926	389,111
General and administrative	4,683,932	3,339,086
Loss on settlement of promissory notes and accounts payable	-	249,739
Total operating expenses	5,543,321	4,011,020
Loss from operations	(5,281,442)	(3,945,693)
Other expenses:		
Interest expense and financing costs	23,727	1,104,557
Change in fair value of note	-	698,147
Total other expenses	23,727	1,802,704
Net loss	(5,305,169)	(5,748,397)
Adjustments related to Series A 8% convertible preferred stock:		
Accretion of deemed dividend	(601,952)	(760,011)
Dividend declared	(308,628)	(35,018)
Net loss attributable to common shareholders	**$ (6,215,749)**	**$ (6,543,426)**
Net loss per common share – basic and diluted	$ (0.22)	$ (0.30)
Weighted average common shares outstanding – basic and diluted	27,868,353	21,800,719

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, 2015	-	$ -	-	$ -	21,548,924	$ 21,549	$ 12,857,682	$ (14,106,781)	$ (1,227,550)
Issuance of common stock for services	-	-	-	-	740,000	740	1,424,944	-	1,425,684
Fair value of warrants issued for services	-	-	-	-	-	-	344,846	-	344,846
Fair value of post-maturity warrants issued as additional interest on notes payable	-	-	-	-	-	-	575,673	-	575,673
Issuance of common stock – conversion of accrued management fees	-	-	-	-	684,933	685	602,056	-	602,741
Issuance of preferred stock	1,170,000	1,170	-	-	-	-	1,168,830	-	1,170,000
Fair value of preferred stock – conversion of notes payable and related interest	535,154	535	-	-	-	-	784,353	-	784,888
Fair value of common stock – conversion of notes payable and related interest	-	-	-	-	1,651,732	1,652	1,383,864	-	1,385,516
Fair value of warrants issued with convertible notes payable	-	-	-	-	-	-	270,076	-	270,076
Issuance of convertible notes payable – beneficial conversion feature	-	-	-	-	-	-	70,949	-	70,949
Accretion of beneficial conversion feature on preferred stock	-	-	-	-	-	-	760,011	(760,011)	-
Dividend on preferred stock	-	-	-	-	58,377	58	34,960	(35,018)	-
Net loss	-	-	-	-	-	-	-	(5,748,397)	(5,748,397)
Balance at December 31, 2016	1,705,154	1,705	-	-	24,683,966	24,684	20,278,244	(20,650,207)	(345,574)
Fair value of common stock issued for acquisition	-	-	-	-	3,050,000	3,050	2,284,450	-	2,287,500
Issuance of common stock for services	-	-	-	-	649,300	649	657,142	-	657,791
Sale of common stock	-	-	-	-	4,347,827	4,348	4,995,653	-	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)	6,981,938	6,982	(2,172)	-	-
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	-	-	-	-	18,082	18	13,182	-	13,200
Accretion of beneficial conversion feature on preferred stock	-	-	-	-	-	-	601,952	(601,952)	-
Dividend on preferred stock	-	-	-	-	452,362	452	308,176	(308,628)	-
Net loss	-	-	-	-	-	-	-	(5,305,169)	(5,305,169)
Balance at December 31, 2017	-	$ -	-	$ -	40,183,475	$ 40,183	$ 33,696,049	$ (26,865,956)	$ 6,870,276

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2017	**2016**
Operating Activities		
Net loss	$ (5,305,169)	$ (5,748,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	118,821	60,129
Amortization of debt discount	-	431,681
Change in fair value of note	-	698,147
Accrued interest expense included in notes payable	(8,818)	86,711
Fair value of warrants issued as post-maturity interest	-	575,673
Stock-based compensation	1,932,268	787,684
Stock-based compensation – related parties	183,051	982,846
Management fee compensation expense	-	191,781
Loss on settlement of promissory notes payable and accounts payable	-	249,739
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	(20,993)	(537)
Inventories	(17,439)	(13,436)
Deposits and prepaid expenses	(87,251)	14,587
Increase (decrease) in -		
Accounts payable and accrued expenses	(121,919)	84,605
Accrued and deferred rent costs	(76,247)	(54,787)
Net cash used in operating activities	(3,403,696)	(1,653,574)
Investing Activities		
Purchase of property and equipment	(37,280)	(3,354)
Cash assumed upon acquisition	4,895	-
Net cash used in investing activities	(32,385)	(3,354)
Financing Activities		
Proceeds from issuance of convertible notes payable	-	136,000
Proceeds from issuance of promissory notes – related party	-	140,000
Proceeds from issuance of promissory notes	100,000	220,000
Payments on promissory notes	(149,000)	(151,000)
Proceeds from issuance of preferred stock	3,105,000	1,145,000
Proceeds from issuance of common stock	5,000,001	-
Line of credit	(1,860)	-
Increase in due to related parties	54,650	215,598
Net cash provided by financing activities	8,108,791	1,705,598
Cash:		
Net increase	4,672,710	48,670
Balance at beginning of period	62,520	13,850
Balance at end of period	$ 4,735,230	$ 62,520
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$ 23,532	$ 385
Income taxes	$ -	$ -
Non-cash financing activities:		
Issuance of common stock dividends on preferred stock	$ 308,628	$ 35,018
Issuance of common stock upon conversion of accrued management fees	$ -	$ 410,960
Issuance of preferred stock upon conversion of notes payable and related interest	$ -	$ 535,149
Issuance of common stock upon conversion of notes payable and related interest	$ 13,562	$ 687,369
Fair value of warrants issued in connection with promissory and convertible notes payable	$ -	$ 270,075
Beneficial conversion feature associated with promissory and convertible notes payable	$ -	$ 70,949
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.

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 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 and dementia.

The Company recently acquired VectorVision, 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 of VectorVision expands our technical portfolio and we believe it further establishes our 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, and has primarily been engaged in research, development, commercialization, and capital raising.

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 $3,403,696 and $1,653,574 during the years ended December 31, 2017 and 2016, respectively, and had an accumulated deficit of $26,865,956 and $20,650,207 as of December 31, 2017 and 2016, respectively. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the consolidated financial statements are issued.

The Company's auditors have also included explanatory language in their opinion that there is substantial doubt about the Company's ability to continue as a going concern. 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.

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.

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, convertible notes payable and promissory notes approximates their carrying value given the interest rates of such notes.

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.

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, 2017 and 2016, no allowance for doubtful accounts and returns was recorded.

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.

Intangible Assets

In connection with our acquisition of VectorVision, Inc., we 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, we determined whether these assets are expected to have indefinite (such as goodwill) or limited useful lives, and for those with limited lives, we established an amortization period and method of amortization. Our goodwill and other intangible assets are subject to periodic impairment testing.

We utilized the services of an independent third party valuation firm to assist us in identifying intangible assets and in estimating their fair values. The useful lives for our 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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, identifiable intangible assets, and goodwill for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The Company has not historically recorded any impairment to its long-lived assets. In the future, if events or market conditions affect the estimated fair value to the extent that a long-lived asset is impaired, the Company will adjust the carrying value of these long-lived assets in the period in which the impairment occurs. As of December 31, 2017 and 2016, the Company had not deemed any long-lived assets as impaired, and was not aware of the existence of any indicators of impairment at such dates.

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 consumers both in the U.S. and internationally. Revenue is recognized when the risk of loss transfers to our customers, and collection of the receivable is reasonably assured, which generally occurs when the product is 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. Product returns for the years ended December 31, 2017 and 2016 were insignificant.

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 patent related costs and stock compensation expense, are expensed as incurred and totaled $259,463 and $33,084 for the years ended December 31, 2017 and 2016, respectively.

Patent Costs

The Company is the owner of one issued domestic patent, three pending domestic patent applications, 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, 2017 and 2016, patent costs were $30,789 and $30,942, respectively, and are included in general and administrative costs in the statements of operations.

Convertible Notes Payable

When conventional convertible debt is issued with detachable warrants, the proceeds from issuance are allocated to the two instruments based on their relative fair values. This method is generally appropriate if debt is issued with any other freestanding instrument that is classified in equity.

When the convertible debt instrument includes both detachable instruments such as warrants, and a beneficial conversion option, the proceeds of issuance are allocated among the convertible instrument and the other detachable instruments based on their relative fair values as indicated above, and the amount allocated to the convertible instrument is further analyzed to determine if the embedded conversion option has intrinsic value. If the conversion features of conventional convertible debt provide for a rate of conversion that is below market value, then the conversion option has intrinsic value and this feature is characterized as a beneficial conversion feature ("BCF"). The Company calculates an effective conversion price based on the fair value allocated to the convertible instrument divided by the number of conversion shares based upon the conversion terms of the instrument. The resulting calculation or effective conversion price is used to measure the intrinsic value, if any, of the embedded conversion option. Stated differently, intrinsic value is calculated at the commitment date as the difference between the conversion price (effective or otherwise) and the fair value of the common stock or other securities into which the security is convertible, multiplied by the number of shares into which the security is convertible.

If the intrinsic value of the BCF is greater than the proceeds allocated to the convertible instrument, the amount of the discount assigned to the BCF is limited to the amount of the proceeds allocated to the convertible instrument. A BCF is recorded by the Company as a debt discount and in those circumstances, the convertible debt will be recorded net of the discount related to the BCF. The Company amortizes the discount to interest expense over the life of the debt using the effective interest rate method or the straight-line method, as an approximation of effective interest amortization.

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 and directors, and to 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 based on a graded vesting schedule 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 common stock was determined based on management’s judgment. In order to assist management in calculating such fair value, we retained a third-party valuation firm in determining the value of our Company. The third-party valuation firm’s input was utilized in determining the related per unit or share valuations of our equity used during 2017 and 2016. Management used valuations of $1.00 per share in its fair value calculations for the periods between January 1, 2015 and September 30, 2016, and $0.88 per share for periods between October 1, 2016 and 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 $0.88 and $1.00 share values used during 2017 and 2016, respectively. This methodology used multiple years of balance sheet and income statement projections along with the following primary assumptions:

	Year Ended December 31,	
	2017	**2016**
Discount rate	16%	16%
Risk-free rate	2.48%	2.27%
Rate of return	16%	16%
Sustainable growth rate	5%	5%
Company survival probability	65%	63%
Liquidation value	$ 0	$ 0

Due to the availability of historical data from the Company’s recent preferred and common stock sales, Management used a valuation of $0.75 for accounting purposes during the third quarter of 2017 and $1.15 during the fourth quarter of 2017. Management considered business and market factors affecting the Company during the twelve-month periods ended December 31, 2017 and 2016, including capital raising efforts, its proprietary technology, and other factors. Based on this evaluation, management believes that $1.15 and $0.88 per share valuations are appropriate for accounting purposes at December 31, 2017 and 2016.

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.

During the years ended December 31, 2017 and 2016, we recognized aggregate stock-compensation expense of $2,115,346 and $1,962,311, respectively, based upon stock prices ranging from $0.88 to $1.25 per share, of which $2,094,360 and $1,811,990 was recorded in general and administrative expense, $20,357 and $145,214 was recorded in sales and marketing expense, and $628 and $5,107 was recorded in research and development expense, respectively.

Segment Information

The Company operates and manages its business as one reporting and operating segment, which is 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, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

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, 2017 and 2016 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, 2017, 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,	
	2017	**2016**
Warrants	2,983,666	2,923,666
Options	950,000	-
Shares issuable upon conversion of convertible preferred stock	-	2,841,930
	3,933,666	5,765,596

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB's Exposure Draft Update issued on April 29, 2015, and approved in July 2015, Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date, ASU 2014-09 is now effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The adoption of ASU 2014-09 is not expected to have any impact on the Company's financial statement presentation or disclosures.

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 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation or disclosures.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (ASU 2016-09), Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. The adoption of ASU 2016-09 has not had any impact on the Company's financial statement presentation or disclosures.

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. Inventories

Inventories consisted of the following:

	December 31,	
	2017	2016
Raw materials	$ 133,354	$ 40,679
Finished goods	21,376	3,320
	$ 154,730	$ 43,999

4. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2017	2016
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	150,603	145,503
Furniture and fixtures	50,300	15,348
Computer equipment	16,464	15,277
Office equipment	8,193	2,694
	323,917	277,179
Less accumulated depreciation and amortization	(228,320)	(163,159)
	$ 95,597	$ 114,020

For the years ended December 31, 2017 and 2016, depreciation and amortization expense was $65,161 and $60,129, respectively, of which $29,574 and $27,490 was included in research and development expense, respectively, and $35,587 and $32,639 was included in general and administrative expense, respectively.

5. Convertible Notes Payable

	December 31,	
	2017	2016
Year of issuance:		
2010	$ -	$ 25,000
Accrued interest	-	19,323
Convertible notes payable	**$ -**	**$ 44,323**

2016 and Prior Issuances

In July 2010, the Company issued an unsecured convertible note payable in the amount of $25,000. The note carries simple interest at a rate of 12% per annum and became due and payable on August 1, 2013. The outstanding amounts are convertible into shares of common stock of the Company at conversion prices of $0.08 per share. This note is currently outstanding and past due, and $19,323 of accrued interest is recorded as of December 31, 2016.

In May 2015, the Company issued a convertible note in the principal amount of $500,000, with interest at 5% per year, and a two-year maturity. On December 31, 2016, the $500,000 note and related accrued interest of $41,644 was converted into 1,408,854 shares of common stock with a fair value of $1,239,792. Pursuant to ASC 480-10-25-14(b), the Company determined that the note is a conditional obligation to issue a variable number of shares with a monetary value that varies based on something other than the fair value of the shares, and is appropriately recorded as a liability under ASC 480-10. Per ASC 480-10-30, obligations to issue a variable number of shares should be measured subsequently at fair value with changes in fair value recognized in earnings, unless other GAAP specifies another measurement attribute. Due to the terms of the note, at issuance in May 2015 it was not practicable to determine a relative fair value for the conversion feature at that time. On December 27, 2016, a conversion event occurred when the Company's Form S-1 was declared effective by the SEC. On December 31, 2016, the holder converted a total of $500,000 note principal and accrued interest of $41,644, into 1,408,854 shares of common stock. At December 31, 2016, the Company had an outside valuation firm determine that the market price of the Company's stock was $0.88 per share. The fair value of the note principal and accrued interest was $1,239,792 as evidenced by the fair value of shares received upon conversion. Accordingly, at December 31, 2016, the Company recorded a change in fair value expense of $698,147.

6. Promissory Notes

	December 31,	
	2017	**2016**
Year of issuance:		
2016	$ -	$ 10,000
Accrued interest	-	251
Promissory notes payable, net	**$ -**	**$ 10,251**

In 2016, the Company issued $170,000 of promissory notes to various outside investors, with simple interest rates ranging from 4% - 9% and a weighted average term at issuance of approximately three months. As of December 31, 2016, a $10,000 note remained outstanding and was past due. The note was repaid in July 2017 along with the associated $449 of accrued interest.

In January 2017, the Company issued a $100,000 unsecured promissory note to an outside investor, with a term of 120 days and a fixed interest charge consisting of 6% of the principal in cash plus 6% interest per annum. The interest was payable in shares of common stock at a price of $0.75 per share, or 8,000 shares. The note was repaid in July 2017, and 18,082 shares of common stock were issued in settlement of $13,200 of accrued interest.

7. Promissory Notes – Related Party

	December 31,	
	2017	**2016**
Year of issuance:		
2016	$ -	$ 14,000
Accrued interest	-	2,805
Promissory notes payable – related party, net	$ -	**$ 16,805**

In 2016, the Company issued $140,000 of unsecured promissory notes to various related party investors, with interest rates ranging from 6% to 12% and a weighted average term at issuance of approximately four months. As of December 31, 2016 the remaining balance of the unpaid notes was $14,000, and this amount plus accrued interest was repaid during the first quarter of 2017.

8. 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 3,050,000 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 3,050,000 shares of common stock, 250,000 shares were held back as security for VectorVision's indemnification obligations to the Company and the remaining 2,800,000 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 preliminary 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 $0.75, 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, 2016 and had been included in the Company's consolidated statements of operations during the years ended December 31, 2017 and 2016:

	Year ended December 31,	
	2017	**2016**
Pro forma net revenues	$ 824,028	$ 372,487
Pro forma net loss attributable to common shareholders	$ (6,500,590)	$ (6,910,705)
Pro forma net loss per share	$ (0.21)	$ (0.28)

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. As of December 31, 2017, remaining average monthly lease payments were $10,387 through July 2018. Upon entering into the agreement, the Company paid a deposit of $47,449, of which $36,979 represented prepaid rent. As of December 31, 2017, $10,470 remained on deposit under the lease agreement.

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. As of December 31, 2017, remaining average monthly lease payments were $1,799 through February 2023.

As of December 31, 2017 and 2016, the Company had accrued and deferred rent payable for its office and warehouse facilities under its lease agreement in the aggregate of $1,650 and $88,290, respectively.

The approximate future minimum lease payments under non-cancelable operating leases at December 31, 2017 are as follows:

Years ending December 31,

2018	$ 93,000
2019	20,898
2020	21,520
2021	22,174
2022 and thereafter	26,670
	$ 184,262

Rent expense was $111,167 and $106,217 for the years ended December 31, 2017 and 2016, 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 condensed financial statements at December 31, 2017 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 is owed approximately $192,000 for services rendered. The Company has disputed this demand and attempts to resolve this matter were unsuccessful. On January 29, 2018, the Company filed a lawsuit against the consultant and its related entities in the United States District Court for the Southern District of California (Case No. 18CV200-W-KSC) seeking declaratory relief regarding advisory fees and ownership interest in the Company. The Company cannot predict the outcome of this matter and believes it has provide appropriate provision for any settlement of this matter as of December 31, 2017.

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 has a stated value of $1.00 per share and accrues an annual dividend at the rate of 8% of the stated value, calculated quarterly, to be paid in shares of common stock at the rate of $0.60 per share. Dividends are payable to holders of record quarterly, on the last business day of each calendar quarter, from the date of issuance, as may be declared by the Board of Directors, and are cumulative.

At the option of each holder, the Series A Preferred Stock (including accrued but unpaid dividends) may be converted into shares of the Company's common stock commencing January 1, 2017 at $0.60 per share. The Series A Preferred Stock (including accrued but unpaid dividends) shall automatically convert into shares of common stock in the event that the Company receives gross proceeds of at least $4,000,000 in one or more equity financing transactions subsequent to September 30, 2016, or if the ten (10) day Volume Weighted Average Price per share of common stock is $2.00 or more. If not converted by September 30, 2019, the Series A Preferred Stock (including accrued but unpaid dividends) shall automatically and mandatorily convert into shares of common stock at $0.60 per share. Such mandatory conversion shall be subject to either a registration statement having been filed with the Securities and Exchange Commission, including the common stock underlying the Series A Preferred Stock, and being in effect, or all shares of underlying common stock being saleable under Rule 144 pursuant to the Securities Act without regard to volume limitations.

The issuance of the 1,170,000 shares of Series A Preferred Stock gave rise to a beneficial conversion feature due to the stated conversion price of $0.60 per share being less than the market price of the shares of Series A Preferred Stock at the issuance date as determined by an independent third-party valuation firm. The Company accounted for the beneficial conversion features in accordance with ASC 470-20, Accounting for Debt with Conversion and Other Options. The Company calculated a total deemed dividend on the Series A Preferred Stock of $779,586 at December 31, 2016, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series A Preferred Stock exceeded the proceeds from such issuances on the date of issuance. The deemed dividend on the Series A Preferred Stock is accreted using the effective interest method from the respective issuance dates through the earliest conversion date of January 1, 2017. The accretion of the deemed dividend for the year ended December 31, 2016 was $760,011. The remaining balance of $19,575, representing the amount allocable to the January 1, 2017 earliest conversion date, was accreted in January 2017.

During the year ended December 31, 2017, the Company declared dividends of $114,736 on its Series A Preferred Stock payment of which was satisfied in full through the issuance of an aggregate of 191,227 shares of common stock. See below discussion of preferred stock conversion event that occurred on November 3, 2017.

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 has a stated value of $1.00 per share and accrues an annual dividend at the rate of 6% of the stated value, calculated quarterly, to be paid in shares of common stock at the rate of $0.75 per share. Certain purchasers of 300,000 shares of Series A preferred stock that previously purchased Series A preferred stock were issued in the aggregate warrants to acquire 60,000 shares of common stock at purchase price of $.75 per share. Series B Preferred Stock is convertible commencing December 31, 2017, or earlier upon the approval of the Board of Directors, by the holders thereof into common stock at a conversion rate of $0.75 per share. The stock is automatically convertible by the Company upon an equity financing of at least $5,000,000 subsequent to June 30, 2017, or in the event the Company's common stock is publicly traded for at least $2.00 per share for 10 consecutive trading days, or upon completion of a Major Transaction (as defined in the Certificate of Designation). Dividends are payable to holders of record quarterly, on the last business day of each calendar quarter, from the date of issuance, as may be declared by the Board of Directors, and are cumulative. Series B Preferred Stock is senior to all common stock and junior to the Series A Preferred Stock in terms of liquidation preferences. Sale of the Company's Series B Preferred Stock closed on July 31, 2017.

The issuance of the Series B Preferred Stock gave rise to a beneficial conversion feature due to the stated conversion price of $0.75 per share being less than the market price of the shares at the issuance date. In addition, 60,000 warrants were issued to purchasers of the Series B Preferred Stock who had previously participated in the 2016 Series A Preferred Stock offering. The Company accounted for the beneficial conversion feature, including an allocation of proceeds for the warrants on a relative fair value basis, in accordance with ASC 470-20, Accounting for Debt with Conversion and Other Options. The Company calculated a total deemed dividend on the Series B Preferred Stock of $582,377. The deemed dividend on the Series B Preferred Stock is accreted using the effective interest method from the respective issuance dates through the earliest conversion date of December 31, 2017. The accretion of the deemed dividend for the twelve months ended December 31, 2017 prior to the preferred stock conversion event (see below) was $414,293.

During the year ended December 31, 2017, the Company declared dividends of $193,892 on its Series B Preferred Stock which were satisfied in full through the issuance of an aggregate of 261,135 shares of common stock. See below discussion of preferred stock conversion event that occurred on November 3, 2017.

Both classes of preferred stock will vote with the common stock on an "as converted" basis and have standard anti-dilution rights, exclusive of price protection. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, no distribution shall be made to the holders of any shares of common stock of the Company unless, prior thereto, the holders of all classes of preferred stock shall have received out of the available assets of the Company, whether capital or surplus, an amount equal to 100% of the stated value, plus any accrued and unpaid dividends thereon. If the assets of the Company are insufficient to pay in full such amounts due the holders of the preferred stock, then the entire assets shall be distributed ratably among the holders of the preferred stock, first to holders of Series A Preferred Stock, then to holders of Series B Preferred Stock, in accordance with the respective preferences and amounts that would be payable on such shares of preferred stock if all amounts payable thereon were paid in full.

Preferred shareholders of both series have unlimited piggyback registration rights. Holders of a majority of the shares of preferred stock (based on the $1.00 stated value) outstanding shall have the right to one demand registration during the three (3) years following the effective date of the Company's registration statement under the Securities Exchange Act of 1934, so long as at least $500,000 of preferred stock was sold of that series, and at least $250,000 of the related class of preferred stock is still outstanding. This demand registration right and the piggyback registration rights will terminate when all shares of preferred stock have been converted into common stock.

Preferred Stock Conversion Event

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 4,347,827 shares of common stock (see below). The completion of the private placement triggered, at the Company's election, the automatic conversion of the 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 preferred stock into 6,981,938 shares of common stock (excluding accrued but unpaid dividends) effective November 3, 2017. The Company issued 205,242 shares of common stock for the accrued but unpaid dividends from October 1, 2017 through November 3, 2017, representing the payment in full of all Preferred Stock dividend obligations.

Common Stock

Sale of shares

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 4,347,827 shares of common stock, par value $0.001 per share, at a purchase price of $1.15 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 to service providers that vest over time. As of December 31, 2015, there were 1,007,500 of previously issued shares of restricted common stock to service providers valued at $833,680 that had not yet vested.

During 2016, the Company issued an additional 145,000 shares of restricted common stock for services rendered. These shares are subject to vesting requirements over 9 to 12 months and remain subject to forfeiture if vesting conditions are not met. The aggregate fair value of the stock was $145,438 based on a valuation per share of $1.00 on the date of grant. During 2016, the Company recorded $864,752 of expense related to the vested portion of restricted stock issued in 2015 and 2016. As of December 31, 2016, $113,754 was expected to be recorded in future periods related to the restricted stock.

During 2017, the Company issued an additional 162,500 shares of restricted common stock for services rendered. These shares are subject to vesting requirements over 6 months and remain subject to forfeiture if vesting conditions are not met. The aggregate fair value of the stock was $143,000 based on a valuation per share of $0.88 on the date of grant. During 2017, the Company recorded $256,754 expense related to the vested portion of restricted stock issued in 2017 and in prior periods. 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, 2015	1,007,500	$ 833,068	$ 1.14
Issued	145,000	145,438	1.00
Vested	(800,000)	(864,752)	1.12
Forfeited	-	-	-
Non-vested, December 31, 2016	352,500	113,754	1.13
Issued	162,500	143,000	0.88
Vested	(515,000)	(256,754)	1.05
Forfeited	-	-	-
Non-vested, December 31, 2017	-	$ -	$ -

Other issuances

During 2016, the Company also issued 595,000 fully vested shares of common stock for services rendered. During the year ended December 31, 2016, the Company recognized $560,932 in stock compensation expense related to these shares.

During 2017, the Company also issued 486,800 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.

On December 31, 2016, the Company issued 684,933 shares of common stock with a fair value of $602,741 to our CEO, Michael Favish, in settlement of $410,960 of previously accrued management and other fees earned by Mr. Favish from December 2013 through December 2016. The difference of $191,781 between the fair value of the shares issued and accrued fees was reflected as additional compensation expense in general and administrative expenses.

During 2016, the Company issued 1,651,732 shares of common stock with a fair value of $1,385,516 upon conversion of notes payable and accrued interest of $687,368 resulting in a loss on conversion of $698,147.

Share adjustment

In 2015, the Company issued 1,053,227 shares of common stock to a consultant pursuant to an agreement for the consultant to provide services to the Company. The number of shares to be issued were stated as a percentage of the total outstanding shares of the Company after the issuance. The Company later determined that the number of shares issued was incorrect and recalculated the number of shares according to the agreement. In December 2017, the Company corrected the error, issued the consultant 690,755 shares, and cancelled the issuance of the previous 1,053,227 shares. This has resulted in a 362,472 share reduction to the Company's total outstanding shares at December 31, 2017. The Company has retroactively adjusted the opening equity balances to reflect the share reduction as of December 31, 2015. Management considered the effect of the recalculation on previously issued financial statements and determined that its effect was not quantitatively or qualitatively material. The Company has filed a lawsuit against this consultant, as more fully described in footnote 9.

Warrants

During 2016, in connection with a related party investor's short-term loan agreements with maturity dates ranging from December 29, 2015 to April 24, 2016, the Company agreed to issue interest in the form of warrants (the "post-maturity warrants") in addition to the continued accrual of the stated interest (12%) on these loans, for which principal and accrued interest had not been paid as of December 31, 2016. The loans were originally issued with accompanying warrants at a rate of 2 warrants for each dollar of investment. Additional post-maturity warrants were granted monthly, beginning December 30, 2015, at the rate of 1/10 of the number of original warrant shares held, until the related loans and interest are paid in full. Post-maturity warrants have an exercise price of $0.25, are immediately vested, and are exercisable for a period of three years. Accordingly, as of December 31, 2016, the Company has granted 585,000 post-maturity warrants to this investor. The warrants were valued at $575,673, based upon the Black-Scholes option-pricing model, with a stock price of $1.00, average volatility of 118% and average risk-free interest rate of 1.01%. The Company recognized $575,673 of interest expense from this transaction.

In May 2016, the Company issued warrants to purchase 250,000 shares of its common stock, with an exercise price of $0.25 per share, as compensation for services rendered. The warrants were valued at $246,341, based upon the Black-Scholes option-pricing model, with a stock price of $1.00, volatility of 116% and a risk-free interest rate of 1.08%. The warrants are fully vested and non-forfeitable. The Company recognized $246,341 in stock compensation from this transaction, which was recorded in general and administrative expenses in the statement of operations.

In June 2016, the Company issued warrants to purchase 100,000 shares of its common stock, with an exercise price of $0.25 per share, as compensation for services rendered. The warrants were valued at $98,505, based upon the Black-Scholes option-pricing model, with a stock price of $1.00, volatility of 116% and a risk-free interest rate of 1.07%. The warrants are fully vested and non-forfeitable. The Company recognized $98,505 in stock compensation from this transaction, which was recorded in general and administrative expenses in the statement of operations.

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

	Shares
December 31, 2015	**1,335,166**
Granted	1,588,500
Forfeitures	-
Exercised	-
December 31, 2016	**2,923,666**
Granted	60,000
Forfeitures	-
Exercised	-
December 31, 2017, all exercisable	**2,983,666**

As of December 31, 2017, the Company had an aggregate of 2,983,666 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $0.37, weighted average remaining life of 0.9 years and aggregate intrinsic value of $1,293,512, based upon a stock valuation of $0.88 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

On September 30, 2017, the Company entered into a consulting agreement pursuant to which the Company issued a total of 1,250,000 common stock options. 650,000 of the options vested immediately and the remaining will vest ratably over the next twelve months on a quarterly basis. The options are non-qualified, have an exercise price of $1.00 per share, and will expire after 5 years. The options were valued in total at $934,804 based upon the Black-Scholes option-pricing model, with a stock price of $0.75, volatility of 123%, and an average risk-free rate of 1.63%. Based upon a graded vesting schedule, $878,818 has been recorded as stock compensation in the Company's condensed consolidated statement of operations during the twelve months ended December 31, 2017.

On November 10, 2017, the Company issued 125,000 common stock options to an employee. The options vested immediately. The options are non-qualified, have an exercise price of $1.15 per share, and will expire after 10 years. The options were valued in total at $143,750 based upon the Black-Scholes option-pricing model, with a stock price of $1.15, volatility of 123%, and an average risk-free rate of 2.01%. $143,750 has been recorded as stock compensation in the Company's condensed consolidated statement of operations during the twelve months ended December 31, 2017.

On December 30, 2017, the Company entered into a consulting agreement pursuant to which the Company issued a total of 750,000 common stock options. 250,000 of the options vested immediately and the remaining will vest ratably over the next six months on a quarterly basis. The options are non-qualified, have an exercise price of $1.25 per share, and will expire after 5 years. The options were valued in total at $936,834 based upon the Black-Scholes option-pricing model, with a stock price of $1.25, volatility of 123%, and an average risk-free rate of 2.01%. Based upon a graded vesting schedule, $434,959 has been recorded as stock compensation in the Company's condensed consolidated statement of operations during the twelve months ended December 31, 2017.

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 3,050,000 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 for the first six months of the term of the Consulting Agreement and $7,500 per month for the remainder of the term of the Consulting Agreement.

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, 2017 and 2016, the Company had $146,133 and $91,483, respectively, due to related parties.

During the twelve months ended December 31, 2017, the Company incurred $250,000 of salary expense and paid $170,000 in salary to our CEO, Michael Favish. During the twelve-month period ended December 31, 2016, the Company incurred salary expense of $250,000 and paid $48,500 in salary to Mr. Favish. Accrued amounts are included in general and administrative expenses.

On December 31, 2016, the Company issued 684,933 shares of common stock with a fair value of 602,741 to our CEO, Michael Favish, in settlement of $410,960 of previously accrued management and other fees earned by Mr. Favish from 2013 through 2016. The difference of $191,781 between the fair value of the shares issued and accrued fees was reflected as additional compensation in general and administrative expenses.

On December 31, 2016, the Company awarded stock grants to its management and directors as compensation for services rendered. This included 50,000 shares each to Michael Favish, our CEO, Mark Goldstone, a Director, and Robert Weingarten, a Director. 20,000 shares were awarded to Gordon Bethwaite, our Vice President of Sales and Marketing, 15,000 shares were awarded to Vincent J. Roth, our General Counsel and Corporate Secretary, and 5,000 shares were awarded to John Townsend, our Controller. All of these shares were fully vested on December 31, 2016. The Company recorded $162,800 of stock-based compensation as a result of these awards.

12. Income Taxes

As of December 31, 2017 and 2016, significant components of the Company's deferred tax assets were as follows:

	December 31,	
	2017	2016
Net operating loss carryforwards	$ 1,551,000	$ 3,356,000
Stock-based compensation	504,000	2,016,000
Deferred rent	-	9,000
Accrued compensation	17,000	-
Depreciation	5,000	1,000
Total deferred tax assets	2,077,000	5,382,000
Valuation allowance	(2,077,000)	(5,382,000)
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, 2017, 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, 2017 and 2016, 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, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
U. S. federal statutory tax rate	(35.0)%	(35.0)%
Share-based compensation	4.3%	0.0%
State taxes, net of Federal benefit	0.0%	(6.0)%
Adjustment to beginning deferred tax asset	68.5%	0.0%
Change in valuation allowance	(38.0)%	41.0%
Other	0.2%	0.0%
Effective tax rate	0.0%	0.0%

At December 31, 2017, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $5,566,000 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 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 issued a stock option on January 26, 2018 to the consultant to purchase a total of 500,000 shares of the common stock of the Company. The stock option is for a term of 5 years with an exercise price of $1.25 per share. 250,000 shares of the option vested immediately. 125,000 shares vest on December 31, 2018 and the remaining 125,000 shares vest on December 31, 2019 provided the consultant is still an active service provider.

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 27th day of February, 2018.

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 27, 2018
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Financial and Principal Accounting Officer)	February 27, 2018
/s/ Robert N. Weingarten Robert N. Weingarten	Director	February 27, 2018
/s/ Mark Goldstone Mark Goldstone	Director	February 27, 2018
/s/ David W. Evans David W. Evans	Director	February 27, 2018

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*
3.2	Articles of Conversion; Delaware and California*
3.3	Certificate of Incorporation in Delaware and amendment thereto*
3.4	Certificate of Designation of the Rights, Preferences, Privileges and Restrictions of Series A Convertible Preferred Stock with Certificate of Correction (filed on Form 8-K on January 5, 2017 and incorporated herein by reference)
3.5	Certificate of Designation of the Rights, Preferences, Privileges and Restrictions of Series B Convertible Preferred Stock (filed on Form 8-K on March 23, 2017 and incorporated herein by reference)
3.6	Bylaws*
4.1	May 1, 2015 Promissory Note Purchase Agreement*
4.2	May 1, 2015 Promissory Note*
4.3	November 30, 2015 Amendment to May 1, 2015 Promissory Note*
4.4	November 30, 2015 Promissory Note*
4.5	November 30, 2015 Warrant Agreement*
4.6	Form of Preferred Stock Purchase Agreement (filed on Form 8-K on January 5, 2017 and incorporated herein by reference)
4.7	Restricted Stock Purchase Agreement by and between Michael Favish Living Trust dated January 31, 2007 and Guardion Health Sciences, Inc. (filed on Form 8-K on January 5, 2017 and incorporated herein by reference)
4.8	Form of Series B Preferred Stock Purchase Agreement (filed on Form 8-K on March 23, 2017 and incorporated herein by reference)
10.1	Lease for 15150 Avenue of the Sciences, Suite 200, San Diego California and amendments thereto*
10.2	Form of Restricted Unit Purchase Agreement from Round 3 Funding in 2013*
10.3	Form of Bridge Loan from September 30, 2015 - January 25, 2016*
10.4	Form of Indemnification Agreement*
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)
23.1	Consent of Weinberg & Company, P.A., independent registered public accounting firm for Guardion Health Sciences, Inc.**
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, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2017 and 2016, (ii) Statements of Operations for the years ended December 31, 2017 and 2016, (iii) Statements of Changes in Stockholders' Equity for the years ended December 31, 2017 and 2016, (iv) Statements of Cash Flows for the years ended December 31, 2017 and 2016, and (v) Notes to Financial Statements.

* filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016 and incorporated herein by reference

** filed herewith

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-1 (No. 333-209488, and No. 333-221813) of our report dated February 27, 2018, with respect to the financial statements of Guardion Health Sciences, Inc. of December 31, 2017 and 2016 and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2017.

/s/ Weinberg & Company, P.A.
Weinberg & Company, P.A.
Los Angeles, California
February 27, 2018

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 27, 2018

/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 27, 2018

/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, 2017 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 27, 2018 /s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

February 27, 2018 /s/ John Townsend

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