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, 2020

OR

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

For the transition period from ____ to ____

Commission file number: 000-55723

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

[ ] Yes [X] No

On June 30, 2020, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value (based on the closing per share sales price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was approximately $37.5 million.

As of March 25, 2021, there were 24,426,993 shares of the registrant’s common stock, par value $0.001 per share, issued and outstanding.

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2020 contains "forward-looking statements" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects, and other similar matters. These forward-looking statements are based on management's current expectations and assumptions about future events, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. These statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning.

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

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

PART I

ITEM 1. BUSINESS

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

Overview

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

Medical Foods:

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

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

Medical Devices:

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

- **VectorVision, CSV-1000 and CSV-2000:** In September 2017, the Company, through its wholly owned subsidiary VectorVision Ocular Health, Inc., acquired substantially all of the assets and certain liabilities of VectorVision, Inc., a company that specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study ("ETDRS") visual acuity testing. VectorVision's standardization system(s) are designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing for use by eye doctors in clinics, for researchers to use in clinical trials, for real-world vision evaluation, and industrial vision testing. The acquisition expands the Company's technical portfolio.

  In September 2019, the Company announced that it completed development of its new proprietary, digital CSV-2000 standardized contrast sensitivity testing device. The Company believes that the CSV-2000 is the only computer-generated vision testing instrument available that will provide the optical marketplace with the Company's proprietary, industry-standard contrast sensitivity test, along with a full suite of standard vision testing protocols. The proprietary standardization methodology incorporated into the CSV-2000 includes a patented technology known as AcQviz, embodied in its own device, that automatically and constantly measures and adjusts screen luminance to a fixed standard light level for vision testing. The Company began selling the new CSV-2000 and AcQviz devices at the end of the first quarter of 2020 but was impacted by COVID-19. The Company plans to put significant focus on sales and marketing efforts of the new CSV-2000, although the CSV-1000 will continue to be sold. The Company believes the VectorVision product portfolio further establishes the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

Nutraceuticals:

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

- **ImmuneSF**: The first new nutraceutical product developed after the acquisition of NutriGuard is ImmuneSF, a unique proprietary nutraceutical formulation designed to support and maintain an effective immune system. This formulation contains a synergistic blend of antioxidant and anti-inflammatory nutrients. The Company has arranged for the manufacture and packaging of ImmuneSF at contract facilities in the United States and began marketing the product during the second quarter of 2020. The Company anticipates that ImmuneSF will also be exported for sales in international markets.

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

Recent Developments

January and February 2021 At the Market Offerings

On January 8, 2021, we filed a prospectus supplement pursuant to which we could sell up to $10,000,000 worth of shares of our common stock in an "at the market" offering (the "January 2021 1st ATM Offering"). On January 15, 2021, we completed the January 2021 1st ATM Offering, pursuant to which we sold an aggregate of 2,559,834 shares of our common stock, raised gross proceeds of approximately $10,000,000 and net proceeds of approximately $9,500,000.

On January 28, 2021, we filed a prospectus supplement pursuant to which we could sell up to $25,000,000 worth of shares of our common stock in an "at the market" offering (the "January 2021 2nd ATM Offering"). On February 10, 2021, we completed the January 2021 2nd ATM Offering, pursuant to which we sold an aggregate of 5,006,900 shares of our common stock, raised gross proceeds of approximately $25,000,000 and net proceeds of approximately $24,100,000.

In addition, in January and February 2021, the Company issued an aggregate of 1,647,691 shares of common stock upon the exercise of warrants and received cash proceeds of $3,608,509.

Appointment of New CEO

Effective as of January 6, 2021, the Board of Directors appointed Bret Scholtes as President and Chief Executive Officer and as a director of the Company.

Prior to his appointment, Mr. Scholtes, age 51, served as the President and Chief Executive Officer of Omega Protein Corporation ("Omega") since 2012 and as a director of Omega since 2013. Omega was listed on The New York Stock Exchange until January 2018 when it was sold. Prior to his selection as Chief Executive Officer of Omega, Mr. Scholtes served as the Omega's Senior Vice President-Corporate Development from April 2010 to December 2010 and as Omega's Executive Vice President and Chief Financial Officer from January 2011 to December 2011. From 2006 to April 2010, Mr. Scholtes served as a Vice President at GE Energy Financial Services, a global energy investment firm. Prior to that, Mr. Scholtes held positions with two publicly traded energy companies. Mr. Scholtes also has five years of public accounting experience. Mr. Scholtes holds an MBA degree in Finance from New York University and a degree in Accounting from the University of Missouri – Columbia.

Reverse Stock Split and Nasdaq Compliance

On September 20, 2019, we received notice from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the previous 30 consecutive business days, the Company no longer satisfied the requirement to maintain a minimum bid price of $1.00 per share, as required by Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). In accordance with the Nasdaq Listing Rules, the Company was afforded 180 days, or until March 18, 2020, to regain compliance with the Bid Price Rule by evidence of a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. Thereafter, the Company had been afforded a second 180-calendar day compliance period (which 180-day period was extended due to circumstances related to COVID-19), or until November 30, 2020, to regain compliance with the Bid Price Rule.

The Company was unable to regain compliance with the Bid Price Rule by November 30, 2020. Accordingly, on December 1, 2020, the Company received a letter from the Staff notifying it that its Common Stock would be subject to delisting from Nasdaq unless the Company timely appealed Nasdaq's determination to a Nasdaq Listing Qualifications Panel (the "Panel"). The Company timely appealed Nasdaq's determination to the Panel.

On January 26, 2021, the Company received written notification that the Panel granted the Company an extension for continued listing through March 15, 2021.

On March 1, 2021, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-six (1:6) reverse stock split (the "Reverse Stock Split") of its common stock without any change to its par value. Proportional adjustments for the Reverse Stock Split were made to the Company's outstanding common stock, stock options, and warrants as if the split occurred at the beginning of the earliest period presented in this Annual Report.

On March 15, 2021, we received a letter from the Staff notifying us that we had regained compliance with the Bid Price Rule. The letter stated the staff had determined that for the prior 10 consecutive business days, from March 1, 2021 to March 12, 2021, the closing bid price of the Company's common stock had been at $1.00 per share or greater and that accordingly, the Company had regained compliance under the Bid Price Rule, and that the matter was closed.

Background

Medical Foods

Medical foods are regulated as foods under the federal Food, Drug, and Cosmetic Act. The Company believes that there is an increasing level of acceptance of medical foods as a primary therapy by patients and healthcare providers to manage pain syndromes, sleep and cognitive disorders, obesity, hypertension, and viral infection. In clinical practice, medical foods are being prescribed as both a standalone therapy and as an adjunct therapy to low doses of commonly prescribed drugs. The Company believes that medical foods will continue to grow in importance over the coming years.

Lumega-Z® is a medical food product that has a patent-pending formula that is designed to replenish and restore the macular protective pigment simultaneously delivering critical and essential nutrients to the eye. Management believes, based on review of products on the market and knowledge of the industry, that Lumega-Z is the first liquid ocular health formula to be sold as a medical food (as defined in Section 5(b) of the "Orphan Drug Act"). However, the FDA has not monitored nor approved Lumega-Z as a medical food. Formulated by Dr. Sheldon Hendler in 2010, modifications were made over the lifetime of the formula to improve the efficacy, taste, and method of delivery. The current formulation has been delivered to patients and used in clinics since 2019.

Lumega-Z 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 has marketed Lumega-Z to patients through ophthalmologists and optometrists. The Company intends to also market Lumega-Z through direct-to-consumer strategies such as, television, social media and paid search advertising.

Lumega-Z® has published two peer-review scientific articles, demonstrating its beneficial efficacy, in 2020. Both articles were published in the journal *Nutrients*. The first published study assessed the level of absorption of the carotenoids in Lumega-Z compared to absorption of the carotenoids in the industry leading eye vitamin, PreserVision™ (AREDS 2 formula sold by Bausch and Lomb), and determined whether an elevated level of carotenoid absorption leads to increased MPOD. The study found that despite only a 2.3-fold higher carotenoid concentration than PreserVision™, Lumega-Z supplementation provides approximately 3–4-fold higher absorption, which leads to a significant elevation of MPOD levels (*Nutrients* 2020, 12, 132: Published May 2, 2020).The second study evaluated the visual benefits in a group of patients taking Lumega-Z compared to a group of patients taking AREDS 2 (PreserVision™) soft gel supplements, as well as a third control group taking no supplementation.. Each study participant had retinal drusen, significantly delayed dark adaptation recovery time and was at risk of developing vision loss from AMD. The results showed significant improvements in visual function, as measured by contrast sensitivity, in the group of patients taking Lumega-Z. The patients taking PreserVision™ showed a trend toward an improvement, but no statistical change, while the control group showed no change. (Nutrients 2020, 12, 3271: Published October 26, 2020).

Sales of Lumega Z remained flat throughout 2020, as many eye doctor offices were closed, or operating with limited capacity, due to COVID-19 related "shelter at home" orders.

GlaucoCetin is the Company's second medical food. It offers a patent-pending formula that is designed to support proper mitochondrial function in the optic nerve cells of glaucoma patients. Loss of optic nerve cells is thought to be the primary cause of vision loss in glaucoma patients. Like Lumega-Z, GlaucoCetin has also been distributed primarily through eye doctors, however, the Company plans to offer direct-to-consumer marketing programs. GlaucoCetin sales grew by 112% during 2020. The Company believes this growth rate, despite COVID-19 related issues affecting patient access to eye doctor offices, is due to limited competition for glaucoma related nutritional products and a wider acceptance by clinicians of the potential efficacy of the nutritional therapies.

Vision loss from eye disease is a rapidly growing problem in the United States and across the globe. The National Academics of Sciences, Engineering, and Medicine projects that "every four minutes, one American will experience partial or complete loss of sight." According to The Lancet, AMD cases in the US are projected to pass 18 million in 2017, and 20 million by 2022. According to an EpiCast Report, the number of glaucoma patents is expected to grow yearly by 15% and for there to be 15.7 million cases worldwide by 2023, with most of these cases in the United States and Japan.

The US Food and Drug Administration (FDA) took steps in 1988 to encourage the development of medical foods by creating a regulatory category for medical foods 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 enterally (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.

The field of candidates for development into medical foods is expanding due to continuing advances in the understanding of the science of nutrition and disease, coupled with advances in food technology thereby increasing the number of products that can be formulated and commercialized. The Company distributes its medical food products through E-commerce in an online store that is operated at www.guardionhealth.com. Information about VectorVision products can be found at www.vectorvision.com. Information about NutriGuard Formulations products can be found at www.nutriguard.com.

The Company also distributes its medical foods products through E-commerce in an online store that is operated at www.guardionhealth.com. The Company plans to expand its E-commerce capabilities in 2021.

Medical foods consist of food-based ingredients that are part of the normal human diet and are Generally Recognized as Safe ("GRAS") under FDA standards. Medical foods must make claims for which there is scientific evidence that nutrient deficiencies cannot be corrected by normal diet. All ingredients must be designated GRAS and used in therapeutic concentrations to address the particular nutritional needs of the patient. Medical foods are taken under the supervision of a physician or professional healthcare provider who monitors and adjusts the food 'dosage.' In addition, under FDA guidelines and congressionally approved laws, medical foods do not require FDA 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 or a condition and cannot claim that they prevent, mitigate or treat a given disease or condition. Dietary supplements do not require physician supervision and can be self-administered without supervision.

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

Medical Devices

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

The variability described above has caused the FDA and other agencies to require standardized test lighting for vision tests. Because VectorVision specializes in the standardization of vision tests, VectorVision is the only company that offers fully standardized vision testing products that ensure consistent, repeatable and highly accurate results using automated light calibration systems. The CSV-1000 device offers auto-calibrated tests to ensure the correct testing luminance and contrast levels for consistent, highly accurate and repeatable results, which is why the VectorVision instruments can detect and quantify subtle changes in vision. Consistency, repeatability and accuracy are also why the VectorVision CSV-1000 instrument is used worldwide by eye doctors in more than 60 countries to accomplish contrast sensitivity testing. The Company's research has revealed there are no competing products that offer auto-calibration of ambient illumination or test lighting. Competitive devices do not correct for variations in test light levels, resulting in variability of test results. The CSV-1000 uses self-calibrated test lighting. The self-calibrated test lighting is proprietary. For the CSV-2000, the follow-on computerized device for the CSV-1000, the self-calibrated test lighting technology is a proprietary and patented technology known as AcQviz, which constantly measures the luminance of the CSV-2000 computer screen and automatically adjusts screen luminance to a fixed standard light level for vision testing. The test faces of the CSV-1000 are proprietary, and their intellectual property is protected under copyright and trade secret law. CSV-1000 is currently sold worldwide, and the Company expects this global distribution to continue. The first sale of the CSV-2000 occurred in Q1, 2020 and the Company believes this product will also be sold worldwide. There is a training requirement for incorporating the CSV-1000 and the CSV-2000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy.

The MapcatSF device offers a proprietary technology to effectively evaluate the MPOD, which is a measure of the health of the macular pigment. The MapcatSF device is used primarily in eye doctor's offices as a means to demonstrate to patients the current status of their MPOD and the potential benefits of Lumega-Z after treatment. The first MapcatSF was sold in 2020. No major sales and marketing strategy is currently planned for the direct sales of the device, as it will be used more as a measurement tool to educate patients and their eye doctors about the need for taking Lumega-Z to replenish the macular pigment. The MapcatSF will be sold to doctors or researchers upon request.

Nutraceutical Industry Overview

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

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

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

Competitive Advantage and Strategy

Medical Foods

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

Lumega-Z is a medical food designed to enhance the bioavailability of "difficult to absorb" ingredients like carotenoids. In contrast to other formulations, Lumega-Z is a liquid formulated using a proprietary molecular micronization process ("MMP") to maximize efficiency of absorption and to minimize compatibility issues. The MMP is a proprietary homogenization process whereby the particle size of the ingredients is reduced to facilitate more efficient absorption into the body. As noted earlier, clinical studies have shown Lumega-Z offers significantly higher absorption of carotenoids, than the leading AREDS-based formula PreserVision™ (*Nutrients*, 12, 1321: Published May 2, 2020). In a subsequent study, Lumega-Z was also found to provide significantly better vision benefit than the AREDS-based formula in patients with drusen and at risk of vision loss from AMD, as measured by contrast sensitivity (*Nutrients* 12, 3271: Published October 26, 2020). The Company believes we have a competitive advantage with Lumega-Z because of these two published studies showing superiority over the leading formula, PreserVision™, and because a growing body of evidence, particularly the results from the AREDS studies, that has demonstrated the importance of supplementation with carotenoids to offset vision loss in patients with macular degeneration. Lumega-Z has demonstrated in studies to have higher absorption of carotenoids, which the Company believes leads to better visual outcomes, and a superiority over the competitive formulas.

GlaucoCetin is a medical food designed to support mitochondrial function in the optic nerve cells of glaucoma patients. For glaucoma, the primary risk factor for disease progression has been thought to be elevated intraocular pressure which in turn damages the optic nerve cells leading to vision loss. As such, the primary means for treating the disease, to slow or stop vision loss, is to lower the intraocular pressure through pharmaceutical or surgical means. However, new studies suggest that many glaucoma patients do not exhibit elevated intraocular pressure. Further, many patients who have displayed high intraocular pressure and have been treated to lower the pressure, continue to lose vision. These trends have led clinicians and researchers to suggest that other mechanisms of disease progression are occurring, one of which is mitochondrial dysfunction of optic nerve cells. The Company believes we have a competitive advantage with GlaucoCetin because it is the first to market medical food specifically designed to offset the mitochondrial dysfunction of cells in glaucoma patients.

Medical Devices

VectorVision specializes in the standardization of vision tests, specifically, contrast sensitivity, glare testing and early treatment diabetic retinopathy study, or ETDRS, acuity. The variability in test lighting has caused the FDA and other agencies to require standardized test lighting for vision tests. Contrast sensitivity testing measures how people see in the real world. A depleted macular pigment greatly affects contrast sensitivity. Research suggests that contrast sensitivity is a better measure than standard acuity tests for real-world vision applications such as military pilots and highway driving. The Company believes that VectorVision is the only company that offers fully standardized vision testing products that ensure consistent, repeatable and highly accurate results. These qualities are why the VectorVision instruments can detect and quantify subtle changes in vision, and why the VectorVision CSV-1000 instrument is used worldwide by eye doctors in more than 60 countries to accomplish contrast sensitivity testing. On July 10, 2018, the USPTO issued US Patent No. 10,016,128, titled Method and Apparatus for Visual Acuity Testing. This patent describes an invention pertaining to automatic light calibration of the display screens used for vision testing. The Company has acquired the exclusive rights to this patent, and its VectorVision CSV-2000 device embodies this invention. On July 17, 2018, the USPTO issued US Patent No. 10,022,045, also titled Method and Apparatus for Visual Acuity Testing, which describes a methodology to continuously calibrate display monitors to automatically hold display luminance constant for vision testing. This second patent also covers a methodology to compensate for other testing factors, such as room illumination and when patients view the vision test through a mirror, which is a common practice in eye doctors' offices worldwide. The Company also acquired the rights to this patent. The Company's new AcQviz device embodies this invention, which is now used in conjunction with the VectorVision CSV-2000 device.

The Company believes the CSV-1000 is the current standard of care for testing contrast sensitivity in clinical practice. The first sale of the CSV-2000 was made in February 2020. There is a training requirement in incorporating the CSV-1000 and CSV-2000 device into clinical practice, which the Company plans to provide as part of its commercialization strategy.

The CSV-1000 and CSV-2000 offer self-calibrated test lighting for vision testing. The self-calibrated test lighting technology for both instruments is proprietary to the Company. The patented technology known as AcQviz, applies to the CSV-2000. It constantly measures the luminance of the display monitor of the CSV-2000 and automatically adjusts screen luminance to a fixed standard light level for vision testing. Although the CSV-1000 will continue to be sold, the Company plans to put a greater focus on sales and marketing efforts on the new CSV-2000. There can be no assurances that the marketing efforts will be successful, and sales of the CSV-2000 will be comparable or exceed sales of the CSV-1000. The Company believes we have a competitive advantage because of the unique and proprietary vision testing luminance standardization technologies employed by the CSV-1000 and CSV-2000. This standardization has led to the publication of many research studies showing the accuracy of the contrast sensitivity testing protocol used in both the CSV-1000 and CSV-2000, and to the publication of population normal ranges for contrast sensitivity. The Company believes that there are no other devices with published normative values for contrast sensitivity.

Nutraceuticals

The Company intends to build a portfolio, in addition to the current product line, of nutraceutical products under the NutriGuard brand by developing or acquiring new condition-specific formulations. NutriGuard markets these products to patients directly through direct-to-consumer (“DTC”) channels. The Company also intends to conduct research and publish papers demonstrating the efficacy of the NutriGuard products, which the Company believes will also lead to distribution of products to patients through recommendations by their physicians.

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

Growth Strategy

The Company believes that marketing its products is critical in ensuring its success. The Company has several marketing initiatives and will implement them according to the success and product feedback that the Company and products create. Marketing initiatives will include not only distribution through eye doctor recommendation, but also direct-to-consumer programs. The Company will also explore acquiring other companies, product lines and intellectual property that may be complementary or supplementary as part of its efforts to expand the business, which acquisitions could be for cash, stock or a combination thereof.

Sales Force

The Company plans to use a combination of digital strategies, virtual communication, direct-to-consumer campaigns and direct sales activity with eye doctors to promote its products. At the end of 2020, the Company had two highly experienced sales personnel, both Doctors of Naturopathy. During 2021, the Company intends to add sales team members in the field to conduct direct sales activities for eye doctors, to perform virtual educational campaigns for practice follow-up with doctors and their staffs and to support the direct-to-consumer campaigns. The Company also intends to initiate significant follow-on communication activity with patients who have begun taking the nutritional products, to spur higher compliance and patient retention.

International Expansion Strategy

The Company intends to continue to pursue strategies for distribution of its existing products and unique nutritional formulations in Asian markets. In the quarter ended March 31, 2020, the Company received its first order for a novel immune support product from the Malaysian company, Ho Wah Genting Berhad "HWGB." The order was subsequently delivered in the quarter ended June 30, 2020. The total order value was $890,000. The Company also has several products under development for the U.S. market, most notably a vision support and energy drink known as EPIQ-V, which the Company believes it may be successfully distributed in Asia.

Ocular Care

Based on management's knowledge of the industry, the Company believes that Lumega-Z and GlaucoCetin are the only medical foods in the ocular health space. Thus, with regard to the ocular health market no such data is available regarding medical foods. In an attempt to illustrate the market potential for Lumega-Z and GlaucoCetin, 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 the Council for Responsible Nutrition, 73% of adults in the United States reported taking dietary supplements in 2020. According to Global Newswire, worldwide sales of supplements is estimated to reach $230.73 billion by 2027. Supplementation has recently generated much interest among eye health professionals, due largely to the publication of the AREDS study, which was supported by the prestigious US National Eye Institute, showing nutrition can potentially slow the AMD epidemic.

U.S. Statistics

- According to Ocular Surgery News, there are 4 million cataract surgeries in the United States each year.
- According to the CDC, more than 3 million Americans are living with glaucoma, and this number is expected to rise to 6.3 million by 2050.
- According to the American Glaucoma Society, glaucoma is the second leading cause of blindness and accounts for 9-12% of all cases of blindness in the U.S.
- According to BrightFocus Foundation, 11 million Americans have AMD, and the number is expected to double to nearly 22 million by 2050.
- According to Am Fam Physician, one in three people in the U.S. over age 65 will develop some form of vision-reducing eye disease with AMD being the top cause of critical vision loss and legal blindness.
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Worldwide Statistics

- According to Grand View Research, the "Global Medical Foods Market" was valued at $20.15 billion in 2020. North America dominated the global market revenue with 29.9% of the 2020 total.
- According to the International Council of Ophthalmology, AMD is the third leading cause of blindness throughout the world, exceeded only by cataracts and glaucoma.
- A meta-analysis by Tham et al. indicated that globally, the number of people with glaucoma was estimated to be 64.3 million in 2013, increasing to 76.0 million in 2020 and projected to be 111.8 million in 2040.
- According to Globe Newswire, the global glaucoma therapeutics market was valued at $6.59 billion in 2018 and is projected to reach $7.34 billion by 2026.
- According to Daxue Consulting, in 2018, approximately 25 million elderly people had AMD in China.
- BrightFocus Foundation has indicated that globally, 196 million people had AMD in 2020 and the number is expected to increase to 288 million by 2040.
- In 2020, BrightFocus Foundation estimated the global cost of visual impairment due to AMD was $343 billion, including $255 billion in direct health care costs. It further estimated the direct health care costs of visual impairment due to AMD in the U.S., Canada and Cuba to be approximately $98 million.
- In 2020, BrightFocus Foundation estimated the global cost of vision loss, due to all causes, to be nearly $3 trillion for the 733 million people living with low vision and blindness worldwide. BrightFocus Foundation also estimated the direct costs for vision loss due to all causes was $512.8 billion in North America alone, with indirect costs of $179 billion.

- Expert Market Research indicates that the global market for AMD treatments was $1.58 billion in 2020 and is projected to reach $2.64 billion by 2026.
- According to Sina and Daily Headlines, there are roughly 44,800 Ophthalmologists and 4,000 Optometrists in China, respectively.
- The prevalence of AMD appears to be lower and more variable in the developing nations as compared to more developed countries. Healthcare experts believe this will likely change for the worse with increasing life expectancy, changing lifestyles and increase in viewing computer monitors and other devices.

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

Marketing Lumega-Z to Practitioners

In order to reach the large, expanding AMD patient population, the Company has primarily marketed Lumega-Z and GlaucoCetin to patients through ophthalmologists and optometrists. In the U.S. alone, there are more than 19,216 ophthalmologists and over 44,000 optometrists currently practicing. There are more than 213,000 ophthalmologists worldwide. This marketing reach will be achieved through a combination of collaboration with industry-specific publishers, peer-to-peer promotion using key opinion leader clinicians, organic and paid search engine optimization and marketing, and other content-driven & educational approaches.

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

As noted earlier, these marketing efforts targeting eye doctors will be supplemented by a variety of direct-to-consumer campaigns and the use of more efficient and cost-effective virtual strategies for educating and connecting with consumers.

Marketing the CSV-1000 and CSV-2000 to Practitioners

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

The Company expects to continue to sell the CSV-1000 for the foreseeable future and add the CSV-2000 to these marketing efforts. The CSV-2000 is not yet approved by the local organizations equivalent to the FDA in many countries, and this process can take up to one or more years. The CSV-1000 will continue to be sold exclusively in those countries during that time period. The Company sold its first CSV-2000 in February of 2020 and sold two units for the year ended December 31, 2020.

Proprietary Technology and Intellectual Property

Patents

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

Trade Secrets

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

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

The AcQviz technology, the basis for vision test standardization for the CSV-2000 product line, is protected by two ITUS patents.

The formulations for Lumega-Z and GlaucoCetin have been submitted for US patent protection.

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 five U.S. registered trademarks on the principal register at the USPTO. These marks are listed below. The Company has three foreign registered trademarks for its products and product candidates at this time and is evaluating whether additional foreign trademark protection is appropriate. U.S. trademark registrations are generally for fixed, but renewable, terms. The Company also currently has common law trademark rights for the use of its marks, including common law trademark rights to the NUTRIGUARD mark. Other trademarks include Lumega-Z, GlaucoCetin, VectorVision, CSV-1000 and CSV-2000.

Copyrights

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

Products Manufacturing and Sources and Availability of Raw Materials

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

Government Regulation

Medical Foods

Under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), products are regulated on the basis of their intended use. Their intended use is determined by the objective factors surrounding their use. Numerous categories and subcategories of products exist under the FDCA that could relate to the Company's products, such as foods, food additives, dietary supplements, GRAS food components, new drugs, GRAS and Effective ("GRAS/E") drugs for over the counter use, and GRAS/E drugs 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 is primarily responsible for regulating medical foods. A medical food is defined under the FDCA as a "food which is formulated to be consumed or administered enterally 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. FDA regulations further describe medical foods as a product that: (i) 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) 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) 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) is intended to be used under medical supervision; and (v) 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.

Medical foods do not require approval or review by FDA prior to marketing. FDA does not require pre-market safety or efficacy studies (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 or condition.

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. The Company and its Scientific Advisory Board examine the distinctive nutritional requirements of a disease.

The labeling for medical foods must comply with all applicable food labeling requirements, except for those specific requirements from which medical foods are exempt. Medical foods are exempt, for example, from the labeling requirements for nutrient content claims and health claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343(r)(5)(A)). As with 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.

All ingredients in medical foods must be either generally recognized as safe (GRAS) or approved food-additives. 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. Because medical foods are typically taken with prescription drugs, the developer must assess whether any medical food/drug interactions pose a risk.

Medical foods manufacturers must register with FDA pursuant to the Bioterrorism Act before producing foods. Manufacturers of foods also must follow current Good Manufacturing Practice ("cGMP") regulations. Entities that manufacture, package, label or hold food products must follow applicable cGMP regulations. These regulations focus on practices that ensure sanitary and cleanly conditions of manufacturing facilities. The Company engages contract manufacturers to manufactures its medical foods. .

The Federal Trade Commission has primarily responsibility to regulate the advertising of foods, including medical foods. Under the FTC Act, all advertising claims, both express and implied, must be truthful, non-misleading, and substantiated.

Enforcement by the regulators is post-market, mostly via FDA inspections of food facilities, including packaging, distribution facilities, and fulfillment houses, as well as the manufacturer. The FDA and FTC also gathers material at trade shows and conferences and examine websites.

Nutraceutical Regulation

The FDA regulates nutraceuticals as “dietary supplements” under the Dietary Supplement, Health and Education Act of 1994 (“DSHEA”) as a separate regulatory category of food. Under DSHEA, a company is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. Dietary supplements do not need approval from FDA before they are marketed. Except in the case of a “new dietary ingredient,” where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after marketing a product.

Dietary supplement manufacturers must register with FDA pursuant to the Bioterrorism Act before producing supplements. Manufacturers of dietary supplements also must follow current Good Manufacturing Practice (“cGMP”) regulations. Entities that manufacture, package, label or hold dietary supplement products must follow applicable cGMP regulations. These regulations focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements.

Congress defined the term “dietary supplement” in DSHEA as “a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins, minerals, amino acids, herbs or other botanicals; a concentrate, metabolite, constituent, extract or combination of the ingredients listed above.” A dietary supplement is a product taken by mouth that contains a “dietary ingredient” intended to supplement the diet. The “dietary ingredients” in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites and can also be extracts or concentrates. Dietary supplements are produced in the form of tablets, capsules, softgels, gelcaps, liquids, or powders.

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

The DSHEA requires that a manufacturer or distributor notify FDA if it intends to market a dietary supplement in the U.S. that contains a “new dietary ingredient.” A new dietary ingredient is an ingredient marketed after October 15, 1994. The manufacturer must demonstrate to FDA that the new ingredient is reasonably expected to be safe for use in a dietary supplement. There is no authoritative list of dietary ingredients that were marketed before October 15, 1994. Therefore, manufacturers are responsible for determining if a dietary ingredient is “new.”

Under DSHEA, a company is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. Dietary supplements must meet all applicable regulations for food labeling. The DSHEA also requires certain disclaimers if structure/function or other health claims are made on the product label.

Medical Device Regulatory Requirements

To fall within the purview of the FDA, a product must first meet the definition of a “device” under the FDCA.. 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.”

FDA categorizes medical devices in three distinct classes based on the potential health risks to the public – Class I, Class II, and Class III. Device classifications are determined by the FDA based on the risk the medical device presents to the patient and the level of regulatory control required to ensure the safety and effectives of the device. Medical devices are classified as Class I, II or III based upon the controls necessary to provide a reasonable assurance of the safety and effectiveness of the device, and factors relevant to this determination include the device’s intended use, technological characteristics, and the risk to patients if the device were to fail. Class I devices, which are subject only to general controls, generally represent the lowest-risk category of devices, while Class III devices, which are subject to general controls and premarket approval, generally represent the highest-risk devices. Class II devices typically require premarket notification to FDA and clearance under Section 510(k) of the FDCA prior to marketing (unless an exemption applies).

The FDA also regulates the labeling and manufacturing of medical devices. Medical device manufacturers must register the facilities and list their devices with the FDA. Manufacturers are subject the current good manufacturing practice (cGMP) regulations, which govern activities such as the design, processing, testing, packaging, distribution, and storage of devices. Manufacturers are subject to periodic inspection by the FDA.

While the FDA governs the labels and labeling of medical devices, the FTC governs the advertising of most devices. Under the FTC Act, all advertising claims, both express and implied, must be truthful, non-misleading, and substantiated.

The Company is registered with the FDA as a medical device manufacturer under registration number 3010367547. The MapcatSF is listed with the FDA as a Class I medical device. With the assistance of regulatory affairs consultants, the Company has determined the 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 and does not require any premarket approval.

VectorVision is registered with the FDA as a medical device manufacturer under registration number 1527853. The CSV-1000, CSV-2000 and the ESV-3000 medical devices are listed with the FDA as Class I medical devices. The applicable product code for these devices is HOX and the applicable Code of Federal Regulation is 886.1150. As Class I medical devices, the CSV-1000, CSV-2000 and the ESV-3000 devices do not require premarket approval.

Stark Law

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

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

Anti-Kickback Statute and HIPAA Criminal Laws

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

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

HIPAA Compliance and Privacy Protection

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

HITECH Act

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

Physician Sunshine Act

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

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

The Federal False Claims Act

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

State Regulatory Requirements

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

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

Other United States Regulatory Requirements

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

Foreign Regulatory Requirements

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

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.

Reverse Stock Split

On March 1, 2021, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-six (1:6) reverse stock split (the "Reverse Stock Split") of its common stock without any change to its par value. Proportional adjustments for the Reverse Stock Split were made to the Company's outstanding common stock, stock options, and warrants as if the split occurred at the beginning of the earliest period presented in this Annual Report.

Employees and Human Capital Resources

As of March 25, 2021, we had 13 full-time employees, including 12 full-time employees and one part-time employee. We consider our relationship with our employees to be good. Our future performance depends significantly upon the continued service of our key personnel and our ability to attract highly skilled employees. We provide our employees with opportunities for equity ownership.

Advisory Boards

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

Science Advisory Board

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

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

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

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

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

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

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

Medical Advisory Board

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

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

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

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

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

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

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

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

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

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

RISK FACTORS SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors, but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors", together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

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

- The COVID-19 global pandemic could adversely impact our business, including the commercialization of our medicines, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities.

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

- Our stock price has fluctuated significantly in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.

- Additional risks and uncertainties include:

- Our ability to integrate a new management team;

- Our ability to comply with the continued listing requirements of the Nasdaq Capital Market;

- Our ability to successfully pursue our business plan and execute our strategy, design and implement systems and programs to develop products and deliver to market on a timely basis; and

- The effect of economic and political conditions in the United States or other nations that could impact our ability to sell our products and services or gain customers.

ITEM 1A. RISK FACTORS

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

Risks Related to the Company's Business

As the Company has incurred recurring losses and negative cash flows since our inception, there is no assurance that the Company will be able to reach and sustain profitability. If it cannot, the Company will be required to secure additional financing, which the Company may not be able to obtain on favorable terms or at all.

The Company has incurred net losses since inception in 2009 and cannot be certain if or when the Company will produce sufficient revenue from operations to support costs. The Company had a net loss of $8,571,657 for the year ended December 31, 2020 and a net loss of $10,878,308 for the year ended December 31, 2019. The Company had an accumulated deficit of $54,083,328 as of December 31, 2020. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. At December 31, 2020, the Company had cash on hand of $8,518,732 and working capital of $8,021,152. Subsequent to December 31, 2020, the Company sold an aggregate of 7,566,733 shares of its common stock for net proceeds of approximately $33,600,000 in two offerings, one completed in January 2021, and one completed in February 2021. In addition, in January and February 2021, the Company issued an aggregate of 1,647,691 shares of common stock upon the exercise of warrants and received cash proceeds of $3,608,509. Notwithstanding the net loss for 2020, management believes that its current cash balance, plus the net proceeds from issuance of common stock and exercise of warrants in January and February 2021, is sufficient to fund operations for at least one year from the date the Company's 2020 financial statements are issued.

The Company will continue to incur significant expenses related to commercialization of its products and with respect to efforts to build its infrastructure, expand its operations, and execute on its business plans. The Company may also utilize cash to fund acquisitions.

Even if profitability is achieved in the future, the Company may not be able to sustain profitability on a consistent basis. The Company expects to continue to incur substantial losses and negative cash flow from operations for the foreseeable future.

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

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

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

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

The COVID-19 global pandemic could adversely impact our business, including the commercialization of our medicines, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities.

On March 11, 2020, the World Health Organization made the assessment that a novel strain of coronavirus, which causes the COVID-19 disease, can be characterized as a pandemic. The President of the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the Unites States have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions). The effects of government actions and our policies and those of third parties to reduce the spread of COVID-19 may negatively impact productivity and our ability to market and sell our products, cause disruptions to our supply chain and impair our ability to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

The commercialization of our products may be adversely impacted by COVID-19 and actions taken to slow its spread. For example, patients may postpone visits to healthcare provider facilities, certain healthcare providers have temporarily closed their offices or are restricting patient visits, healthcare provider employees may become generally unavailable and there could be disruptions in the operations of payors, distributors, logistics providers and other third parties that are necessary for our products to be recommended and administered to patients.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, it may make any additional debt or equity financing more difficult, more costly or more dilutive. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position or our business development activities.

COVID-19 continues to rapidly evolve. The extent to which COVID-19 may impact the commercialization of our products, our supply chain, our access to capital and our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions and the impact on the economy and capital markets.

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

Development and commercialization of medical foods, nutraceuticals, and medical devices involves a lengthy and complex process. The Company has limited experience in developing products and has only two commercialized medical food products on the market, Lumega-Z and GlaucoCetin. The Company cannot assure you that it is possible to successfully commercialize the MapcatSF. The Company launched the CSV-2000 in Q1 2020, but there is no assurance the introduction of the instrument will be successful. Furthermore, there is no guarantee that the NutriGuard nutraceuticals will be marketable or that the Company will achieve commercial success with the product line.

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

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

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

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

As a participant in the healthcare industry, the Company's operations and relationships, and those of the Company's customers, are regulated by a number of federal, state, local, and foreign governmental entities with oversight of various aspects of product manufacture, distribution, sale, and use. The regulations are very complex, have become more stringent over time, and are subject to changing and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other federal and state governmental agencies regulate numerous elements of our business, including:

- Product design and development;
- pre-clinical and clinical testing;
- labeling, and storage;
- establishment registration and product listing;
- product safety, including product recalls or other field-safety actions;
- marketing, manufacturing, sales, and distribution;

- premarket clearance or approval;
- record keeping procedures;
- advertising and promotion;
- post-market surveillance, including reporting of adverse events; and
- product import and export.

We may be subject to similar foreign laws that govern all of the above elements of our business, including pre-market and post marketing obligations for our medical foods and nutraceuticals. The time required to obtain authorization to sell our products in foreign countries may be longer or shorter than that required by the FDA, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements. In the European Union (EU), member states are responsible for enforcing the EU's rules and for ensuring that only compliant products are placed on the market in their jurisdictions. Member states have powers to suspend the marketing and use, or demand the recall, of unsafe or non-compliant medical products. They also have the power to bring enforcement action against companies or individuals for breaches of the rules governing certain medical products.

The FDA, states, and other regulatory authorities have broad enforcement powers. Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, or regulatory authorities, which may include the following:

- untitled letters or warning letters;
- fines, disgorgement, restitution, or civil penalties;
- injunctions (e.g., total or partial suspension of production) or consent decrees;
- product recalls, administrative detention, or seizure;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant requests for future product approvals, new intended uses, or modifications to existing products; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition, and results of operations.

Foods and nutraceuticals do not require premarket approval by FDA before they may be distributed in the United States (with limited exceptions). Unless an exemption applies, medical devices distributed in the United States must receive either premarket clearance under Section 510(k) of the FDCA, grant of a *de novo* classification request, or premarket approval of a premarket application before they may be commercially distributed. Medical devices are classified into one of three classes - Class I, Class II, or Class III - depending on the degree of risk associated with the device and the extent of control needed to ensure safety and effectiveness. Medical devices deemed to pose relatively low risk are placed in Class I, which generally do not require premarket notification or premarket approval.

In the US, the FDA and Federal Trade Commission (FTC) largely govern the promotion of food, supplements, and medical devices, and the Company's products must be promoted in compliance with the laws and regulations of these and other regulators. FDA defines a "drug" as an article that is intended for use in the cure, treatment, prevention or mitigation of a disease. A medical food is defined as "a food which is formulated to be consumed or administered enterally 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." While the Company believes Lumega-Z and GlaucoCetin are medical foods, if the FDA determines Lumega-Z or GlaucoCetin to be a drug, the Company and the product would be subject to considerable additional FDA regulation.

The Company believes the MapcatSF is classified as a Class I medical device that does not require premarket approval. The Company also believes the CSV-2000 is a Class I medical device that does not require premarket approval. If, however, the FDA were to determine that the MapcatSF or CSV-2000 is a Class II medical device, the products would be subject to additional regulatory requirements, including premarket approval.

The NutriGuard line of products are nutraceuticals and are regulated as dietary supplements under the Dietary Supplement, Health and Education Act of 1994 ("DSHEA"). DSHEA places dietary supplements in a special regulatory category under the general umbrella of "foods," with differing requirements from consumer food products and medical foods. Dietary supplements are supposed to enhance the diet and not be represented as a conventional food or as the sole item of a meal or diet. Nutraceuticals are not intended to cure or treat disease, but they may be intended to affect the structure or function of the body. Dietary supplements that contain structure/function claims on their labels must bear the disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." The manufacturer is responsible for ensuring the accuracy and truthfulness of product claims; product claims are not approved by FDA. Dietary supplements also are subject to the Nutrition, Labeling and Education Act ("NLEA"), which regulates health claims, ingredient labeling and nutrient content claims characterizing the level of a nutrient in a product.

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

If we or our third-party manufacturers fail to comply with the FDA's good manufacturing practice regulations or fail to adequately, timely, or sufficiently respond to an FDA Form 483 or subsequent Warning Letter, this could impair our ability to market our products in a cost-effective and timely manner and could result in FDA enforcement action.

The FDA requires facilities that manufacture FDA-regulated products to comply with cGMP regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our product. The Company does not manufacture any of its products internally and instead relies on contract manufacturers to manufacture its products. We and our third-party manufacturers are required to comply with cGMP. The FDA audits compliance with cGMP and related regulations through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct these inspections at any time.

The Company may be subject to fines, penalties, injunctions or other administrative actions if it is deemed to be promoting its nutritional or medical foods products as a drug, or if it's using false or misleading claims in its promotional materials.

The Company's business and future growth depend on the development, use and ultimate sale of products that are subject to FDA regulation. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, the Company is prohibited from promoting its nutritional and medical foods products for treatment of a condition or disease. Our promotional materials and marketing activities must comply with FDA and other applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the off-label use of our products or that make false or misleading statements. FDA also could conclude that a performance claim is misleading if it determines that there are inadequate non-clinical and/or clinical data supporting the claim.

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, or that our promotional materials include false or misleading statements. The Company also faces the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that the Company discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

To the extent we continue 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.

We now sell our products to customers outside the U.S. and we intend to continue expansion of our international operations. As a result, our business is increasingly exposed to risks inherent in international operations. These risks, which can vary substantially by location, include the following:

- governmental laws, regulations and policies adopted to manage national economic and macroeconomic conditions, such as increases in taxes, austerity measures that may impact consumer spending, monetary policies that may impact inflation rates, currency fluctuations and sustainability of resources;

- changes in environmental, health and safety regulations, such as the continued implementation of the European Union's REACH regulations and similar regulations that are being evaluated and adopted in other markets, and the burdens and costs of our compliance with such regulations;

- increased environmental, health and safety regulations or the loss of necessary environmental permits in certain countries, arising from growing consumer sensitivity concerning the inclusion of flavor additives in food products and the fact that regulators perceive nutraceuticals, medical foods and functional food products as having medicinal attributes;

- the imposition of or changes in tariffs, quotas, trade barriers, other trade protection measures and import or export licensing requirements, by the U.S. or other Countries, which could adversely affect our cost or ability to import raw materials or export our flavors and fragrance products to surrounding markets;

- risks and costs arising from language and cultural differences;

- changes in the laws and policies that govern foreign investment in the countries in which we operate, including the risk of expropriation or nationalization, and the costs and ability to repatriate the profit that we generate in these countries;

- risks and costs associated with political and economic instability, bribery and corruption, anti-American sentiment, and social and ethnic unrest in the countries in which we operate;

- difficulty in recruiting and retaining trained local personnel;

- natural disasters, pandemics or international conflicts, including terrorist acts, or national and regional labor strikes in the countries in which we operate, which could interrupt our operations or endanger our personnel; or

- the risks of operating in developing or emerging markets in which there are significant uncertainties regarding the interpretation, application and enforceability of laws and regulations and the enforceability of contract rights and intellectual property rights.

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

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

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

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

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

Although medical foods do not require pre-market approval by the FDA, manufacturers of medical foods and dietary supplements 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"). Manufactures of medical devices also are required to be registered with the FDA. Manufacturers of FDA-regulated products are subject to periodic inspection by the FDA and state health authorities. The manufacture of our nutraceuticals, medical foods, and devices is outsourced in its entirety to three third-party manufacturers. We are evaluating additional manufacturers for selection as second source or back-up providers.

Our products have not been reviewed by the FDA. There is no certainty that the FDA will favorably review our products or our manufacturers' facilities. If the outcome of an inspection is negative or if we or our manufacturers fail to comply with any law or regulation, we could be subject to penalties and restrictions on our manufacturers' ability to manufacture and distribute products. Any such action may result in a material adverse effect on our business and results of operations. For a more complete discussion of the laws and regulations to which we are subject, see the section of this annual report titled "Business - Government Regulation."

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

In the years ended December 31, 2020 and 2019, the Company's billings were derived from a limited number of individual customers and distributors. During the year ended December 31, 2020, the Company had one customer who accounted for approximately 47% of the Company's sales; and during the year ended December 31, 2019, the Company had one customer who accounted for approximately 22% of the Company's sales. 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 customers do not accept the Company's products or delay in deciding whether to recommend the Company's products and services, its business, financial condition and results of operations may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In September 2018, California enacted SB 826 requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by the end of 2019, at least one woman on its board, by the end of 2020, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors.

In September 2020, California enacted AB 979, which requires that by the end of 2021 California-headquartered public companies have at least one director on their boards who is from an underrepresented community, defined as "an individual who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or who self-identifies as gay, lesbian, bisexual, or transgender."

In addition to that initial 2021 requirement, the law mandates that the number of directors from underrepresented communities be increased by the end of calendar year 2022, depending on the size of the board.

In addition, NASDAQ has proposed to adopt new listing rules related to board diversity and disclosure. If approved by the SEC, the new listing rules would require all companies listed on Nasdaq's U.S. exchanges to publicly disclose consistent, transparent diversity statistics regarding their board of directors. Additionally, the rules would require most Nasdaq-listed companies to have, or explain why they do not have, at least two diverse directors, including one who self-identifies as female and one who self-identifies as either an underrepresented minority or LGBTQ+.

Failure to achieve designated minimum gender and diversity levels in a timely manner exposes such companies to financial penalties and reputational harm. We cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender and diversity quotas as a result of the California laws or future NASDAQ rules, which may expose us to penalties and/or reputational harm.

Our acquisition strategy involves a number of risks.

We are regularly engaged in acquisition discussions with other companies and anticipate that one or more potential acquisition opportunities, including those that would be material or could involve businesses with operating characteristics that differ from our existing business operations, may become available in the near future. If and when appropriate acquisition opportunities become available, we intend to pursue them actively. Acquisitions involve a number of special risks, including:

- failure of the acquired business to achieve expected results, as well as the potential impairment of the acquired assets if operating results decline after acquisition;
- diversion of management's attention;
- additional financing, if necessary and available, which could increase leverage and costs, dilute equity, or both;
- the potential negative effect on our financial statements from the increase in goodwill and other intangibles;
- difficulties in integrating the operations, systems, technologies, products and personnel of acquired companies;
- initial dependence on unfamiliar supply chains or relatively small supply partners;
- the potential loss of key employees, customers, distributors, vendors and other business partners of the companies we acquire after the acquisition;
- the high cost and expenses of identifying, negotiating and completing acquisitions; and
- risks associated with unanticipated events or liabilities.

These risks could have a material adverse effect on our business, results of operations and financial condition. We have faced, and expect to continue to face, intense competition for acquisition candidates, which may limit our ability to make acquisitions and may lead to higher acquisition prices. We cannot assure you that we will be able to identify, acquire or manage profitably any acquisition opportunity.

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

While we believe Lumega-Z® and Glauco-Cetin™ to be medical foods and not drugs, they are only available under the supervision of a physician. While not available in pharmacies, we are mindful that the act of physicians prescribing, particularly if conducted across state lines, could potentially be subject to certain pharmacy regulations. Each state has its own regulations concerning physician dispensing, restrictions on the corporate practice of medicine, anti-kickback and false claims. In addition, each state has a board of pharmacy that regulates the sale and distribution of drugs and other therapeutic agents. Some states require a physician to obtain a license to dispense prescription products. While we do not believe these pharmacy requirements are applicable, should a pharmacy board or medical board determine otherwise, there can be no assurance that we will be able to comply with the regulations of particular states into which we may expand or that we will be able to maintain compliance with the states in which we currently distribute our products. We currently have Lumega-Z customers in Alabama, Alaska, 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 Malaysia 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.

For distribution of products in Malaysia, China and throughout Asia, our nutritional compounds are affected by the regulatory agencies in each country. Each country has unique requirements related to the amount of ingredients allowed in the product and the labelling of each product. We believe that by obtaining regulatory approval in advance of marketing and distribution in each country, we will be protected from these regulatory restrictions affecting our ongoing operations. However, many factors can affect our ability to maintain compliance that are out of our control, including the availability of approved ingredients and sudden changes in regulatory restrictions imposed by each country.

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

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

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

In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

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

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

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

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

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

Risks Related to the Company's Industry

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

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

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

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

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

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

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

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

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

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

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

Risks Related to The Company's Common Stock

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an emerging growth company, we have elected to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which we refer to as the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. As a result of these reduced reporting and disclosure requirements our financial statements may not be comparable to SEC registrants not classified as emerging growth companies. We may be an emerging growth company for up to five years following the first sale our equity securities in a public offering (April 2019), although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million before that time or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would immediately cease to be an emerging growth company. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. Additionally, over the course of the past year, our shareholder base has increased in size due to the prevalence of new platforms and ease of access to stock trading brought on by new technologies. We may incur rapid and substantial increases or decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. In addition, the recent outbreak of the novel strain of coronavirus (COVID-19) has caused broad stock market and industry fluctuations. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- investor reaction to our business strategy;
- investor reaction to our acquisition strategy;
- the success of competitive products or technologies;
- our continued compliance with the listing standards of NASDAQ;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- actions taken by regulatory agencies with respect to our products, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations or partners;
- declines in the market prices of stocks generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID-19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability; and

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Further, recent increases are inconsistent with any improvements in actual or expected operating performance, financial condition or other indicators of value. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our common stock will not be at prices lower than those sold to investors.

Additionally, recently, securities of certain companies have experienced significant and extreme volatility in stock price due short sellers of shares of common stock, known as a "short squeeze." These short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. While we have no reason to believe our shares would be the target of a short squeeze, there can be no assurance that we won't be in the future, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value.

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

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

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

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

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

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.

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

Maintaining effective internal control over financial reporting and effective disclosure controls and procedures are necessary for us to produce reliable financial statements. As discussed in Item 9A – "Controls and Procedures" of this Form 10-K, we have re-evaluated our internal control over financial reporting and our disclosure controls and procedures and concluded that they were not effective as of December 31, 2020.

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we identified was inadequate segregation of duties within accounting processes.

The Company is committed to remediating its material weaknesses as promptly as possible. Implementation of the Company's remediation plans has commenced and is being overseen by the audit committee. However, there can be no assurance as to when these material weaknesses will be remediated or that additional material weaknesses will not arise in the future. Even effective internal control can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. Any failure to remediate the material weaknesses, or the development of new material weaknesses in our internal control over financial reporting, could result in material misstatements in our financial statements, which in turn could have a material adverse effect on our financial condition and the trading price of our common stock and we could fail to meet our financial reporting obligations.

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

On September 20, 2019, we received notice from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the previous 30 consecutive business days, the Company no longer satisfied the requirement to maintain a minimum bid price of $1.00 per share, as required by Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule").

In accordance with the Nasdaq Listing Rules, the Company was afforded 180 days, or until March 18, 2020, to regain compliance with the Bid Price Rule by evidence of a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. Thereafter, the Company had been afforded a second 180-calendar day compliance period (which 180-day period was extended due to circumstances related to COVID-19), or until November 30, 2020, to regain compliance with the Bid Price Rule.

The Company was unable to regain compliance with the Bid Price Rule by November 30, 2020. Accordingly, on December 1, 2020, the Company received a letter from the Staff notifying it that its Common Stock would be subject to delisting from Nasdaq unless the Company timely appealed Nasdaq's determination to a Nasdaq Listing Qualifications Panel (the "Panel"). The Company timely appealed Nasdaq's determination to the Panel.

On January 26, 2021, the Company received written notification that the Panel granted the Company an extension for continued listing through March 15, 2021.

On March 1, 2021, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-six (1:6) reverse stock split (the "Reverse Stock Split") of its common stock without any change to its par value. Proportional adjustments for the Reverse Stock Split were made to the Company's outstanding common stock, stock options, and warrants as if the split occurred at the beginning of the earliest period presented in this Annual Report.

On March 15, 2021, we received a letter from the Staff notifying us that we had regained compliance with the Bid Price Rule. The letter stated the staff had determined that for the prior 10 consecutive business days the closing bid price of the Company's common stock had been at $1.00 per share or greater and that accordingly, the Company had regained compliance under the Bid Price Rule, and that the matter was now closed.

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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

In connection with the VectorVision acquisition, the Company assumed a lease agreement for 5,000 square feet of office and warehouse space in Greenville Ohio which commenced October 1, 2017 through February 2023.

ITEM 3. LEGAL PROCEEDINGS

The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained. As of March 25, 2021, the Company is not subject to any such proceedings or claims.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

The Company's common stock is listed on The NASDAQ Capital Market under the symbol "GHSI." As of March 25, 2021, there were approximately 169 record holders of the Company's common stock.

Dividend Policy

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

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Presentation of Information

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

Overview

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

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

We see opportunities to grow our business and create value by developing and distributing condition-specific, clinically proven nutrition, medical foods, and diagnostic devices. Our portfolio of science-based, clinically supported products support healthcare professionals, their patients, and consumers in achieving health goals.

Recent Trends – Market Conditions

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

Recent Developments

January and February 2021 At the Market Offerings

On January 8, 2021, we entered into the Sales Agreement and filed a prospectus supplement pursuant to which we could sell up to $10,000,000 worth of shares of our common stock in an "at the market" offering through the Distribution Agent (the "January 2021 1st ATM Offering"). On January 15, 2021, we completed the January 2021 1st ATM Offering, pursuant to which we sold an aggregate of 2,559,834 shares of our common stock, raised gross proceeds of approximately $10,000,000 and net proceeds of approximately $9,500,000.

On January 28, 2021, we entered into the Sales Agreement and filed a prospectus supplement pursuant to which we could sell up to $25,000,000 worth of shares of our common stock in an "at the market" offering through the Distribution Agent (the "January 2021 2nd ATM Offering"). On February 10, 2021, we completed the January 2021 2nd ATM Offering, pursuant to which we sold an aggregate of 5,006,900 shares of our common stock, raised gross proceeds of approximately $25,000,000 and net proceeds of approximately $24,100,000.

In addition, in January 2021 and February 2021, the Company issued an aggregate of 1,647,691 shares of common stock upon the exercise of warrants and received $3,608,509.

2019 Initial Public Offering and 2019 Follow-On Public Offerings

On April 9, 2019, the Company closed its initial public offering (the "IPO") of 208,334 shares of common stock, par value $0.001 per share, at an IPO price to the public of $24.00 per share resulting in net proceeds to the Company of $3,888,000 after all costs and expenses. The shares began trading on the NASDAQ Capital Market on April 5, 2019 under the symbol "GHSI."

On August 15, 2019, the Company completed a second public offering (the "August Offering") of (i) 2,000,000 shares of common stock, (ii) pre-funded warrants exercisable for 166,667 shares of common stock (the "Pre-Funded Warrants"), and (iii) warrants to purchase up to an aggregate of 2,166,667 shares of common stock (the "August Warrants"). The August Offering was conducted pursuant to an Underwriting Agreement, dated August 13, 2019 by and between the Company and Maxim Group LLC and WallachBeth Capital, LLC. On August 16, 2019, the Company sold an additional 325,000 August Warrants upon exercise of the underwriters' over-allotment option. The net proceeds to the Company from the August Offering, after deducting underwriting discounts and commissions and other estimated expenses were $4,944,340.

The public offering price was $2.64 per share of common stock and $0.01 per accompanying August Warrant. Each August Warrant represents the right to purchase one share of common stock at an exercise price of $3.51 per share. The August Warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) September 11, 2019 and (ii) the date on which the common stock traded an aggregate of more than 6,666,667 shares after the announcement of the pricing of the August Offering, and ending on the twelve (12) month anniversary thereof, each August Warrant may be exercised at the option of the holder on a cashless basis at a ratio of one August Warrant for one share of common stock, in whole or in part, if the weighted average price of the Common Stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the August Warrant

On October 30, 2019, the Company completed a third public offering of 4,083,334 shares of its common stock (including 283,334 pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 4,083,334 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $2.052 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but will be issued separately and will be immediately separable upon issuance. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7.4 million.

The Series B warrants are exercisable at a price of $2.05 per share of common stock and will expire five years from the date on which the Series B warrants become initially exercisable.

Warrant Exercises

From January 1, 2020 through December 31, 2020, the Company received total gross proceeds of $5,451,892 from the exercise of 2,656,868 warrants issued in the Company's October 2019 follow-on offering.

NutriGuard Acquisition

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

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

Nutraceutical Sales to Malaysian Customer

In February 2020, the Company contracted with a Malaysian company to develop an immune-supportive formula for its consumer base. An initial order was placed, and the Company completed shipment of the product, received payment in full, and recognized revenue for this order of $890,000 during the year ended December 31, 2020.

Recent Accounting Pronouncements

See Note 1 to the financial statements regarding recent accounting pronouncements.

Concentration of Risk

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

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*. Revenue is recognized when control of promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products or services. The Company reviews its sales transactions to identify contractual rights, performance obligations, and transaction prices, including the allocation of prices to separate performance obligations, if applicable.

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

Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Payments for sales of medical foods and dietary supplements are generally made by approved credit cards. Payments for medical device sales are generally made by check, credit card, or wire transfer. Historically the Company has not experienced any significant payment delays from customers.

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

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. The Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. The difference is recognized as a loss in the period in which it occurs. Once inventory has been written down, it creates a new cost basis for inventory that is not subsequently written up.

Stock-Based Compensation

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

Stock-based payments to officers, directors, consultants, contractors, and employees, which include grants of employee stock options, are recognized in the financial statements based on their fair values. Stock option grants, which are generally time or performance vested, are 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.

Plan of Operations

General Overview

Based on the availability of sufficient funding, the Company intends to increase its commercialization activities and capitalize on growth opportunities. Our significant business development and commercialization activities include:

- expand the Company's domestic sales and marketing efforts, including increased digital marketing to consumers and health care professionals;
- explore sales and marketing opportunities in foreign markets such as Asia and Europe;
- increase the marketing and production of Lumega-Z® and GlaucoCetin™ to support the additional sales resulting from increased marketing and promotional activity;
- expand the Company's direct-to-consumer capabilities for both medical foods and nutraceutical products;
- increase the utilization of medical research and clinical studies to support the Company's products;
- increase the existing NutriGuard customer base through NutriGuard Formulations, Inc. and build on its product platform, by making NutriGuard products available to customers directly through direct-to-consumer (DTC) channels, third party eCommerce platforms and through recommendations by their physicians;
- utilize a team of experts and digital tools to educate and train eye care physicians on the benefits of our products;
- review our product portfolio to and improve the product and the customer experience;
- increased new product development to address unmet consumer needs;
- increased distribution of nutraceutical products, including more distribution via third party eCommerce retailers;
- improve the Company's eCommerce capabilities, including installation of new SaaS ecommerce platform; and
- improve our approach and service levels to Eye Care Practitioners and customers.

In addition to the commercialization and business development activities described above, we will also seek opportunities to utilize mergers and acquisitions and similar transactions to advance our business strategy.

Results of Operations

Through December 31, 2020, the Company has primarily been engaged in product development, commercialization, building infrastructure and raising capital. The Company has incurred and will continue to incur significant expenditures for the development of its products and intellectual property, which includes medical foods and medical devices for the treatment of various eye diseases and nutraceuticals. The Company had limited revenue during the years ended December 31, 2020 and 2019.

Comparison of Years Ended December 31, 2020 and 2019

	Years Ended December 31,			
	2020	2019	Change	
Revenue	$ 1,889,844	$ 902,937	$ 986,907	109%
Cost of goods sold (includes write down of inventory of $971,719 during the year ended December 31, 2020)	1,946,635	341,315	1,605,320	470%
Gross profit (loss)	(56,791)	561,622	618,413	(110%)
Operating expenses:				
Research and development	160,978	194,311	(33,333)	(17%)
Sales and marketing	1,450,205	1,874,901	(424,696)	(23%)
General and administrative	7,450,245	7,425,827	24,418	0%
Costs related to resignation of former officer (including the reversal of previously recognized stock compensation expense of $965,295 during the year ended December 31, 2020)	(615,936)	-	(615,936)	-
Loss on sales of equipment	18,500	-	18,500	-
Equipment impairment	30,948	-	30,948	-
Goodwill impairment	-	1,563,520	(1,563,520)	(100%)
Total operating expenses	8,494,940	11,058,559	(2,563,619)	(23%)
Loss from operations	(8,551,731)	(10,496,937)	(1,945,206)	19%
Other (income) expense:				
Interest expense	7,271	258,365	(251,094)	(97%)
Finance cost upon issuance of warrants	-	415,955	(415,955)	(100%)
Change in fair value of derivative warrants	12,655	(292,949)	305,604	(104%)
Net loss	$ (8,571,657)	$ (10,878,308)	$ 2,306,651	21%

Revenue

For the year ended December 31, 2020, revenue from product sales was $1,889,844 compared to $902,937 for the year ended December 31, 2019, resulting in an increase of $986,907 or 109%. The increase is due primarily to a sale to a Malaysian company of $890,000 for an immune-supportive formula that was delivered by the Company in June 2020.

Cost of Goods Sold

For the year ended December 31, 2020, cost of goods sold was $1,946,635 compared to $341,315 for the year ended December 31, 2019, resulting in an increase of $1,605,320 or 470%. One part of the increase in 2020 reflects the costs of goods sold associated with the Malaysian order noted above. In addition, as a result of the deterioration of the forecasted marketability of certain of the Company's inventory, management recorded a write-down of inventory of $971,719 in cost of goods sold for the year ended December 31, 2020. Without the impact of the inventory write-down in the year ended December 31, 2020, cost of goods sold increased $633,601 or 186%.

Gross Profit (Loss)

For the year ended December 31, 2020, gross loss was $(56,791) compared to gross profit of $561,622 for the year ended December 31, 2019, resulting in a decrease of $618,413 or 110%. Gross profit (loss) represented (3)% of revenues for the year ended December 31, 2020, versus 62% of revenue for the year ended December 31, 2019. The lower gross profit in 2020 is primarily as a result of lower distributor pricing given to the Malaysian customer and the write-down of certain inventory that increased cost of goods sold by $971,719.

Research and Development

For the year ended December 31, 2020, research and development costs were $160,978 compared to $194,311 for the year ended December 31, 2019, resulting in a decrease of $33,333 or 17%. Research and development costs in our current yearly-period consist primarily of clinical studies related to our medical foods and nutraceuticals versus engineering efforts related to our medical devices in our prior period.

Sales and Marketing

For the year ended December 31, 2020, sales and marketing expenses were $1,450,205 compared to $1,874,901 for the year ended December 31, 2019. The decrease in sales and marketing expenses of $424,696 or 23% compared to the prior period was primarily due to a decrease of trade show activity as a result of COVID-19 “stay at home” measures.

General and Administrative

For the year ended December 31, 2020, general and administrative expenses were $7,450,245 compared to $7,425,827 for the year ended December 31, 2019. The increase of $24,418 or 0% compared to the prior period was primarily due to an increase in consulting costs, professional fees, and corporate insurance costs, largely offset by a $1,266,000 decrease in stock compensation expense primarily related to the reversal of compensation from prior periods related to forfeited unvested options of a former officer.

Goodwill Impairment

Management concluded that as of December 31, 2019, the fair value of the goodwill associated with the VectorVision acquisition was less than its carrying amount. For the year ended December 31, 32019, the Company recorded a goodwill impairment charge of $1,563,520. There was no goodwill impairment recorded in 2020.

Costs Related to Resignation of Former Officer

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer and as an employee of the Company and resigned from the Company’s Board of Directors. Terms of the settlement agreement included the continuation of his previous annual salary of $325,000 during the following twelve months. The full amount of stock compensation costs were recorded in costs related to resignation of former officer.

Mr. Favish’s unvested options at the time of his separation were forfeited. All compensation from prior periods related to these unvested options was reversed, resulting in an adjustment to stock compensation expense during the year ended December 31, 2020 of $(965,295) that was recorded in costs related to resignation of former officer.

In connection with Mr. Favish’s separation, the expiration date of his vested stock options was extended for twelve months from June 15, 2020. In accounting for the modification, the Company calculated the fair value of the vested options immediately before modification and immediately following the modification and recorded incremental stock compensation charge of $24,359 in costs related to resignation of former officer.

Impairment Loss on Equipment Held for Sale

During June 2020, in an effort to reduce costs and focus on other segments of the business, the Company decided to wind down the Transcranial Doppler Solutions, Inc. (“TDSI”) subsidiary and ceased its operations. The wind down was completed in July 2020. TDSI held a group of ultrasound machines as fixed assets. The Company sold these machines, and recorded a loss on sale of $18,500 during the year ended December 31, 2020. There was no loss on equipment during 2019.

Interest Expense

For the year ended December 31, 2020, interest expense was $7,271 compared to $258,365 for the year ended December 31, 2019. The decrease of $251,094 or 97%, was due primarily to the amortization of the valuation discount of the March 2019 convertible notes of $233,455 that was reflected as an expense when the notes were converted to equity in April 2019.

Finance Cost Upon Issuance of Warrants

Finance costs for the year ended December 31, 2020 were $0. Finance costs for the year ended December 31, 2019 were $415,955. The 2019 finance costs result from the two transactions. First, in March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019), and due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019. The fair value of the warrants at the closing of the IPO was determined to be $436,034, of which $250,000 was recorded as a valuation discount, and $186,034 was recorded as a finance cost. Second, on April 4, 2019, the Company issued 10,417 warrants with an exercise price of $30.00 per share to the Underwriter in connection with the Company's IPO, that were accounted for as a derivative liability. The fair value of the warrants at the date of issuance was determined to be $229,921 and was recorded as a finance cost.

Change in Fair Value of Derivative Warrants

In 2019, the fair value of warrants classified as derivative liabilities totaled $665,955 upon issuance. During 2019, derivative warrants with a fair value of $359,683 were reclassified to equity, and a decrease in the fair value of derivatives warrant liabilities of $292,949 was recorded. At December 31, 2019, the balance of derivative warrant liabilities was $13,323. During 2020, an increase in the fair value of derivative warrant liabilities of $12,655 was recorded, and at December 31, 2020, the balance of derivative warrant liabilities was $25,978. The decrease in change in derivative warrant liabilities was primarily due to the reclassification of derivative warrant liabilities to equity in 2019. There was no such reclassification in 2020.

Net Loss

For the year ended December 31, 2020, the Company incurred a net loss of $8,571,657, compared to a net loss of $10,878,308 for the year ended December 31, 2019. The decrease in net loss of $2,306,651 or 21% compared to the prior year period was primarily due to increased revenues, a decrease in certain operating costs, and an offsetting increase to cost of goods sold for write off of inventory.

Segment Information

The following tables set forth our results of operations by segment:

The. Medical Foods and Nutraceuticals segment provides a portfolio of science-based, clinically supported nutrition, medical foods, and supplements. Our products include, among others, Lumega-Z, GlaucoCetin and ImmuneSF.

The Medical Devices segment includes a portfolio of medical diagnostic devices currently focused on the ocular space and is the industry leader in contrast testing. Our products include VectorVision CSV-1000, CSV-1000HGT, CSV-2000 and associated accessories as well as the MapcatSF.

See Note 13 for further details on our reportable segments.

	For the Year Ended December 31, 2020			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ 4,500	$ 1,609,482	$ 275,862	$ 1,889,844
Cost of goods sold	2,478	1,599,510	344,647	1,946,635
Gross profit (loss)	2,022	9,972	(68,785)	(56,791)
Stock compensation expense	544,127		-	544,127
Operating expenses	3,757,945	3,892,899	299,969	7,950,813
Loss from operations	**$ (4,300,050)**	**$ (3,882,927)**	**$ (368,754)**	**$ (8,551,731)**

	For the Year Ended December 31, 2019			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ 24,270	$ 444,657	$ 434,010	$ 902,937
Cost of goods sold	7,288	155,212	178,815	341,315
Gross profit	16,982	289,445	255,195	561,622
Stock compensation expense	2,717,731	-	-	2,717,731
Goodwill impairment charge	-	-	1,563,520	1,563,520
Operating expenses	360,257	5,308,508	1,108,543	6,777,308
Loss from operations	**$ (3,061,006)**	**$ (5,019,063)**	**$ (2,416,868)**	**$ (10,496,937)**

Revenue

For the year ended December 31, 2020, revenue from our Medical Foods and Nutraceuticals segment was $1,609,482 compared to $444,657 for the year ended December 31, 2019, resulting in an increase of $1,164,825 or 262%. The increase is due primarily to the completion of an order to a Malaysian customer for an immune-supportive formula that was delivered in June 2020 and the Company recognized revenue for this order of $890,000 at such time. For the year ended December 31, 2020, revenue from our Medical Devices segment was $275,862 compared to $434,010 for the year ended December 31, 2019, resulting in a decrease of $158,148 or 36%, primarily as a result of medical facility and office closures due to COVID-19 “Stay at Home” orders. The decrease was offset in part from the sale of a MapCat device in January 2020. The severity of the impact of the COVID-19 pandemic on the Company’s business will continue to depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company’s customers, service providers and suppliers, all of which are uncertain and cannot be predicted.

Cost of Goods Sold

For the year ended December 31, 2020, cost of goods sold from our Medical Foods and Nutraceuticals segment was $1,599,510 compared to $155,212 for the year ended December 31, 2019, resulting in an increase of $1,444,298 or 931%. The increase was primarily due to the increase in cost associated with the Malaysian order in addition to a write down of $760,488 for allowance of excess and obsolete nutraceutical inventory. For the year ended December 31, 2020, cost of goods sold from our Medical Devices segment was $344,647 compared to $178,815 for the year ended December 31, 2019, resulting in an increase of $165,832 or 93%. The increase was due to a write down of $211,231 for allowance of excess and obsolete medical device inventory. In addition, a $13,000 inventory adjustment affecting cost of sales due primarily to the write off of scrap materials was recorded in March 2020.

Gross Profit (Loss)

For the year ended December 31, 2020, gross loss from the Medical Foods and Nutraceuticals segment was $9,972 compared to $289,445 for the year ended December 31, 2019, resulting in a decrease of $279,473 or 97%. For the year ended December 31, 2020, gross profit from the Medical Devices segment was $(68,785) compared to $255,195 for the year ended December 31, 2019, resulting in a decrease of $323,980 or 127 %. Gross loss represented (3)% of revenues for the year ended December 31, 2020, versus 62% of revenue for the year ended December 31, 2019. The lower gross profit percentage in FY 2020 is primarily a result of the write down of inventory.

Goodwill Impairment Charge

Management concluded that as of December 31, 2019, the fair value of the goodwill associated with the VectorVision acquisition was less than its carrying amount. For the year ended December 31, 32019, the Company recorded a goodwill impairment charge of $1,563,520.

Liquidity and Capital Resources

Since its formation in 2009, the Company has devoted substantial effort and capital resources to the development and commercialization activities related to its product candidates. For the year ended December 31, 2020, the Company incurred a net loss of $8,571,657 and used cash in operating activities of $8,013,929. At December 31, 2020, the Company had cash on hand of $8,518,732 and working capital of $8,021,152. Subsequent to December 31, 2020, the Company sold an aggregate of 7,566,734 shares of its common stock for net proceeds of approximately $33,600,000 in two offerings, one completed in January 2021, and one completed in February 2021. In addition, in January and February 2021, the Company issued an aggregate of 1,647,691 shares of common stock upon the exercise of warrants and received cash proceeds of $3,608,509. Notwithstanding the net loss for 2020, management believes that its current cash balance, plus net proceeds from issuance of common stock and exercise of warrants in January 2021 and February 2021, is sufficient to fund operations for at least one year from the date the Company's 2020 financial statements are issued.

The Company's financing has historically come primarily from the issuance of convertible notes, promissory notes and from the sale of common and preferred stock. The Company will continue to incur significant expenses for continued commercialization activities related to its medical foods, medical devices and its nutraceuticals product line, and building its infrastructure. Development and commercialization of medical foods, medical devices and nutraceuticals involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines.

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

Sources and Uses of Cash

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

	Year Ended December 31,	
	2020	**2019**
Net cash used in operating activities	$ (8,013,929)	$ (6,030,004)
Net cash used in investing activities	(34,733)	(171,076)
Net cash provided by financing activities	5,451,892	16,645,634
Net increase (decrease) in cash	$ (2,596,770)	$ 10,444,554

Operating Activities

Net cash used in operating activities was $8,013,929 during the year ended December 31, 2020, versus $6,030,004 used during the comparable prior year period. The increase in 2020 was due primarily to inventory purchases and higher insurance, professional services fees, consulting, and labor costs paid in the current period.

Investing Activities

Net cash used in investing activities was $34,733 for the year ended December 31, 2020 and $171,076 for the year ended December 30, 2019. Cash was used in both periods for the purchase of testing equipment, furniture and fixtures.

Financing Activities

Net cash provided by financing activities was $5,451,892 for the year ended December 31, 2020, and was due to warrant exercises during the period. Net cash provided by financing activities was $9,236,167 for the year ended December 31, 2019 was due primarily to the completion of our IPO, which resulted in net proceeds of $3,888,000. In addition, in March 2019, the Company issued $350,000 in promissory and convertible promissory notes and received cash of $131,875 from the exercise of warrants. These proceeds were partially offset by payment of $100,000 to settle a promissory note.

On August 15, 2019, the Company completed a second public offering (the "August Offering") of (i) 2,000,000 shares of common stock, (ii) pre-funded warrants exercisable for 166,667 shares of common stock (the "Pre-Funded Warrants"), and (iii) warrants to purchase up to an aggregate of 2,166,667 shares of common stock (the "August Warrants"). The August Offering was conducted pursuant to an Underwriting Agreement, dated August 13, 2019 by and between the Company and Maxim Group LLC and WallachBeth Capital, LLC. On August 16, 2019, the Company sold an additional 325,000 August Warrants upon exercise of the underwriters' over-allotment option. The net proceeds to the Company from the August Offering, after deducting underwriting discounts and commissions and other estimated expenses were $4,944,340.

The public offering price was $2.64 per share of common stock and $0.01 per accompanying August Warrant. Each August Warrant represents the right to purchase one share of common stock at an exercise price of $3.51 per share. The August Warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) September 11, 2019 and (ii) the date on which the common stock traded an aggregate of more than 6,666,667 shares after the announcement of the pricing of the August Offering, and ending on the twelve (12) month anniversary thereof, each August Warrant may be exercised at the option of the holder on a cashless basis at a ratio of one August Warrant for one share of common stock, in whole or in part, if the weighted average price of the Common Stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the August Warrant.

On October 30, 2019, the Company completed a third public offering of 4,083,334 shares of its common stock (including 283,334 pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 4,083,334 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $2.052 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but will be issued separately and will be immediately separable upon issuance. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7.4 million.

The Series B warrants are exercisable at a price of $2.052 per share of common stock and will expire five years from the date on which the Series B warrants become initially exercisable. On December 6, 2019, pursuant to shareholder approval, the Company filed a Certificate of Amendment to amends its Certificate of Incorporation to increase its authorized shares of common stock to 250 million shares. Thus, the Company has a sufficient number of authorized shares of common stock to issue the shares of common stock issuable upon the exercise of the Series B warrants.

Off-Balance Sheet Arrangements

At December 31, 2020 and December 31, 2019, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

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

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

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework 2013. Based on this evaluation, our Chief Executive Officer and our Chief Accounting Officer determined, based upon the existence of the material weakness described below, that we did not maintain effective internal control over financial reporting as of December 31, 2020.

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

While we have designed and implemented, or expect to implement, measures that we believe address or will address this control weakness, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, and designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight. We plan to remediate the identified material weakness through the redistribution of job responsibilities, by hiring additional senior accounting staff, and through the design and implementation of additional internal controls in order to promote adequate segregation of duties. We expect to complete the remediation in 2021. We expect to incur additional costs to remediate this weakness, primarily personnel costs.

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

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

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

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

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position
Bret Scholtes	51	President and Chief Executive Officer, and Director
Robert Weingarten	68	Chairman of the Board of Directors
Mark Goldstone	57	Director
David W. Evans	64	Director, Chief Science Officer
Donald A. Gagliano	68	Director
Kelly Anderson	53	Director
Andrew Schmidt	59	Chief Financial Officer

Management Team

Bret Scholtes has been Chief Executive Officer and a director since January 2021. Prior to his appointment, he served as the President and Chief Executive Officer of Omega Protein Corporation ("Omega") since 2012 and as a director of Omega since 2013. Prior to his selection as Chief Executive Officer of Omega, Mr. Scholtes served as the Omega's Senior Vice President-Corporate Development from April 2010 to December 2010 and as Omega's Executive Vice President and Chief Financial Officer from January 2011 to December 2011. From 2006 to April 2010, Mr. Scholtes served as a Vice President at GE Energy Financial Services, a global energy investment firm. Prior to that, Mr. Scholtes held positions with two publicly traded energy companies. Mr. Scholtes also has five years of public accounting experience. Mr. Scholtes holds an MBA degree in Finance from New York University and a degree in Accounting from the University of Missouri – Columbia. These skills and experiences make Mr. Scholtes particularly suitable to serve as our Chief Executive Officer and as a director of the Company.

Robert N. Weingarten has been a Director of the Company since June 2015 and Chairman of the board of directors since July 2020. Previously, Mr. Weingarten served as Lead Director on our board of directors from January 2017 to March 2020. 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 several public companies in various stages of development, operation or reorganization. From July 2017 to June 2018, Mr. Weingarten was the Chief Financial Officer of Alltemp, Inc. From April 2013 to February 2017, Mr. Weingarten served on the board of directors of RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) and also served as Vice President and Chief Financial Officer. Mr. Weingarten received a B.A. in Accounting from the University of Washington in 1974, a M.B.A. in Finance from the University of Southern California in 1975, and is a Certified Public Accountant (inactive) in the State of California. In August 2020, Mr. Weingarten was appointed as Vice President and Chief Financial Officer of Lixte Biotechnology Holdings, Inc., a company listed on The Nasdaq Stock Market. Mr. Weingarten has considerable accounting and finance experience, particularly with regard to public reporting requirements. The Company believes that Mr. Weingarten's accounting and finance experience qualifies him to serve on the board of directors.

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

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

Donald A. Gagliano has served as a Director since the Company's initial public offering on April 9, 2019. Dr. Gagliano had been a member of our Scientific Advisory Board since June 2015. Since October 2018, Dr. Gagliano has been the principal of GMIC LLC, which provides healthcare consultation services primarily for health systems engineering and ophthalmology subject matter expertise. From April 2013 to October 2013, Dr. Gagliano was the Vice President for Global Medical Affairs for Bausch+Lomb, Inc. From 2016 to present, Dr. Gagliano has served as the President of the Prevention of Blindness Society. From November 2008 to March 2013, Dr. Gagliano served as the Assistant Secretary of Defense for Health Affairs as the first Executive Director of the Joint Department of Defense (DoD) and Department of Veterans Affairs (VA) Vision Center of Excellence (VCE). In 1975, Dr. Gagliano graduated from the US Military Academy at WestPoint with a degree in Engineering. In 1981, he received a Bachelor of Science in medicine from Chicago Medical School and in 1998 he received his Master of Healthcare Administration from Penn State University. Dr. Gagliano's breadth of experience in the healthcare industry is particularly useful to the Company as it develops its business, commercializes products and builds its marketing channels. The Company believes that these experiences make Dr. Gagliano particularly suitable to serve as a director and guide the Company in the complexities of the life science and healthcare services industries.

David W. Evans has been a Director since September 2017. Dr. Evans acted as interim chief executive officer of the Company from June 2020 to January 2021. Dr. Evans is the founder of VectorVision and serves as the Company's Chief Science Officer. Dr. Evans is recognized as the leading expert in clinical contrast sensitivity and glare testing. He has provided his testing expertise and data analysis capability to a wide range of leading ophthalmic companies. Dr. Evans has published more than 30 scientific articles and 3 book chapters in the areas of refractive surgery, glaucoma, ocular blood flow and visual function, and is the inventor of 5 patents related to vision testing devices. Dr. Evans received his Bachelor of Science degree in Human Factors Engineering from the United States Air Force Academy, a Master of Science degree and Masters in Business Administration from Wright State University in Dayton, Ohio, and a Ph.D. in Ocular Physiology from Indiana University. The Company believes that these experiences make Dr. Evans particularly suitable to serve as a director and guide the Company in the complexities of the life science and healthcare services industries.

Kelly Anderson has over 25 years of experience in finance, accounting and operations roles in various industries. Since 2015, Ms. Anderson has been a managing partner in C Suite Financial Partners, a financial consulting services company dedicated to serving private, public, private equity, entrepreneurial, family office and government-owned firms in all industries. Between July 2014 and March 2015, Ms. Anderson was CFO of Mavenlink, a SaaS company. Between October 2012 and January 2014, Ms. Anderson was Chief Accounting Officer of Fisker Automotive. Between April 2010 and February 2012, Ms. Anderson was the President and Chief Financial Officer of T3 Motion, Inc. ("T3"), an electric vehicle technology company. Between March 2008 and April 2010, she served as T3's Executive Vice President and Chief Financial Officer, and as a director from January 2009 until January 2010. From 2006 until 2008, Ms. Anderson was Vice President at Experian, a leading credit reporting agency. From 2004 until 2006, Ms. Anderson was Chief Accounting Officer for TripleNet Properties and its affiliates. From 1996 to 2004, Ms. Anderson held senior financial positions with The First American Corp., a Fortune 500 title insurance company. Ms. Anderson has served on the board of directors for Tomi Environmental Services (OCTQB: TOMZ) since 2016 and Concierge Technologies since May 2019 (OTCQB: CNCG). Ms. Anderson is also a founder of CXO Executive Solutions, which is now a Hawkstone Capital Portfolio Company. Ms. Anderson is a CPA (Inactive). Ms. Anderson holds a B.A. degree in Business Administration with an accounting concentration from California State University Fullerton.

Andrew Schmidt has served as our Chief Financial Officer since July 20, 2020. Prior to his appointment with the Company, Mr. Schmidt served as Vice President of Finance, Chief Financial Officer and Secretary of Iteris, Inc. (NASD: "ITI"), a publicly traded technology company from March 2015 through December 2019. Prior to joining Iteris, Mr. Schmidt served as the Chief Financial Officer and Corporate Secretary of Smith Micro Software, Inc., a publicly-held provider of wireless and mobility software solutions from 2005 to May 2014. Mr. Schmidt holds a B.B.A. degree in Finance from the University of Texas and an M.S. degree in Accountancy from San Diego State University.

Director or Officer Involvement in Certain Legal Proceedings

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

Family Relationships

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

Director Independence

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

The Company's Board of Directors has undertaken a review of the independence of the Company's directors and director nominees and considered whether any director has a material relationship with it that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, the Board of Directors has determined that as of December 31, 2020, each of Messrs. Weingarten, Goldstone, Gagliano and Anderson, representing four (4) of the Company's six (6) directors, are "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of the NASDAQ Capital Market. In making these determinations, the Board of Directors considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances the Board of Directors deemed relevant in determining their independence, including the beneficial ownership of the Company's capital stock by each non-employee director, and any transactions involving them described in the section captioned "—Certain Relationships and Related Transactions and Director Independence."

Code of Business Conduct and Ethics

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

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the total compensation paid or accrued during the fiscal years ended December 31, 2020 and 2019 to of our "Named Executive Officers".

Executive	Year	Salary	Bonus	Stock Awards	All Other Compensation	Total
Michael Favish (1)	2020	$ 325,000	$ -	$ -	$ 32,197	$ 357,197
	2019	$ 300,000	$ -	$ 4,122,750	$ 38,972	$ 4,461,722
David W. Evans (2)	2020	$ 273,211	$ -	$ 22,204	$ -	$ 295,415
	2019	$ 210,000	$ -	$ -	$ -	$ 210,000
John Townsend (3)	2020	$ 101,771	$ -	$ -	$ 6,146	$ 107,917
	2019	$ 185,000	$ 25,000	$ -	$ 4,031	$ 214,031
Andrew Schmidt (4)	2020	$ 114,583	$ -	$ 66,512	$ -	$ 181,095
	2019	$ -	$ -	$ -	$ -	$ -

(1) Effective June 12, 2020, Michael Favish terminated as Chief Executive Officer and President of the Company and resigned as a member of the Board. Mr. Favish was awarded a stock option grant on April 9, 2019 for 208,334 shares of the Company's common stock at an exercise price of $26.40 per share (110% of the IPO price per common share) pursuant to his employment agreement (the "Favish Option"). In connection with the termination of employment, the Company agreed to pay Mr. Favish a severance payment of $325,000, to be paid out over 12 months. Additionally, the Company agreed that the Favish Option shall remain exercisable for a period of twelve (12) months from June 12, 2020 in lieu of the ninety (90) days provided for under the terms of the original stock option agreement following the termination. The Favish Option ceased to vest upon his separation from the Company. All Other Compensation for 2019 associated with Mr. Favish includes Company reimbursed personal meals, personal automobile expense, club membership fees, health care related expenses that fall outside of the Company provided health insurance plan and use of American Express membership rewards points acquired under the Company's corporate American Express card. Compensation for 2020 consists of cash-based compensation. All Other Compensation for 2020 associated with Mr. Favish primarily includes payout of accrued vacation upon his termination. Due to Mr. Favish's separation, an accrual was recorded in the Company's fiscal second quarter ended June 30, 2020 of $311.458 as balance due of salary compensation expense and a reversal related to forfeited fully expensed stock option awards of $1,401,582.

(2) Dr. Evans acted as interim chief executive officer of the Company from June 12, 2020 to January 6, 2021. The Company entered into a Consulting Agreement with Dr. Evans, dated as of September 29, 2017 (as amended, the "Evans Consulting Agreement"). The Evans Consulting Agreement provided that Dr. Evans would serve as the Company's Chief Science Officer and is currently being paid $17,500 per month as an employee of the Company. The Company and Dr. Evans entered into an amendment to the Evans Consulting Agreement, which amendment, effective as of June 12, 2020, (1) acknowledged his appointment as Interim Chief Executive Officer and Interim President and (2) increased his compensation by Ten Thousand Dollars ($10,000) per month for each month that he remains Interim Chief Executive Officer and Interim President.

(3) Effective as of September 2, 2020, John Townsend resigned as the Controller and Chief Accounting Officer of the Company. All Other Compensation associated with Mr. Townsend includes Company reimbursed personal meals and personal automobile expense.

(4) Effective July 20, 2020, Mr. Schmidt was appointed as Chief Financial Officer of the Company. The Company and Mr. Schmidt entered into an employment agreement (the "Employment Agreement"), dated July 20, 2020 (the "Effective Date"), pursuant to which Mr. Schmidt's annual base salary is $250,000. In addition, effective as of the Effective Date, Mr. Schmidt was granted an award of 166,667 stock options under the Company's 2018 Equity Incentive Plan, at an exercise price of six dollars ($6.00) per share.

Employment Agreements

Bret Scholtes

The Company and Mr. Scholtes entered into an employment agreement (the "Scholtes Employment Agreement"), effective on January 6, 2021 (the "Effective Date"), pursuant to which Mr. Scholtes' annual base salary is $400,000. The Scholtes Employment Agreement provides that Mr. Scholtes shall have an annual target cash bonus opportunity of no less than $400,000 (the "Bonus") based on the achievement of Company and individual performance objectives to be determined in good faith by the Board in advance and in consultation with Mr. Scholtes (the "Performance Objectives"). The initial term of the Scholtes Employment Agreement is through December 31, 2023, with automatic one-year renewals, unless either party provides written notice of a non-renewal in accordance with the terms of the Scholtes Employment Agreement (the "Term"). The Scholtes Employment Agreement also includes standard benefits, as well as customary non-compete, non-solicitation, intellectual property assignment and confidentiality provisions that are customary in the Company's industry.

In addition, effective as of the Effective Date, Mr. Scholtes shall be granted an award of a number of stock options equal to one percent (1%) of the issued and outstanding number of shares of the Company's common stock (the "Stock Options") pursuant to the Company's 2018 Equity Incentive Plan (the "Incentive Plan"), at an exercise price equal to the closing price of the Company's common stock on the Effective Date. One third (1/3) of the Stock Options shall vest and become exercisable the first anniversary of the Effective Date, and the balance of the Stock Options shall vest ratably in equal installments for the twenty-four (24) months thereafter, subject to continued service, and shall vest in full upon a Change in Control (as defined in the Incentive Plan). Additionally, the Company shall grant unvested shares of common stock in an amount equal to one percent (1%) of the number of shares of Company common stock issued and outstanding on the Effective Date (the "Stock Grant") to Mr. Scholtes under the Incentive Plan. The shares underlying the Stock Grant shall become vested in full on the first anniversary of the Effective Date.

Additionally, Mr. Scholtes shall be granted (i) additional stock options equal to two percent (2%) of the Company's issued and outstanding shares of common stock on the date of grant if the Company achieves specified written performance objectives established by the Board for the Company's fiscal years ending December 31, 2021 and December 31, 2022 and (ii) additional stock options equal to either two percent (2%) or three percent (3%) of the Company's issued and outstanding shares of common stock on the date of grant if the Company meets certain financial objectives during the first five years following the Effective Date.

If Mr. Scholtes's employment is terminated by the Company without cause (as defined in the Scholtes Employment Agreement), if the Term expires after a notice of non-renewal is delivered by the Company or if Mr. Scholtes's employment is terminated following a change of control (as defined in the Incentive Plan), Mr. Scholtes will be entitled to (a) twelve months' base salary, (b) the prorated portion of the Bonus for the year in which the termination occurs, based on actual performance and (c) base salary and benefits accrued through the date of termination.

David Evans

The Company entered into a Consulting Agreement with Dr. Evans, dated as of September 29, 2017 (as amended, the "Evans Consulting Agreement"). The Evans Consulting Agreement provided that Dr. Evans would serve as the Company's Chief Science Officer and is currently being paid $17,500 per month as an employee of the Company. The Company and Dr. Evans entered into an amendment to the Evans Consulting Agreement, which amendment, effective as of June 12, 2020, (1) acknowledged his appointment as Interim Chief Executive Officer and Interim President and (2) increased his compensation by Ten Thousand Dollars ($10,000) per month for each month that he remained Interim Chief Executive Officer and Interim President.

Andrew C. Schmidt

The Company and Mr. Schmidt entered into an employment agreement (the "Employment Agreement"), dated July 20, 2020 (the "Effective Date"), pursuant to which Mr. Schmidt's annual base salary is $250,000. The Employment Agreement provides that Mr. Schmidt shall have an annual target cash bonus opportunity of no less than $175,000 (the "Bonus") based on the achievement of Company and individual performance objectives to be determined in good faith by the Board in advance and in consultation with Mr. Schmidt (the "Performance Objectives"), provided, however, that the parties acknowledged and agreed that up to an aggregate of $100,000 of the Bonus shall be payable upon the closing(s) of one or more mergers and acquisition transactions as determined at the discretion of the Board, and $75,000 shall be based upon the satisfactory completion of the Performance Objectives. The initial term of the Employment Agreement is through July 20, 2021, with automatic one-year renewals, unless either party provides written notice of a non-renewal in accordance with the terms of the Employment Agreement (the "Term").

Mr. Schmidt is also entitled to certain other benefits consistent with those provided to other senior executives of the Company. In addition, effective as of the Effective Date, Mr. Schmidt shall be granted an award of 166,667 stock options (the "Stock Options") under the Company's 2018 Equity Incentive Plan (the "Incentive Plan"), at an exercise price of six dollars ($6.00) per share. The Stock Options shall vest and become exercisable in twelve (12) equal installments on the last day of each of the subsequent twelve (12) calendar quarter-end dates following the Effective Date (the first of such dates to be September 30, 2020), subject to continued service, and shall vest in full upon a Change in Control (as defined in the Incentive Plan). The Sock Options granted shall be subject, to the extent necessary, to the approval of the Company's stockholders of a proposal to increase the authorized number of shares available under the Incentive Plan.

If Mr. Schmidt's employment is terminated by the Company without cause (as defined in the Employment Agreement), if the Term expires after a notice of non-renewal is delivered by the Company or if Mr. Schmidt's employment is terminated following a change of control (as defined in the Incentive Plan), Mr. Schmidt will be entitled to (a) six months' base salary, (b) the prorated portion of the Bonus for the year in which the termination occurs, based on actual performance and (c) base salary and benefits accrued through the date of termination.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2020:

NAME	GRANT DATE	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE
Michael Favish	4/9/2019	4/9/2019	69,445	-	$ 26.40	6/12/2021
David W. Evans	6/30/2020	6/30/2020	4,167	12,500	6.00	6/30/2030
John Townsend	-	-	-	-	-	-
Andrew Schmidt	7/20/2020	7/20/2020	24,962	141,705	6.00	7/20/2030

Director Compensation

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

Director	Year	Stock Awards	Fees Earned or Paid in Cash	Total
Mark Goldstone (1)	2020	$ 80,494	$ 60,000	$ 140,494
	2019	$ -	$ -	$ -
Robert Weingarten (2)	2020	$ 80,494	$ 90,500	$ 170,994
	2019	$ -	$ 60,000	$ 60,000
David W. Evans	2020	$ 22,204	$ -	$ 22,204
	2019	$ -	$ -	$ -
Michael Favish	2020	$ -	$ -	$ -
	2019	$ -	$ -	$ -
Donald A. Gagliano (3)	2020	$ 23,963	$ 20,000	$ 43,963
	2019	$ -	$ -	$ -
Kelly Anderson (4)	2020	$ 80,494	$ 55,500	$ 135,994
	2019	$ -	$ -	$ -

(1) Mr. Goldstone earned $60,000 during 2020 as compensation for services as a member of the Board of Directors, member of the Audit Committee, Chairman of the Strategy Committee and Chairman of the Compensation Committee, of which $37,500 was paid in 2020, and $22,500 paid in 2021.

(2) Mr. Weingarten earned $100,500 as compensation for services as Chairman of the Board, Chairman of the Audit Committee, member of the Strategy Committee, and member of the Compensation Committee, of which $68,375 was paid in 2020, and $32,125 paid in 2021.

(3) Mr. Gagliano earned $20,000 as compensation for services as a member of the Board of Directors, of which $15,000 was paid in 2020, and $5,000 paid in 2021.

(4) Ms. Anderson earned $55,500 during 2020 as compensation for services as a member of the Board of Directors, member of the Audit Committee, member of the Strategy Committee and member of the Compensation Committee, of which $34,625 was paid in 2020, and $20,875 paid in 2021.

On December 5, 2019, the board of directors adopted a director compensation program for the Company's independent directors consisting of both cash and equity compensation, beginning in 2020, and in July 2020, the board of directors adopted a director compensation program for the Company's independent directors consisting of both cash and equity compensation for service on the newly formed Strategy Committee . The programs consist of the following compensation for directors:

Cash Compensation (payable quarterly)

- Board service - $20,000 per year
- Chairman of the Board - $60,000 per year (inclusive of the Board service compensation)
- Chairman of the Audit Committee – additional $10,000 per year
- Chairman of the Compensation Committee – additional $5,000 per year
- Chairman of the Strategy Committee – additional $40,000 per year, plus $1,000 per formal meeting held
- Member of the Audit Committee – additional $5,000 per year
- Member of the Compensation Committee – additional $2,500 per year
- Member of the Strategy Committee – additional $36,000 per year, plus $1,000 per formal meeting held
- Chairman of the Science Committee – additional $7,500 per year (established in February 2021)

Equity Compensation

- Initial grant for new director – five year stock option to purchase 41,667 shares of Company common stock at the closing price of the Company's common stock on the grant date, vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, subject to continued service.

- Annual grant – five year stock option to purchase 16,667 shares of Company common stock granted on the earlier of the date of the Company's annual meeting of stockholders or the last business day of the month ending June 30, vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, subject to continued service.

- Strategy Committee – five year stock option to purchase 41,667 shares of Company common stock at $6.00 per share, vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, subject to continued service.

  For 2020 stock option awards issued to Strategy Committee members were issued at $6.00 per share which was priced above the existing market price at the date of stock option issuance.

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 25, 2021 by (i) each person known to us to beneficially own more than 5% of our common stock, (ii) each executive officer and director, and (iii) all officers and directors as a group. The following table is based on the Company having 24,426,993 as of March 25, 2021. shares of common stock issued and outstanding as of March 25, 2021. 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 25, 2021 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 24,426,993 shares of common stock outstanding at March 25, 2021, 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 25, 2021. Beneficial ownership generally includes voting and dispositive power with respect to securities. Unless otherwise indicated below, the persons and entities named in the table have sole voting and sole dispositive power with respect to all shares beneficially owned. Unless otherwise indicated, the address for each person listed is: c/o Guardion Health Sciences, Inc., 15150 Avenue of Science, Suite 200, San Diego, CA 92128.

Name of Beneficial Owner and Title of Officers and Directors	Shares of Common Stock Beneficially Owned	Percentage
Bret Scholtes, Chief Executive Officer and Director [(1)]	322,154	1.3%
Robert N. Weingarten, Chairman of the Board of Directors [(2)]	143,646	*%
Mark Goldstone, Director	122,446	*%
Donald A. Gagliano, Director	29,000	*%
David Evans, Director [(a)]	264,000	1.1%
Kelly Anderson, Director	76,563	*%
Andrew Schmidt, Chief Financial Officer	38,661	*%
All Officers and Directors as a Group (7 persons)	**996,470**	**4.1%**

* Less than 1%.

(1) Includes (i) 169,484 shares of common stock held by Mr. Scholtes; and (ii) 152,671 restricted common stock units.

(2) Includes (i) 108,750 shares of common stock held by Mr. Weingarten; and (ii) 34,896 options to purchase common stock that will vest within 60 days of the Filing Date held by Mr. Weingarten.

(3) Includes (i) 87,550 shares of common stock held by Mr. Goldstone; and (ii) 34,896 options to purchase common stock that will vest within 60 days of the Filing Date held by Mr. Goldstone.

(4) Includes (i) 22,750 shares of common stock held by Mr. Gagliano; and (ii) 6,250 options to purchase common stock that will vest within 60 days of the Filing Date held by Mr. Gagliano.

(5) Includes (i) 228,500 shares of common stock issued on September 29, 2017 in connection with the 2017 acquisition of VectorVision, Inc.; (ii)1,084 shares of common stock purchased April 9, 2019 in the Company's initial public offering, which shares were registered on the registration statement on Form S-1 that the SEC declared effective on April 4, 2019; (iii) 6,667 shares purchased in the Company's August 2019 follow-on public offering; (iv) 334 shares purchased in the Company's October 2019 follow-on public offering; (v) 20,834 of the shares issued in exchange for the VectorVision, Inc. acquisition that also serve as security for VectorVision, Inc.'s indemnification obligations under the related Asset Purchase Agreement; (vi) 334 Series B warrants to purchase common stock held by Dr. Evans; and (vii) 6,250 options to purchase common stock that will vest within 60 days of the Record Date held by Dr. Evans.

(6) Includes 76,563 options to purchase common stock that will vest within 60 days of the Filing Date held by Ms. Anderson.

(7) Includes 38,661 options to purchase common stock that will vest within 60 days of the Filing Date held by Mr. Schmidt.

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

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

During the years ended December 31, 2020, 2019 and 2018, the Company incurred and paid $325,000, $300,000 and $275,000, respectively, of salary expense to our former Board Chairman and CEO, Mr. Michael Favish. In addition, compensation cost of $2,339,560 was recognized on amortization of stock option awards during the year ended December 31, 2019. During the years ended December 31, 2020, 2019 and 2018, the Company incurred and paid salaries of $75,000, $114,000 and $103,000, respectively, to Karen Favish, spouse of Michael Favish. During the year ended December 31, 2020, 2019 and 2018, the Company incurred and paid salaries of $60,000, $55,000 and $33,000, respectively, to Kristine Townsend, spouse of our former Controller and Chief Accounting Officer John Townsend.

On September 29, 2017, the Company completed the acquisition of substantially all of the assets and liabilities of VectorVision Ohio in exchange for 254,167 shares of the Company's common stock, pursuant to the Asset Purchase and Reorganization Agreement ("Asset Purchase Agreement"), which was entered into on an arm's-length basis. David W. Evans, a Director of the Company, owned 28% of the issued and outstanding shares of VectorVision Ohio and his wife, Tamara Evans, owned 72% of the issued and outstanding shares of VectorVision Ohio. VectorVision Ocular Health, Inc is a wholly owned subsidiary of the Company formed by the Company in connection with the acquisition of assets from VectorVision Ohio. Dr. Evans was appointed as a director of the Company on September 29, 2017 pursuant to the Asset Purchase Agreement. The Company entered into a Consulting Agreement with Dr. Evans, dated as of September 29, 2017 (the "Consulting Agreement"), whereby Dr. Evans has been engaged to serve as a consultant to the Company to further the Company's planned development and commercialization of the Company's portfolio of products and technology. The Consulting Agreement has an initial term of 3 years, with automatic one-year renewals unless earlier terminated. Dr. Evans is entitled to compensation of $10,000 per month for the first six months of the term of the Consulting Agreement and $7,500 per month for the remainder of the term of the Consulting Agreement. Additionally, on the same date, the Company and Dr. Evans entered into an Intellectual Property Purchase Agreement wherein the Company agreed to pay to Dr. Evans a commercially reasonable royalty payments on sales of goods relating to vision acuity testing during the term of the agreement. The Company and Dr. Evans entered into an amendment to the Consulting Agreement, which amendment, effective as of June 12, 2020, (1) acknowledged his appointment as Interim Chief Executive Officer and Interim President and (2) increased his compensation by Ten Thousand Dollars ($10,000) per month for each month that he remains Interim Chief Executive Officer and Interim President.

Dr. Evans, together with his spouse, wholly owns Ceatus Media Group LLC, a California limited liability company ("Ceatus"), founded in 2004 specializing in digital marketing in the eye health care sector. The Company paid Ceatus $55,000 in 2018, $81,000 in 2019 and $95,750 in 2020, for services related to digital marketing for the Company.

Dr. Evans, together with his spouse, wholly owns DWT Evans LLC, an Ohio limited liability company ("DWT"), founded in 2000 which holds several pieces of real estate. One of these holdings includes real property in Greenville, Ohio where the Company's subsidiary, VectorVision Ocular Health, leases office and warehouse space. The Company paid DWT rent in the amounts of $19,770 and $20,898 in 2020 and 2019, respectively.

When the Company acquired VectorVision, it also acquired AcQviz from Dr. Evans, which is a patented methodology for auto-calibrating and standardizing the testing light level for computer generated vision testing systems. Dr. Evans is entitled to receive a royalty on net revenue from AcQviz. As part of the development of the CSV-2000, AcQviz was embedded in the product by Radiant Technologies, Inc. in exchange for a 3% royalty on the sales of AcQviz. Radiant Technologies is owned by Joseph T. Evans, the brother of Dr. David Evans.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Weinberg & Company, P.A. acted as the Company's independent registered public accounting firm for the years ended December 31, 2020 and 2019 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by the Company for audit and other services provided by Weinberg & Company, P.A. for the years ended December 31, 2020 and 2019.

	Year Ended December 31,	
	2020	**2019**
Audit Fees [(a)]	$ 95,500	$ 92,467
Tax Fees [(b)]	39,200	31,818
Other Fees [(c)]	120,500	240,093
Total	$ 255,200	$ 364,378

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

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

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

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) Exhibits

(b) Exhibits:

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

Guardion Health Sciences, Inc.
Consolidated Financial Statements
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Guardion Health Sciences, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020 and 2019, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

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

/s/ Weinberg & Company, P.A.

Los Angeles, California
March 26, 2021

Guardion Health Sciences, Inc.

Consolidated Balance Sheets

	December 31,	
	2020	**2019**
Assets		
Current assets		
Cash	$ 8,518,732	$ 11,115,502
Accounts receivable	11,248	78,337
Inventories	384,972	310,941
Prepaid expenses	179,931	362,938
Total current assets	**9,094,883**	**11,867,718**
Deposits	11,751	11,751
Property and equipment, net	285,676	374,638
Operating lease right-of-use asset, net	418,590	572,714
Intangible assets, net	50,000	50,000
Total assets	**$ 9,860,900**	**$ 12,876,821**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 608,313	$ 129,132
Accrued expenses	127,637	116,211
Payable to former officer	148,958	-
Derivative warrant liability	25,978	13,323
Operating lease liability - current	162,845	151,568
Total current liabilities	**1,073,731**	**410,234**
Operating lease liability – long-term	271,903	434,747
Total liabilities	**1,345,634**	**844,981**
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 15,170,628 and 12,497,094 shares issued and outstanding at December 31, 2020 and December 31, 2019	15,171	12,497
Additional paid-in capital	62,583,423	57,531,014
Accumulated deficit	(54,083,328)	(45,511,671)
Total stockholders' equity	**8,515,266**	**12,031,840**
Total liabilities and stockholders' equity	**$ 9,860,900**	**$ 12,876,821**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Operations

	Years Ended December 31,	
	2020	**2019**
Revenue		
Medical foods	$ 1,609,482	$ 444,657
Medical devices	275,862	434,010
Other	4,500	24,270
Total revenue	1,889,844	902,937
Cost of goods sold		
Medical foods (includes inventory write-down of $760,488 during the year ended December 31, 2020)	1,599,510	155.212
Medical devices (includes inventory write-down of $211,231 during the year ended December 31, 2020)	344,647	178,815
Other	2,478	7,288
Total cost of goods sold	1,946,635	341,315
Gross profit (loss)	(56,791)	561,622
Operating expenses		
Research and development	160,978	194,311
Sales and marketing	1,450,205	1,874,901
General and administrative	7,450,245	7,425,827
Costs related to resignation of former officer (including the reversal of previously recognized stock compensation expense of $965,295 during the year ended December 31, 2020)	(615,936)	-
Loss on sales of equipment	18,500	-
Equipment impairment	30,948	-
Goodwill impairment	-	1,563,520
Total operating expenses	8,494,940	11,058,559
Loss from operations	(8,551,731)	(10,496,937)
Other income (expenses):		
Interest expense	(7,271)	(258,365)
Finance cost upon issuance of warrants	-	(415,955)
Change in fair value of derivative liability	(12,655)	292,949
Total other income (expenses)	(19,926)	(381,371)
Net loss	**(8,571,657)**	**(10,878,308)**
Net loss per common share – basic and diluted	$ (0.60)	$ (1.79)
Weighted average common shares outstanding – basic and diluted	14,256,856	6,078,014

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	3,427,388	$ 3,427	$ 37,815,699	$ (34,633,363)	$ 3,185,763
Fair value of vested stock options – officer and director	-	-	2,339,560	-	2,339,560
Fair value of vested stock options	-	-	254,170	-	254,170
Reclass of warrant liability to equity	-	-	359,683	-	359,683
Sale of common stock	6,008,333	6,008	16,218,799	-	16,224,807
Issuance of common stock for services	9,065	10	123,992	-	124,002
Issuance of common stock – warrant exercises	3,034,135	3,034	168,341	-	171,375
Fair value of common stock – conversion of notes payable and related interest	18,173	18	250,770	-	250,788
Net loss	-	-	-	(10,878,308)	(10,878,308)
Balance at December 31, 2019	12,497,094	12,497	57,531,014	(45,511,671)	12,031,840
Reversal of previously recognized stock compensation expense – former officer	-	-	(940,936)	-	(940,936)
Fair value of vested stock options	-	-	494,677	-	494,677
Issuance of common stock for services	16,667	17	49,433	-	49,450
Issuance of common stock – warrant exercises	2,656,867	2,657	5,449,235	-	5,451,892
Net loss	-	-	-	(8,571,657)	(8,571,657)
Balance at December 31, 2020	15,170,628	$ 15,171	$ 62,583,423	$ (54,083,328)	$ 8,515,266

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2020	**2019**
Operating Activities		
Net loss	$ (8,571,657)	$ (10,878,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65,476	477,346
Impairment loss on equipment	30,948	-
Loss on sale of equipment	18,500	-
Inventory write-down	971,719	-
Goodwill impairment	-	1,563,520
Amortization of debt discount	-	250,000
Accrued interest expense included in notes payable	-	788
Amortization of operating lease right of use asset	154,124	148,440
Stock-based compensation	544,127	378,172
Stock-based compensation – former officer	-	2,339,560
Reversal of previously recognized stock compensation expense–former officer	(940,936)	-
Finance cost upon issuance of warrants	-	415,955
Change in fair value of derivative liability	12,655	(292,949)
Changes in operating assets and liabilities:		
(Increase) / decrease:		
Accounts receivable	67,089	(50,135)
Inventories	(728,801)	47,056
Deposits and prepaid expenses	(125,171)	(315,165)
Increase / (decrease):		
Accounts payable and accrued expenses	479,181	(14,244)
Operating lease liability	(151,567)	(140,888)
Accrued expenses	11,426	40,848
Payable to former officer	148,958	-
Net cash used in operating activities	(8,013,929)	(6,030,004)
Investing Activities		
Purchase of property and equipment	(40,733)	(171,076)
Proceeds from sales of equipment	6,000	-
Net cash used in investing activities	(34,733)	(171,076)
Financing Activities		
Proceeds from initial public offering	-	3,888,000
Proceeds from follow-on public offerings	-	12,336,807
Proceeds from issuance of convertible notes	-	250,000
Proceeds from issuance of promissory note	-	100,000
Payments on promissory note	-	(100,548)
Proceeds from exercise of warrants	5,451,892	171,375
Net cash provided by financing activities	5,451,892	16,645,634
Cash:		
Net increase (decrease)	(2,596,770)	10,444,554
Balance at beginning of period	11,115,502	670,948
Balance at end of period	$ 8,518,732	$ 11,115,502
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$ 7,271	$ -
Income taxes	$ -	$ -
Non-cash financing activities:		
Fair value of warrant liability in connection with issuance of convertible notes	$ -	$ 436,034
Recording of lease asset and liability	$ -	$ 721,154
Reclassification of prepaid costs to inventory	$ 308,178	$ -
Reclassification of property and equipment to inventory	$ 8,771	$ -
Reclassification of warrant liability to equity	$ -	$ 359,683
Fair value of common stock issued upon conversion of convertible notes and accrued interest	$ -	$ 250,788
Reclass of deferred offering costs to equity	$ -	$ 270,000

See accompanying notes to consolidated financial statements.

1. Business and Summary of Significant Accounting Policies

Business

Guardion Health Sciences, Inc. (the "Company") is a specialty health sciences company (1) that has developed medical foods and medical devices in the ocular health space and (2) that is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers. The Company has been primarily engaged in research and development, product commercialization and capital raising activities.

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.

Liquidity

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. For the year ended December 31, 2020, the Company incurred a net loss of $8,571,657 and used cash in operating activities of $8,013,929. At December 31, 2020, the Company had cash on hand of $8,518,732 and working capital of $8,021,152. Subsequent to December 31, 2020, the Company sold an aggregate of 7,566,734 shares of its common stock for net proceeds of approximately $33,600,000 in two offerings, one completed in January 2021, and one completed in February 2021. In addition, in January and February 2021, the Company issued an aggregate of 1,647,691 shares of common stock upon the exercise of warrants and received cash proceeds of $3,608,509. Notwithstanding the net loss for 2020, management believes that its current cash balance, plus net proceeds from issuance of common stock and exercise of warrants in January and February 2021, is sufficient to fund operations for at least one year from the date the Company's 2020 financial statements are issued.

The Company expects to continue to incur net losses and negative operating cash flows in the near-term, and will continue to incur significant expenses for development and commercialization of its medical foods and medical devices, and the successful development and commercialization of any new products or product lines. The Company may also utilize cash to fund acquisitions.

The Company may seek 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. Over time, 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.

COVID-19

The Company is subject to risks and uncertainties of the COVID-19 pandemic that could adversely impact our business, including the commercialization of our medicines, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities. The Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, including curtailing employee travel and working from its executive offices, with many employees continuing their work remotely. During 2020, sales of certain products remained flat, as many eye doctor offices were closed, or operating with limited capacity, due to COVID-19 related "shelter at home" orders. During 2020, we did not experience a jeopardization of our supply chain due to the COVID-19 outbreak.

The extent of the impact of the COVID-19 pandemic has had and will continue to have on the Company's business is highly uncertain and difficult to predict and quantify. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, including vaccination efforts, as well as the economic impact on local, regional, national and international markets.

NASDAQ Notice and Compliance

On September 20, 2019, the Company received notice from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the previous 30 consecutive business days, the Company no longer satisfied the requirement to maintain a minimum bid price of $1.00 per share, as required by Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). In accordance with the Nasdaq Listing Rules, the Company was afforded 180 days, or until March 18, 2020, to regain compliance with the Bid Price Rule by evidence of a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. Thereafter, the Company had been afforded a second 180-calendar day compliance period (which 180-day period was extended due to circumstances related to COVID-19), or until November 30, 2020, to regain compliance with the Bid Price Rule.

The Company was unable to regain compliance with the Bid Price Rule by November 30, 2020. Accordingly, on December 1, 2020, the Company received a letter from the Staff notifying it that its Common Stock would be subject to delisting from Nasdaq unless the Company timely appealed Nasdaq's determination to a Nasdaq Listing Qualifications Panel (the "Panel"). The Company timely appealed Nasdaq's determination to the Panel.

On January 26, 2021, the Company received written notification that the Panel granted the Company an extension for continued listing through March 15, 2021.

On March 1, 2021, the Company implemented the Reverse Stock Split (as defined below).

On March 15, 2021, the Company received a letter from the Staff notifying it that it had regained compliance with the Bid Price Rule. The letter stated the staff had determined that for the prior 10 consecutive business days, from March 1, 2021 to March 12, 2021, the closing bid price of the Company's common stock had been at $1.00 per share or greater and that accordingly, the Company had regained compliance under the Bid Price Rule, and that the matter was closed.

Reverse Stock Splits

On January 30, 2019, following stockholder and board approval, the Company effected a 1-for-2 reverse split of its outstanding shares of common stock, without any change to its par value. The authorized number of shares of common stock were not affected by the reverse stock split. No fractional shares were issued in connection with the reverse stock split, as all fractional shares were rounded up to the next whole share.

On March 1, 2021, following stockholder and board approval, the Company effectuated a 1-for-6 reverse split of its outstanding shares of common stock, without any change to its par value. The authorized number of shares of common stock were not affected by the reverse stock split. No fractional shares were issued in connection with the reverse stock split, as all fractional shares were rounded up to the next whole share.

Accordingly, all share and per share amounts presented herein with respect to common stock have been retroactively adjusted to reflect the above described reverse stock splits for all periods presented.

Basis of presentation

The Company has prepared its consolidated financial statements in accordance with accounting practices generally accepted in the United States ("U.S. GAAP") and has adopted accounting policies and practices which are generally accepted in the industry in which it operates. The Company's significant accounting policies are summarized below.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, VectorVision Ocular Health, Inc., NutriGuard Formulations, Inc., and Transcranial Doppler Solutions, Inc. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates. On an ongoing basis, management reviews its estimates and if deemed appropriate, those estimates are adjusted. Significant estimates include those related to assumptions used in valuing inventories at net realizable value, assumptions used in valuing assets acquired in business acquisitions, impairment testing of goodwill and other long-term assets, assumptions used in valuing stock-based compensation, the valuation allowance for deferred tax assets, accruals for potential liabilities, and assumptions used in the determination of the Company's liquidity. Actual results could differ from those estimates.

Revenue Recognition

The Company generates its revenue from two business segments:

- Medical Foods and Nutraceuticals Segment
- Medical Devices Segment

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*. Revenue is recognized when control of promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products or services. The Company reviews its sales transactions to identify contractual rights, performance obligations, and transaction prices, including the allocation of prices to separate performance obligations, if applicable.

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

Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Payments for sales of medical foods and dietary supplements are generally made by approved credit cards. Payments for medical device sales are generally made by check, credit card, or wire transfer. Historically the Company has not experienced any significant payment delays from customers.

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

Revenues by segment:

	Years Ended December 31,	
	2020	**2019**
Medical Foods and Nutraceuticals	$ 1,609,482	$ 444,657
Medical Devices	275,862	434,010
Other	4,500	24,270
	$ 1,889,844	$ 902,937

During the year ended December 31, 2020, the Company recorded a sale to the Malaysian company of approximately $890,000. The remainder of the Company's Medical Foods and Nutraceuticals revenues earned during the year ended December 31, 2020 are derived from individual retail customers in North America. During the year ended December 31, 2019, all the Company's Medical Foods and Nutraceuticals revenues are derived from individual retail customers in North America. Medical Devices revenues are derived from a worldwide customer base consisting of both retail customers and distributors. Sales to distributors were approximately 51% and 62% of total revenues for the years ended December 31, 2020 and 2019, respectively.

Revenues by geographical area:

	Years Ended December 31,	
	2020	**2019**
North America	$ 891,768	$ 725,520
Malaysia	889,508	
Other Asia	58,688	129,453
Europe and Other	49,880	47,964
	$ 1,889,844	$ 902,937

Medical Devices revenues are derived from a worldwide customer base consisting of both retail customers and distributors. Sales to distributors were approximately 51% and 62% of total revenues for the years ended December 31, 2020 and 2019, respectively.

Cash

Cash consists of cash and demand deposits with banks. The Company holds no cash equivalents as of December 31, 2020 and 2019, respectively.

Accounts Receivable

Accounts receivable are recorded at the invoiced amounts. Management evaluates the collectability of its trade accounts receivable and determines an allowance for doubtful accounts based on historical write-offs, known or expected trends, and the identification of specific balances deemed uncollectible based on a customer's financial condition, credit history and the current economic conditions.

At December 31, 2020 and 2019, based on management's assessment, no allowance for doubtful accounts was considered necessary.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. The Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. When evidence exists that the net realizable value of inventory is lower than its cost, the difference is recognized as a loss in the period in which it occurs. Once inventory has been written down, it creates a new cost basis for inventory that may not subsequently written up. For the year ended December 31, 2020, the Company wrote-down inventory of $971,719, which was recorded in cost of sales (see Note 3). For the year ended December 31, 2019, there were no write-downs of inventory.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Additions, improvements, and major renewals or replacements that substantially extend the useful life of an asset are capitalized. Repairs and maintenance expenditures are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the remaining lease term.

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value at that time. At December 31, 2020 and 2019, management determined there were no impairments of the Company's property and equipment.

Leases

The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments.

Intangible Assets

Finite-lived intangible assets

Amortizable identifiable intangible assets are stated at cost less accumulated amortization, and represent customer relationships, technology, trade names, and noncompetition agreements acquired in business combinations. The Company follows ASC 360 in accounting for intangible assets, which requires impairment losses to be recorded when indicators of impairment are present and the undiscounted cash flows estimated to be generated by the assets are less than the assets' carrying amounts. As of December 31, 2019, the recorded value of the Company's finite-lived intangible assets had been fully amortized.

Indefinite-lived intangible assets

Intangible assets are comprised of an indefinite-lived trademark acquired, so classified because the Company can renew the underlying rights to the trademark indefinitely at nominal cost. Indefinite-lived intangible assets are not amortized but are assessed for impairment annually and evaluated annually to determine whether the indefinite useful life is appropriate. As part of our impairment test, we first assess qualitative factors to determine whether it is more likely than not the asset is impaired. If further testing is necessary, we compare the estimated fair value of our asset with its book value. If the carrying amount of the asset exceeds its fair value, as determined by its discounted cash flows, an impairment loss is recognized in an amount equal to that excess. For the years ended December 31, 2020 and 2019, the Company determined there were no impairments of its indefinite-lived brand names (see Note 5).

Goodwill

Goodwill is the excess of cost of an acquired entity over the fair value of amounts assigned to assets acquired and liabilities assumed in a business combination. Under the guidance of ASC 350, goodwill is not amortized, rather it is tested for impairment annually, and will be tested for impairment between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss generally would be recognized when the carrying amount of the reporting unit's net assets exceeds the estimated fair value of the reporting unit and would be measured as the excess carrying value of goodwill over the derived fair value of goodwill. The Company's policy is to perform an annual impairment testing for its reporting units on December 31 of each fiscal year. During the year ended December 31, 2019, the Company recorded an impairment of its remaining goodwill of $1,563,520 (see Note 5). Accordingly, at December 31, 2020, the Company did not have any goodwill.

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 employees, directors, and for acquiring goods and services from nonemployees, which include grants of employee stock options, are recognized in the financial statements based on their grant date fair values in accordance with ASC 718, *Compensation-Stock Compensation*. Stock option grants, which are generally time or performance vested, are measured at the grant date fair value and depending on the conditions associated with the vesting of the award, compensation cost is recognized on a straight-line or graded basis over the vesting period. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

Income Taxes

The Company uses an asset and liability approach for accounting and reporting for income taxes that allows recognition and measurement of deferred tax assets based upon the likelihood of realization of tax benefits in future years. Under the asset and liability approach, deferred taxes are provided for the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A valuation allowance is provided for deferred tax assets if it is more likely than not these items will either expire before the Company is able to realize their benefits, or that future deductibility is uncertain. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense.

Research and Development Costs

Research and development costs are expensed as incurred and 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 products. Research and development expenditures, which include stock compensation expense, totaled $160,978 and $194,311 for the years ended December 31, 2020 and 2019, respectively.

Patent Costs

The Company is the owner of three issued domestic patents, three pending domestic patent applications, one issued foreign patent in Europe, one issued foreign patent in Hong Kong, and three foreign patent applications in Canada, Europe and Hong Kong. Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, patent costs, including patent-related legal fees, filing fees and internally generated costs, are expensed as incurred. During the years ended December 31, 2020 and 2019, patent costs were $124,806 and $137,183, respectively, and are included in general and administrative costs in the statements of operations.

Advertising Costs

Advertising costs are expensed as incurred and are included in sales and marketing expense. Advertising costs aggregated $44,429 and $19,645 for the years ended December 31, 2020 and 2019, respectively.

Loss per Common Share

Basic loss per share is computed by dividing net loss by the weighted-average common shares outstanding during a period. Diluted earnings per share is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method. Dilutive potential common shares include shares from unexercised warrants and options. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive. 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 options are anti-dilutive.

The following potentially dilutive shares were excluded from the shares used to calculate diluted earnings per share:

	December 31,	
	2020	**2019**
Warrants	2,132,758	4,800,456
Options	778,195	493,750
	2,910,953	5,294,206

Fair Value of Financial Instruments

Accounting standards require certain assets and liabilities be reported at fair value in the financial statements and provide a framework for establishing that fair value. Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it transacts, and considers assumptions that market participants would use when pricing the asset or liability. The framework for determining fair value is based on a hierarchy that prioritizes the inputs and valuation techniques used to measure fair value:

Level 1 - Quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date.

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.

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.

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.

As of December 31, 2020, and 2019, the Company's balance sheet included Level 2 liabilities comprised of the fair value of warrant liabilities aggregating $25,978 and $13,323, respectively (see Note 9).

Derivative Financial Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

Concentrations

Cash balances are maintained at large, well-established financial institutions. At times, cash balances may exceed federally insured limits. Insurance coverage limits are $250,000 per depositor at each financial institution. The Company believes that no significant concentration of credit risk exists with respect to its cash balances because of its assessment of the creditworthiness and financial viability of the financial institutions.

During the year ended December 31, 2020, one customer accounted for approximately 47% of the Company's sales. During the year ended December 31, 2019, one customer who accounted for approximately 22% of the Company's sales. No other customer accounted for more than 10% of sales in either year.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06") "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity." ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective January 1, 2024, for the Company. Early adoption is permitted, but no earlier than January 1, 2021, including interim periods within that year. Management is currently evaluating the effect of the adoption of ASU 2020-06 on the consolidated financial statements, but currently does not believe ASU 2020-06 will have a significant impact on the Company's financial statements. The effect will largely depend on the composition and terms of the outstanding financial instruments at the time of adoption.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions and enhances and simplifies various aspects of the income tax accounting guidance in ASC 740. ASU 2019-12 is not expected to have any impact on the Company's consolidated financial statement presentation or disclosures subsequent to its adoption.

In June 2016, the FASB issued ASU No. 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments ("ASC 326"). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. As a smaller reporting company, ASU 2016-13 will be effective for us beginning January 1, 2023, with early adoption permitted. The Company is currently assessing the impact of adopting this standard on the Company's financial statements and related disclosures.

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

2. Acquisition of NutriGuard

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

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

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

The operations of Nutriguard have been included in the Company's consolidated results of operations starting September 20, 2019.

The following unaudited pro forma financial information gives effect to the Company's acquisition of NutriGuard as if the acquisition had occurred on January 1, 2019:

	Year Ended December 31, 2019
Pro forma net revenues	$ 963,167
Pro forma net loss attributable to common shareholders	$ (10,913,833)
Pro forma net loss per share	$ (1.80)

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

Pursuant to the consulting agreement, the Company granted Mr. McCarty stock options to purchase 16,667 shares of the Company's common stock with a grant date fair value of $54,004 and an exercise price of $3.24 per share, which was the closing market price of the Company's common stock on the Effective Date. The stock options were granted under the terms of the Company's 2018 Equity Incentive Plan, and the options vest as follows: 25% on the Effective Date, 25% on the first anniversary following the Effective Date, 25% on the second anniversary following the Effective Date, and 25% on the third anniversary following the Effective Date.

3. Inventories

Inventories consisted of the following:

	December 31,	
	2020	2019
Raw materials	$ 218,307	$ 246,875
Finished goods	166,665	64,066
Inventory	$ 384,972	$ 310,941

The Company's inventories are stated at the lower of cost or net realizable value on a FIFO basis. At December 31, 2020, as a result of the deterioration of the forecasted marketability of certain of the Company's inventory, management determined that the inventory's revenue-generating ability was diminished, and the net realizable value of this inventory had fallen below its historical carrying cost. Accordingly, for the year ended December 31, 2020, the Company recorded a write down of inventory of $971,719, which is included in cost of goods sold. At December 31, 2020, the balance of inventory reflects its new cost basis after the write down. For the year ended December 31, 2019, there were no write-downs of inventory. At December 31, 2020 and 2019, inventory has been reduced by cumulative write-downs totaling $1,028,324 and $56,605, respectively.

4. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2020	2019
Leasehold improvements	$ 103,255	$ 98,357
Testing equipment	348,124	394,427
Furniture and fixtures	197,349	185,799
Computer equipment	68,460	68,460
Office equipment	9,835	8,193
	727,023	755,236
Less accumulated depreciation and amortization	(441,347)	(380,598)
	$ 285,676	$ 374,638

For the years ended December 31, 2020 and 2019, depreciation and amortization expense was $65,476 and $71,242, respectively, of which $35,846 and $33,004 was included in research and development expense, $13,252 and $15,641 was included in sales and marketing expense, and $16,378 and $22,597 was included in general and administrative expense, respectively. The following table shows where depreciation expense was recorded for the years ended December 31, 2019 and 2020:

	Years Ended December 31,	
	2020	2019
Research and development expense	$ 35,846	$ 33,004
Sales and marketing expense	13,252	15,641
General and administrative expense	16,378	22,597
	$ 65,476	$ 71,242

5. Intangible Assets

The Company's intangible assets consisted of the following:

	December 31,	
	2020	2019
Trademark	$ 50,000	$ 50,000

Indefinite-lived intangible trademark asset

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

The Company determined that the acquired intangible asset met the definition of a defensive intangible asset under ASC 350, and the Company accounted for the $50,000 payment as an acquired intangible asset. As the Company can renew the underlying rights to the IP Assets indefinitely at nominal cost, the assets have been classified as a non-amortizable intangible asset on the Company's balance sheet. The Company evaluates the status of the assets for impairment annually or more frequently if warranted. Based on management's assessment, there were no indications of impairment at December 31, 2020 or 2019 for the IP Assets.

Identifiable finite-lived intangible assets and goodwill related to VectorVision

In September 2017, the Company acquired VectorVision, Inc. ("VectorVision") in exchange for 508,334 shares of the Company's common stock, valued at $2,300,000 million. In accordance with ASC 805, the purchase consideration was allocated to tangible and intangible assets at their estimated fair values on the date of acquisition. The intangible assets included $674,400 of finite-lived intangible assets including customer relationships, technology, trade names, and noncompetition, and $1,563,520 of goodwill. At December 31, 2018, the net book value of the finite-lived intangible assets was $406,104, and the net book value of the goodwill was $1,563,520. During the fourth quarter of 2019, the Company conducted its annual impairment analysis, considering multiple qualitative observations and indicators, including our customer relationships, the regulatory environment as it impacts medical devices, market penetration expectations and barriers, and our anticipated competitive environment.

Although management believes in the future growth and success of the VectorVision business, development of the CSV-2000 took longer than expected due to software engineering and other factors. Although we believe we will enjoy a significant market share over time, there is subjectivity of predicting the amount and timing of that value. Recent changes in the regulatory environment may cost us more than anticipated to begin marketing the new device in Europe.

Accordingly, management concluded that as of December 31, 2019, the fair value of the goodwill and finite-lived intangible assets associated with the VectorVision acquisition were less than their respective carrying amounts. For the year ended December 31, 2019, the Company recorded a goodwill impairment charge of $1,563,520, and an additional charge of $406,104 to fully amortize the balance of the finite-lived intangible assets recorded in the VectorVision acquisition.

6. Operating Leases

The Company leases certain office and warehouse spaces under operating leases. In October 2012, the Company entered into a lease agreement for 9,605 square feet of office and warehouse space commencing March 1, 2013. The lease ("Lease 1") was renewed for an additional five years in 2018 through July 2023. In connection with the VectorVision acquisition (see Note 5), the Company assumed a lease agreement ("Lease 2") for 5,000 square feet of office and warehouse space which commenced October 1, 2017 through February 2023.

In accounting for the leases, the Company adopted ASC 842 *Leases* on January 1, 2019, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. The Company classified the leases as operating leases and at January 1, 2019, determined that the present value of Lease 1 payments was $639,520 and that the present value of Lease 2 payments was $81,634, or an aggregate of $721,154, using a discount rate of 3.9%. In accordance with ASC 842, the right-of-use assets are being amortized over the life of the underlying leases. During the year ended December 31, 2020, the Company reflected amortization of right-of-use asset of $154,124. At December 31, 2020, accumulated amortization of the right-of-use assets was $302,564, resulting in a net asset balance of $418,590.

During the year ended December 31, 2020, the Company made combined payments on both leases of $151,767 towards the lease liabilities. As of December 31, 2020, the lease liability for Lease 1 was $388,001, and the lease liability for Lease 2 was $46,746, or an aggregate of $434,747. ASC 842 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. Combined rent expense for both leases for the years ended December 31, 2020 and 2019 was $174,323 and $174,323, respectively.

Maturities of the Company's lease liabilities are as follows:

Year ending	**Operating Leases**
2021	$ 176,934
2022	182,249
2023	98,417
Total lease payments	457,600
Less: Imputed interest/present value discount	(22,852)
Present value of lease liabilities	434,748
Less Current portion	(162,845)
	$ 271,903

7. Settlement with Former Officer

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer and as an employee of the Company and resigned from the Company's Board of Directors. Terms of the settlement agreement between the parties included the continuation of his previous salary of $325,000 during the twelve months subsequent to his resignation. The $325,000 of aggregate settlement payments was recorded in costs related to resignation of former officer expense in the accompanying consolidated statements of operations for the year ended December 31, 2020. As of December 31, 2020, $148,958 of the amount due remains accrued on our consolidated balance sheet and is payable through June 2021. In addition, 138,889 options previously granted to the former officer were forfeited (see Note 10).

8. Notes Payable

Promissory Note

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

Convertible Notes

In March 2019, the Company issued two convertible notes with aggregate principal in the amount of $250,000, simple interest of 5% annually, and with maturity dates of September 30, 2019. The convertible notes (principal and accrued interest) were mandatorily convertible upon the consummation of the Company's IPO. In April 2019, upon the consummation of the IPO, the convertible notes and accrued interest with an aggregate balance of $250,788 were mandatorily converted into 18,173 shares of common stock based on a conversion price of $13.80 per share in April 2019. Upon conversion a valuation discount of $250,000 was recognized as interest expense.

Concurrent with the issuance of the notes, the Company issued warrants to the note holders equal to the number of shares of common stock that the holders receive in connection with the converted notes. The per share exercise price of the warrants was set at 125% of the conversion price of the notes, defined in the note agreements, as the lower of (a) 75% of the price per share of common stock of the IPO or (b) $13.80. The Company issued 18,173 warrants based upon the completion of the IPO in April 2019.

Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as a derivative liability upon issuance (see Note 9). The aggregate fair value of the warrant derivative liability was determined to be $436,034 based on a probability effected Black-Scholes option pricing model with a stock price of $24.00, volatility of 138%, and risk-free rates ranging from 2.34% - 2.39%. The Company recognized a debt discount of $250,000 equal to the face amount of the convertible notes and recorded a financing cost of $186,034 equal to the difference between the fair value of the warrants and the debt discount. (see Note 9)

9. Derivative Warrant Liability

Derivative for warrants issued to underwriter

On April 9, 2019, the Company issued 10,417 warrants with an exercise price of $30.00 per share to the underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants is remeasured at each reporting period, and the change in the fair value is recognized in earnings in the accompanying statements of operations. The fair value of the warrants at the date of issuance was determined to be $229,921 and was recorded as a finance cost. During the year ended December 31, 2019, a decrease in the fair value of the derivative warrant liability of $216,598 was recorded, and at December 31, 2019, the fair value of the derivative warrant liability was $13,323. During the year ended December 31, 2020, an increase in the fair value of the derivative warrant liability of $12,655 was recorded, and at December 31, 2020, the fair value of the derivative warrant liability was $25,978.

Derivative for warrants issued with convertible notes in 2019 and reclassified to equity in 2019

In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at the issuance date. The Company estimated that the issuance of 18,173 warrants with an exercise price of $17.28 per share would correspond to the number of shares of common stock that the holders would receive in connection with the completion of the IPO. The fair value of the warrants at date of issuance was determined to be $436,034, of which $250,000 was recorded as a valuation discount and $186,034 was recorded as a finance cost. Upon completion of the IPO, the exercise price and the number of warrants were fixed, and the warrants are no longer accounted for as liabilities. The fair value of the warrants at the completion of the IPO was determined to be $359,683, and such amount was reclassified to equity. This resulted in the Company recognizing a decrease in derivative warrant liability of $76,351 during the year ended December 31, 2019.

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

	Convertible Notes issued March 2019	Underwriter warrants issued April 2019	Warrant Liability December 31, 2019	Warrant Liability December 31, 2020
Stock price	$ 24.00	$ 22.08	$ 1.32	2.49
Risk free interest rate	2.34 – 2.39%	2.29%	1.62%	0.17%
Expected volatility	138%	137%	145%	148%
Expected life in years	5.00	5.00	4.3	3.8
Expected dividend yield	0%	0%	0%	0%
Number of warrants	18,173	10,417	10,417	10,417
Fair value of derivative warrant liability	$ 436,034	$ 229,921	$ 13,323	25,978

10. Stockholders' Equity

Common Stock

Sales of common stock

On April 9, 2019, the Company closed its initial public offering (the "IPO") and issued 208,334 shares of its common stock at a public offering price of $24.00 per share for total gross proceeds of $5.0 million pursuant to an underwriting agreement by and between the Company, WallachBeth Capital, LLC, and WestPark Capital, Inc., acting as the representatives. On April 9, 2019, the Company issued 10,417 warrants with an exercise price of $30.00 per share to the underwriters and affiliates in connection with the IPO. The Company accounted for these warrants as a derivative liability (see Note 9) upon issuance because they were associated with a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. Net proceeds to the Company were $3,888,000 after deducting underwriting discounts, commissions, and other offering expenses.

On August 15, 2019, the Company closed a second public offering consisting of (i) 2,000,000 shares of common stock, par value $0.001 per share, of the Company, (ii) pre-funded warrants exercisable for 166,667 shares of common stock, and (iii) warrants to purchase up to an aggregate of 2,166,667 shares of common stock pursuant to an underwriting agreement by and between the Company, Maxim Group LLC, and WallachBeth Capital LLC, acting as the representatives. On August 16, 2019, the Company sold an additional 325,000 warrants upon exercise of the underwriters' over-allotment option. The public offering price was $2.64 per share of common stock, $2.58 per pre-funded warrant and $0.06 per accompanying warrant. On August 15, 2019, the Company issued 173,334 warrants with an exercise price of 3.00 per share to the underwriters in connection with the offering. Net proceeds to the Company were $4,944,340 after deducting underwriting discounts, commissions, and other offering expenses.

On October 30, 2019, the Company completed an underwritten public offering of 3,800,000 shares of its common stock plus 283,334 pre-funded warrants to purchase common stock in lieu thereof and Series B warrants to purchase up to 4,083,334 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $2.05 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but issued separately and were immediately separable upon issuance. Warrants to purchase 140,000 shares of common stock upon the exercise of the underwriters' over-allotment option and warrants to purchase 326,667 shares of common stock were issued to the underwriters as representatives of the public offering. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7,400,000.

Common stock issued for services

During the year ended December 31, 2020, the Company issued 16,667 fully vested shares of common stock for services rendered and recognized $49,350 in stock compensation expense related to these shares.

Warrants

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
December 31, 2018	**210,946**	**$ 4.26**	**0.29**
Granted	7,693,590	2.52	4.81
Forfeitures	-	-	-
Expirations	(46,572)	(10.98)	-
Exercised	(3,057,508)	(3.00)	-
December 31, 2019	**4,800,456**	**2.28**	**4.91**
Granted	-	-	-
Forfeitures	-	-	-
Expirations	(10,830)	(9.00)	-
Exercised	(2,656,868)	(2.04)	-
December 31, 2020, all exercisable	**2,132,758**	**$ 2.40**	**3.81**

The exercise prices of warrants outstanding and exercisable as of December 31, 2020 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
1,566,466	$ 2.05
326,668	2.67
173,334	3.00
37,700	3.51
28,590	17.25
2,132,758	

During the year ended December 31, 2019, the Company granted a total of 7,693,590 warrants consisting of: (a) 10,417 warrants associated with our IPO financing in April 2019, (b) 18,173 warrants in connection with the conversion of certain notes (c) 2,831,667 warrants associated with our August public offering, and (d) 4,833,334 warrants associated with our October public offering. No warrants were granted in the year ended December 31, 2020.

The August and October 2019 pre-funded warrants were sold to purchasers whose purchase of shares of common stock in the offerings would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the Company's outstanding common stock immediately following the consummation of the offerings, in lieu of shares of common stock. Each pre-funded warrant represents the right to purchase one share of common stock at an exercise price of $0.01 per share.

The August 2019 public offering price was $2.64 per share of common stock and $0.01 per accompanying warrant. Each warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $3.51 per share. The warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) 30 days from the effective date of the Registration Statement and (ii) the date on which the Common Stock trades an aggregate of more than 6,666,667 shares after the announcement of the pricing of the offering, and ending on the twelve month anniversary thereof, each warrant may be exercised at the option of the holder on a cashless basis at a ratio of one warrant for one share of common stock, in whole or in part, if the weighted average price of the common stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the warrant.

The October 2019 public offering price was $1.99 per share of common stock and $0.06 per accompanying warrant. Each warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $2.05 per share.

During the year ended December 31, 2019, investors exercised a total of 3,057,509 warrants for 3,034,135 shares of common stock, consisting of (i) 2,559,384 warrants exercised on a cashless basis for 2,536,010 net common shares, and (ii) 498,125 warrants exercised for a total of $171,375 in proceeds to the Company (450,000 of these warrants were exercisable for $0.06 per share, and 48,125 were exercisable for $3.00 per share).

During the year ended December 31, 2020, investors exercised warrants exercisable into 2,656,868 shares of common stock for total proceeds of $5,451,892. The warrants were exercisable at $2.05 per share.

As of December 31, 2020, the Company had an aggregate of 2,132,758 outstanding warrants to purchase shares of its common stock. The aggregate intrinsic value of warrants outstanding as of December 31, 2020 was $0.

Stock Options

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
December 31, 2018	**227,083**	**$ 13.56**	**3.78**
Granted	266,667	21.06	4.38
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2019	**493,750**	**13.56**	**3.64**
Granted	423,333	5.58	9.51
Forfeitures	(138,889)	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2020, outstanding	**778,194**	**$ 9.48**	**6.38**
December 31, 2020, exercisable	**500,764**	**$ 11.64**	**4.74**

The exercise prices of options outstanding and exercisable as of December 31, 2020 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
41,667	41,667	$ 1.48
5,000	5,000	1.91
41,667	20,833	2.34
1,667	1,667	2.46
16,667	8,333	3.24
375,000	126,738	6.00
104,166	104,166	12.00
10,416	10,416	13.80
112,500	112,500	15.00
69,445	69,445	26.40
778,194	**500,765**	

The Company accounts for share-based payments in accordance with ASC 718 wherein grants are measured at the grant date fair value and charged to operations over the vesting periods.

During the year ended December 31, 2020, the Company granted options to purchase 215,000 shares of common stock to six employees with a grant date fair value determined to be $554,775 using a Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 141% to 147%, (ii) discount rate of 0.18%, (iii) zero expected dividend yield, and (iv) expected life of 5.25 to 6 years. The options have an exercise price of $1.92 to $6.00 per share. Options for 41,667 shares vest on a quarterly basis over two years and options for 6,667 shares vest in full six months after the grant date. Options for 166,667 shares vest ratably over three years.

On June 30, 2020, the Company granted options to purchase 208,334 shares of common stock to the members of the Company's Board of Directors with a grant date fair value determined to be $478,735 using a Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 142% to 148%, (ii) discount rate of 0.18%, (iii) zero expected dividend yield, and (iv) expected life of 5.25 years. The options have an exercise price of $6.00 per share. The options vest on a quarterly basis over two years beginning three months after the grant date.

The Company's volatility is based on an average volatility of similar companies in the same industry. The risk-free interest rate was based on rates established by the Federal Reserve Bank. The expected dividend yield was based on the fact that the Company has not paid dividends to its common stockholders in the past and does not expect to pay dividends to its common stockholders in the future. The expected life of the stock options granted is estimated using the "simplified" method, whereby the expected term equals the average of the vesting term and the original contractual term of the stock option.

For the years ended December 31, 2020 and 2019, the Company recognized aggregate stock-compensation expense of $494,677 and $2,593,730 respectively, related to the fair value of vested options.

As of December 31, 2020, the Company had an aggregate of 230,556 remaining unvested options outstanding, with a remaining fair value of $629,568 to be amortized over an average of 3.0 years, weighted average exercise price of $5.58, and weighted average remaining life of 9.3 years. Based on the closing price of the Company's common stock on December 31, 2020 of $2.49, the aggregate intrinsic value of options outstanding as of December 31, 2020 was zero.

Settlement of stock options issued to former officer

In connection with a separation agreement entered into with Michael Favish, the Company's former CEO (see Note 7), the expiration date of his vested stock options was extended for twelve months from June 15, 2020. In accordance with ASC 718, the extension of the exercise period for the vested options constitutes a modification of the original option agreement. In accounting for the modification, the Company calculated the fair value of the vested options immediately before modification using current valuation inputs including the Company's closing stock price of $2.94 on June 15, 2020, volatility of 142%, and discount rate of 0.22%. The Company also calculated the fair value of the vested options immediately following the modification using the extended 12-month exercise period. An incremental stock compensation charge of $24,359 was recorded in costs related to resignation of former officer.

Mr. Favish's unvested options of 138,889 at the time of his separation were forfeited. All compensation from prior periods related to these unvested options was reversed, resulting in an adjustment to stock compensation expense during the year ended December 31, 2020 of $(965,295), which was recorded in costs related to resignation of former officer.

11. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2020 and 2019 are summarized below.

	December 31,	
	2020	2019
Net operating loss carryforwards	$ 5,893,000	$ 3,961,000
Stock-based compensation	1,362,000	1,479,000
Amortization of intangibles	106,000	83,000
Accrued expenses	12,000	12,000
Right of use	(4,000)	-
Research and development credit	(13,000)	(7,000)
Depreciation	(57,000)	(43,000)
Total deferred tax assets	7,299,000	5,485,000
Valuation allowance	(7,299,000)	(5,485,000)
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, 2020, 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, 2020 and 2019, due to the losses incurred during the periods. Reconciled below is the difference between the income tax rate computed by applying the U.S. federal statutory rate and the effective tax rates for the years ended December 31, 2020 and 2019:

	Years Ended December 31,	
	2020	2019
U. S. federal statutory tax rate	(21.0)%	(21.0)%
State, net of federal benefit	(7.0)%	(7.0)%
Non-deductible goodwill impairment charge	-%	3.0%
	(28.0)%	(25.0)%
Change in valuation allowance	28.0%	25.0%
Effective tax rate	0.0%	0.0%

At December 31, 2020, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $23,338,000 which, if not utilized earlier, will begin to expire in 2035. Due to restrictions imposed by Internal Revenue Code Section 382 regarding substantial changes in ownership of companies with loss carryforwards, the utilization of the Company's NOLs may be limited as a result of changes in stock ownership.

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

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of December 31, 2020 and 2019 and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company accounts for uncertainty 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, 2020, 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.

12. Related Party Transactions

During the years ended December 31, 2020 and 2019, the Company incurred and paid $325,000 and $300,000, respectively, of salary expense to our former CEO, Michael Favish. During the years ended December 31, 2020 and 2019, the Company incurred and paid salaries of $75,000 and $114,000, respectively, to Karen Favish, spouse of Michael Favish. During the years ended December 31, 2020 and 2019, the Company incurred and paid salaries of $60,000 and $55,000, respectively, to Kristine Townsend, spouse of former Controller and Chief Accounting Officer John Townsend.

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

Pursuant to the terms of the Agreement, Mr. Favish was entitled to receive an annual base salary of $300,000 in 2019, $325,000 in 2020, and $350,000 in 2021. Effective June 15, 2020, Mr. Favish resigned as CEO of the Company and resigned from the Company's Board of Directors. Terms of the settlement agreement between the parties included the continuation of his previous salary of $325,000 during the twelve months subsequent to his resignation. The $325,000 of aggregated settlement payments was recorded in costs related to resignation of former officer expense in the accompanying consolidated statement of operations for the year ended December 31, 2020. As of December 31, 2020, $148,958 of the settlement amount remains payable on our consolidated balance sheet and is payable through June 2021.

Dr. Evans, together with his spouse, wholly owns Ceatus Media Group LLC, a California limited liability company (“Ceatus”), founded in 2004 specializing in digital marketing in the eye health care sector. The Company paid Ceatus $81,000 in 2019 and $95,750 in 2020, for services related to digital marketing for the Company.

Dr. Evans, together with his spouse, wholly owns DWT Evans LLC, an Ohio limited liability company (“DWT”), founded in 2000 which holds several pieces of real estate. One of these holdings includes real property in Greenville, Ohio where the Company’s subsidiary, VectorVision Ocular Health, leases office and warehouse space. The Company paid DWT rent in the amounts of $19,770 and $20,898 in 2020 and 2019 respectively.

When the Company acquired VectorVision, it also acquired AcQviz from Dr. Evans, which is a patented methodology for auto-calibrating and standardizing the testing light level for computer generated vision testing systems. Dr. Evans is entitled to receive a royalty on net revenue from AcQviz. As part of the development of the CSV-2000, AcQviz was embedded in the product by Radiant Technologies, Inc. in exchange for a 3% royalty on the sales of AcQviz. Radiant Technologies is owned by Joseph T. Evans, the brother of Dr. David Evans.

13. Segment Reporting

The Company determined its reporting units in accordance with ASC 280, “Segment Reporting”. The Company currently operate in two reportable segments: Medical Foods and Nutraceuticals and Medical Devices.

The Medical Foods and Nutraceuticals segment provides a portfolio of science-based, clinically supported nutrition, medical foods, and supplements. The Medical Devices segment includes a portfolio of medical diagnostic devices currently focused on the ocular space and contrast testing. The Company’s medical devices and accessories are used to measure visual function and certain anatomical features of the eye that detect early disease and monitor changes over time.

The segments are based on the discrete financial information reviewed by the Chief Executive Officer, who is the Company’s Chief Operating Decision Maker (“CODM”), to make resource allocation decisions and to evaluate performance. The reportable segments are each managed separately because they manufacture and distribute distinct products or provide services with different processes. All reported segment revenues are derived from external customers.

The accounting policies of the Company's reportable segments are the same as those described in the summary of significant accounting policies (see Note 1). Certain corporate general and administrative expenses, including general overhead functions such as information systems, accounting, human resources, Board of Director fees, corporate legal fees, other compliance costs and certain administrative expenses, as well as interest and tax expense, are not allocated to the segments. The following tables set forth our results of operations by segment:

	For the Year Ended December 31, 2020			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ 4,500	$ 1,609,482	$ 275,862	$ 1,889,844
Cost of goods sold	2,478	1,599,510	344,647	1,946,635
Gross profit (loss)	2,022	9,972	(68,785)	(56,791)
Stock compensation expense	544,127	-	-	544,127
Operating expenses	3,757,945	3,892,899	299,969	7,950,813
Loss from operations	**$ (4,300,050)**	**$ (3,882,927)**	**$ (368,754)**	**$ (8,551,731)**

	For the Year Ended December 31, 2019			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ 24,270	$ 444,657	$ 434,010	$ 902,937
Cost of goods sold	7,288	155,212	178,815	341,315
Gross profit	16,982	289,445	255,195	561,622
Stock compensation expense	2,717,731	-	-	2,717,731
Goodwill impairment charge	-	-	1,563,520	1,563,520
Operating expenses	360,257	5,308,508	1,108,543	6,777,308
Loss from operations	**$ (3,061,006)**	**$ (5,019,063)**	**$ (2,416,868)**	**$ (10,496,937)**

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

	As of December 31, 2020			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Current assets				
Cash	$ 8,518,732	$ -	$ -	$ 8,518,732
Inventories, net	-	254,879	130,093	384,972
Other	-	89,333	101,846	191,179
Total current assets	**8,518,732**	**344,212**	**231,939**	**9,094,883**
Right of use asset	-	374,447	44,143	418,590
Property and equipment, net	-	135,641	150,035	285,676
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	**$ 8,518,732**	**$ 916,051**	**$ 426,217**	**$ 9,860,900**

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

14. Commitments and Contingencies

The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. In the opinion of management of the Company, adequate provision has been made in the Company's financial statements at December 31, 2020 with respect to such matters. See notes 6,7, 11 and 13.

15. Subsequent Events

The Company performed an evaluation of subsequent events through the date of filing of these consolidated financial statements with the SEC. Other than those matters described below, there were no material subsequent events which affected, or could affect, the amounts or disclosures in the consolidated financial statements.

Sale of common stock

On January 8, 2021, we entered into the Sales Agreement and filed a prospectus supplement pursuant to which we could sell up to $10,000,000 worth of shares of our common stock in an "at the market" offering through the Distribution Agent (the "January 2021 1st ATM Offering"). On January 15, 2021, we completed the January 2021 1st ATM Offering, pursuant to which we sold an aggregate of 2,559,833 shares of our common stock, raised gross proceeds of approximately $10,000,000 and net proceeds of approximately $9,500,000.

On January 28, 2021, we entered into the Sales Agreement and filed a prospectus supplement pursuant to which we could sell up to $25,000,000 worth of shares of our common stock in an "at the market" offering through the Distribution Agent (the "January 2021 2nd ATM Offering"). On February 10, 2021, we completed the January 2021 2nd ATM Offering, pursuant to which we sold an aggregate of 5,006,900 shares of our common stock, raised gross proceeds of approximately $25,000,000 and net proceeds of approximately $24,100,000.

In addition, in January 2021 and February 2021, the Company issued an aggregate of 1,647,691 shares of common stock upon the exercise of warrants and received $3,608,509.

The following table sets forth the Company's assets, liabilities, and stockholders' equity as December 31, 2020 on:

- an actual basis; and
- a pro forma basis giving effect to the January 2021 1st ATM Offering and January 2021 2nd ATM Offering as well as the exercise of warrants.

	As of December 31, 2020	
	Actual	Pro Forma (unaudited)
Cash and cash equivalents	$ 8,518,732	$ 45,727,241
Other current assets	576,151	576,151
Non-current assets	766,017	766,017
Total assets	$ 9,860,900	$ 47,069,409
Current liabilities	$ 1,073,731	$ 1,073,731
Non-current liabilities	271,903	271,903
Total liabilities	1,345,634	1,345,634
Stockholders' equity:		
Common stock	15,171	24,427
Additional paid-in capital	62,583,423	99,782,676
Accumulated deficit	(54,083,328)	(54,083,328)
Total stockholders' equity	8,515,266	45,723,775
Total liabilities and stockholders' equity	$ 9,860,900	$ 47,069,409

The Company had a total of 15,170,628 shares of common stock (actual) and 24,426,993 shares of common stock (pro forma, which includes an addition of 41,941 shares attributed to the reverse-split fractional share adjustment) issued and outstanding at December 31, 2020.

Appointment of New CEO

Effective as of January 6, 2021, the Board of Directors appointed Bret Scholtes as President and Chief Executive Officer and as a director of the Company.

The Company and Mr. Scholtes entered into an employment pursuant to which Mr. Scholtes's annual base salary is $400,000. The Employment Agreement provides that Mr. Scholtes shall have an annual target cash bonus opportunity of no less than $400,000 (the "Bonus") based on the achievement of Company and individual performance objectives to be determined by the Board of Directors.

Mr. Scholtes was granted an award of a number of stock options equal to one percent (1%) of the issued and outstanding number of shares of the Company's common stock (the "Stock Options") pursuant to the Company's 2018 Equity Incentive Plan (the "Incentive Plan"), at an exercise price equal to the closing price of the Company's common stock on the Effective Date (152,671 shares, exercise price of $3.95 per share) . One third (1/3) of the Stock Options shall vest and become exercisable the first anniversary of the Effective Date, and the balance of the Stock Options shall vest ratably in equal installments for the twenty-four (24) months thereafter, subject to continued service, and shall vest in full upon a Change in Control (as defined in the Incentive Plan). Additionally, the Company shall grant unvested shares of common stock in an amount equal to one percent (1%) of the number of shares of Company common stock issued and outstanding on the Effective Date (the "Stock Grant") to Mr. Scholtes under the Incentive Plan (152,671 shares). The shares underlying the Stock Grant shall become vested in full on the first anniversary of the Effective Date. Additionally, Mr. Scholtes shall be granted (i) additional stock options equal to two percent (2%) of the Company's issued and outstanding shares of common stock on the date of grant if the Company achieves specified written performance objectives established by the Board for the Company's fiscal years ending December 31, 2021 and December 31, 2022 and (ii) additional stock options equal to either two percent (2%) or three percent (3%) of the Company's issued and outstanding shares of common stock on the date of grant if the Company meets certain financial objectives during the first five years following the Effective Date.

If Mr. Scholtes's employment is terminated by the Company without cause (as defined in the Employment Agreement), if the Term expires after a notice of non-renewal is delivered by the Company or if Mr. Scholtes's employment is terminated following a change of control (as defined in the Incentive Plan), Mr. Scholtes will be entitled to (a) twelve months' base salary, (b) the prorated portion of the Bonus for the year in which the termination occurs, based on actual performance and (c) base salary and benefits accrued through the date of termination.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Certificate of Incorporation in Delaware and amendment thereto (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
3.2	Certificate of Amendment to Certificate of Incorporation (filed on Form 8-K on February 1, 2019 and incorporated herein by reference)
3.3	Certificate of Amendment to Certificate of Incorporation filed and effective with the Delaware Secretary of State on December 6, 2019 (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on December 10, 2019)
3.4	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on October 22, 2019)
3.5	Second Amended and Restated Bylaws, effective October 22, 2019 (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on October 22, 2019)
4.1*	Description of Securities
10.1	Lease for 15150 Avenue of the Sciences, Suite 200, San Diego California and amendments thereto (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.2	Form of Indemnification Agreement (filed with the Registration Statement on Form S-1 filed with the SEC on February 11, 2016)
10.3	Intellectual Property Assignment Agreement with David W. Evans and VectorVision, Inc. dated as of September 29, 2017 (filed on Form 8-K on October 5, 2017 and incorporated herein by reference)
10.4	Consulting Agreement with David W. Evans dated as of September 29, 2017 (filed on Form 8-K on October 5, 2017 and incorporated herein by reference)
10.5	Guardion Health Sciences, Inc. 2018 Equity Incentive Plan (filed with the Definitive Proxy Statement on Schedule 14A on October 22, 2018 and incorporated herein by reference)
10.6	Warrant Agreement, including form of Warrant, made as of August 15, 2019, between the Company and VStock Transfer LLC (incorporated by reference to Exhibit 10.3 to the Company's current report on Form 8-K, filed with the SEC on August 19, 2019)
10.7	Warrant Agreement, including form of Series B Warrant, made as of October 30, 2019, between the Company and VStock (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed with the SEC on October 31, 2019)
10.8	Employment Agreement, by and between the Company and Andrew C. Schmidt (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed with the SEC on July 23, 2020)
10.9	Employment Agreement, by and between the Company and Bret Scholtes (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, filed with the SEC on December 29, 2020)
21.1*	List of Subsidiaries
23.1*	Consent of Weinberg & Company
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Accounting and Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Principal Executive Officer and the Principal Accounting and Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.

* filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 26th day of March 2021.

GUARDION HEALTH SCIENCES, INC.

By: */s/ Bret Scholtes*
Name: Bret Scholtes
Title: Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of GUARDION HEALTH SCIENCES, INC., hereby severally constitute and appoint Bret Scholtes and Andrew Schmidt, 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/ Bret Scholtes Bret Scholtes	CEO, President and Director (Principal Executive Officer)	March 26, 2021
/s/ Andrew Schmidt Andrew Schmidt	Chief Financial Officer Officer (Principal Financial and Principal Accounting Officer)	March 26, 2021
/s/ Robert N. Weingarten Robert N. Weingarten	Director	March 26, 2021
/s/ Mark Goldstone Mark Goldstone	Director	March 26, 2021
/s/ David W. Evans David W. Evans	Director	March 26, 2021
/s/ Donald A. Gagliano Donald A. Gagliano	Director	March 26, 2021
/s/ Kelly Anderson Kelly Anderson	Director	March 26, 2021

EXHIBIT 4.1

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

As of March 25, 2021, Guardion Health Sciences, Inc. ("the Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")—our common stock, par value $0.001 per share ("Common Stock").

Description of Common Stock

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

Authorized Capital Shares

Our authorized capital shares consist of 250,000,000 shares of Common Stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). As of March 25, 2021, there were 24,426,993 shares of Common Stock issued and outstanding. There were no shares of Preferred Stock issued or outstanding as of March 25, 2021.

Voting Rights

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

Dividend Rights

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

Liquidation Rights

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

Applicable Anti-Takeover Provisions

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

Ability of Stockholders to Call Special Meetings

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

Advance Notice Requirements

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

Blank Check Preferred Stock

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

Exclusive Forum Provision

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

Listing

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

Transfer Agent

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

EXHIBIT 21.1

LIST OF SUBSIDIARIES

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-1 (No. 333-232544, No. 333-234322 and No. 333-233067), Form S-3 (No. 333-248895), and Form S-8 (No. 333-231603) of Guardion Health Sciences, Inc. of our report dated March 26, 2021, with respect to the consolidated financial statements of Guardion Health Sciences, Inc. of December 31, 2020 and 2019, and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 26, 2021

EXHIBIT 31.1

CERTIFICATION

I, Bret Scholtes, 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 26, 2021

/s/ Bret Scholtes

Bret Scholtes
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Andrew Schmidt, 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 26, 2021

/s/ Andrew Schmidt

Andrew Schmidt
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

EXHIBIT 32.1

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

In connection with the Annual Report of Guardion Health Sciences, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Bret Scholtes, Chief Executive Officer of the Company, and Andrew Schmidt, Chief Financial Officer 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 26, 2021

/s/ Bret Scholtes
Bret Scholtes
Chief Executive Officer
(Principal Executive Officer)

March 26, 2021

/s/ Andrew Schmidt
Andrew Schmidt
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)