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, 2016
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from ____ to ____

Commission file number: 000-55723

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

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

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT:
None

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer (Do not check if a smaller reporting company)	☐	Smaller reporting company	x

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 March 17, 2017, there were outstanding 25,146,438 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.

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (the "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 conditions and changes in the external competitive market factors which might impact the Company's results of operations; (ii) unanticipated working capital or other cash requirements including those created by the failure of the Company to adequately anticipate the costs associated with acquisitions and other critical activities; (iii) changes in the Company's corporate strategy or an inability to execute its strategy due to unanticipated changes; and (iv) the failure of the Company to complete any or all of the transactions described herein on the terms currently contemplated. As a result of these risks and uncertainties, many of which are described in greater detail elsewhere in the Risk Factors discussion, there can be no assurance that the forward-looking statements contained in this Annual Report will in fact transpire.

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

PART I

ITEM 1. BUSINESS

Overview

The Company is a specialty health sciences company formed to develop, formulate and distribute condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that replenishes and restores the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as age-related macular degeneration ("AMD"), computer vision syndrome ("CVS") and diabetic retinopathy. 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 has had limited commercial operations to date, and has primarily been engaged in research and development and marketing.

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 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") based on the Company's determination. 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 1,500 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 in the patient's home 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 MapcastSF is specifically designed to measure the MPOD, the Company and the physicians 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 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 products through E-commerce in an online store that is operated at www.guardionhealth.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.

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, althought 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.

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.

Growth Strategy

Our 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 and product lines 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. 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, 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 $53 billion in 2007. 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.

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 tactics.

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 (pre-tax)

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

Proprietary Technology and Intellectual Property

Patents

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

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

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 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.

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.

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. 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

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"). The guidance has not been formalized, however, 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 Congressional 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.

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 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 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 healthcare 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.

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, 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.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during its most recently completed fiscal year, the Company qualifies as an “emerging growth company” as defined in Section 2(a) of the Securities Act of 1933, as amended (the “Securities Act”), as modified by the Jumpstart Our Business Startups Act of 2012, (“JOBS ACT”). As an emerging growth company, the Company may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

- Reduced disclosure about our executive compensation arrangements;
- No requirement for a non-binding shareholder advisory votes on executive compensation or golden parachute arrangements;
- Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- Reduced disclosure of financial information in this Annual Report, limited to two years of audited financial information and two years of selected financial information.

As a smaller reporting company, each of the foregoing exemptions is currently available. The Company may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. The Company would cease to be an emerging growth company if we have more than $1.0 billion in annual revenues as of the end of a fiscal year, if we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (“SEC”), or if we issue more than $1.0 billion of non-convertible debt over a three-year-period.

The JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. Therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Employees

As of March 17, 2017, the Company had a staff of eight, consisting of three officers, four full-time staff and one part-time staff person.

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 audited financial statements for the year ended December 31, 2016 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. 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. 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 has significant working capital requirements and has historically experienced negative working capital balances. If the Company continues to experience such negative working capital balances in the future, it could have a material adverse effect on its business, financial condition and results of operations.

As a result of its continued losses, the Company's current liabilities significantly exceed current assets, resulting in negative working capital of $470,064 at December 31, 2016. The Company is dependent upon obtaining additional financing to meet working capital needs and repay outstanding debt. Since its formation, the Company has relied on convertible notes and direct stock purchases from unrelated parties to fund its operating cash flow deficits. There is no assurance that it will generate the necessary net income or operating cash flows to meet its working capital requirements and pay its debts as they becomes due in the future due to a variety of factors and other factors discussed in this "Risk Factors" section. There can be no assurance, however, that it will be able to successfully take any of these actions, including adjusting expenses sufficiently or in a timely manner, or raising additional equity, increasing borrowings or completing a refinancing on any terms or on terms that are acceptable to it. The Company's inability to take these actions as and when necessary would materially adversely affect its liquidity, results of operations, financial condition and ability to operate.

The Company's future success is largely dependent on the successful commercialization of Lumega-Z® and the MapcatSF®.

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. 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. If this occurs, it will have an adverse impact on operations and the Company's ability to fund any future development.

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 product on the market, our medical food 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.

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 and local governmental entities and our products must be capable of being used by our customers in a manner that complies with those laws and regulations. Inability of our customers to do so could affect the marketability of our products or our compliance with our customer contracts, or even expose us to direct liability on a theory that we had assisted our customers in a violation of healthcare laws or 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 our product, the MapcatSF, is a medical device, 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 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. If, however, the FDA were to determine that the MapcatSF is a Class II medical device, the Company and the product would be subject to additional regulatory requirements.

In addition, we cannot anticipate how changes in regulations or determinations by regulatory agencies may evolve. Thus, application of many 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.

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.

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 believe that 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 and the MapcatSF.

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.

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.

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*."

A significant portion of the Company's billings and revenues are derived from the sale of a single product.

In the years ended December 31, 2016 and 2015, the Company derived 100% 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.

All of 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, 2016 and 2015, the Company's billings were derived from a limited number of individual customers. The Company does not receive volume commitments from its customers. Customers may stop purchasing our products with little or no warning. Loss of customers may have an immediate adverse effect on our financial results.

If 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 and understand and appreciate the benefits of Lumega-Z in order to recommend it to their patients. 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. 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 one pending patent application related to its products. 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 litigations.

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; enhance the Lumega-Z® brand in the U.S. and potentially the Lumega-Z brand internationally; 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, are integral to the execution of our business strategy. We believe that the loss of the services of Mr. Favish could adversely affect our business, financial condition and results of operations. We cannot assure you that Mr. Favish 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 therof), which may not be successful or which may cause dilution to investors.

The Company will also 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. The Company has signed a non-binding Letter of Intent to acquire VectorVision, Inc. in a stock for stock acquisition. There can be no assurance that even if this acquisition is completed, the acquisition will be successful. 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.

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 Our 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, 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 Commission 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 37.3% 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 the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies. If we are unable to comply with the internal controls requirements of 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 the Sarbanes-Oxley Act. Notwithstanding our diligence, certain internal controls deficiencies may not be detected. As a result, any internal control deficiencies may adversely affect our financial condition, results of operations and access to capital. We have not performed an in-depth analysis to determine if historical undiscovered failures of internal controls exist, and may in the future discover areas of our internal controls that need improvement.

Risks Related to Our Securities

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

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

Our stock price may be volatile and you may not be able to resell your shares at or above the purchase price.

The market price of our common stock is 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 $9,893 per month.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may become involved in litigation relating to claims arising out of its operations in the normal course of business. No legal proceedings, government actions, administrative actions, investigations or claims are currently pending or threatened against us or involve the Company.

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 the OTCQB maintained by OTC Markets Group, 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 our common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business, and we do not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our Board of Directors, in their discretion, and will depend on our financial condition, results of operations, capital requirements and other factors that our 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. 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. All dollar amounts in this registration statement refer to U.S. dollars unless otherwise indicated.

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 and development.

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 accurately measures the MPOD, the lens optical density and lens equivalent age, thereby creating an evidence-based protocol that is shared with the patient. A non-mydriatic device is one that does not require dilation of the pupil for it to function. The MapcatSF is 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, the only reliable two-pronged, evidence-based protocol for replenishing and restoring the macular protective pigment and increasing overall retinal health.

Recent Developments

On March 1, 2017, the Company entered into a non-binding letter of intent ("LOI") with Vector Vision, Inc., a Delaware corporation ("VectorVision"), whereby the parties set forth an outline of the terms and conditions pursuant to which the Company would acquire all of the outstanding shares of stock of VectorVision in exchange for a to be determined number of shares of common stock of the Company. VectorVision specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS acuity vision testing. Its 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. VectorVision's CSV-1000 device is considered the standard of care for clinical trials. Upon closing of the transaction, VectorVision would become a wholly-owned subsidiary of the Company. The Company believes the acquisition of VectorVision would expand the Company's technical portfolio and further establish the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases. The transaction is subject to significant conditions precedent to closing, including, but not limited to, the satisfactory completion of due diligence, the determination of the amount of purchase consideration, the negotiation of definitive transaction documents, the completion of an audit of VectorVision's financial statements, and other matters, no later than the June 30, 2017 expiration date of the LOI.

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 $1,653,574 and $1,139,758 during the years ended December 31, 2016 and 2015, respectively, and had a total stockholders' deficiency of $345,574 and $1,227,550 as of December 31, 2016 and 2015, 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 is not expected to have 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. The Company has never experienced any losses related to these balances. Insurance coverage limits are $250,000 per depositor at each financial institution. All cash balances were fully insured at December 31, 2016 and 2015.

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.

Revenue Recognition

Revenue is recognized on the sale of a product 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.

Patent Costs

We hold one issued patent and one pending patent application for our MapcatSF and Lumega-Z products. Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on our research efforts and any related patent applications, all patent costs, including patent-related legal fees, filing fees and other costs, including internally generated costs, are expensed as incurred. During the years ended December 31, 2016 and 2015, patent costs were $30,942 and $26,407, respectively, and are included in total research and development costs in the statements of operations.

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 costs are expensed as incurred.

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

We periodically issue stock-based compensation to officers, directors, and other 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 in the future which will 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 risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until we have established a trading market for our 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; we have never declared or paid dividends on our common stock and have no plans to do so for the foreseeable future.

The fair value of members' units or 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 at December 31, 2016 and 2015. Management used a valuation of $1.00 per share for the period January 1, 2015 to September 30, 2016, and a valuation of $0.88 per share for the period October 1, 2016 to December 31, 2016 in its fair value calculations for the years ended December 31, 2016 and 2015, respectively, based on various inputs, including valuation reports prepared by the third-party valuation firm for December 31, 2016 and 2015. The fully diluted per share equivalent price is lower in 2016 than in 2015 due to the dilutive effect of the issuance of common shares as compensation during the period. There are numerous acceptable ways to estimate company value, including using net tangible assets, a market-based approach, or discounted cash flows. We 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 using multiple years of balance sheet and income statement projections along with the following primary assumptions:

	Year Ended December 31,	
	2016	**2015**
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

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, option grants are immediately vested and the total stock-based compensation charge is recorded in the period of the measurement date. We recognize 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.

We recognize the fair value of stock-based compensation within our statements of operations with classification depending on the nature of the services rendered. We issue new shares to satisfy stock option exercises.

During the years ended December 31, 2016 and 2015, we recognized aggregate stock-compensation expense of $1,962,311 and $4,885,589, respectively, based upon stock prices ranging from $0.88 to $1.14 per share, of which $1,811,990 and $4,419,959 was recorded in general and administrative expense, $145,214 and $119,429 was recorded in sales and marketing expense, and $5,107 and $346,201 was recorded in research and development expense, respectively.

Income Taxes

We were a limited liability company prior to June 30, 2015 and taxed as a pass-through entity whereby substantially all income tax attributes were passed through to the individual members except the minimum state income tax and an LLC fee based on revenues. As of June 30, 2015, we became a corporation subject to U.S. federal income taxes and California state income taxes.

We currently account for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, we recognize deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

We account 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, 2016, we 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.

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. In the event we determine that we would be able to realize our 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 we determine that we would not be able to realize all or part of our 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;
- 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.

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, 2016, we had limited operations and have primarily been engaged in research and development and raising capital. We have incurred significant expenditures for the development of the Company's 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, 2016 and 2015, all of which was generated by the sale of the Company's proprietary product, Lumega-Z. In late 2014, the Company changed its focus from the dietary supplement category to the medical food category based on consultation with the Company's intellectual property counsel and regulatory affairs consultants, as a result of which Lumega-Z was categorized and sold as a medical food in 2015 and 2016. The financial impact of this transition to the medical food category in 2015 and 2016 is discussed below at sales and cost of goods sold. There were no other material impacts to revenue or expenses in 2015 or 2016 that resulted from the shift of Lumega-Z from the dietary supplement category to the medical food category.

Comparison of Years Ended December 31, 2016 and 2015

	Year Ended December 31,		Change	
	2016	**2015**		
Revenue	$ 141,029	$ 112,811	$ 28,218	25%
Cost of goods sold	75,702	50,072	25,630	51%
Gross Profit	65,327	62,739	2,588	4%
Operating Expenses:				
Research and development	64,026	401,909	(337,883)	(84)%
Sales and marketing	389,111	180,133	208,978	116%
General and administrative	3,308,144	5,610,830	(2,302,686)	(41)%
Loss on settlement of promissory notes and accounts payable	249,739	258,606	(8,867)	(3)%
Total Operating Expenses	4,011,020	6,451,478	(2,440,458)	(38)%
Loss from Operations	(3,945,693)	(6,388,739)	2,443,046	(38)%
Other Expense:				
Interest expense	1,802,704	752,948	1,049,756	139%
Cost to induce conversion of notes payable	-	1,699,609	(1,699,609)	(100)%
Net Loss	$ (5,748,397)	$ (8,841,296)	$ 3,092,899	(35)%

Revenue

For the year ended December 31, 2016, revenue from the sale of Lumega-Z was $141,029 compared to $112,811 for the year ended December 31, 2015, reflecting an increase of $28,218 or 25%. The increase is reflective of an increased customer base as we expand into new clinics.

Cost of Goods Sold

For the year ended December 31, 2016, cost of goods sold from the sale of Lumega-Z was $75,702 compared to $50,072 for the year ended December 31, 2015, reflecting an increase of $25,630 or 51%. We incurred certain inventory adjustments of approximately $11,000 related to the disposal of packaging materials that were determined to be obsolete during 2016 and approximately $(9,000) related to the transition from the dietary supplement category to the medical foods category in 2015. These inventory adjustments were identified and recorded in 2016 and 2015 based on decisions made by management in response to business developments occurring during the respective periods. As a result of these adjustments, cost of goods sold was 54% of revenue for the year ended December 31, 2016 compared to 44% of revenue for the year ended December 31, 2015.

Research and Development

For the year ended December 31, 2016, research and development costs were $64,026 compared to $401,909 for the year ended December 31, 2015. The decrease in research and development costs of $337,883 or 84% compared to the prior year was due primarily to stock-based compensation expense in 2015 of $342,000 for shares of common stock issued to a Science Advisor to the Company for services rendered.

Sales and Marketing

For the year ended December 31, 2016, sales and marketing expenses were $389,111 compared to $180,133 for the year ended December 31, 2015. The increase in sales and marketing expenses of $208,978 or 116% compared to the prior year was due primarily to the engagement of a Vice President of Sales and Marketing in 2016.

General and Administrative

For the year ended December 31, 2016, general and administrative expenses were $3,308,144 compared to $5,610,830 for the year ended December 31, 2015. The decrease in general and administrative expenses of $2,302,686 or 41% compared to the prior year was primarily due to the fair value of stock issued to consultants and service providers during 2015 of $4,419,959. During 2016, we recognized $1,811,990 in comparable stock compensation expense. This decrease was partially offset by an increase of $229,941 for legal and professional fees incurred primarily related to our SEC registration activities.

Loss on Settlement of Promissory Notes and Accounts Payable

In December 2016, the Company issued 534,154 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.

In August 2015, the Company issued 441,358 shares of common stock valued at $503,149 upon the conversion of $260,900 of outstanding principal and interest. The Company recognized a loss on settlement of the promissory notes of $242,249.

In August 2015, the Company issued warrants to purchase 28,176 shares of common stock at an exercise price of $0.01 per share and a 3-year term in settlement of $15,497 of accounts payable. The warrants were valued at $31,853, based upon the Black-Scholes option pricing model with a stock price of $1.14, volatility of 105% and a risk-free rate of 1.09%. The Company recognized a loss on settlement of accounts payable of $16,357.

Interest Expense

For the year ended December 31, 2016, interest expense was $1,802,704 compared to $752,948 for the year ended December 31, 2015. The increase in interest expense of $1,049,756 or 139% compared to the prior year was due to an increase in non-cash interest expense resulting from the amortization of debt discount related to the beneficial conversion features and warrants issued with our convertible notes as well as from the valuation of post-maturity warrants issued in 2016.

Cost to induce conversion of notes payable

Costs to induce conversion of our notes payable was $1,699,609 for the year ended December 31, 2015. There was no such comparable cost in 2016. In connection with the May 1, 2015 conversion of notes payable, we issued 995,926 membership units valued at $1,135,356 or $1.14 per share to the holders of the notes as an inducement to convert their notes payable. In addition, we offered certain holders 146,000 warrants valued at $165,072 to acquire membership units. The fair value of the warrants was based on a Black-Scholes option pricing model with a stock price of $1.14, volatility of 113% and risk-free rate of 0.97%. In connection with the May 1, 2015 conversion of related party notes payable, we issued 350,001 warrants valued at $341,785 to certain holders to acquire membership units as inducement to convert the notes. The fair value of the warrants was based on a Black-Scholes option pricing model with a stock price of $1.14, volatility of 113% and risk-free rate of 0.97%. In connection with the August 10, 2015 conversion of notes payable, the Company issued 50,348 shares of its common stock valued at $57,396 to the holders of the notes as an inducement to convert their notes payable.

Net Loss

For the year ended December 31, 2016, the Company incurred a net loss of $5,748,397, compared to a net loss of $8,841,296 for the year ended December 31, 2015. The decrease in net loss of $3,092,899 or 35% compared to the prior year period was primarily due to the stock issued to consultants and service providers during 2015, resulting in stock compensation expense of $4,885,589 (versus $1,962,311 during 2016), and inducement expense of $1,699,609 recognized in 2015 to convert notes payable. These year over year decreases were partially offset by the $1,049,756 increase in interest expense.

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 a result of our activities we utilized cash in operating activities of $1,653,574 and $1,139,758 during the years ended December 31, 2016 and 2015, respectively. We had negative working capital of $470,064 and $892,240 at December 31, 2016 and 2015, respectively. As of December 31, 2016, we had cash in the amount of $62,520 and no available borrowings. During the year ended December 31, 2016, we converted $1,222,518 in outstanding principal and interest on our convertible notes and promissory notes into 1,651,732 shares of our common stock and 535,154 shares of our preferred stock. Our financing has historically come from the issuance of convertible notes and promissory notes and to a lesser extent from the sale of common and preferred stock and exercise of warrants.

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.

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 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,	
	2016	2015
Net cash used in operating activities	$ (1,653,574)	$ (1,139,758)
Net cash used in investing activities	(3,354)	(2,162)
Net cash provided by financing activities	1,705,598	1,149,610
Net increase (decrease) in cash	$ 48,670	$ 7,690

Operating Activities

Net cash used in operating activities was $1,653,574 during the year ended December 31, 2016, versus $1,139,758 used during the year ended December 31, 2015. The increase in 2016 was due primarily to additional general and administrative costs incurred in 2016 for consulting and other professional services related to the filing with the SEC of our registration statement on Form S-1.

Investing Activities

Net cash used in investing activities was $3,354 for the year ended December 31, 2016 and $2,162 for the year ended December 31, 2015, and consisted of investments in property and equipment for both years.

Financing Activities

Net cash provided by financing activities was $1,705,598 for 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.

Net cash provided by financing activities was $1,149,610 the year ended December 31, 2015. Financing activities for 2015 provided proceeds of $542,500 from the issuance of convertible notes payable, $300,000 from the issuance of promissory notes, $75,000 from the exercise of warrants, and $232,110 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, 2016:

		Payments Due by Year				
	Total	2017	2018	2019	2020	2021
Convertible notes payable, currently due	$ 44,323	$ 44,323	$ —	$ —	$ —	$ —
Promissory notes payable, currently due	27,056	27,056	—	—	—	—
Operating lease commitments	194,309	121,599	72,710	—	—	—
Total	$ 265,688	$ 192,978	$ 72,710	$ —	$ —	$ —

Off-Balance Sheet Arrangements

At December 31, 2016 and 2015, 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 Company’s consolidated financial statements and notes thereto and the related report of its independent registered public accounting firm follow Part IV, Item 16 beginning on page F-1.

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

Not applicable.

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, 2016.

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 executive officers and directors. 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	68	President, Chief Executive Officer and Chairman of the Board of Directors
Robert Weingarten	64	Director
Mark Goldstone	53	Director
Gordon Bethwaite	40	Vice President of Sales and Marketing
John Townsend	55	Controller, Chief Accounting Officer
Vincent J. Roth	49	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.

Gordon Bethwaite has been Vice President of Sales and Marketing since December 2015. He is a senior figure in the ophthalmic space, with over 15 years of experience in the sales and marketing of diagnostic, surgical and optical products. After graduating with a degree in Applied Biology from Liverpool John Moores University, Gordon transitioned into the corporate healthcare environment. Throughout his career, Gordon has held senior management positions in both the ophthalmology & optometry, and audiology industries. From October 2012 to December 2015, he served as Market Development Manager and subsequently, Director of Marketing for the ophthalmic diagnostic and surgical portfolio at Carl Zeiss Meditec, a global leader and innovator in the industry.

Through his collaborations with thought leading doctors in cataract, refractive, retina and glaucoma specialties, Mr. Bethwaite brings a wealth of expertise and knowledge to the table. A passion for the technological, clinical and surgical application, and business environment of the industry, coupled with an in-depth understanding of the dynamics of the eye care market and years of collaboration with his customers, all combine to provide Mr. Bethwaite with a rich skill set invaluable to his role as Vice President of Sales and Marketing for the Company.

John Townsend has served as Controller since July 2016. 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 16 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 seven 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 recently 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.

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 table below sets forth, for the last two fiscal years, the compensation earned by (i) each individual who served as our principal executive officer or principal financial officer, and (ii) our most highly compensated executive officers, other than those listed in clause (i) above, who were serving as executive officers at the end of the last fiscal year (together, the "Named Executive Officers"). No other executive officer had annual compensation in excess of $100,000 during the last fiscal year.

Executive	Year	Salary	Bonus	Stock Awards	All Other Compensation	Total
Michael Favish (1)	2016	$ 250,000	$ -	$ 4,500	$ -	$ 254,500
	2015	$ 200,000	$ -	$ -	$ -	$ 200,000
Vincent J. Roth (2)	2016	$ 156,000	$ -	$ 10,350	$ -	$ 166,350
	2015	$ 104,000	$ -	$ 1,500	$ -	$ 105,500
Gordon Bethwaite (3)	2016	$ 208,800	$ -	$ 1,800	$ -	$ 210,600
	2015	$ -	$ -	$ 2,500	$ -	$ 2,500
John Townsend (4)	2016	$ 68,000	$ -	$ 450	$ -	$ 68,450
	2015	$ -	$ -	$ -	$ -	$ -

(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 $200,000 for Mr. Favish in fiscal year 2015 and $250,000 in fiscal year 2016. 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. It is expected that Mr. Favish will be engaged with a formal employment agreement in 2017.

(2) Vincent J. Roth began as the Company's General Counsel and Corporate Secretary on May 6, 2015 with annual compensation of $156,000. Mr. Roth was awarded a stock grant on August 7, 2015 for services rendered for 150,000 shares of the Company's common stock valued at $0.01 per share. Mr. Roth was awarded stock grants on April 1, 2016 and December 31, 2016, for services rendered for 100,000 and 15,000 shares, respectively, of the Company's common stock valued at $0.09 per share. It is expected that Mr. Roth will be engaged with a formal employment agreement in 2017.

(3) 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. Favish 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. It is expected that Mr. Bethwaite will be engaged with a formal employment agreement in 2017.

(4) 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. It is expected that Mr. Townsend will be engaged with a formal employment agreement in 2017.

Outstanding Equity Awards at Fiscal Year-End

Other than as set forth below, there were no outstanding unexercised options, unvested stock, and/or equity incentive plan awards issued to our named executive officers as of December 31, 2016.

	Option Award					Stock Award			
Name	Number of Securities Underlying Unexercised Warrants/ Options Exercisable	Number of Securities Underlying Unexercised Warrants/ Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Warrants	Warrant Exercise Price ($)	Warrant Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Vincent Roth						100,000(a)			
Gordon Bethwaite						250,000(b)			

(a) These shares were 75% vested as of December 31, 2016. The remaining 25% vested in January 2017.
(b) These shares were 75% vested as of December 31, 2016. The remaining 25% vest in June 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 (1)	Year	Stock Awards
Mark Goldstone	2016	$ 4,500
	2015	$ -
Robert Weingarten	2016	$ 4,500
	2015	$ -

(1) 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.

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

The following table sets forth certain information regarding our common stock, beneficially owned as of March 17, 2017 (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 25,146,438 shares of common stock issued and outstanding as of March 17, 2017. We calculated beneficial ownership according to Rule 13d-3 of the Securities Exchange Act of 1934, as amended as of that date. Shares of our common stock issuable upon exercise of options or warrants or conversion of notes that are exercisable or convertible within 60 days after March 17, 2017 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 25,146,438 shares of common stock outstanding at March 17, 2017, plus the number of shares of common stock that such person or group had the right to acquire on or within 60 days after March 17, 2017. 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	25.83%
Robert N. Weingarten, Director	1,300,000	5.17%
Mark Goldstone, Director [(b)]	1,050,000	4.18%
Gordon Bethwaite, Vice President [(c)]	270,000	1.07%
John Townsend, Controller [(d)]	5,000	0.02%
Vincent J. Roth, General Counsel and Corporate Secretary [(e)]	265,000	1.05%
All Officers and Directors as a Group (5 persons) [(f)]	9,384,933	37.32%
5% Shareholders:		
Christopher Scangas [(g)]	2,608,489	10.36%
Leon Krajian [(h)]	3,674,789	13.64%
Edward Grier [(i)]	2,110,186	8.16%
Jeffrey Morris [(j)]	1,278,211	5.08%

(a) Includes 260,000 shares held by Mr. Favish's spouse.
(b) Includes 1,000,000 shares of restricted common stock of the Company that vest semiannually over twenty-one months. These shares are 75% vested as of March 17, 2017.
(c) Includes 250,000 shares of restricted common stock of the Company that vest semiannually over twenty-one months. These shares are 75% vested as of March 17, 2017.
(d) Includes 5,000 shares of common stock.
(e) Includes 100,000 shares of restricted common stock of the Company that vest quarterly over a one-year period. These shares are fully vested as of March 17, 2017.
(f) 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.
(g) 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.

(h) 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 that may be issued upon conversion of 310,855 shares of preferred stock owned by Mr. Krajian.

(i) Includes 327,500 shares that may be purchased pursuant to exercisable warrants issued to Edward Grier that are vested and expire at various dates between November 30, 2018 and August 24, 2019; and 373,832 shares of common stock that may be issued upon conversion of 224,299 shares of preferred stock owned by Mr. Grier.

(j) Shares are held in the name of Jeff and Phyllis Morris Family Trust UDT Dated June 11, 1999; includes an exercisable warrant to purchase 30,237 shares that is vested and expires May 1, 2018.

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

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, 2016 and 2015, the Company had $91,483 and $286,844, respectively, due to related parties.

The Company paid management fees directly to Michael Favish prior to the Company's conversion to a corporation. During the first six months of 2015, the Company accrued management fees of $106,250 and paid $6,250. During the remaining six-month period ended December 31, 2015 (subsequent to conversion to a corporation in June of 2015), the Company accrued salary expense of $100,000 and paid $0. During the twelve-month period ended December 31, 2016, the Company accrued salary expense of $250,000 and paid $48,500. For all periods presented, accrued amounts are included in general and administrative expenses.

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 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.

As of December 31, 2016, $14,000 of principal and $2,085 of accrued interest was outstanding for a note held by Terrence Favish, son of our CEO, Michael Favish. The note carries a 12% interest rate.

For the year ended December 31, 2015, the Company recorded $2,485,450 of stock-based compensation, for services rendered, to individuals that were related parties at the time of issuance. This included $1,423,750 recorded for stock issued to Robert Weingarten, a director, $477,714 recorded for stock issued to Mark Goldstone, a director, $285,000 recorded for stock issued to Karen M. Favish, wife of CEO Michael Favish, $119,419 recorded for stock issued to Gordon Bethwaite, Vice President of Sales and Marketing, $171,000 recorded for stock issued to Vincent J. Roth, General Counsel and Corporate Secretary, and $8,557 recorded for stock issued to Marie Powell, mother of Karen M. Favish whose investment was purchased on Ms. Powell's behalf by Mrs. Favish.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Weinberg & Company, P.C. acted as the Company's independent registered public accounting firm for the years ended December 31, 2016 and 2015 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.C. for the years ended December 31, 2016 and 2015.

	Year Ended December 31,	
	2016	**2015**
Audit Fees [(a)]	$ 84,426	$ 87,185
Tax Fees [(b)]	37,350	-
Other Fees [(c)]	19,073	-
Total	$ 140,849	$ 87,185

(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.C. 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.

ITEM 16. FORM 10-K SUMMARY

None.

Guardion Health Sciences, Inc.
Financial Statements and Footnotes
Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Guardion Health Sciences, Inc. (the "Company") as of December 31, 2016 and 2015 and the related statements of operations, members' and stockholders' deficiency, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform our audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that we considered appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Guardion Health Sciences, Inc. as of December 31, 2016 and 2015, and the 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.

The accompanying 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 and has a stockholders' deficiency as of December 31, 2016. 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.

Weinberg & Company, P.A.
Los Angeles, California
March 30, 2017

Guardion Health Sciences, Inc.

Balance Sheets

	December 31,	
	2016	**2015**
Assets		
Current assets		
Cash	$ 62,520	$ 13,850
Accounts receivable	1,673	1,136
Inventories	43,999	30,563
Current portion of deposits and prepaid expenses	29,363	18,950
Total current assets	**137,555**	**64,499**
Deposits and prepaid expenses, less current portion	10,470	10,470
Property and equipment, net	114,020	170,795
Total assets	**$ 262,045**	**$ 245,764**
Liabilities, and Members' and Stockholders' Deficiency		
Current liabilities		
Accounts payable and accrued liabilities	$ 356,467	$ 271,863
Accrued expenses and deferred lease costs	88,290	143,077
Due to related parties	91,483	286,844
Current portion of convertible notes payable	44,323	41,315
Current portion of promissory notes payable, net of debt discount of $0 and $36,018, respectively	10,251	64,407
Current portion of promissory notes payable related party, net of debt discount of $0 and $54,639, respectively	16,805	149,233
Total current liabilities	**607,619**	**956,739**
Convertible notes payable	-	516,575
Total liabilities	**607,619**	**1,473,314**
Commitments and contingencies		
Members' and Stockholders' Deficiency		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 1,705,154 shares issued and outstanding at December 31, 2016	1,705	-
Common stock, $0.001 par value; 90,000,000 shares authorized; 25,046,438 and 21,911,396 shares issued and outstanding at December 31, 2016 and December 31, 2015	25,046	21,911
Additional paid-in capital	20,277,882	12,857,320
Accumulated deficit	(20,650,207)	(14,106,781)
Total members' and stockholders' deficiency	**(345,574)**	**(1,227,550)**
Total liabilities, and members' and stockholders' deficiency	**$ 262,045**	**$ 245,764**

See accompanying notes to financial statements.

Guardion Health Sciences, Inc.

Statements of Operations

	Years Ended December 31,	
	2016	**2015**
Revenue	$ 141,029	$ 112,811
Cost of goods sold	75,702	50,072
Gross profit	65,327	62,739
Operating expenses		
Research and development	64,026	401,909
Sales and marketing	389,111	180,133
General and administrative	3,308,144	5,610,830
Loss on settlement of promissory notes and accounts payable	249,739	258,606
Total operating expenses	4,011,020	6,451,478
Loss from operations	(3,945,693)	(6,388,739)
Other expenses:		
Interest expense and financing costs	1,104,557	752,948
Change in fair value of note	698,147	-
Cost to induce conversion of notes payable	-	1,699,609
Total other expenses	1,802,704	2,452,557
Net loss	(5,748,397)	(8,841,296)
Adjustments related to Series A 8% convertible preferred stock:		
Accretion of deemed dividend	(760,011)	-
Dividend declared	(35,018)	-
Net loss attributable to common shareholders	**$ (6,543,426)**	**$ (8,841,296)**
Net loss per common share – basic and diluted	$ (0.30)	$ (0.54)
Weighted average common shares outstanding – basic and diluted	21,800,719	16,391,665

See accompanying notes to financial statements.

Guardion Health Sciences, Inc.

Statements of Members' and Stockholders' Deficiency

	Members' Capital		Preferred Stock		Common Stock				
	Units	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Members' and Stockholders' Deficiency
Balance at December 31, 2014	10,821,827	$ 3,452,852	-	$ -	-	$ -	$ -	$ (5,265,485)	$ (1,812,633)
Fair value of warrants issued with convertible notes payable	-	16,656	-	-	-	-	-	-	16,656
Issuance of convertible notes payable - beneficial conversion feature	-	25,844	-	-	-	-	-	-	25,844
Issuance of membership units – conversion of notes payable and related interest	2,659,294	1,429,035	-	-	-	-	-	-	1,429,035
Issuance of membership units as inducement to convert	995,926	1,135,356	-	-	-	-	-	-	1,135,356
Issuance of warrants as inducement to convert	-	506,857	-	-	-	-	-	-	506,857
Issuance of membership units for consulting services	2,303,227	2,625,679	-	-	-	-	-	-	2,625,679
Issuance of membership units to related party upon warrant exercise	450,000	90,000	-	-	-	-	-	-	90,000
Net loss – January 1, 2015 through June 30, 2015	-	-	-	-	-	-	-	(5,094,421)	(5,094,421)
Conversion of membership units to common stock on June 30, 2015	(17,230,274)	(9,282,279)	-	-	17,230,274	17,230	9,265,049	-	-
Issuance of common stock – conversion of notes payable, promissory notes payable and related interest	-	-	-	-	1,328,346	1,290	982,699	-	983,989
Issuance of common stock as inducement to convert	-	-	-	-	50,348	56	57,341	-	57,397
Issuance of common stock for services	-	-	-	-	2,719,091	2,752	2,261,052	-	2,263,804
Issuance of common stock – warrant exercises	-	-	-	-	583,337	583	77,750	-	78,333
Fair value of warrants issued with notes payable	-	-	-	-	-	-	181,576	-	181,576
Fair value of warrants issued in conversion of accounts payable	-	-	-	-	-	-	31,853	-	31,853
Net loss – July 1, 2015 through December 31, 2015	-	-	-	-	-	-	-	(3,746,875)	(3,746,875)
Balance at December 31, 2015	-	-	-	-	21,911,396	21,911	12,857,320	(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	25,046,438	$ 25,046	$ 20,277,882	$ (20,650,207)	$ (345,574)

See accompanying notes to financial statements.

Guardion Health Sciences, Inc.

Statements of Cash Flows

	Years Ended December 31,	
	2016	**2015**
Operating Activities		
Net loss	$ (5,748,397)	$ (8,841,296)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	60,129	53,741
Amortization of debt discount	431,681	642,029
Change in fair value of note	698,147	-
Accrued interest expense included in notes payable	86,711	110,919
Fair value of warrants issued as post-maturity interest	575,673	-
Stock-based compensation	787,684	2,400,139
Stock-based compensation – related parties	982,846	2,485,450
Management fee compensation expense	191,781	-
Loss on settlement of promissory notes payable and accounts payable	249,739	258,606
Inducement expense on conversions of notes payable to equity	-	1,699,609
Warrants issued in payment of accounts payable	-	7,993
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	(537)	(97)
Inventories	(13,436)	(6,335)
Deposits and prepaid expenses	14,587	(9,345)
Increase (decrease) in -		
Accounts payable and accrued expenses	84,605	76,112
Accrued and deferred rent costs	(54,787)	(17,283)
Net cash used in operating activities	(1,653,574)	(1,139,758)
Investing Activities		
Purchase of property and equipment	(3,354)	(2,162)
Net cash used in investing activities	(3,354)	(2,162)
Financing Activities		
Proceeds from issuance of convertible notes payable	136,000	542,500
Proceeds from issuance of promissory notes – related party	140,000	200,000
Proceeds from issuance of promissory notes	220,000	100,000
Payments on promissory notes	(151,000)	-
Proceeds from issuance of preferred stock	1,145,000	-
Proceeds from exercise of warrants	-	75,000
Increase in due to related parties	215,598	232,110
Net cash provided by financing activities	1,705,598	1,149,610
Cash:		
Net increase (decrease)	48,670	7,690
Balance at beginning of period	13,850	6,160
Balance at end of period	$ 62,520	$ 13,850
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash financing activities:		
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	$ 687,369	$ 2,412,809
Fair value of warrants issued in connection with promissory and convertible notes payable	$ 270,075	$ 198,232
Beneficial conversion feature associated with promissory and convertible notes payable	$ 70,949	$ 25,844
Accrued interest on notes payable utilized to exercise warrants	$ -	$ 93,333
Fair value of warrants issued in conversion of accounts payable	$ -	$ 7,504

See accompanying notes to financial statements.

Guardion Health Sciences, Inc.
Notes to Financial Statements
Years Ended December 31, 2016 and 2015

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. 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 has developed a proprietary, patented medical device called the MapcatSF® that accurately measures the macular pigment optical density ("MPOD").

Through December 31, 2016, the Company has had limited operations, but has been primarily engaged in research and development and capital raising. The Company has incurred significant expenditures for the development of the Company's products and intellectual property, which includes research and development of both medical foods and medical diagnostic equipment for the treatment of various eye diseases. The Company had limited revenue during the years ended December 31, 2016 and 2015, all of which was generated by the sale of the Company's proprietary product, Lumega-Z, during such periods. In late 2014, the Company changed its focus from the dietary supplement category to the medical food category based on consultation with the Company's intellectual property counsel and regulatory affairs consultants, as a result of which Lumega-Z was categorized and sold as a medical food in 2015 and 2016.

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 $1,653,574 and $1,139,758 during the years ended December 31, 2016 and 2015, respectively, and had a deficit of $345,574 and $1,227,550 as of December 31, 2016 and 2015, 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

Basis of Presentation and Use of Estimates

The 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.

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 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. The Company has never experienced any losses related to these balances. Insurance coverage limits are $250,000 per depositor at each financial institution. All cash balances were fully insured at December 31, 2016 and 2015.

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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, consisting of property and equipment, 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, 2016 and 2015, 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. 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, 2016 and 2015 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 $64,026 and $401,909 for the years ended December 31, 2016 and 2015, respectively.

Patent Costs

The Company is the owner of one issued domestic patent, one pending domestic patent application, 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 other costs, including internally generated costs, are expensed as incurred. During the years ended December 31, 2016 and 2015, patent costs were $30,942 and $26,407, respectively, and are included in total research and development 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 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 risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading market for its common stock, estimated volatility is based on the average historical volatilities of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date; the Company has never declared or paid dividends on its common stock and has no plans to do so for the foreseeable future.

The fair value of members' units or 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 at December 31, 2016 and 2015. Management used valuations of $1.00 per unit or share in its fair value calculations for the periods between December 31, 2014 and September 30, 2016, and $0.88 per share for periods after September 30, 2016, respectively, based on various inputs, including valuation reports prepared by the third-party valuation firm as of December 31, 2016 and 2015. The fully diluted per share equivalent price is lower in 2016 than in 2015 due to the dilutive effect of the issuance of common shares as compensation during the period. There are numerous acceptable ways to estimate company value, including using net tangible assets, a market-based approach, or discounted cash flows. We 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 using multiple years of balance sheet and income statement projections along with the following primary assumptions:

	Year Ended December 31,	
	2016	2015
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

Management considered business and market factors affecting the Company during the twelve-month periods ended December 31, 2016 and 2015, including capital raising efforts, its proprietary technology, and other factors. Based on this evaluation, management believes that $0.88 and $1.00 per share valuations are appropriate for accounting purposes at December 31, 2016 and 2015.

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 was a limited liability company prior to June 30, 2015, and taxed as a pass-through entity whereby substantially all income tax attributes were passed through to the individual members, except for the minimum state income tax and an LLC fee based on revenues. As of June 30, 2015, the Company became a corporation subject to U.S. federal income taxes and California state 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, 2016, 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.

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. The Company considers membership units to be equivalent to common shares for purposes of the computation of net loss per share. Potential common shares such as from unexercised warrants 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,	
	2016	**2015**
Warrants	2,923,666	1,345,166
Estimated shares issuable upon conversion of convertible notes payable	-	1,136,519
Shares issuable upon conversion of convertible preferred stock	2,841,930	-
	5,765,596	2,481,685

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 is not expected to have 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,	
	2016	**2015**
Raw materials	$ 40,679	$ 26,534
Finished goods	3,320	4,029
	$ 43,999	$ 30,563

4. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2016	**2015**
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	145,503	145,503
Furniture and fixtures	15,348	15,189
Computer equipment	15,277	12,082
Office equipment	2,694	2,694
	277,179	273,825
Less accumulated depreciation and amortization	(163,159)	(103,030)
	$ 114,020	$ 170,795

For the years ended December 31, 2016 and 2015, depreciation and amortization expense was $60,129 and $53,741, respectively, of which $27,490 and $37,508 was included in research and development expense, respectively, and $32,639 and $16,233 was included in general and administrative expense, respectively.

5. Convertible Notes Payable

	December 31,	
Year of issuance:	**2016**	**2015**
2010 (due August 2013)	$ 25,000	$ 25,000
2015 (due May 2017)	-	500,000
Accrued interest	19,323	32,890
Total principal and interest	44,323	557,890
Non-current portion of convertible notes payable	-	516,575
Current portion of notes payable	**$ 44,323**	**$ 41,315**

Notes Issued in 2016 and Converted

During 2016, the Company issued convertible notes payable in the principal amount of $136,000, with simple interest of 10% per year, due at maturity and an average term of 8 months. The notes were convertible at a price of $0.60 upon the occurrence of a public company event or upon voluntary election of the majority of note holders, all as defined in the notes. The holders received warrants, with three-year terms, to purchase 136,000 shares of common stock at an exercise price of $1.00 per share. The Company recognized a debt discount at the dates of issuance in the aggregate amount of $136,000 related to the relative fair value of the warrants and beneficial conversion features, which comprised $70,949 related to the intrinsic value of beneficial conversion features and $65,051 related to the relative fair value of the warrants. The aggregate fair value allocated to the warrants of $65,051 was based on a probability effected Black-Scholes option pricing model with a stock price of $1.00, volatility of 111% - 113% and risk-free rates of 0.81% - 0.90%.

During 2016, the Company issued 242,878 shares of the Company's common stock upon the conversion of $145,724 of outstanding principal and interest pursuant to the terms of the convertible notes. During the year ended December 31, 2016 the Company amortized a total of $136,000 of valuation discount as interest expense, including applicable portions upon conversion of the notes.

2015 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. The note was convertible within 10 business days after a Going Public Event, which is defined as the occurrence of any of the following:

- The registration of any class of securities of the Borrower pursuant to an effective registration statement under the Securities Act of 1933, as amended;
- The registration of any class of securities of the Borrower pursuant to an effective registration statement under the Securities Exchange Act of 1934, as amended;
- The merger by and between the Company and an entity subject to the reporting obligations under the Securities Exchange Act of 1934, as amended, including both shell and non-shell companies; provided, however, that the Borrower and its equity holders must receive 50% or more of the equity interest in the Reporting Company immediately after the merger.

Upon conversion of the principal amount of the note, the holder was entitled to an undiluted 4.76% equity interest in the Company (as defined). This note was fully converted in 2016, as follows:

On December 27, 2016, the Company received a Notice of Effectiveness from the SEC pursuant to its registration of common stock under the Securities Act of 1933, as amended. 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, the going public 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.

As of December 31, 2014, the Company had outstanding $1,137,500 of convertible notes, $237,937 of accrued interest, and $338,510 of unamortized note discount related to the conversion features and warrants issued to the note holders. In addition, during 2015, the Company issued convertible notes payable in the principal amount of $42,500, with simple interest of 10 - 12% per year, due at maturity and an average term of 3 years. The notes are convertible at a price of $0.50 upon the occurrence of a public company event or the next equity financing, or upon voluntary election of the majority of note holders, all as defined in the notes. Certain holders received warrants to purchase 31,687 membership interests equal to 50% of the number of membership units issued upon conversion of the notes, at a price per unit of $0.60 for 50% of the warrants and a price per unit of $0.75 for the remaining 50% of the warrants, with three year terms and contingent upon the conversion of the related note. The Company recognized a debt discount at the dates of issuance in the aggregate amount of $42,500 related to the relative fair value of the warrants and beneficial conversion features, which comprised $25,844 related to the intrinsic value of beneficial conversion features and $16,656 related to the relative fair value of the warrants. The aggregate fair value allocated to the warrants of $16,656 was based on a probability effected Black-Scholes option pricing model with a stock price of $1.50, volatility of 104% - 109% and risk-free rates of 0.83% - 1.03%. All of these notes were converted in 2015, as follows:

During 2015, the Company issued 1,793,692 membership units upon the conversion of $986,542 of outstanding principal and interest pursuant to the terms of the convertible note agreements. Upon conversion, the remaining unamortized debt discount of $119,972 was charged to interest expense. In August 2015, the Company issued 886,988 shares of the Company's common stock upon the conversion of $480,833 of outstanding principal and interest pursuant to the terms of the convertible notes. Upon conversion, the remaining unamortized debt discount of $143,971 was charged to interest expense.

In connection with the 2015 conversion of notes payable, the Company issued 995,926 membership units valued at $1,135,356 to the holders of the notes as an inducement to convert their notes payable. In addition, as a further inducement to convert the notes, the Company offered to certain holders of the notes 146,000 warrants valued at $165,072 to acquire membership units. The fair value of the warrants was based on a Black-Scholes option pricing model, with a stock price of $1.14, volatility of 113%, and a risk-free interest rate of 0.97%. In connection with the August 2015 conversion of notes payable, the Company issued 50,348 shares of its common stock valued at $57,397 to the holders of the notes as an inducement to convert their notes payable, which was calculated as the excess of the shares actually received over the shares the holder was entitled to receive per the terms of their respective note agreements, multiplied by the fair value of the Company's common stock of $1.14 per share. Upon conversion, the remaining unamortized debt discount of $381,009 was charged to interest expense.

As of December 31, 2014, the Company had Convertible notes payable of $400,000 and accrued interest of $114,693 outstanding from loans provided to the Company from various related party unit holders. These notes carried simple interest at a rate of 12% per annum and approximate three year terms. In lieu of the repayment of the principal and accrued interest, the outstanding amounts were convertible into membership units at conversion prices ranging from $0.45 - $0.55 per share. The debt discount associated with the notes payable to related parties at December 31, 2014 of $62,052 represented the unamortized discount related to beneficial conversion features and outstanding warrants to purchase membership units, which was amortized to interest expense over the life of the corresponding note payable. These notes were converted in 2015, as follows:

In May 2015, the Company issued 865,602 membership units upon the conversion of $442,493 of outstanding principal and a portion of accrued interest. Upon conversion, the remaining unamortized debt discount was charged to interest expense. In addition, as an inducement to convert the notes, the Company offered to certain holders 350,001 warrants valued at $341,785 to acquire membership units. The fair value of the warrants was based on a Black-Scholes option-pricing model, with a stock price of $1.14, volatility of 113%, a risk-free interest rate of 0.97%, and was recognized as a financing cost.

6. Promissory Notes

	December 31,	
Year of issuance:	**2016**	**2015**
2015 (due June 2016)	$ -	$ 100,000
2016 (due November 2016)	10,000	-
Accrued interest	251	425
Total principal and interest	10,251	100,425
Debt discount – unamortized balance	-	(36,018)
Promissory notes payable, net	**$ 10,251**	**$ 64,407**

2016 Issuances

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. The holders received 187,500 warrants to purchase shares of the Company's common stock at a price per share of between $0.25 and $0.50 with three year terms. The Company recognized a debt discount at the dates of issuance in the aggregate amount of $87,627 related to the relative fair value of the warrants. The aggregate fair value of the warrants of $183,753 was based on a Black-Scholes option-pricing model with a stock price of $1.00, volatility of 111 - 116%, and risk-free interest rates of 0.91 – 1.06%. In addition, in August of 2016, the Company issued a $50,000 promissory note to an investor with simple interest of 8% and a term at issuance of two months. The holder received 50,000 warrants to purchase shares of the Company's common stock at a price per share of $0.25 with three year terms. The Company recognized a debt discount at the date of issuance in the aggregate amount of $24,726 related to the fair value of the warrants. The aggregate fair value of the warrants of $48,917 was based on a Black-Scholes option-pricing model with a stock price of $1.00, volatility of 122%, and a risk-free interest rate of 0.87%. Of the total $220,000 of these notes, $210,000 has been repaid or converted to common stock in 2016, as follows:

In June of 2016, $100,000 of the promissory notes was repaid to an outside investor. In December 2016, $110,000 in principal plus $5,462 in accrued interest was converted into 115,462 shares of preferred stock with a fair value of $169,344, resulting in a cost of extinguishment of $53,882. Upon conversion, the remaining unamortized debt discount was charged to interest expense. The remaining $10,000 note is currently outstanding and past due, and $251 of accrued interest is recorded as of December 31, 2016.

2015 and Prior Issuances

In November 2015, the Company issued a $100,000 promissory note to an outside investor with a term of six months. The holder received 100,000 warrants to purchase shares of the Company's common stock at a price per share of $0.25 and a term of three years. The Company recognized a debt discount at the date of issuance in the aggregate amount of $49,339 related to the fair value of the warrants. The aggregate fair value of the warrants of $97,392 was based on a Black-Scholes option-pricing model with a stock price of $1.14, volatility of 101%, and a risk-free interest rate of 1.24%. During the year ended December 31, 2015, debt discount of $13,321 was amortized to interest expense. On December 31, 2016, the promissory note for $100,000 plus accrued interest of $8,836 was converted into 108,836 shares of preferred stock with a fair value of $159,626, resulting in a cost of extinguishment of $50,790. The remaining of unamortized debt discount was charged to interest expense.

As of December 31, 2014, the Company had outstanding promissory notes of $235,000, accrued interest of $18,158, and unamortized debt discount of $108,049. In August 2015, the Company issued 441,358 shares of its common stock valued at $503,149 upon the conversion of $260,900 of outstanding principal and interest. Upon conversion, the remaining unamortized debt discount was charged to interest expense. The Company recognized a loss on settlement of promissory notes of $242,249.

7. Promissory Notes – Related Party

	December 31,	
Year of issuance:	**2016**	**2015**
2015 (due December 2015 through March 2016)	$ -	$ 200,000
2016 (due September 2016)	14,000	-
Accrued interest	2,805	3,872
Total principal and interest	16,805	203,872
Debt discount – unamortized balance	-	(54,639)
Promissory notes payable – related party, net	**$ 16,805**	**$ 149,233**

2016 Issuances

In 2016, the Company issued $140,000 of promissory notes to various related party investors, with a weighted average term at issuance of approximately four months. The holders received 280,000 warrants to purchase shares of the Company's common stock at a price per share of between $0.25 and $0.50 with three-year terms. The Company recognized a debt discount at the dates of issuance in the aggregate amount of $92,671 related to the relative fair value of the warrants. The aggregate fair value of the warrants of $272,748 was based on a Black-Scholes option-pricing model with a stock price of $1.00, volatility of 109 - 113%, and risk-free interest rates of 0.93 – 1.31%.

During 2016, $51,000 of the promissory notes were repaid. On December 31, 2016, $75,000 in principal plus $7,833 in accrued interest was converted into 82,834 shares of preferred stock with a fair value of $121,490, resulting in a cost of extinguishment of $38,657. Upon conversion, the remaining unamortized debt discount was charged to interest expense. The remaining $14,000 note is currently outstanding and past due, and $2,805 of accrued interest is recorded as of December 31, 2016.

2015 and Prior Issuances

In 2015, the Company issued $200,000 of promissory notes to a related party investor, with three month terms at issuance. The holder received 400,000 warrants to purchase shares of the Company's common stock at a price per share of between $0.25 and $0.50 with three year terms. The Company recognized a debt discount at the dates of issuance in the aggregate amount of $132,237 related to the fair value of the warrants. The aggregate fair value of the warrants of $390,292 was based on a Black-Scholes option-pricing model with a stock price of $1.14, volatility of 100 - 105%, and risk-free interest rates of 0.92 – 1.33%. On December 31, 2016, $200,000 in principal plus $28,019 in accrued interest was converted into 228,021 shares of preferred stock with a fair value of $334,431, resulting in a cost of extinguishment of $106,412. Upon conversion, the remaining unamortized debt discount was charged to interest expense.

8. 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, 2016, remaining average monthly lease payments were $10,227 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, 2016, $10,470 remained on deposit under the lease agreement.

As of December 31, 2016 and 2015, the Company had accrued and deferred rent payable for its office and warehouse facilities under its lease agreement in the aggregate of $85,399 and $143,077, respectively.

The approximate future minimum lease payments under non-cancelable operating leases at December 31, 2016 are as follows:

Years ending December 31,

2017	$ 121,599
2018	72,710
	$ 194,309

Rent expense was $106,217 and $106,217 for the years ended December 31, 2016 and 2015, respectively.

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

9. Stockholders' Deficit

As of December 31, 2016, the Company is authorized to issue is 100,000,000 shares of stock, consisting of 90,000,000 shares of common stock with a par value of $0.001 per share and 10,000,000 shares of preferred stock with a par value of $0.001 per share. At December 31, 2016, the Company had 25,046,438 shares of common stock issued and outstanding, and 1,705,154 shares of preferred stock issued and outstanding.

On October 30, 2015, the Company amended its Certificate of Incorporation to change the par value of its common stock and preferred stock from $0.0001 per share to $0.001 per share.

On June 30, 2015 the Company changed its form of organization from a limited liability company to a corporation under the laws of the State of Delaware and all LLC membership units were converted to common stock on a one for one basis. The Company was previously governed by the terms and conditions of the Guardion Health Sciences, LLC Second Amended and Restated Operating Agreement dated January 28, 2012 (the "Operating Agreement") and had one authorized class of units, and one class of members which consisted of four members. The LLC's business, property, and affairs were managed exclusively by the manager. Members' voting rights were in direct proportion to their Membership Interests.

Preferred Stock

2016

During 2016, the Company sold 1,170,000 shares of the Company's Series A Senior Convertible Preferred Stock to various investors. The purchase price of the stock was $1.00 per share, for an aggregate purchase price of $1,170,000. In addition, the Company issued 535,154 shares of its preferred stock with a fair value of $784,888 upon conversion of $535,149 of notes payable and accrued interest. The 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 the holder, the 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 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 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 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 convertible 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 at the issuance date as determined by a third-party valuation. 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 Senior Convertible 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 preferred stock exceeded the proceeds from such issuances. The deemed dividend on the 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, will be accreted in January 2017.

The Preferred Stock will vote with the common stock on an "as converted" basis and has 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 the 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 in accordance with the respective amounts that would be payable on such shares of Preferred Stock if all amounts payable thereon were paid in full. The Preferred Stock will be senior to any other classes or series of preferred stock that may subsequently be issued.

Preferred shareholders 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 has been sold in this Preferred Stock private placement and $250,000 of Preferred Stock is still outstanding. This demand registration right will terminate when all shares of Preferred Stock have been converted into common stock.

In the event of a merger or acquisition or change in control of the Company, the Preferred Stock (including all accrued but unpaid dividends) will be deemed converted into shares of common stock immediately prior to the closing of such a transaction.

Sale of the Company's Series A Senior Convertible Preferred Stock was completed on December 31, 2016. There was no preferred stock issued during the year ended December 31, 2015.

During the year ended December 31, 2016, the Company declared dividends of $35,018 to its preferred shareholders which were paid through the issuance of 58,377 shares of common stock.

Common Stock

2016

Prior to 2016, the Company issued 1,260,000 shares of restricted common stock to service providers valued at $1,435,024, of which $601,344 had been recognized as expense.

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 $145,348 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, $111,369 is expected to be recorded in future periods related to the restricted stock.

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

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Non-vested, December 31, 2014	-	$ -
Issued	1,260,000	1.14
Vested	(252,500)	1.14
Forfeited	-	-
Non-vested, December 31, 2015	1,007,500	1.14
Issued	145,000	1.00
Vested	(800,000)	1.12
Forfeited	-	-
Non-vested, December 31, 2016	352,500	$ 1.13

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 2016, the Company issued 1,651,732 shares of common stock with a fair value of $1,385,515 upon conversion of notes payable and accrued interest of $687,368 resulting in a loss on conversion of $698,147.

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.

2015

During 2015, the Company sold 2,303,227 membership units to two consultants for aggregate cash consideration of $2,303. These membership units had a fair value of $2,625,679 or $1.14 per unit. Accordingly, the Company recognized $2,623,376 in stock compensation from this transaction in 2015. During 2015, the Company issued 1,459,091 shares of the Company's common stock for services rendered. The shares were valued in total at $1,662,676, or $1.14 per share.

Warrants

2016

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:

	Membership Units or Shares
December 31, 2014	**1,317,894**
Granted	1,832,916
Forfeitures	(782,307)
Exercised	(1,033,337)
December 31, 2015	**1,335,166**
Granted	1,588,500
December 31, 2016, all exercisable	**2,923,666**

Additional details of the Company's outstanding and exercisable warrants are as follows:

Outstanding at:	Membership Units or Shares	Weighted Average Exercise Price
December 31, 2014	1,317,894	$ 0.37
December 31, 2015	1,335,166	$ 0.56
December 31, 2016	2,923,666	$ 0.37

As of December 31, 2016, the Company had an aggregate of 2,923,666 outstanding warrants to purchase shares of its common stock with a weighted average remaining life of 1.4 years and aggregate intrinsic value of $1,285,712, 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.

2015

During 2015, in connection with the issuance of notes payable of $42,500 convertible at a price of $0.50 per membership unit upon certain events, the Company issued 31,687 warrants to purchase membership units equal to 50% of the number of units issued upon conversion of the notes, at a price per unit of $0.60 for 50% of the warrants and a price per unit of $0.75 for the remaining 50% of the warrants, with three year terms and contingent upon the conversion of the related notes.

On May 1 2015, the Company issued warrants valued at $506,857 to purchase 496,001 membership units at a weighted average exercise price of $0.21 per unit with 3 year terms, as inducements to convert notes payable, as more fully described at Note 5 and Note 6.

On May 1, 2015, the Company issued 450,000 membership units to a related party upon exercise of 450,000 warrants at a weighted average exercise price of $0.20 per unit. In lieu of the aggregate cash payment of $90,000, the holder applied $90,000 of accrued interest towards the exercise price of the warrants.

During 2015, the Company issued 250,001 shares of the Company's common stock upon exercise of 250,001 warrants for aggregate cash consideration of $75,000. The Company also issued 333,336 shares of the Company's common stock upon exercise of 333,336 warrants at an average exercise price of $0.01 per share. In lieu of the aggregate cash payment of $3,334, the holder applied $3,334 of accrued interest toward the exercise price of the warrants.

On August 10, 2015, the Company issued warrants to purchase 28,176 shares of its common stock at an exercise price of $0.01 per share and a three-year term in settlement of $15,497 of accounts payable. The warrants were valued at $31,853, based upon the Black-Scholes option-pricing model, with a stock price of $1.14, volatility of 105% and a risk-free interest rate of 1.09%. The Company recognized a loss on settlement of accounts payable of $16,357.

10. Related Party Transactions

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, 2016 and 2015, the Company had $91,483 and $286,844, respectively, due to related parties.

The Company paid management fees directly to Michael Favish prior to the Company's conversion to a corporation. During the first six months of 2015, the Company accrued management fees of $106,250 and paid $6,250. During the remaining six-month period ended December 31, 2015 (subsequent to conversion to a corporation in June of 2015), the Company accrued salary expense of $100,000 and paid $0. During the twelve-month period ended December 31, 2016, the Company accrued salary expense of $250,000 and paid $48,500. For all periods presented, 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.

As of December 31, 2016, $14,000 of principal and $2,085 of accrued interest was outstanding for a note held by Terrence Favish, son of our CEO, Michael Favish. The note carries a 12% interest rate.

For the year ended December 31, 2015, the Company recorded $2,485,450 of stock-based compensation, for services rendered, to individuals that were related parties at the time of issuance. This included $1,423,750 recorded for stock issued to Robert Weingarten, a director, $477,714 recorded for stock issued to Mark Goldstone, a director, $285,000 recorded for stock issued to Karen M. Favish, wife of CEO Michael Favish, $119,419 recorded for stock issued to Gordon Bethwaite, Vice President of Sales & Marketing, $171,000 recorded for stock issued to Vincent J. Roth, General Counsel and Corporate Secretary, and $8,557 recorded for stock issued to Marie Powell, mother of Karen M. Favish whose investment was purchased on Ms. Powell's behalf by Mrs. Favish.

11. Income Taxes

As of December 31, 2016 and 2015, significant components of the Company's deferred tax assets were as follows:

	December 31,	
	2016	**2015**
Net operating loss carryforwards	$ 3,356,000	$ 1,414,000
Stock-based compensation	2,016,000	1,131,000
Deferred rent	9,000	11,000
Accrued compensation due to related party	-	60,000
Depreciation	1,000	2,000
Total deferred tax assets	5,382,000	2,618,000
Valuation allowance	(5,382,000)	(2,618,000)
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, 2016, 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, 2016 and 2015, due to the losses incurred during the period. Prior to July 1, 2015, the Company operated as a limited liability company, and as such, all profits, losses, revenues, expenses and other income tax attributes were passed through to the limited liability company owners. 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, 2016 and 2015:

	Year Ended December 31,	
	2016	**2015**
U. S. federal statutory tax rate	(35.0)%	(35.0)%
Net losses passed through to owners while operating as a limited liability company	0.0%	18.5%
State taxes, net of Federal benefit	(6.0)%	(6.0)%
Change in valuation allowance	41.0%	22.5%
Effective tax rate	0.0%	0.0%

At December 31, 2016, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $8,234,000 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.

12. Subsequent Events

On January 31, 2017, the Company borrowed $100,000 from a related party investor pursuant to an unsecured promissory note, with a 120-day term and a fixed interest charge of $6,000.

On March 1, 2017, the Company entered into a non-binding letter of intent ("LOI") with Vector Vision, Inc., a Delaware corporation ("VectorVision"), whereby the parties set forth an outline of the terms and conditions pursuant to which the Company would acquire all of the outstanding shares of stock of VectorVision in exchange for a to be determined number of shares of common stock of the Company. VectorVision specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS acuity vision testing. The transaction is subject to significant conditions precedent to closing, including, but not limited to, the satisfactory completion of due diligence, the determination of the amount of purchase consideration, the negotiation of definitive transaction documents, the completion of an audit of VectorVision's financial statements, and other matters, no later than the June 30, 2017 expiration date of the LOI.

On March 1, 2017, the Company issued 162,500 shares of restricted common stock to a consultant for services rendered.

Between January 1, 2017 and March 13, 2017, the Company issued 700,000 shares of Series B Preferred Stock to investors for an aggregate purchase price of $700,000. The 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. The Series B Preferred Stock is convertible commencing December 31, 2017, or earlier upon the approval of the Board of Directors, by the holder into Common Stock at $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 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. The Series B Preferred Stock is senior to all Common Stock and junior to the Series A Preferred Stock. For investors in the Series B offering that previously invested in the Company's Series A preferred stock offering in 2016, the Company issued a total of 60,000 warrants as additional incentive to invest. These warrants are fully vested, are immediately exercisable at $0.75 per share, and expire between March 6, 2020 and March 8, 2020.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 30th day of March, 2017.

GUARDION HEALTH SCIENCES, INC.

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

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Michael Favish Michael Favish	CEO, President and Chairman of the Board (Principal Executive Officer)	March 30, 2017
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Accounting Officer)	March 30, 2017
/s/ Robert N. Weingarten Robert N. Weingarten	Director	March 30, 2017
/s/ Mark Goldstone Mark Goldstone	Director	March 30, 2017

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Articles of Organization of P4L Health Sciences, LLC and restatement changing name to Guardion Health Sciences, LLC filed in California (1)
3.2	Articles of Conversion; Delaware and California (1)
3.3	Articles of Incorporation in Delaware and amended thereto (1)
3.4	Certificate of Designation of the Rights, Preferences, Privileges and Restrictions of Series A Convertible Preferred Stock with Certificate of Correction (2)
3.5	Certificate of Designation of the Rights, Preferences, Privileges and Restrictions of Series B Convertible Preferred Stock (3)
3.6	Bylaws (1)
4.1	May 1, 2015 Promissory Note Purchase Agreement (1)
4.2	May 1, 2015 Promissory Note (1)
4.3	November 30, 2015 Amendment to May 1, 2015 Promissory Note (1)
4.4	November 30, 2015 Promissory Note (1)
4.5	November 30, 2015 Warrant Agreement (1)
4.6	Form of Preferred Stock Purchase Agreement (2)
4.7	Restricted Stock Purchase Agreement by and between Michael Favish Living Trust dated January 31, 2007 and Guardion Health Sciences, Inc. (2)
4.8	Form of Series B Preferred Stock Purchase Agreement (3)
10.1	Lease for 15150 Avenue of the Sciences, Suite 200, San Diego, CA and amendments thereto (1)
10.2	Form of Restricted Unit Purchase Agreement from Round 3 Funding in 2013 (1)
10.3	Form of Bridge Loan from September 30, 2015 - January 25, 2016 (1)
10.4	Form of Indemnification Agreement (1)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Accounting Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer and Chief Accounting Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101	The following materials from the Company’s Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Cash Flows, (v) Consolidated Statement of Stockholders’ Equity and (vi) Notes to Consolidated Financial Statements

(1) filed with the Registration Statement on Form S-1 (File No. 333-209488) filed with the SEC on February 11, 2016 and incorporated herein by reference.

(2) filed on Form 8-K on January 5, 2017 and incorporated herein by reference.

(3) filed on Form 8-K on March 23, 2017 and incorporated herein by reference.

EXHIBIT 31.1

CERTIFICATION

I, Michael Favish, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2017

/s/ Michael Favish
Michael Favish
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, John Townsend, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2017

/s/ John Townsend
John Townsend
Controller and Chief Accounting Officer
(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, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Michael Favish, Chief Executive Officer of the Company, and John Townsend, Controller of the Company, certify, pursuant to 18 U.S.C. § 1350, as enacted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 30, 2017 /s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

March 30, 2017 /s/ John Townsend

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