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

FORM 10-K

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

For the fiscal year ended December 31, 2021

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: 001-38861

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

Delaware	**47-4428421**
(State or jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
2925 Richmond Avenue, Suite 1200, Houston, TX	**77098**
(Address of principal executive offices)	*(Zip code)*

800-873-5141
(Registrant's telephone number, including area code)

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**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ 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	☒	Smaller reporting company	☒
		Emerging growth company	☒

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 ☒ No

On June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $41.8 million based upon the closing price of the registrant's common stock of $1.76 on The Nasdaq Capital Market as of that date.

As of March 25, 2022, there were 61,426,993 shares of the registrant’s common stock, par value $0.001 per share, issued and outstanding.

Documents Incorporated by Reference:

Portions of the registrant’s definitive proxy statement relating to its 2022 annual meeting of stockholders (the “2022 Proxy Statement”) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2022 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, the forward-looking statements discussed in this Annual Report on Form 10-K 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 Annual Report on Form 10-K. 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. We qualify all of the information presented in this Annual Report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

RISK FACTOR 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.

Risks Related to the Company's Business

- As the Company has incurred recurring losses and negative cash flows since its inception, there is no assurance that the Company will be able to reach and sustain profitability.
- The COVID-19 global pandemic has and may continue to adversely impact the Company's business.
- Inflationary pressure may adversely impact the Company's business.
- The Company has limited experience in developing dietary supplements and medical foods and it may be unable to commercialize some of the products it develops or acquires.
- The Company's investment in new businesses and new products, services, and technologies is inherently risky, and could disrupt its current operations.
- 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.

- Competitors may develop products similar to the Company's products, and the Company may therefore need to modify or alter its business strategy, which may have a material adverse effect on the Company.

- 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.

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

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

- 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.

- The Company's acquisition strategy involves a number of risks.

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

Risks Related to the Company's Acquisition of Activ Nutritional, LLC ("Activ")

- Integrating Activ's business with the Company's business may be more difficult, costly, or time-consuming than expected, and the Company may not realize the expected benefits of its acquisition of Activ, which may adversely affect the Company's business, financial condition, and results of operations.

Risks Related to Government Regulations

- 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.

- 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, or result in a product recall that could harm the Company's reputation, business and financial results.

Risks Related to the Company's Common Stock

- The Company received a written notice from Nasdaq that it has failed to comply with certain listing requirements of the Nasdaq Stock Market, which could result in the Company's being delisted from the Nasdaq Stock Market.

- 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.

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

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

We are a clinical nutrition company that develops and distributes clinically supported nutrition, including foods and dietary supplements. We offer a portfolio of science-based, clinically supported products designed to support consumers in achieving their health goals.

Our profile and focus fundamentally changed with the acquisition of Activ Nutritional, LLC ("Activ" or "Viactiv" as the context requires) in June 2021, the owner and distributor of the Viactiv® line of supplements for bone health, immune health and other applications.

The acquisition and integration of the Viactiv line of products has changed our financial position, market profile and brand focus, and has also expanded our search for additional business opportunities in the short-term, both internal and external.

We believe the Activ acquisition added valuable attributes, including (1) Viactiv's brand awareness and acceptance from the consumer; (2) experienced management; (3) established distribution networks and relationships; (4) product development potential; and (5) a long track record of revenue growth and profitability.

- Brand awareness – Viactiv was initially launched by industry leaders Mead Johnson/Johnson & Johnson approximately twenty years ago, and we believe this history, along with the product's marketing campaigns, taste profile and receipt of consistently positive consumer reviews, have led to strong consumer awareness and acceptance.

- Experienced management – As part of the Activ acquisition, we appointed Craig Sheehan as our Chief Commercial Officer. Mr. Sheehan was the senior executive responsible for the Viactiv brand as a member of the executive leadership team of Adare Pharmaceuticals, Inc. ("Adare"), the previous owner of Viactiv.

- Established distribution – Viactiv's products are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target, CVS and Amazon.

- Track record of profitability – Viactiv generated net revenues of approximately $11,900,000 and operating income of approximately $1,200,000 in the year-ended December 31, 2020. For the year ended December 31, 2021, on a pro forma basis and assuming Viactiv was owned by the Company for the entire year, our total revenues would have been $12,765,911 and the Viactiv products would have accounted for 96% of our pro forma total revenues for the period. We expect the acquisition of Viactiv to contribute increasing revenue and consistent operating margins and profitability, as well as a multitude of growth opportunities, to our Company.

Acquisition of Activ Nutritional, LLC

On June 1, 2021, we completed our acquisition of Activ. The acquisition was made pursuant to an Equity Purchase Agreement, dated May 18, 2021, between us, Adare and Activ. We acquired all of the issued and outstanding equity of Activ from Adare for $26 million in cash, subject to certain adjustments as provided in the Equity Purchase Agreement.

Activ owns the Viactiv® line of supplement chews for bone health, immune health and other applications which are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target and Amazon. The Viactiv product lines will be our most prominent product lines for the foreseeable future absent any additional significant acquisitions.

Recent Developments

Equity Distribution Agreement

On January 28, 2022, we entered into an Equity Distribution Agreement (the "Sales Agreement") with Maxim Group LLC, and Roth Capital Partners LLC as co-agents (collectively, the "Agents"), pursuant to which we may offer and sell, from time to time through the Agents, shares of our common stock having an aggregate offering price of up to $25,000,000 in one or more at-the-market offerings. As of March 25, 2022, we have not sold any shares of our common stock pursuant to the Sales Agreement. As a result of the February Offering (described below), we are restricted from utilizing the at-the-market offering for a period of time.

February 2022 Securities Offering

On February 18, 2022, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which we issued and sold, in a best-efforts offering by the Company (the "February Offering"), (i) 32,550,000 units, priced at an offering price of $0.30 per unit, with each unit consisting of one share of our common stock, one warrant to purchase one share of our common stock at an exercise price of $0.37 per share that expires on the fifth anniversary of the date of issuance ("Series A Warrant") and one warrant to purchase one share of our common stock at an exercise price of $0.37 per share that expires on the eighteen month anniversary of the date of issuance ("Series B Warrant"), and (ii) 4,450,000 pre-funded units, priced at an offering price of $0.2999 per unit, with each unit consisting of one pre-funded warrant to purchase one share of our common stock at an exercise price of $0.0001 per share that is exercisable at any time after issuance until exercised in full (a "Pre-Funded Warrant" and together with the Series A Warrants and Series B Warrants, the "Warrants"), one Series A Warrant and one Series B Warrant.

On February 18, 2022, we entered into a Placement Agency Agreement (the "Placement Agency Agreement") with the Agents pursuant to which we paid the Agents an aggregate fee equal to 7.0% of the gross proceeds from the units sold in the February Offering and reimbursed the Agents $100,000 for expenses incurred in connection with the February Offering. In addition, we issued Roth warrants (the "Placement Agent Warrants") to purchase up to 1,850,000 shares of our common stock exercisable at an exercise price of $0.37 per share. The Placement Agent Warrants will be exercisable immediately and expire on the fifth anniversary of the date of the issuance.

On February 23, 2022, we closed the February Offering, and issued (i) 32,550,000 shares of common stock, (ii) Series A Warrants to purchase 37,000,000 shares of common stock, (iii) Series B Warrants to purchase 37,000,000 shares of common stock, and (iv) Pre-Funded Warrants to purchase 4,450,000 shares of common stock. The net proceeds from the February Offering, after deducting the placement agent fees and estimated offering expenses payable by us were approximately $10.0 million. In the event that the Company fails to deliver shares by the required delivery date upon exercise of the warrants, the Company may be subject to cash penalties in an amount up to $20 per trading day for each $1,000 of warrant shares until such shares are delivered. In addition, if the warrant holder purchases shares in the market following the Company's failure to deliver shares upon exercise of the warrants, the Company will be required to cover the cost of any buy-ins and, at the option of the warrant holder, either reinstate the portion of the warrant for the shares that were not delivered or deliver the number of shares that should have been issued.

In connection with the February Offering, we and our executive officers and directors entered into lock-up agreements providing that we and each of our executive officers and directors, subject to limited exceptions, may not offer, sell, transfer or otherwise dispose of our Company's securities for a period of (i) 90 days for executive officers and directors and (ii) 120 days for our Company following the February Offering, without the prior written approval of Roth (and in the case of our Company lockup, Roth and the investors party to the Securities Purchase Agreement).

In addition, until the 18 month anniversary of the February Offering, we are prohibited from entering into a variable rate transaction (as defined in the Securities Purchase Agreement), provided, however, we will be permitted to utilize the at-the-market offering facility, described above, commencing 120 days following the closing of the February Offering.

On February 18, 2022, we entered into a warrant agency agreement with our transfer agent, VStock Transfer, LLC, who will also act as our warrant agent, setting forth the terms and conditions of the Series A Warrants and Series B Warrants sold in the February Offering.

Product Offerings

Our product profile and focus fundamentally changed with the acquisition of Activ in June 2021, the owner and distributor of the Viactiv® line of supplements for bone health, immune health and other applications. In 2021, sales of the Viactiv line of supplements represented approximately 90% of our consolidated net sales. The Viactiv line of supplements contains several flavored nutritional supplement products, but the milk chocolate and caramel flavored calcium chews constitute the main product category.

Viactiv was first introduced to the market over 20 years ago as a calcium-fortified soft chew intended to deliver clinical nutrition to women in a way that is enjoyable to taste and easy to consume. Since the original chocolatey-chew, multiple chews have been introduced, each delivering nutrition to help consumers maintain health goals, such as strong bones and immune support. Viactiv is regulated in the U.S. as a dietary supplement.

We also sell Lumega-Z, our medical food product that has a formula designed to replenish and restore the macular protective pigment, simultaneously delivering critical and essential nutrients to the eye. The current formulation has been delivered to patients and used in clinics since 2019.

As a medical food, Lumega-Z must be administered under the supervision of a physician or professional healthcare provider. We also use a variety of marketing strategies to increase awareness of Lumega-Z among ophthalmologists and optometrists. We also market Lumega-Z through direct-to-consumer strategies such as social media and paid search advertising.

In 2020, two peer-review scientific articles were published demonstrating the beneficial efficacy of Lumega-Z®. 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 macular pigment optical density (“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. 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 that were ocular normals taking no supplements. Each study participant had retinal drusen, delayed dark adaptation recovery time and was at risk of developing vision loss from age-related macular degeneration (“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.

GlaucoCetin, also currently considered a medical food, offers a formula that is designed to support proper mitochondrial function in the optic nerve cells in glaucoma patients. Loss of optic nerve cells is thought to be the primary cause of vision loss in glaucoma patients. Like Lumega-Z, we market GlaucoCetin through direct-to-consumer strategies such as social media and paid search advertising. We also use a variety of marketing strategies to increase awareness of GlaucoCetin among ophthalmologists and optometrists.

We distribute Lumega-Z and GlaucoCetin through E-commerce, in an online store that is operated at www.guardionhealth.com, and we intend to expand our E-commerce capabilities in 2022.

Prior Product Offerings

Nutriguard: We had marketed a brand of dietary supplement products under the NutriGuard brand, which we acquired in 2019, but decided to stop marketing the brand after acquiring the Viactiv line of supplements in June of 2021. ImmuneSF, a unique proprietary nutraceutical formulation designed to support and maintain an effective immune system was the first product developed after the acquisition of NutriGuard. This formulation contained a synergistic blend of antioxidant and anti-inflammatory nutrients. While we still intend to build a portfolio of nutraceutical products, we plan to launch such products under the Viactiv brand rather than the NutriGuard brand.

VectorVision, CSV-1000 and CSV-2000: In September 2017, we, through our wholly owned subsidiary VectorVision Ocular Health, Inc., acquired VectorVision, Inc. ("VectorVision"), a company that specialized in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision developed, manufactured and sold 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.

During December 2021, as part of management's comprehensive evaluation of our Company's business and in order to focus on those brands and lines of business that management believes provide the greatest growth opportunities, we determined to restructure the operations of our VectorVision business. We are completing the process of substantially winding down the day-to-day operations of VectorVision, which is expected to significantly reduce costs, and we intend to explore various alternative ways to preserve, manage and exploit our intellectual property rights, including our U.S. patents, associated with the VectorVision technology. We are exploring both domestic and international business opportunities, such as licensing and distribution arrangements, with experienced parties, which could assist us in the economic exploitation of these intellectual property rights. As a result of this change to the VectorVision business strategy, management believes that it will be able to better focus its efforts and deploy capital resources to more growth-oriented brands and product lines, like Viactiv, and other products in development, that it hopes to bring to market in 2022.

Competitive Advantage and Strategy

Dietary Supplements

We intend to formulate high quality scientifically credible dietary supplements with a goal to become a globally respected clinical nutrition company. We believe our dietary supplements can play an important role in optimizing, preserving and restoring health.

Our products compete primarily in the consumer product category of dietary supplements. Successfully competing in this category requires a continuous flow of new products and line extensions, and significant sales and marketing expenses. We will also invest in research and development that will help guide our new product development process. We will compete in this category primarily on the basis of product innovation and performance, brand recognition, price, value and other consumer benefits. Consumer products, particularly dietary supplements, are subject to significant price competition. As a result, we, from time to time, may need to reduce the prices for some of our products to respond to competitive and customer pressures and to maintain market share. Product introductions typically involve heavy marketing and trade spending in the year of launch, and we usually are not able to determine whether the new products and line extensions will be successful until a period of time has elapsed following the introduction of the new products or the extension of the product line.

Our products are marketed primarily through a broad distribution platform that includes supermarkets, mass merchandisers, wholesale clubs, drugstores, and other discount and other specialty stores, and websites and other e-commerce channels, all of which sell our products to consumers. We also utilize the services of independent brokers, who represent our products in the food, mass, club, and numerous other classes of trade. Our products are stored in third-party owned warehouses and are delivered by independent trucking companies.

Medical Foods

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™. 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. We believe we have an 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, 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 we believe may lead 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. We believe that we have an advantage with GlaucoCetin because it is designed to offset the mitochondrial dysfunction of cells in glaucoma patients.

Growth Strategy

We believe that developing new products, growing our established distribution and cost effectively marketing our products are the keys to growing our business. We have several innovation initiatives underway that are aimed at increasing the number of new products in our product portfolio and expanding our total addressable market, and we plan to grow our established distribution network. Our current network includes many of the nation's largest retailers, including, among others, Walmart (retail and online), Target, CVS and Amazon. We are also focused on our direct-to-consumer website. We are working to add additional retailers that sell our products and adding new sales channels. We are also focused on marketing initiatives that strengthen our brand and target consumers who would benefit most from our specific products. We also intend to explore the acquisition of other companies, product lines and intellectual property rights that may be complementary or supplementary as part of our efforts to expand our business.

Sales

Viactiv has traditionally sold the majority of its products through traditional retailers via third party brokers. We have continued to utilize these brokers to sell the Viactiv products to retailers rather than employing an internal sales force. Online retailers have represented a smaller portion of sales, but we believe these sales can be meaningful and play an important role in our eCommerce strategy. In addition, we sell a limited amount of Viactiv products directly to consumers via our website, and plan to invest in this channel to grow sales. While the footprint for our direct-to-consumer channel is currently small, we expect this channel to play an important role in our new product launches and growth. Furthermore, the Company is evaluating its medical food product portfolio in order to determine whether it would be advantageous to fold those products into the Viactiv brand of supplements and utilize those distribution channels.

Marketing – Digital

We are focused on marketing initiatives that strengthen our brand and target consumers who would benefit most from our products. We utilize digital marketing for the majority of our marketing expenditures, and we believe that such methods have been among the most cost-effective way to market our products.

Marketing – Practitioners

Healthcare practitioners are important stakeholders for our products, especially Lumega-Z and GlaucoCetin. We have deemphasized our direct sales approach that involved our sales representatives in favor of a more cost-effective approach to increase the awareness of our products with health care practitioners. This approach is designed to increase marketing reach 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 and educational approaches.

Domestic and International Expansion Strategy

We are primarily focused on expanding our business domestically rather than internationally. The acquisition of Activ in 2021 shifted our strategic focus towards the Viactiv line of supplements, which has historically focused on domestic markets. As a result, the domestic markets allow us to leverage Viactiv's strong consumer brand awareness, distribution networks and key third party vendors relationships.

Although we have decreased our focus on international expansion, we maintain relationships that we hope will lead to increased distribution of our existing products and unique nutritional formulations in Asian markets. In March 2020, we received our first order for a novel immune support product from a Malaysian company, which order was valued at $890,000 and we believe that we could have similar opportunities in the future.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes and methods, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek the broadest intellectual property protection possible for our products and proprietary information through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

Patents

We currently own and have exclusive rights to four U.S. patents, one Canadian patent, and one Hong Kong patent application with respect to various products and product candidates, as follows:

(1) U.S. Patent No. 9,486,136 entitled “Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye,” issued on November 8, 2016.

(2) U.S. Patent No. 10,016,128 entitled “Method and Apparatus for Vision Acuity Testing,” issued on July 10, 2018.*

(3) U.S. Patent No. 10,022,045 entitled “Method and Apparatus for Vision Acuity Testing,” issued on July 17, 2018.*

(4) U.S. Patent No. 10,456,028 entitled “Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye,” issued on October 29, 2019.

(5) Canadian Patent No. 2864154, titled “Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye,” granted on May 18, 2021.

(6) Hong Kong Patent Appl. No. HK15105364.0A, titled “Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye,” filed June 5, 2015 and published Dec. 4, 2015 as HK1204758A1.

* The patents marked with an asterisk are assigned to VectorVision Ocular Health, Inc.

Trademarks

We prominently display our trademarks on all Guardion and Viactiv products and believe that having distinctive trademarks is an important factor in the promotion and marketing our product offerings. We have acquired or are in the process of acquiring registered protection for the trademarks most critical to our business. We currently have ten trademarks registered with the United States Patent and Trademark Office (“USPTO”) and three applications pending before the USPTO, all of which are used in association with the Guardion line of products. In addition, we have six trademarks registered with the USPTO which are used in association with the Viactiv line of products.

Furthermore, we have 11 trademarks currently registered in foreign jurisdictions for use with our Guardion line of products, and we have 15 registrations for the Viactiv trademark in a broad range of geographies. We are evaluating whether additional foreign trademark protection may be appropriate. The domestic and foreign trademark registrations/applications referred to herein are set forth in the table below:

Trademark Registrations/Applications

Trademark	Country	Application/ Registration No.	App/Reg Date	Owner
#BEACTIV	United States	5,132,075	01/31/2017	Activ Nutritional, LLC
ACTIVE NUTRITION FOR WOMEN BY WOMEN	United States	2,531,197	1/22/2002	Activ Nutritional, LLC
CHEWS TO BE STRONG	United States	5,118,075	01/10/2017	Activ Nutritional, LLC
CHEWS TO MAKE A DIFFERENCE	United States	5,118,073	01/10/2017	Activ Nutritional, LLC
CSV-1000	United States	4,500,241	03/25/2014	Guardion Health Sciences, Inc.
CSV-2000	Republic of Korea	401593337	04/06/2020	Guardion Health Sciences, Inc.
CSV-2000	United States	5,888,766	10/22/2019	Guardion Health Sciences, Inc.
EPIQ (& Design)	China	54241599	10/21/2021	Guardion Health Sciences, Inc.
				
EPIQ (& Design)	United States	90/566,436	03/08/2021	Guardion Health Sciences, Inc.
				
EPIQ in Chinese Characters	China	42592291	09/28/2020	Guardion Health Sciences, Inc.
EPIQ-V	China	48733586	04/14/2021	Guardion Health Sciences, Inc.
EPIQ-V	Malaysia	TM2021000520	01/07/2021	Guardion Health Sciences, Inc.

Trademark	Country	Application/ Registration No.	App/Reg Date	Owner
EPIQ-V	Philippines	4202100500186	10/29/2021	Guardion Health Sciences, Inc.
EPIQ-V	United States	6,429,847	07/20/2021	Guardion Health Sciences, Inc.
EPIQ-V	United States	6,449,526	08/10/2021	Guardion Health Sciences, Inc.
GLAUCOCETIN	United States	5,933,586	12/10/2019	Guardion Health Sciences, Inc.
GLAUCO-HEALTH	United States	5,092,549	11/29/2016	Guardion Health Sciences, Inc.
GUARDION	United States	5,025,658	08/23/2016	Guardion Health Sciences, Inc.
LUMEGA-Z	China	27151643	11/07/2018	Guardion Health Sciences, Inc.
LUMEGA-Z	United States	5,757,377	05/21/2019	Guardion Health Sciences, Inc.
MAPCAT SF	China	27151644	10/28/2018	Guardion Health Sciences, Inc.
MAPCAT SF	United States	4,997,319	07/12/2016	Guardion Health Sciences, Inc.
OMEGA BOOST	United States	97/061,429	10/06/2021	Guardion Health Sciences, Inc.
OMEGA BOOST (stylized)	United States	97/201,891	01/04/2022	Guardion Health Sciences, Inc.
				
VECTORVISION	China	27151642	02/07/2020	Guardion Health Sciences, Inc.
VECTORVISION	China	39703795	01/28/2021	Guardion Health Sciences, Inc.
VECTORVISION	China	48062177	07/14/2020	Guardion Health Sciences, Inc.
VECTORVISION	United States	4,341,403	05/28/2013	Guardion Health Sciences, Inc.
VIACTIV	Australia	IR13853061902404	10/15/2019	Activ Nutritional, LLC

Trademark	Country	Application/ Registration No.	App/Reg Date	Owner
VIACTIV	Canada	TMA535149	10/19/2000	Activ Nutritional, LLC
VIACTIV	China	IR138530641246868	02/07/2021	Activ Nutritional, LLC
VIACTIV	Egypt	IR1385306	10/02/2017	Activ Nutritional, LLC
VIACTIV	European Union	017257635	01/23/2021	Activ Nutritional, LLC
VIACTIV	France	97707126	01/09/1998	Activ Nutritional, LLC
VIACTIV	Germany	39753876	06/04/1998	Activ Nutritional, LLC
VIACTIV	International Bureau (WIPO)	IR1385306	10/02/1997	Activ Nutritional, LLC
VIACTIV	Israel	IR1385306	02/05/2019	Activ Nutritional, LLC
VIACTIV	Japan	IR1385306	09/06/2018	Activ Nutritional, LLC
VIACTIV	Mexico	IR1385306	09/30/2019	Activ Nutritional, LLC
VIACTIV	Morocco	IR1385306	12/26/2019	Activ Nutritional, LLC
VIACTIV	Norway	IR1385306	01/18/2019	Activ Nutritional, LLC
VIACTIV	Switzerland	IR1385306	12/10/2018	Activ Nutritional, LLC
VIACTIV	Turkey	IR1385306	01/10/2019	Activ Nutritional, LLC
VIACTIV	United States	2,248,302	05/25/1999	Activ Nutritional, LLC
VIACTIV LIFESTYLE	United States	5,073,522	11/01/2016	Activ Nutritional, LLC

Products Manufacturing and Sources and Availability of Raw Materials

We outsource the manufacturing of our medical food products and dietary supplement product line to contract manufacturers. We process orders through purchase orders and invoices with each manufacturer. We believe that there are alternative sources, suppliers and manufacturers available for our products in the event of a termination or a disagreement with any current vendor.

Government Regulation

Dietary Supplement Regulation

The US Food and Drug Administration (FDA) has primary jurisdiction for the regulation of dietary supplements. The FDA regulates dietary supplements, such as Viactiv chews, as “dietary supplements” under the Federal Food, Drug, and Cosmetic Act (“FDCA”) as a distinct, sub-category of “food.” Dietary supplements must meet the requirements of applicable food laws and regulations. A “dietary supplement” is defined under the FDCA 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 enhance the diet and may not be represented as a conventional food or as the sole item of a meal or diet.

Dietary supplements do not require approval from the 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 is not required to provide the FDA with the evidence it relies on to substantiate safety or effectiveness before marketing a supplement product.

A manufacturer or distributor must notify the 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 first marketed as or in a dietary supplement after October 15, 1994. The manufacturer must demonstrate to the 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.”

Owners or responsible parties of any facilities at which dietary supplements are manufactured, packaged, labeled, or held for distribution must register the facility or facilities with FDA pursuant to the Bioterrorism Preparedness and Response Act of 2002 (“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. We engage with contract manufacturers to manufacture our dietary supplements.

Companies are responsible for determining that the dietary supplements they manufacture or distribute are safe, and that any representations or claims made about them are substantiated by adequate evidence to show that the claims are not false or misleading. The Federal Trade Commission (“FTC”) has the primary responsibility to regulate the advertising of foods, including dietary supplements. Under the FTC Act, all advertising claims, both express and implied, must be truthful, non-misleading, and substantiated. In practice, the FDA and FTC share jurisdiction over promotional practices and monitor the promotion and advertising of dietary supplements in multiple media forms, including TV, radio, social media (e.g., Facebook, Twitter), and the internet.

Dietary supplements also are subject to the Nutrition, Labeling and Education Act, which regulates health claims, ingredient labeling, and nutrient content claims characterizing the level of a nutrient in a product. Dietary supplements may be intended to affect the structure or function of the human body. If the label of a dietary supplement contains such structure/function claims, the label must bear the disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” We are responsible for ensuring the accuracy and truthfulness of all product claims.

Medical Foods Regulation

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 the FDA prior to marketing. 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.

We currently consider our Lumega-Z and GlaucoCetin products to be medical foods. 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. If the FDA were to disagree and consider our medical foods to be "drugs" under the FDCA, we and our products would be subject to considerable additional FDA regulation.

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. 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 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 our medical foods are either FDA-approved food additives or have GRAS status.

Foods manufacturers must register with the FDA pursuant to the Bioterrorism Act before producing foods. Manufacturers of foods also must follow cGMP regulations applicable to foods. 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. We engage contract manufacturers to manufacture Lumega-Z and GlaucoCetin.

The FTC has the primary responsibility to regulate the advertising of 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 manufacturing facilities, including packaging, distribution facilities, and fulfillment houses. The FDA and FTC also gathers material at trade shows and conferences and review company websites and social media accounts.

Healthcare Laws and Regulations

Stark Law

The Omnibus Budget Reconciliation Act of 1993 prohibits certain physician self-referrals. 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 Designated Health Service ("DHS") to an entity that furnishes or bills for DHS (a "DHS Entity") and with which the physician has a financial relationship, and prohibits DHS Entities from billing for any DHS that is referred, unless all of the requirements of a 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 ("State Self-Referral Prohibitions"), some of which can apply to all payors and not just governmental payors.

At present, neither Lumega Z nor GlaucoCetin are outpatient prescription drugs nor are they reimbursable under any federal program. Further, we do not furnish any DHS to patients, nor bill any DHS to any federal program. We believe that the federal Stark Law is thus inapplicable. Further, we believe that State Self-Referral Prohibitions are unlikely to apply for similar reasons. To the extent that the products might become reimbursable under a federal program, or otherwise become covered under the Stark Law, we believe that the physicians who recommend our medical foods, Lumega-Z and GlaucoCetin, to their patients are aware of Stark Law and State Self-Referral Prohibition requirements. However, we do not monitor their compliance and have no assurance that the physicians are in material compliance with the Stark Law or State Self-Referral Prohibitions. If it were determined that the physicians who prescribe medical foods purchased from us were not in compliance with the Stark Law or State Self-Referral Prohibitions, it could potentially have an adverse effect on our business, financial condition and results of operations.

Anti-Kickback Statute

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 of 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, we do not participate in any federal programs and our 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 we believe that we are in material compliance with both federal and state AKS laws, the AKS laws present different levels of risks as to our sale of our medical foods, Lumega-Z and GlaucoCetin.

At present, our products are not reimbursable under any federal program. If, however, that changes in the future and we determine that we are not in compliance with the AKS, we could be subject to liability, and our operations could be curtailed. Moreover, if the activities of our customers or other entity with which we have a business relationship were found to constitute a violation of the AKS and we, as a result of the provision of products or services to such customer or entity, were found to have knowingly participated in such activities, we could be subject to 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.

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.

To the extent we were billing governmental health care programs, the False Claims Act may potentially be applicable to such operations. We put a fraud and abuse compliance program in place that was designed to ensure that our documentation, coding and billing were accurate and compliant. Any patterns of uncorrected deficiencies in documenting, coding and billing, however, may result in fines and other liabilities, which may adversely affect our 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, we consult with healthcare counsel regarding the expansion of operations and utilize local counsel when necessary.

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

Foreign Regulatory Requirements

We 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 we 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.

Employees

As of March 25, 2022, we, including our subsidiaries, had a total of 13 full-time employees. and no part-time employees. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

Science Advisory Board

Our research and development efforts are shaped by our Science Advisory Board, a product development and research team composed of industry experts in clinical nutrition. This team is 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.

In addition to developing products based on scientific studies in the public domain, members of our Science Advisory Board conduct and publish their own evidence. Their expertise and the evidence they develop guide the formulation of all of our products.

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. We changed our name to Guardion Health Sciences, LLC in December 2009. In June 2015, we converted into a Delaware "C" corporation.

On October 29, 2020, our stockholders approved an extension of the previously granted discretionary authority of the board of directors to amend our certificate of incorporation to effectuate a reverse stock split, at a specific ratio within a range of no split to a maximum of a one-for-thirty (1-for-30) split, with the exact ratio to be determined by our board of directors in its sole discretion. The former authorization, which expired on December 5, 2020, was extended through October 29, 2021.

On March 1, 2021, we filed a Certificate of Amendment to our 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 our common stock without any change to our par value. Proportional adjustments for the Reverse Stock Split were made to our 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 Form 10-K.

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 its inception, there is no assurance that the Company will be able to reach and sustain profitability. If it cannot reach and sustain profitability, 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 $24,745,009 for the year ended December 31, 2021 and a net loss of $8,571,657 for the year ended December 31, 2020. The Company had an accumulated deficit of $78,802,072 as of December 31, 2021. At December 31, 2021, the Company had cash and short term investments on hand of $9,089,550 and working capital of $10,910,139. In addition, the Company completed an offering in February 2022 that generated additional net cash proceeds of approximately $10 million. Notwithstanding the net loss for 2021, management believes that its current cash balance is sufficient to fund operations for at least one year from the date the Company's 2021 financial statements are issued.

The Company will continue to incur significant expenses related to the commercialization of its products and with respect to its efforts to build its infrastructure, expand its operations, and execute on its business plans.

Even if profitability is achieved in the future, the Company may not be able to sustain profitability on a consistent basis. The Company expects to continue to incur substantial losses and negative cash flow from operations for the foreseeable future. The Company's financial statements for the year ended December 31, 2021 have been prepared assuming that the Company will continue as a going concern.

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 the Company's 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 may require that Company assets secure such debt.

The Company's ability to obtain additional financing in the future will be subject to a number of factors, including but not limited to, 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 its 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 the Company's stockholders losing some or all of their investment.

The future success of the Company's business is largely dependent upon the successful commercialization of its products. 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 is 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 the Company's operations and its ability to fund future development and commercialization efforts.

The COVID-19 global pandemic has and may continue to adversely impact the Company's business, including the commercialization of the Company's products, supply chain, clinical trials, liquidity and access to capital markets and business development activities.

In March 2020, the World Health Organization characterized COVID-19 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 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 the Company's policies and those of third parties to reduce the spread of COVID-19 may negatively impact productivity and the Company's ability to market and sell its products, cause disruptions to its supply chain and impair its ability to execute its business development strategy. These and other disruptions in the Company's operations and the global economy could negatively impact the Company's business, operating results and financial condition.

The commercialization of the Company's products may be adversely impacted by COVID-19 and actions taken to slow its spread. For example, patients may postpone visits to retailers, and healthcare provider facilities, certain healthcare providers may temporarily close their offices or restrict 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 the Company's 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 the Company relies, or the availability or cost of materials, which could disrupt the supply chain for the Company's products.

Moreover, the Company has been experiencing supply chain constraints due to the COVID-19 pandemic. These constraints began in December 2021 and have continued into 2022. These constraints have impacted the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products and may continue to impact the Company's ability to fulfill customer orders going forward which would have a material adverse effect on the Company's business and results of operations. The Company continues to experience challenges to meet customer demands, largely because of broad-based shortages in suppliers' labor which impact the availability of many critical components in the Company's supply chain and distribution. We are subject to out-of-stock fees to certain retailers in the event that we are unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, the Company and its suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs as well as transportation challenges. The Company expects shortages to continue at least through the first half of 2022 and input cost inflation to continue at least throughout 2022.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect the Company economically. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have 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 the Company's ability to access capital, which could in the future negatively affect the Company's liquidity and financial position or the Company's business development activities.

The extent to which the COVID-19 pandemic may impact the commercialization of the Company's products, supply chain, access to capital and 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 dietary supplements and medical foods and it may be unable to commercialize some of the products it develops or acquires.

Development and commercialization of dietary supplements and medical foods involves a lengthy and complex process. The Company has limited experience in developing products and has only a few commercialized products on the market. Furthermore, there is no guarantee that any newly developed products will be marketable or that the Company will achieve commercial success with any new products or product lines.

Even if the Company develops or acquires products for commercial use, these products may not be accepted by the consumer, or medical 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 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.

A key part of the Company's business strategy is to establish collaborative relationships to commercialize and develop its products. 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 products.

While the Company believes that these collaborative relationships help further validate its products, these relationships are not material to the Company because these relationships are not 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 products 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 currently relies upon and expects to continue to 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 be issued to third parties which the Company's technology may infringe on. Because patent applications can take many years to be issued, 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 on.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, and could divert management's attention from the Company's business and have a material negative effect on the Company's business, operating results or financial condition. If such a dispute were to be resolved against the Company, it 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.

Competitors may develop products similar to the Company's products, and the Company may therefore need to modify or alter its business strategy, which may have a material adverse effect on the Company.

Competitors may develop products with similar characteristics to the Company's 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 as well as greater brand recognition than the Company does and represent substantial long-term competition for the Company. Such companies may develop products that are safer, more effective or less costly than any that the Company may develop. Such companies also may be more successful than the Company is 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 which may have a material adverse effect on the Company.

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.

To commercialize the Company's products successfully, the Company must develop more robust capabilities internally or collaborate with third parties that can perform these services. In the process of commercializing the Company's products, the Company 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, it 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 the Company is able to identify one or more acceptable partners, it may not be able to enter into any partnering arrangements on favorable terms, or at all. If the Company enters into any partnering arrangements, its revenues are likely to be lower than if the Company marketed and sold its products itself.

In addition, any revenues the Company receives would depend upon its 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 its control. Depending upon the terms of the Company's agreements, the remedies the Company against an under-performing partner may be limited. If the Company 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 limit commercialization of its products.

The Company faces a risk of product liability exposure related to the use of its products. If the Company cannot successfully defend itself against claims that its products caused injuries, the Company will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current products or products that the Company may develop;
- injury to the Company's reputation and significant negative media attention;
- significant costs to defend the related litigation;
- loss of revenue; and
- reduced time and attention of the Company's management to pursue the Company's business strategy.

The Company's insurance policies may not fully cover liabilities that it may incur in the event of a product liability lawsuit. The Company 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 distributions.

The Company is dependent on third-party sales broker and distribution relationships. These brokers and distributors may not commit the necessary resources to market and sell the Company's products to the level of the Company's expectations. If sales brokers and distributors do not perform adequately, or if the Company is unable to locate distributors in particular geographic areas, the Company's ability to realize long-term revenue growth would be materially adversely affected.

Additionally, the Company's products may require regulatory clearances and approvals from jurisdictions outside the United States. The Company expects that it will be subject to and required to comply with local regulatory requirements before selling its products in those jurisdictions. The Company is not certain that it will be able to obtain these clearances or approvals or compliance requirements on a timely basis, or at all.

The Company has historically sold its products to customers outside the U.S. and may sell products outside of the United States in 2022 and beyond. As a result, the Company's business is 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 Registration, Evaluation, Authorisation and Restriction of Chemicals 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 dietary supplements, 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 the Company's cost or ability to import raw materials or export its 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 the Company operates, including the risk of expropriation or nationalization, and the costs and ability to repatriate the profit that the Company generates 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 the Company operates;

- 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 the Company operates, which could interrupt our operations or endanger its 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.

The Company engages third parties to manufacture its 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 its products and the manufacturing schedule, the Company 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 the Company's estimates and the actual amounts of products it requires. If the Company is unable to obtain from one or more of its vendors the needed materials or components that meet our specifications on commercially reasonable terms, or at all, the Company may not be able to meet the demand for its products. While the Company has not arranged for alternate suppliers, and it may be difficult to find alternate suppliers in a timely manner and on terms acceptable to the Company, the Company believes that there are alternative sources, suppliers and manufacturers available for its products in the event of a termination or a disagreement with any current vendor. Additionally, the Company's supply chain may be jeopardized for a period of time due to the COVID-19 outbreak or challenges related to supply chain constraints.

The Company has been experiencing supply chain constraints due to the COVID-19 pandemic. These constraints began in approximately December 2021 and have continued into 2022. These constraints have impacted our ability the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products and may continue to impact its ability to fulfill customer orders going forward which would have a material adverse effect on the Company's business and results of operations. The Company continues to experience challenges to meet customer demands, largely because of broad-based shortages in suppliers' labor which impact the availability of many critical components in the Company's supply chain and distribution. The Company is subject to out-of-stock fees to certain retailers in the event that the Company is unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, the Company and its suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs as well as transportation challenges. The Company expects shortages to continue at least through the first half of 2022 and input cost inflation to continue at least throughout 2022.

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 the Company's business, the Company collects and stores sensitive data, including intellectual property, its proprietary business information and that of its customers and business partners, including potentially personally identifiable information of its customers, some of which is stored on the Company's network and some of which is stored with the Company's third-party e-commerce vendor. Despite the Company's security measures, its 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 the Company's 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 the Company's operations, and damage the Company's reputation, which could adversely affect the Company's business.

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.

During the years ended December 31, 2021 and 2020, the Company's billings were derived from a limited number of individual customers and distributors. During the year ended December 31, 2021, the Company's clinical nutrition business had one customer who accounted for approximately 49% of the Company's sales; and during the year ended December 31, 2020, the Company's clinical nutrition business had one customer who accounted for approximately 47% of the Company's sales. No other customer accounted for more than 10% of sales in either year. Customers may stop purchasing the Company's products with little or no warning. Loss of customers may have an immediate adverse effect on the Company's financial results.

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

The Company's business model depends on its ability to sell its products. Third party brokers play an important role in the sales of the Viactiv line of supplements since the majority of these sales are made through traditional retailers. The Company utilizes these brokers to sell to it retail customers rather than employing an internal sales force. The Company cannot assure you that these brokers will be successful in selling its products to traditional retail customers. In addition, acceptance of the Company's products greatly benefits from physicians who understand and appreciate the benefits of Lumega-Z and GlaucoCetin and recommend them to their patients. The Company cannot assure you that physicians will integrate its products into their treatment plans or patient recommendations. Achieving market acceptance for the Company's 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 the Company fails to achieve broad acceptance of its products by physicians, and other healthcare industry participants or if the Company fails to position its products as an ocular health remedy, the Company's business, financial condition and results of operations may be adversely affected.

The Company is highly dependent upon consumers' perception of the safety and quality of its products as well as similar products distributed by other companies in its industry, and adverse publicity and negative public perception regarding particular ingredients or products or the Company's industry in general could limit the Company's ability to increase revenue and grow our business.

Decisions about purchasing made by consumers of the Company's products may be affected by adverse publicity or negative public perception regarding particular ingredients or products or the Company's industry in general. This negative public perception may include publicity regarding the legality or quality of particular ingredients or products in general or of other companies or our products or ingredients specifically. Negative public perception may also arise from regulatory investigations, regardless of whether those investigations involve the Company. The Company is highly dependent upon consumers' perception of the safety and quality of its products as well as similar products distributed by other companies. Thus, the mere publication of reports asserting that such products may be harmful could have a material adverse effect on the Company, regardless of whether these reports are scientifically supported. Publicity related to nutritional supplements may also result in increased regulatory scrutiny of the Company's industry and/or the healthy foods channel. Adverse publicity may have a material adverse effect on the Company's business, financial condition, results of operations and cash flows.

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.

The Company could be subject to intellectual property infringement claims as the number of its competitors grows and if its products or the functionality of its products overlap with patents of the Company's competitors. While the Company does not believe that it has infringed or is infringing on any proprietary rights of third parties, the Company cannot assure you that infringement claims will not be asserted against it or that those claims will be unsuccessful. The Company 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 the Company could secure a judgment awarding substantial damages, as well as injunctive or other equitable relief that could effectively block the Company's ability to provide products. In addition, the Company cannot assure you that licenses for any intellectual property of third parties that might be required for its products 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.

Protecting the Company's intellectual property rights is critical to its continued success and its ability to maintain its competitive position. The Company's goal is to protect its proprietary rights through a combination of patent, trademark, trade secret and copyright law, confidentiality agreements and technical measures. The Company generally enters into non-disclosure agreements with its employees and consultants and limits access to its trade secrets and technology. The Company cannot assure you that the steps it has taken will prevent misappropriation of its intellectual property. Misappropriation of the Company's intellectual property would have an adverse effect on its competitive position.

The Company's success, competitive position, and future revenues will depend, in part, on its ability to obtain and maintain patent protection for its products, methods and processes; to preserve its trade secrets; to obtain trademarks for its name, logo and products; to prevent third parties from infringing its proprietary rights; and to operate without infringing the proprietary rights of third parties. To counter infringement or unauthorized use by third parties, the Company 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 the Company will be successful in protecting its 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;

- the Company's competitors, many of which have substantially greater resources than the Company does 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 the Company's ability to make, use, and sell the Company's current and future 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 the Company or any of its 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 the Company's business and the additional obligations that come with being an exchange-listed company, the Company will need to expand its senior management team and attract and retain quality employees. There is no assurance that the Company will be capable of attracting and retaining quality executives and integrating those individuals into the Company's management system. Without experienced and talented management and employees, the growth of the Company's business may be adversely impacted.

The Company's ability to attract and retain qualified members for its board of directors may be impacted due to new potential rules of national securities exchanges.

Nasdaq has adopted new listing rules to become effective on the later of August 8, 2022 and the date a company files its proxy statement for its 2022 annual meeting of stockholders related to board diversity and disclosure, which requires all companies listed on Nasdaq's U.S. exchanges to publicly disclose consistent, transparent diversity statistics regarding their board of directors. Additionally, the rules 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 Nasdaq rules, which may expose us to penalties and/or reputational harm.

The Company's acquisition strategy involves a number of risks.

The Company is 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 the Company's existing business operations, may become available in the future. If and when appropriate acquisition opportunities become available, the Company intends to pursue them actively. Acquisitions involve a number of risks, including, but not limited to:

- 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 the Company's 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 the Company acquires 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 the Company's business, results of operations and financial condition. The Company has faced, and expects to continue to face, intense competition for acquisition candidates, which may limit its ability to make acquisitions and may lead to higher acquisition prices. The Company cannot assure you that it will be able to identify, acquire or manage profitably.

Unfavorable global economic conditions could adversely affect the Company's business, financial condition or results of operations.

The Company's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including changes in inflation and overall economic conditions and uncertainties. Inflation could also adversely affect the ability of the Company's customers to purchase its products. An economic downturn, including as a result of COVID-19, could result in a variety of risks to the Company's business, including weakened demand for the Company's products and the Company's inability to raise additional capital when needed on acceptable terms, if at all. Any of the foregoing could harm the Company's business and the Company cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business.

Risks Related to the Company's Acquisition of Activ Nutritional, LLC

Integrating Activ's business with the Company's business may be more difficult, costly, or time-consuming than expected, and the Company may not realize the expected benefits of its acquisition of Activ, which may adversely affect the Company's business, financial condition, and results of operations.

If the Company experiences greater than anticipated costs to integrate, or is not able to successfully integrate, Activ's business into its operations, the Company may not be able to achieve the anticipated benefits of its acquisition of Activ, including cost savings and other synergies and growth opportunities. Even if the integration of Activ's business is successful, the Company may not realize all of the anticipated benefits of its acquisition of Activ during the anticipated time frame, or at all. For example, events outside of the Company's control, such as changes in regulations and laws, as well as economic trends, including as a result of the COVID-19 pandemic, could adversely affect the Company's ability to realize the expected benefits from its acquisition of Activ. An inability to realize the full extent of the anticipated benefits of the Company's acquisition of Activ could have an adverse effect upon its revenue, level of expenses, and results of operations.

Activ may have liabilities that are not known to the Company.

Activ may have liabilities that the Company failed, or was unable, to discover in the course of performing its due diligence investigations in connection with its acquisition of Activ. The Company may learn additional information about Activ that materially and adversely affects the Company and Activ, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Moreover, Activ may be subject to audits, reviews, inquiries, investigations, and claims of non-compliance and litigation by federal and state regulatory agencies which could result in liabilities or other sanctions. Any such liabilities or sanctions, individually or in the aggregate, could have an adverse effect on the Company's business, financial condition, and results of operations.

The Company has made certain assumptions relating to the Activ acquisition that may prove to be materially inaccurate.

The Company has made certain assumptions relating to the Activ acquisition that may prove to be inaccurate, including as the result of the failure to realize the expected benefits of the Activ acquisition, failure to realize expected revenue growth rates, higher than expected operating and transaction costs, as well as general economic and business conditions that adversely affect the Company.

Risks Related to Government Regulations

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 the Company's ability to carry on or expand its 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 the Company's business, including:

- product formulation and development;
- pre-clinical and clinical testing;
- product labels and labeling;
- establishment registration and product listing;
- product safety, including product recalls or other field-safety actions;
- manufacturing, testing, packaging, storage, distribution;
- premarket approval or authorization;
- record keeping procedures;
- marketing, sales, advertising and promotion;
- post-market surveillance, including reporting of adverse events; and
- product import and export.

The Company may be subject to similar foreign laws that govern all of the above elements of the Company's business, including pre-market and post marketing obligations for our products. The time required to obtain authorization to sell the Company's 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, FTC, states, and other regulatory authorities have broad enforcement powers. Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, FTC, 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 product 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 the Company's reputation, business, financial condition, and results of operations.

Dietary supplements, such as Viactiv, and medical foods do not require premarket approval by FDA before they may be distributed in the United States (with limited exceptions). The company currently considers Lumega-Z and GlaucoCetin to be medical foods, as that term is defined under the FDCA. While the Company believes Lumega-Z and GluacoCetin are medical foods, if the FDA determines Lumega-Z or GlaucoCetin to be a "drug" under the FDCA, the Company and the products would be subject to considerable additional FDA regulation. 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."

Our relationships with healthcare providers may subject us to anti-kickback, fraud and abuse and other healthcare laws and regulations, which could change or expose us to potential penalties, reputational harm and diminished profits and future earnings, among other penalties and consequences.

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 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 the Company's 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 the Company or its third-party manufacturers fail to comply with FDA cGMP regulations or fail to adequately, timely, or sufficiently respond to an FDA Form 483 or subsequent Warning Letter, this could impair the Company's ability to market its 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 the Company's products. The Company does not manufacture any of its products internally and instead relies on contract manufacturers to manufacture its products. The Company and its third-party manufacturers are required to comply with cGMP regulations. 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's products and facility, and the facilities of its manufacturers, are subject to federal laws and regulations and certain state laws. 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 the Company's supplement and food products do not require pre-market approval by the FDA, manufacturers of the Company's products must 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 the Company's FDA-regulated products is outsourced in its entirety to three third-party manufacturers. The Company is evaluating additional manufacturers for selection as second source or back-up providers.

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

The Company may be subject to fines, penalties, injunctions or other administrative actions if it is deemed to be promoting its products outside of their intended use (i.e., as drugs), or if it is 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 FDCA and other laws, the Company is prohibited from promoting its nutritional products for treatment of a condition or disease. The Company's promotional materials and marketing activities must comply with FDCA, FTCA, and other applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the use of the Company's products outside of their intended use as supplements or foods (i.e., as a drug) or that make false or misleading statements. The 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 the Company's sales and marketing activities may constitute the promotion of the Company's products for use as a drug in violation of applicable law, or that its 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, or result in a product recall that could harm the Company's reputation, business and financial results.

If the Company's products are associated with undesirable side effects or adverse events, 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.

Companies may, under their own initiative, recall a product or the government may mandate a recall. A government-mandated or voluntary recall by the Company or one of its distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, labeling defects or other deficiencies and issues. Recalls of any of the Company's products would divert managerial and financial resources and have an adverse effect on the Company's financial condition and results of operations. In addition, the FDA requires companies to maintain certain records of recalls, even if they are not reportable to the FDA. The Company may initiate voluntary recalls involving the Company's products in the future that it determines do not require notification of the FDA. If the FDA disagrees with the Company's determinations, it could require the Company to report those actions as recalls. A future recall announcement could harm the Company's reputation with customers and negatively affect the Company's sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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 the Company believes Lumega-Z® and GlaucoCetin™ to be medical foods and not drugs, they are only available under the supervision of a physician. While not available in pharmacies, the Company is 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 the Company does not believe these pharmacy requirements are applicable, should a pharmacy board or medical board determine otherwise, there can be no assurance that the Company will be able to comply with the regulations of particular states into which the Company currently does business or may expand, or that we will be able to maintain compliance with the states in which we currently distribute our products.

The Company is subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing its 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.

The Company's operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act ("FCPA") and other anti-corruption laws that apply in countries where the Company does business (including in Malaysia) and may do business in the future, particularly as the Company expands its sales and operations to foreign markets. The Bribery Act, FCPA and these other laws generally prohibit the Company, its officers, and its 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.

The Company may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and the Company may participate in collaborations and relationships with third parties whose actions could potentially subject the Company to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, the Company cannot predict the nature, scope or effect of future regulatory requirements to which its international operations might be subject or the manner in which existing laws might be administered or interpreted. If the Company expands its operations outside of the U.S., the Company will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans 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 the Company expands its presence outside of the U.S., the Company will be required to dedicate additional resources to comply with these laws, and these laws may preclude the Company from developing, manufacturing, or selling certain products outside of the U.S., which could limit the Company's growth potential and increase its development costs.

The Company may not be completely effective in ensuring compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If the Company is not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, the Company 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 the Company's 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 the Company's' reputation, business, results of operations and financial condition.

Risks Related to the Company's Common Stock

The Company received a written notice from Nasdaq that it has failed to comply with certain listing requirements of the Nasdaq Stock Market, which could result in the Company's being delisted from the Nasdaq Stock Market.

On January 25, 2022, the Company received a notification from Nasdaq related to its failure to maintain a minimum bid price of $1 per share. Based upon the closing bid price for the last 30 consecutive business days, the Company no longer meets this requirement. However, the Nasdaq Listing Rules also provide the Company a compliance period of 180 calendar days in which to regain compliance. Accordingly, if at any time from the date of this notice until July 25, 2022, the closing bid price the Company's common stock is at least $1 for a minimum of ten consecutive business days, Nasdaq will provide the Company with written confirmation of compliance and the matter will be closed. If the Company does not regain compliance with the minimum bid price requirement by July 25, 2022, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet all other initial listing standards, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period. If the Company does not regain compliance with the minimum bid price requirement by the end of the compliance period (or the second compliance period, if applicable), the Company's common stock will become subject to delisting. If the Company is delisted from Nasdaq, its common stock may be eligible for trading on an over-the-counter market. If the Company is not able to obtain a listing on another stock exchange or quotation service for the Company's common stock, it may be extremely difficult or impossible for stockholders to sell their shares. The Company intends to monitor the closing bid price of the Company's common stock and may be required to seek approval from its stockholders to effect a reverse stock split of the issued and outstanding shares of the Company's common stock. However, there can be no assurance that the reverse stock split would be approved by the Company's stockholders. Further, there can be no assurance that the market price per new share of the Company's common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of the Company's common stock outstanding before the reverse stock split. Even if the reverse stock split is approved by the Company's stockholders, there can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing rules.

If the Company is delisted from Nasdaq, its common stock may be eligible for trading on an over-the-counter market. If the Company is not able to obtain a listing on another stock exchange or quotation service for its common stock, it may be extremely difficult or impossible for stockholders to sell their shares of common stock. Moreover, if the Company is delisted from Nasdaq, but obtains a substitute listing for its common stock, it will likely be on a market with less liquidity, and therefore experience potentially more price volatility than experienced on Nasdaq. Stockholders may not be able to sell their shares of common stock on any such substitute market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if the Company's common stock is delisted from Nasdaq, the value and liquidity of the Company's common stock, warrants and pre-funded warrants would likely be significantly adversely affected. A delisting of the Company's common stock from Nasdaq could also adversely affect the Company's ability to obtain financing for its operations and/or result in a loss of confidence by investors, employees and/or business partners.

If the Company implements a reverse stock split, liquidity of its common stock may be adversely effected.

The Company may be required to seek approval from its stockholders to effect a reverse stock split of the issued and outstanding shares of its common stock in order to regain compliance with the Nasdaq minimum bid price requirement. However, there can be no assurance that the reverse stock split would be approved by the Company's stockholders. Further, there can be no assurance that the market price per new share of the Company's common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of the Company's common stock outstanding before the reverse stock split. The liquidity of the shares of the Company's common stock may be affected adversely by any reverse stock split given the reduced number of shares of the Company's common stock that will be outstanding following the reverse stock split, especially if the market price of the Company's common stock does not increase as a result of the reverse stock split.

Following any reverse stock split, the resulting market price of the Company's common stock may not attract new investors and may not satisfy the investing requirements of those investors. Although the Company believes that a higher market price of the Company's common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of the Company's common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of the Company's common stock may not necessarily improve.

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.

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as the Company continues to be an emerging growth company, it has 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, as amended, (the "Sarbanes-Oxley Act"), (2) reduced disclosure obligations regarding executive compensation in the Company's 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, the Company is only required to provide two years of audited financial statements. As a result of these reduced reporting and disclosure requirements the Company's financial statements may not be comparable to SEC registrants not classified as emerging growth companies. The Company may be an emerging growth company for up to five years following the first sale the Company's equity securities in a public offering (April 2019), although circumstances could cause the Company to lose that status earlier, including if the market value of the Company's common stock held by non-affiliates exceeds $700.0 million before that time or if the Company has total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases the Company would no longer be an emerging growth company as of the following December 31 or, if the Company issues more than $1.0 billion in non-convertible debt during any three-year period before that time, the Company would immediately cease to be an emerging growth company. Even after the Company no longer qualifies as an emerging growth company, the Company may still qualify as a "smaller reporting company" which would allow it 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 its periodic reports and proxy statements. The Company cannot predict if investors will find the Company's common stock less attractive because the Company may rely on these exemptions. If some investors find the Company's common stock less attractive as a result, there may be a less active trading market for the Company's common stock and the Company's stock price may be more volatile.

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. The Company has elected to avail itself 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 the Company's common stock less attractive as a result of its election to utilize these exemptions, which could result in a less active trading market for the Company's common stock and/or the market price of the Company's common stock may be more volatile.

The Company's stock price has fluctuated in the past, has been volatile and may be volatile, and as a result, investors in the Company's common stock could incur substantial losses.

The Company's stock price has fluctuated in the past, has been and may be volatile. The Company may incur rapid and substantial increases or decreases in its stock price in the foreseeable future that are unrelated to its 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 the Company's common stock. The market price for the Company's common stock may be influenced by many factors, including the following:

- investor reaction to the Company's business strategy;
- the success of competitive products;
- the Company's 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 the Company's products;
- actions taken by regulatory agencies with respect to the Company's products, manufacturing process or sales and marketing terms;
- variations in the Company's financial results or those of companies that are perceived to be similar to the Company;
- the success of the Company's efforts to acquire or in-license additional products;
- developments concerning the Company's collaborations or partners;
- declines in the market prices of stocks generally;
- trading volume of the Company's common stock;
- sales of the Company's common stock by the Company or its 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 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 the Company's operations, disrupt the operations of the Company's suppliers or result in political or economic instability.

These broad market and industry factors may seriously harm the market price of the Company's common stock, regardless of its 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 the Company's common stock has fluctuated in the past, has and may be volatile, investors in the Company's 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 the Company could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect the Company's business, financial condition, results of operations and growth prospects. There can be no guarantee that the Company's stock price will remain at current prices or that future sales of the Company's common stock will not be at prices lower than those sold to investors.

Additionally, 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 the Company has no reason to believe its shares would be the target of a short squeeze, there can be no assurance that the Company will not, in the future be subject to a short squeeze and you may lose a significant portion or all of your investment if you purchase the Company's shares at a rate that is significantly disconnected from its 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.

The Company has never paid any dividends to its common stockholders. The Company currently intends to retain any future earnings for funding growth and, therefore, does not expect to pay any cash dividends in the foreseeable future. If the Company determines that it will pay cash dividends to the holders of its common stock, it 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 the 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 the Company.

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

The Company may require additional debt or equity financing to fund its operations, including, but not limited to, working capital. The Company's limited operating history since its recent acquisition of Activ, which fundamentally changed its business, makes it difficult to evaluate the Company's current business model and future prospects. Accordingly, investors should consider the Company's prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, as the Company has, 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 the Company does not have current plans to re-prioritize its business plan, potential investors should consider that there is a significant risk that the Company will not be able to:

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

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

If the Company fails to comply with the rules under the Sarbanes-Oxley Act related to internal controls and procedures in the future, or, if the Company discovers material weaknesses and other deficiencies in its internal controls over financial reporting, the Company's stock price could decline significantly and raising capital could be more difficult.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of the Company's internal controls over financial reporting. If the Company fails to comply with the rules under the Sarbanes-Oxley Act related to disclosure controls and procedures in the future, or, if the Company discovers material weaknesses and other deficiencies in its internal controls over financial reporting, the Company's stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if the Company otherwise fails to achieve and maintain the adequacy of its internal controls, the Company may not be able to ensure that it can conclude on an ongoing basis that it has effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for the Company to produce reliable financial reports and are important to helping prevent financial fraud. If the Company cannot provide reliable financial reports or prevent fraud, its business and operating results could be harmed, investors could lose confidence in the Company's reported financial information, and the trading price of the Company's common stock could drop significantly.

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 the Company's stockholders, which could limit a stockholder's ability to obtain a favorable judicial forum for disputes with it or its directors, officers, employees or agents.

The Company's Second Amended and Restated Bylaws ("Bylaws") designates the Delaware Court of Chancery as 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 stockholders 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 a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers, employees or agents and may result in increased costs to the Company's stockholders, which may discourage such lawsuits against the Company and its directors, officers, employees and agents even though an action, if successful, might benefit the Company's stockholders. 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 the Company than to its stockholders. Alternatively, if a court were to find this provision of the Company's Bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, the Company may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on its business, financial condition or results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our address is 2925 Richmond Avenue, Suite 1200, Houston, Texas 77098. Our corporate offices are rented on a month-to-month basis at a current rent of approximately $1,700 per month. We believe these facilities will be adequate for our needs during the foreseeable future.

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

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

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."

Stockholders

As of March 25, 2022, there were approximately 77 record holders of the Company's common stock. The actual number of holders of the Company's common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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 the Company's 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. [RESERVED]

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

You should read the following discussion and analysis of our financial condition and results of operations together with and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical nutrition company that develops and distributes clinically supported nutrition, medical foods and dietary supplements. The Company offers a portfolio of science-based, clinically supported products designed to support healthcare professionals and providers, and their patients and consumers.

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

Our profile and focus fundamentally changed with the acquisition of Activ Nutritional, LLC ("Activ" or "Viactiv," as the context requires) in June 2021, the owner and distributor of the Viactiv® line of dietary supplements for bone health, immune health and other applications.

The acquisition and integration of the Viactiv line of products has changed our financial position, market profile and brand focus, and has also expanded our search for additional business opportunities in the short-term, both internal and external.

We believe the Activ acquisition has added valuable attributes, including (1) Viactiv's brand awareness and acceptance from the consumer; (2) experienced management; (3) established distribution networks and relationships; (4) product development potential; and (5) a long track record of revenue growth and profitability.

- Brand awareness – Viactiv was initially launched by industry leaders Mead Johnson/Johnson & Johnson approximately twenty years ago, and we believe this history, along with the product's marketing campaigns, taste profile and receipt of consistently positive consumer reviews, have led to strong consumer awareness and acceptance.

- Experienced management – As part of the Activ acquisition, we appointed Craig Sheehan as our Chief Commercial Officer. Mr. Sheehan was the senior executive responsible for the Viactiv brand as a member of the executive leadership team of Adare.

- Established distribution – Viactiv's products are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target, CVS and Amazon.

- Track record of profitability – Viactiv generated net revenues of approximately $11,900,000 in 2020 and operating income of approximately $1,200,000 in 2020. For the year ended December 31, 2021, on a pro forma basis, our total revenues would have been approximately $12,766,000 and the Viactiv products would have accounted for 94% of our pro forma total revenues for the year. We expect the acquisition of Viactiv to contribute increasing revenue and consistent operating margins and profitability, as well as a multitude of growth opportunities, to our Company.

Availability of Capital

We 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 we will be able to secure such additional financing in the amounts necessary to fully fund our operating requirements on acceptable terms or at all. Over time, if we are unable to access sufficient capital resources on a timely basis, we may be forced to reduce or discontinue our product development programs and curtail or cease operations.

The Company will continue to incur significant expenses related to the commercialization of its products and with respect to its efforts to build its infrastructure, expand its operations, and execute on its business plans. 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. If the Company raises additional funds through the issuance of equity or convertible debt securities, the percentage ownership of the Company's 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 may require that Company assets secure such debt.

Recent Developments

Closing of February 2022 Securities Offering

On February 23, 2022, we closed an offering of our securities, and issued and sold (i) 32,550,000 shares of common stock at a purchase price of $0.30 per share, (ii) Series A Warrants to purchase 37,000,000 shares of common stock at an exercise price of $0.37 per share for a term of five years, (iii) Series B Warrants to purchase 37,000,000 shares of common stock at an exercise price of $0.37 per share for a term of 18 months, and (iv) Pre-Funded Warrants to purchase 4,450,000 shares of common stock at a combined price of $0.30 per share. The net proceeds to us, after deducting the placement agent fees and estimated offering expenses payable by us, were approximately $10.0 million. In the event that the Company fails to deliver shares by the required delivery date upon exercise of the warrants, the Company may be subject to cash penalties in an amount up to $20 per trading day for each $1,000 of warrant shares until such shares are delivered. In addition, if the warrant holder purchases shares in the market following the Company's failure to deliver shares upon exercise of the warrants, the Company will be required to cover the cost of any buy-ins and, at the option of the warrant holder, either reinstate the portion of the warrant for the shares that were not delivered or deliver the number of shares that should have been issued.

Nasdaq Notification of Failure to Satisfy a Continued Listing Rule or Standard

On January 25, 2022, we received a notification from Nasdaq related to our failure to maintain a minimum bid price of $1 per share. Based upon the closing bid price for the last 30 consecutive business days, we no longer meet this requirement. However, the Nasdaq Listing Rules also provide us a compliance period of 180 calendar days in which to regain compliance. Accordingly, if at any time from the date of this notice until July 25, 2022, the closing bid price our common stock is at least $1 for a minimum of ten consecutive business days, Nasdaq will provide us with written confirmation of compliance and the matter will be closed. If we do not regain compliance with the minimum bid price requirement by July 25, 2022, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet all other initial listing standards, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period. If we do not regain compliance with the minimum bid price requirement by the end of the compliance period (or the second compliance period, if applicable), our common stock will become subject to delisting. If we are delisted from Nasdaq, our common stock may be eligible for trading on an over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell their shares. We intend to monitor the closing bid price of our common stock and may be required to seek approval from our stockholders to effect a reverse stock split of the issued and outstanding shares of our common stock. However, there can be no assurance that the reverse stock split would be approved by our stockholders. Further, there can be no assurance that the market price per new share of our common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of our common stock outstanding before the reverse stock split. Even if the reverse stock split is approved by our stockholders, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing rules.

Launch of Direct-to-Consumer Online Store for Viactiv Products

During January 2022, we launched our new e-commerce venue through a Shopify store for our Viactiv line of products. The new e-commerce venue offers Viactiv customers the option of shopping via retail outlets (e.g., grocery, pharmacy, etc.) or online through those same retail websites or directly through our new branded website.

Launch of Viactiv® Omega BOOSTTM Gel Bites

We recently launched Viactiv® Omega BOOSTTM Gel Bites, our first expansion of the Viactiv brand since we acquired it in June 2021. The 1,200 mg Omega-3 gel bites are designed to provide total body support, including cardiovascular, brain, joint and eye health. The new dosage form is able to provide the potency of large, hard-to-swallow soft gels, in a great tasting chewable format that has ten times more Omega-3 than the leading fish oil gummies. The gel bite dosage form has been shown to have better absorption and fewer digestive issues than regular soft gel formulas, as well as no unpleasant fishy aftertaste and no sugar, which can all be associated with certain other Omega-3 products.

VectorVision Restructuring

During December 2021, as part of management’s comprehensive evaluation of our business in order to focus on those brands and lines of business that management believes provide the greatest growth opportunities, we determined to restructure the operations of our VectorVision medical device business. The Company has substantially wound down the day-to-day operations of VectorVision, which is expected to significantly reduce costs, and to instead explore various alternative ways to preserve, manage and exploit our various related intellectual property rights, including our U.S. patents, associated with the VectorVision technology, which rights we believe are valuable and marketable. We are exploring both domestic and international business opportunities, such as licensing and distribution arrangements, with experienced parties, which could assist us in the economic exploitation of these intellectual property rights. As a result of this change to the VectorVision business strategy, management believes that it will be able to better focus its efforts and deploy capital to more growth oriented brands and product lines, like Viactiv, and other products in development, that it hopes to expeditiously bring to market in 2022.

Supply Chain Constraints; Inflationary Pressures

We have been experiencing supply chain constraints due to the COVID-19 pandemic. These constraints began in approximately December 2021 and have continued into 2022. These constraints have impacted our ability the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products and may continue to impact its ability to fulfill customer orders going forward which would have a material adverse effect on the Company's business and results of operations. The Company continues to experience challenges to meet customer demands, largely because of broad-based shortages in suppliers' labor which impact the availability of many critical components in the Company's supply chain and distribution. The Company is subject to out-of-stock fees to certain retailers in the event that the Company is unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, the Company and its suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs as well as transportation challenges. The Company expects shortages to continue at least through the first half of 2022 and input cost inflation to continue at least throughout 2022.

Strategic Objectives, Goals and Strategies

The Company's ability to maximize shareholder value requires that we build a solid corporate foundation and demonstrate growth and commercial success on top of that foundation. Guardion took a number of steps in 2021 to strengthen our corporate foundation, including acquiring Viactiv, winding down Vector Vision, hiring key team members and streamlining operations.

Guardion enters 2022 with three primary objectives:

- Demonstrate Commercial Success;
- Strengthen our Commercial Engine; and
- Strengthen our Clinical Nutrition Strategy.

Recent Accounting Pronouncements

In September 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). 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 the Company 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.

In August 2020, the FASB issued 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) ("ASU 2020-06"). ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion models. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. This update simplifies the related settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective January 1, 2024 for the Company and the provisions of this update can be adopted using either the modified retrospective method or a fully retrospective method. Early adoption is permitted, but no earlier than January 1, 2021.

At December 31, 2020, the Company recorded a derivative liability of $25,978 related to 10,417 warrants issued in 2019 because the settlement provisions of the warrants contained language that the shares underlying the warrants are required to be registered. Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. ASU 2020-06 removed the requirement to consider if the warrants would be settled in registered shares, and accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $25,978 and a decrease in derivative warrant liability of $25,978 on January 1, 2021.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of ASU 2021-04 is not expected to have any impact on the Company's consolidated financial statement presentation or disclosures.

Other recent accounting pronouncements issued by the FASB, its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

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. We have never experienced any losses related to these balances.

Revenue

During the year ended December 31, 2021, we had two customers that accounted for 50% and 16% of total revenue, respectively. During the year ended December 31, 2020, we had one customer that accounted for 49% of our total revenue. No other customer accounted for more than 10% of revenue during the years ended December 31, 2021 or 2020.

Accounts receivable

As of December 31, 2021, we had accounts receivable from one customer which comprised approximately 81% of accounts receivable. As of December 31, 2020, we had accounts receivable from two customers which comprised approximately 50% and 48%, respectively of accounts receivable. No other customer accounted for more than 10% of accounts receivable as of December 31, 2021 or 2020.

Purchases from vendors

During the year ended December 31, 2021, we utilized one manufacturer for most our production and packaging of clinical nutrition products. Total purchases from this manufacturer accounted for approximately 70% of all purchases. During the year ended December 31, 2020, our largest vendor accounted for approximately 38% all purchases. No other vendor accounted for more than 10% of purchases during the years ended December 31, 2021 or 2020.

Accounts payable

As of December 31, 2021, one vendor accounted for 46% of total accounts payable. As of December 31, 2020, our largest two vendors accounted for 18% and 13% of the total accounts payable, respectively. No other vendor accounted for more than 10% of accounts payable as of December 31, 2021 or 2020.

Critical Accounting Policies and Estimates

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

Revenue Recognition

We recognize 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 we expect to be entitled in exchange for those products or services. We review our 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 us 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 we have not experienced any significant payment delays from customers.

In certain circumstances, returns of products are allowed. A right of return does not represent a separate performance obligation, but because customers are allowed to return products, the consideration to which we expect to be entitled is variable. Upon evaluation of historical product returns, we determined that less than 1% of products are returned, and therefore believe 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 our products and assessment of performance obligations and transaction pricing for our sales contracts, we do not currently maintain a contract asset or liability balance at this time. We assess our contracts and the reasonableness of out 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. We record adjustments to our 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.

Intangible Assets

Amortizable finite-lived identifiable intangible assets consist of a trade name and customer relationships acquired in the acquisition of Activ, effective June 1, 2021 and are stated at cost less accumulated amortization. The trade name and customer relationships are being amortized over a period of 10 years. We follow ASC 360 in accounting for finite-lived 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.

In connection with the June 2021 acquisition of Activ we identified amortizable intangible assets totaling $11,900,000, consisting of trade names of $9,200,000 and customer lists of $2,700,000. The trade name and customer relationship are being amortized over their expected useful lives of 10 years.

At December 31, 2021 and December 31, 2020, we also had a trademark for $50,000 classified as an indefinite-lived intangible asset.

Goodwill

We evaluate goodwill for impairment annually on December 31, or more frequently if a triggering event occurs. Goodwill impairment exists when the fair value of goodwill is less than its carrying value. The Company is the sole reporting unit as of December 31, 2021. During the fourth quarter of 2021, we experienced a sustained decrease in the Company's share price on NASDAQ, and as of December 31, 2021, our market capitalization was below the carrying value of our net assets. We concluded that this was an impairment triggering event and concluded that there was goodwill impairment of $11,893,134 for the year ended December 31, 2021. Following the impairment, we had no remaining goodwill as of December 31, 2021.

However, we do not believe that the impairment charge reflects a diminution in the economic value of the Viactiv business as determined at the June 1, 2021 acquisition date, or its future performance potential. Although we have experienced certain inventory supply and supply chain challenges during the latter part of 2021 that have continued into 2022, Viactiv's financial performance for June through December 2021, has generally met management's expectations.

Business Combinations

We account for our business combinations using the acquisition method of accounting where the purchase consideration is allocated to the tangible and intangible assets acquired, and liabilities assumed, based on their respective fair values as of the acquisition date. The excess of the fair value of the purchase consideration over the estimated fair values of the net assets acquired is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets. Critical estimates in valuing intangible assets include, but are not limited to, expected future cash flows, which includes consideration of future growth and margins, future changes in technology, expected cost and time to develop in-process research and development, brand awareness and discount rates. Fair value estimates are based on the assumptions that management believes a market participant would use in pricing the asset or liability.

Stock-Based Compensation

We periodically issue 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.

Recent Trends – Market Conditions

We have been experiencing supply chain constraints due to the COVID-19 pandemic. These constraints began in approximately December 2021 and have continued into 2022. These constraints have impacted our ability to obtain inventory to fulfill customer orders for our Viactiv brand and may continue to impact our ability to fulfill customer orders going forward. We continue to experience challenges to meet customer demands, largely because of broad-based shortages in suppliers' labor which impact the availability of many critical components in our supply chain and distribution. We are subject to out-of-stock fees to certain retailers in the event that we are unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, we and our suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs as well as transportation challenges. We expect shortages to continue at least through the first half of 2022 and input cost inflation to continue at least throughout 2022.

Plan of Operations

General Overview

We are focused on building a leading clinical nutrition company with the objective that we become a top performing growth company. Our team continues to assess the business, the core fundamentals, and the market opportunity for our products and services. With the acquisition of Viactiv brand and business in June 2021, management believes that we will be able to accelerate our growth and development.

Our team is focused on building a strong foundation by developing a business model and infrastructure that is designed for long-term commercial success. This process will take time, but we are taking important steps required to build a stronger company. Based on the availability of sufficient funding, we intend to increase our commercialization and business development activities, including engaging in new product development and further strategic acquisitions, to capitalize on growth opportunities.

Over the long-term, we believe one of the critical keys to our success will be to create value in well-differentiated and robust brands through strong clinically proven claims that address consumer needs in growing markets, both domestically and internationally. We are committed to bringing compelling products to market under meaningful and differentiated brands supported by strong science.

We are currently working on a number of initiatives that we believe will help achieve these long-term goals. These include the initiatives described below.

Growth initiatives focused on increasing revenue and bringing compelling products to market under meaningful and differentiated brands that are supported by strong science.

- Strengthen our Clinical Nutrition Strategy: success with this objective requires that we continue to advance clinical evidence around our existing and future products, work with manufacturers and suppliers to leverage our partner's innovations and increase awareness of our products and efforts with the healthcare community.

- Brand Strategy – Brands are an important part of our strategy, and our team is evaluating the best ways to manage our brand portfolio. In particular, we are seeking to develop a strategy that best leverages Viactiv's strong consumer awareness and acceptance.

- Scientific Work – Our team continuously evaluates scientific journals and clinical evidence to improve the science behind our existing products and drive our product development process. In addition, we are working with health care professionals to increase clinical evidence on existing products.

- Product Strategy – Our team is evaluating our current product portfolio and seeking opportunities to improve or discontinue certain of our existing products and technologies and develop new ones. We are focused on differentiated formulations, product taste, compelling product formats, and competitive cost structures.

- Sales Channels – Our team is evaluating opportunities to increase product commercialization through better access to sales channels. The Viactiv products enjoy established distribution through traditional retailers and third-party E-Commerce retailers. Our other clinical nutrition products are sold directly to consumers via our website. By leveraging our collective experience selling in these channels, we seek to increase the distribution of our products.

- Existing Business Lines – Our team is evaluating our non-Viactiv business lines to determine their fit in the strategic direction of our Company. Product development and successful commercialization can be an expensive and time-consuming process. Management intends to focus on those products and technologies that possess the greatest chance for commercial success within a reasonable period of time and with a reasonable deployment of capital.

Results of Operations

Through December 31, 2021, we have primarily been engaged in product development, commercialization, integration of Activ and raising capital. We have incurred and will continue to incur significant expenditures for the development of our products and intellectual property, which includes nutrition, medical foods and supplements. These products support healthcare professionals, their patients and consumers in achieving health goals. With the acquisition of the Viactiv brand and business effective June 1, 2021, and its successful integration into our operations since that date, we have established a significant baseline level of gross revenues.

At December 31, 2021, we ceased operations of VectorVision. The Company plans to explore various alternative ways to preserve, manage and exploit the various related intellectual property rights, including our U.S. patents, associated with the VectorVision technology, which rights we believe are valuable and marketable.

We previously had two reportable segments, a Clinical Nutrition Segment and a Medical Devices Segment. In December 2021, we announced the winding down of VectorVision, which, while representing the bulk of the medical device business, only accounted for approximately 4% of total Company revenue in 2021. As a result, the Company no longer expects to generate any material revenues or expenses in the Medical Devices Segment, and accordingly, as of December 31, 2021, the Company is the sole reporting unit.

The results of operations for the year ended December 31, 2021 are not comparable to the results of operations for the year ended December 31, 2020, as our 2021 operations included the Viactiv business for the seven months ended December 31, 2021.

Comparison of Years Ended December 31, 2021 and 2020

	Years Ended December 31,		Change	
	2021	**2020**		
Revenue	$ 7,233,118	$ 1,889,844	$ 5,343,274	283%
Cost of goods sold (includes write down of inventory of approximately $184,000 during 2021 and $972,000 during 2020)	4,122,684	1,946,635	2,176,049	112%
Gross Profit (Loss)	3,110,434	(56,791)	3,167,225	(5,577%)
Operating Expenses:				
Research and development	64,358	160,978	(96,620)	(60%)
Sales and marketing	2,324,569	1,450,205	874,364	60%
General and administrative	11,204,885	7,450,245	3,754,640	50%
Goodwill impairment	11,893,134	-	11,893,134	
Acquisition transaction costs	2,103,680	-	2,103,680	
Costs related to resignation of former officer (including the reversal of previously recognized stock compensation expense of approximately $965,000 during the year ended December 31, 2020)	-	(615,936)	615,936	
Impairment loss on equipment	-	30,948	(30,948)	
Loss on disposal of equipment	160,137	18,500	141,637	766%
Loss on lease termination, net	106,477	-	106,477	
Total Operating Expenses	27,857,240	8,494,940	19,362,300	230%
Loss from Operations	(24,746,806)	(8,551,731)	(16,195,075)	191%
Other Expense (Income):				
Interest expense	-	7,271	7,271	
Interest income	1,797	-	1,797	
Change in fair value of derivative warrants	-	12,655	12,655	
Net Loss	$ (24,745,009)	$ (8,571,657)	$ (16,173,352)	189%

Revenue

For the year ended December 31, 2021, revenue from product sales was approximately $7,233,000 compared to revenue of approximately $1,890,000 for the year ended December 31, 2020, resulting in an increase of approximately $5,343,000 or 283%. The increase is primarily driven by the approximate $6,473,000 of revenue generated during the year by our Viactiv product line.

Cost of Goods Sold

For the year ended December 31, 2021, cost of goods sold was approximately $4,123,000 compared to cost of goods sold of approximately $1,947,000 for the year ended December 31, 2020, resulting in an increase of approximately $2,176,000 or 112%. This increase is primarily driven by the approximate $3,482,000 cost of sales related to our Viactiv product line.

Gross Profit (Loss)

For the year ended December 31, 2021, gross profit was approximately $3,110,000 compared to gross loss of approximately $(57,000) for the year ended December 31, 2020, resulting in an increase of approximately $3,167,000 or 5,577%. Gross profit (loss) represented 43% of revenues for the year ended December 31, 2021. Approximately $2,991,000 or 96% of the 2021 gross profit was generated from the sale of the Viactiv products. Gross profit (loss) represented (3)% of revenue for the year ended December 31, 2020. During 2020 we recorded an inventory write down of approximately $972,000 which was attributable to the deterioration of the forecasted marketability of certain of the Company’s inventory.

Research and Development

For the year ended December 31, 2021, research and development costs were approximately $64,000 compared to costs of approximately $161,000 for the year ended December 31, 2020, resulting in a decrease of approximately $97,000 or 60%. Research and development costs during the year ended December 31, 2021 consist primarily of clinical studies related to our medical foods and nutraceuticals, as compared to costs of engineering efforts related to our medical devices during the year ended December 31, 2020.

Sales and Marketing

For the year ended December 31, 2021, sales and marketing expenses were approximately $2,325,000 compared to expenses of approximately $1,450,000 for the year ended December 31, 2020. The increase in sales and marketing expenses of approximately $874,000 or 60% compared to the prior period was primarily due to the addition of our Viactiv line of products.

General and Administrative

For the year ended December 31, 2021, general and administrative expenses were approximately $11,205,000 compared to expenses of approximately $7,450,000 for the year ended December 31, 2020. The increase of approximately $3,755,000 or 50% compared to the prior period was primarily due to an increase in stock-based compensation of approximately $251,000, general and administrative costs associated with Activ of approximately $585,000, an increase in professional fees of approximately $177,000, and an increase in directors' and officers' insurance premiums of approximately $161,000.

Acquisition Transaction Costs

For the year ended December 31, 2021, acquisition transaction costs were approximately $2,104,000, all of which relate to our acquisition of Activ. We did not have any acquisition costs in 2020.

Goodwill Impairment

We evaluate goodwill for impairment annually on December 31, or more frequently if a triggering event occurs. Goodwill impairment exists when the fair value of goodwill is less than its carrying value. The Company is the sole reporting unit as of December 31, 2021. During the fourth quarter of 2021, we experienced a sustained decrease in the Company's share price on NASDAQ, and as of December 31, 2021, our market capitalization was below the carrying value of our net assets. We concluded that this was an impairment triggering event and concluded that there was goodwill impairment of $11,893,134 for the year ended December 31, 2021. Following the impairment charge, we had no remaining goodwill as of December 31, 2021.

However, we do not believe that the impairment charge reflects a diminution in the economic value of the Viactiv business as determined at the June 1, 2021 acquisition date, or its future performance potential. Although we have experienced certain inventory supply and supply chain challenges during the latter part of 2021 that that have continued into 2022, Viactiv's financial performance for June through December 2021, has generally met management's expectations.

Costs Related to Resignation of Former Officer

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer and as an employee of our Company and resigned from our board of directors. Terms of the settlement agreement included the continuation of his previous annual salary of $325,000 during the twelve months following his termination. The full amount of stock compensation costs was 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 approximately $(965,000) 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, we calculated the fair value of the vested options immediately before modification and immediately following the modification and recorded incremental stock compensation charge of approximately $24,000 in costs related to resignation of former officer.

Impairment Loss on Equipment

During June 2020, in an effort to reduce costs and focus management's attention on other aspects of our business, we began to wind down the TCD business. The wind down was completed in the third quarter of 2020. The business held a group of ultrasound machines as fixed assets. We sold the machines in the year ended December 31, 2020. An impairment charge of approximately $31,000 was recorded in the consolidated statements of operations for the year ended December 31, 2020. There was no similar charge recorded in 2021.

Loss on Disposal of Fixed Assets

For the year ended December 31, 2021, loss on disposal of fixed assets was approximately $160,000 as compared to a loss of approximately $19,000 for the year ended December 31, 2020, an increase of approximately $142,000 or 766% compared to the prior period. The current year losses are attributable to the termination of our headquarters lease in San Diego, California, and disposal of related fixed assets.

Loss on Lease Termination

For the year ended December 31, 2021, impairment loss on lease termination was approximately $106,000. During 2021, we terminated our corporate office and warehouse lease in San Diego, California and recorded a loss on lease termination. There was no comparable charge in the prior period.

Interest Expense

For the year ended December 31, 2020, interest expense was approximately $7,000. There was no interest expense during the year ended December 31, 2021. In 2020, the interest expense resulted from the financing of certain insurance policies of the Company.

Change in Fair Value of Derivative Warrants

During 2020, an increase in the fair value of derivative warrant liabilities of approximately $13,000 was recorded, and at December 31, 2020, the balance of derivative warrant liabilities was $0.

Net Loss

For the year ended December 31, 2021, we incurred a net loss of approximately $24,745,000 compared to a net loss of approximately $8,572,000 for the year ended December 31, 2020. The increase in net loss of approximately $16,173,000 or 189% compared to the prior year period was primarily due to goodwill impairment of approximately $11,893,000, transaction costs associated with the acquisition of Activ of approximately $2,104,000, coupled with general and administrative costs added as a result of the acquisition.

Liquidity and Capital Resources

For the year ended December 31, 2021, we incurred a net loss of approximately $24,745,000 and used cash in operating activities of approximately $10,644,000. At December 31, 2021, we had cash on hand of approximately $4,094,000, short term investments of approximately $4,996,000 and working capital of approximately $10,910,000.

On February 23, 2022, we closed an offering of our securities, and issued and sold (i) 32,550,000 shares of common stock at a purchase price of $0.30 per share, (ii) Series A Warrants to purchase 37,000,000 shares of common stock at an exercise price of $0.37 per share for a term of five years, (iii) Series B Warrants to purchase 37,000,000 shares of common stock at an exercise price of $0.37 per share for a term of 18 months, and (iv) Pre-Funded Warrants to purchase 4,450,000 shares of common stock at a combined price of $0.30 per share. The net proceeds to us, after deducting the placement agent fees and estimated offering expenses payable by us, were approximately $10.0 million. In the event that the Company fails to deliver shares by the required delivery date upon exercise of the warrants, the Company may be subject to cash penalties in an amount up to $20 per trading day for each $1,000 of warrant shares until such shares are delivered. In addition, if the warrant holder purchases shares in the market following the Company's failure to deliver shares upon exercise of the warrants, the Company will be required to cover the cost of any buy-ins and, at the option of the warrant holder, either reinstate the portion of the warrant for the shares that were not delivered or deliver the number of shares that should have been issued.

Notwithstanding the net loss for 2021, management believes that our current cash balance is sufficient to fund operations for in excess of one year from the date of the Company's 2021 financial statements are issued.

Our financing has historically come primarily from the issuance of convertible notes, promissory notes and from the sale of common and preferred stock. We will continue to incur significant expenses for continued commercialization activities related to our clinical nutrition product lines and building our infrastructure. Development and commercialization of clinical nutrition products involves a lengthy and complex process. Additionally, our long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines.

We 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 we will be able to secure such additional financing in the amounts necessary to fully fund our operating requirements on acceptable terms or at all. Over time, if we are unable to access sufficient capital resources on a timely basis, we may be forced to reduce or discontinue our product development programs and curtail or cease operations.

Sources and Uses of Cash

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

	Years Ended December 31,	
	2021	**2020**
Net cash used in operating activities	$ (10,644,416)	$ (8,013,929)
Net cash used in investing activities	(31,011,401)	(34,733)
Net cash provided by financing activities	37,231,012	5,451,892
Net increase (decrease) in cash	$ (4,424,805)	$ (2,596,770)

Operating Activities

Net cash used in operating activities was approximately $10,644,000 during the year ended December 31, 2021, as compared to approximately $8,014,000 used during the comparable prior year period. The change in operating activities stems primarily from our acquisition of the Viactiv business, the associated purchases of inventory and increases in directors and officers insurance, professional fees and consulting and labor costs during 2021.

Investing Activities

Net cash used in investing activities was approximately $31,011,000 for the year ended December 31, 2021 and approximately $35,000 for the year ended December 30, 2020. For the year ended December 31, 2021, we purchased approximately $71,000,000 in U.S. Treasury Bills which was offset by sales and maturities of those U.S. Treasury Bills of approximately $66,000,000.

As of December 31, 2021, we have approximately $5,000,000 in U.S. Treasury Bills representing the net of those purchases and sales, which is recorded as short-term investments on our Balance Sheet. In 2021, we also used cash of approximately $26,000,000 for the acquisition of Activ and $77,000 for purchases of property and equipment. The net cash used in investing activities during the year ended December 31, 2020 was approximately $35,000 and was primarily for the purchase of property and equipment.

Financing Activities

Net cash provided by financing activities was approximately $37,231,000 for the year ended December 31, 2021 and consisted of the sale of common stock with net proceeds of approximately $33,663,000 and warrant exercises during the period with proceeds of approximately $3,568,000. Net cash provided by financing activities was approximately $5,452,000 for the year ended December 31, 2020 and is all attributable to the exercise of warrants.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

PRINCIPAL COMMITMENTS

Appointment of 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' 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.

If Mr. Scholtes' 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' 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.

Office lease

In July, 2021 the Company entered into a month-to-month lease for its primary corporate office space located in Houston, Texas, with lease payments of approximately $1,700 per month.

Trends, Events and Uncertainties

Other than as discussed above, we are not currently aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on our financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item.

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 on From 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our Chief Executive Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management concluded that as of December 31, 2021, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and directors, as appropriate to allow timely decisions regarding required disclosure.

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

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

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

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

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

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework 2013. Based on this evaluation, our Chief Executive Officer and our Chief Accounting Officer concluded that our internal controls over financial reporting were effective as of December 31, 2021.

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.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) Exhibits

(b) Exhibits

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

ITEM 16. FORM 10-K SUMMARY

None.

Guardion Health Sciences, Inc.
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.
Houston, Texas

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Guardion Health Sciences, Inc. (the "Company") as of December 31, 2021 and 2020, 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 financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 31, 2022

Guardion Health Sciences, Inc.
Consolidated Balance Sheets

	December 31,	
	2021	**2020**
Assets		
Current assets		
Cash	$ 4,093,927	$ 8,518,732
Short-term investments	4,995,623	-
Accounts receivable, net	1,411,567	11,248
Inventories, net	367,691	384,972
Prepaid expenses and other assets	1,200,376	179,931
Total current assets	**12,069,184**	**9,094,883**
Property and equipment, net	111,378	285,676
Intangible assets, net	11,255,833	50,000
Operating lease right-of-use asset, net	24,257	418,590
Deposits	-	11,751
Total assets	**$ 23,460,652**	**$ 9,860,900**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 241,347	$ 608,313
Accrued expenses	895,477	127,637
Operating lease liability - current	22,221	162,845
Payable to former officer	-	148,958
Warrant liability	-	25,978
Total current liabilities	**1,159,045**	**1,073,731**
Operating lease liability – long-term	3,807	271,903
Total liabilities	**1,162,852**	**1,345,634**
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 24,426,993 and 15,170,628 shares issued and outstanding at December 31, 2021 and December 31, 2020	24,427	15,171
Additional paid-in capital	101,075,445	62,583,423
Accumulated deficit	(78,802,072)	(54,083,328)
Total stockholders' equity	**22,297,800**	**8,515,266**
Total liabilities and stockholders' equity	**$ 23,460,652**	**$ 9,860,900**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2021	**2020**
Revenue		
Clinical nutrition	$ 6,952,359	$ 1,609,482
Diagnostics equipment	280,758	275,862
Other		4,500
Total revenue	7,233,118	1,889,844
Cost of goods sold		
Clinical nutrition (includes inventory write-down of $51,489 and $760,488 during the years ended December 31, 2021 and 2020, respectively)	3,838,990	1,599,510
Diagnostics equipment (includes inventory write-downs of $127,733 and $211,231 during the years ended December 31, 2021 and 2020, respectively)	283,694	344,647
Other	-	2,478
Total cost of goods sold	4,122,684	1,946,635
Gross profit (loss)	3,110,434	(56,791)
Operating expenses		
Research and development	64,358	160,978
Sales and marketing	2,324,569	1,450,205
General and administrative	11,204,885	7,450,245
Transaction costs related to acquisition of Activ Nutritional, LLC	2,103,680	-
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)
Goodwill impairment	11,893,134	-
Loss on lease termination, net	106,477	-
Loss on disposal of property and equipment	160,137	18,500
Impairment of equipment held for sale	-	30,948
Total operating expenses	27,857,240	8,494,940
Loss from operations	(24,746,806)	(8,551,731)
Other income (expense):		
Interest income	1,797	-
Interest expense	-	(7,271)
Change in fair value of warrant liability	-	(12,655)
Total other income (expense)	1,797	(19,926)
Net loss	**(24,745,009)**	**(8,571,657)**
Net loss per common share – basic and diluted	$ (1.04)	$ (0.60)
Weighted average common shares outstanding – basic and diluted	23,688,623	14,256,856

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, 2019	12,497,094	$ 12,497	$ 57,531,014	$ (45,511,671)	$ 12,031,840
Fair value of vested stock options – former officer and director	-	-	(940,936)	-	(940,936)
Fair value of vested stock options	-	-	494,677	-	494,677
Common stock issued for services	16,667	17	49,433	-	49,450
Common stock issued upon exercise of warrants	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
Cumulative effect adjustment from the impact of adoption of Accounting Standards Update (ASU) 2020-06 related to warrants (See Notes 2 and 9)	-	-	-	26,265	26,265
Common stock issued for cash, net of offering costs	7,608,674	7,608	33,654,989	-	33,662,597
Common stock issued upon exercise of warrants	1,647,691	1,648	3,566,767	-	3,568,415
Fair value of vested stock options	-	-	600,887	-	600,887
Fair value of vested restricted stock	-	-	669,379	-	669,379
Net loss	-	-	-	(24,745,009)	(24,745,009)
Balance at December 31, 2021	24,426,993	$ 24,427	$ 101,075,445	$ (78,802,072)	$ 22,297,800

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2021	**2020**
Operating Activities		
Net loss	$ (24,745,009)	$ (8,571,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	782,920	65,476
Goodwill impairment	11,893,134	-
Loss on lease termination, net	106,477	-
Impairment loss on equipment	-	30,948
Loss on disposal of property and equipment	160,137	-
Loss on sale of equipment	-	18,500
Allowance for accounts receivable	20,695	
Inventory write-down	179,222	971,719
Amortization of operating lease right of use asset	124,628	154,124
Fair value of vested stock options	600,887	544,127
Fair value of common stock issued for services	669,379	-
Reversal of previously recognized stock compensation expense–former officer	-	(940,936)
Change in fair value of derivative liability	-	12,655
Changes in operating assets and liabilities:		
(Increase) / decrease:		
Accounts receivable	378,681	67,089
Inventories	451,122	(728,801)
Prepaid expenses and other	(971,420)	(125,171)
Increase / (decrease):		
Accounts payable	(680,697)	479,181
Accrued expenses	768,127	11,426
Operating lease liability	(233,741)	(151,567)
Payable to former officer	(148,958)	148,958
Net cash used in operating activities	(10,644,416)	(8,013,929)
Investing Activities		
Purchase of property and equipment	(74,592)	(40,733)
Purchase of U.S. Treasury Bills	(70,952,562)	-
Sale of U.S. Treasury Bills	65,956,939	-
Cash paid for acquisition, net of cash acquired	(25,941,186)	6,000
Net cash used in investing activities	(31,011,401)	(34,733)
Financing Activities		
Proceeds from sale of common stock, net	33,662,597	-
Proceeds from exercise of warrants	3,568,415	5,451,892
Net cash provided by financing activities	37,231,012	5,451,892
Cash:		
Net increase (decrease)	(4,424,805)	(2,596,770)
Balance at beginning of period	8,518,732	11,115,502
Balance at end of period	$ 4,093,927	$ 8,518,732
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$	$ 7,271
Income taxes	$	$ -
Non-cash financing activities:		
Adjust warrant liability for adoption of ASU 202-06	$ 26,265	-
Reclassification of prepaid costs to inventory	$	$ 308,178
Reclassification of property and equipment to inventory	$	$ 8,771

See accompanying notes to consolidated financial statements.

1. Organization and Business and Business Operations

Business

Guardion Health Sciences, Inc. (the "Company") is a clinical nutrition and diagnostics company that offers a portfolio of science-based, clinically supported products and devices designed to support healthcare professionals and providers, and their patients and consumers. In June 2021, the Company acquired Activ Nutritional, LLC ("Activ"), the owner and distributor of the Viactiv® line of supplements for bone health and other applications (see Note 3). The Company was formed in 2009 as a California limited liability company under the name P4L Health Sciences, LLC, and in 2015 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, 2021, the Company incurred a net loss of $24,745,009 and used cash in operating activities of $10,644,416. As of December 31, 2021, the Company had cash and short-term investments on hand of approximately $9,089,550 and working capital of $10,910,139. Subsequent to December 31, 2022, the Company completed an offering of shares of its common stock and warrants in February 2022 (See Note 15) and the net proceeds to the Company, after deducting offering costs, were approximately $10 million. In the event that the Company fails to deliver shares by the required delivery date upon exercise of the warrants, the Company may be subject to cash penalties in an amount up to $20 per trading day for each $1,000 of warrant shares until such shares are delivered. In addition, if the warrant holder purchases shares in the market following the Company's failure to deliver shares upon exercise of the warrants, the Company will be required to cover the cost of any buy-ins and, at the option of the warrant holder, either reinstate the portion of the warrant for the shares that were not delivered or deliver the number of shares that should have been issued.

Notwithstanding the net loss for 2021, management believes that its cash and short-term investments as of December 31, 2021, plus the net proceeds of the February 2022 financing are sufficient to fund operations for at least one year from the date the Company's 2021 financial statements are issued.

The amount and timing of future cash requirements will depend, in part, on the Company's ability to ultimately achieve operating profitability. 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 the development, commercialization and distribution of its clinical nutrition products (including the Viactiv® product line), the development and commercialization of its diagnostics equipment, and the successful development and commercialization of any new products or product lines. The Company may also utilize cash to fund additional 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. The Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, including curtailing employee travel and primarily working remotely. During 2020 and through the end of 2021, sales of certain products remained flat as compared to prior comparable periods, as many professional offices were closed for long periods, or were operating with limited capacity, due to COVID-19 related orders and protocols. Management is actively focusing on supply chain matters in light of industry-wide supply chain constraints. Through December 31, 2021, the Company has not experienced negative impacts to its supply chain, however, the Company cannot make any assurances in future periods.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

The Company previously had two reportable segments, a Clinical Nutrition Segment and a Medical Devices Segment. During the fourth quarter of 2021, the Company announced it would be winding down the Medical Devices Segment, which accounted for approximately 4% of revenue in 2021. As a result, the Company no longer has any material revenues or expenses in the Medical Devices Segment, and accordingly, as of December 31, 2021, the Company is the sole reporting unit. At December 31, 2021, as there is only one reporting unit, all of the Company's prior period segment information has been eliminated.

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 of its common stock without any change to its par value. Accordingly, all common shares, stock options, stock warrants and per share amounts in these consolidated financial statements have been adjusted retroactively to reflect the reverse stock split as if the split occurred at the beginning of the earliest period presented in this Annual Report.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Activ Nutrititionals, Inc., 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 recognizes revenue in accordance with Financial Accounting Standard Board's ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*. To determine revenue recognition under ASC 606, an entity performs the following five-steps (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-steps to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

Revenue and costs of sales are recognized when control of the products transfers to our customer, which generally occurs upon delivery to the customer. The Company's performance obligations are satisfied at that time. The Company does not have any significant contracts with customers requiring performance beyond delivery, and 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.

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. Historically the Company has not experienced any significant payment delays from customers.

In certain circumstances, returns of products are allowed. 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 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.

Revenue by product:

	Years Ended December 31,	
	2021	**2020**
Clinical Nutrition	$ 6,952,359	$ 1,609,482
Diagnostics Equipment	280,758	275,862
Other	-	4,500
	$ 7,233,118	$ 1,889,844

The Company's revenues earned during the year ended December 31, 2021, are derived primarily from retail customers in North America. During the year ended December 31, 2020, our revenue was derived from retail customers in North America, plus a large sale to a single Malaysian distributor in the amount of approximately $890,000.

Revenues by geographical areas:

	Years Ended December 31,	
	2021	**2020**
North America	$ 7,052,645	$ 891,768
Malaysia	-	889,508
Other Asia	158,738	58,688
Europe and Other	21,735	49,880
	$ 7,233,118	$ 1,889,844

Cost of Goods Sold

Cost of goods sold is comprised of the costs for third-party contract manufacturing, packaging, manufacturing fees, and in-bound freight charges.

Third-party outsourcing

On June 1, 2021, the Company completed the acquisition of Activ Nutritional LLC (see Note 3). Activ owns the Viactiv® line of supplement chews for bone health, immune health and other applications. As part of the acquisition, the Company assumed third-party agreements for the manufacture and product fulfillment of the Viactiv® products.

Subsequent to the acquisition of Activ, the Company derives substantially all of its revenue from the sale of products using a third-party fulfillment center to provide order processing and sales fulfillment, customer invoicing and collections, and product warehousing. Fees for these services are provided under a services and warehousing agreement based on 2% of the Company's monthly gross invoiced sales, as defined. The services and warehousing agreement automatically renews every six months unless either party provides notice of its intent not to renew at least six months in advance. Substantially all of our products are shipped through the third-party fulfillment center to the customer and the customer takes title to product and assumes risk and ownership of the product when it is delivered. Shipping charges to customers are included in revenues.

In addition, the Company uses the third-party fulfillment center to provide sales and inventory management, and marketing and promotional services. Fees for these services are provided under a sales representation agreement based on 4% of the Company's monthly net invoiced sales, as defined. The sales representation services and warehousing agreement automatically renews every three months unless either party provides notice of its intent not to renew at least three months in advance.

Subsequent to the acquisition of Activ, the Company has outsourced the production of substantially all of its products with a third party that manufactures and packages the finished products under a product supply agreement. The Company's purchase price for each product includes costs for raw materials, production, and amounts for fees and profit, as defined, for the manufacturer.

For the year ended December 31, 2021, costs incurred related to third-party outsourcing were:

Services and warehousing agreement	$ 171,817
Sales representation agreement	301,031
Product supply agreement	2,925,781
	$ 3,398,629

At December 31, 2021, the Company recorded a receivable of $420,497 from its third-party fulfillment center for amounts collected on behalf of the Company. The balance is included in prepaid expenses and other assets and was received in January 2022.

Shipping Costs

Shipping costs associated with product distribution after manufacture are included as part of cost of goods sold. Shipping and handling expense totaled $338,829 and $24,029 for the years ended December 31, 2021 and 2020, respectively.

Business Combinations

The Company accounts for its business combinations using the acquisition method of accounting where the purchase consideration is allocated to the tangible and intangible assets acquired, and liabilities assumed, based on their respective fair values as of the acquisition date. The excess of the fair value of the purchase consideration over the estimated fair values of the net assets acquired is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets. Critical estimates in valuing intangible assets include, but are not limited to, expected future cash flows, which includes consideration of future growth and margins, future changes in technology, brand awareness and discount rates. Fair value estimates are based on the assumptions that management believes a market participant would use in pricing the asset or liability.

Cash

Cash consists of cash and demand deposits with banks. The Company holds no cash equivalents as of December 31, 2021 and 2020, respectively.

Investments

Short-term investments held by the Company as of December 31, 2021, consist of a U.S. Treasury Bill, which is classified as held-to-maturity. The Company's U.S. Treasury Bill is scheduled to mature approximately 30 days from the date of purchase. Unrealized gains and losses were not material. As of December 31, 2021, the carrying value of the Company's U.S. Treasury Bill approximates its fair value due to its short-term maturity.

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, 2021, the allowance for doubtful accounts was $20,695. At December 31, 2020, there was no allowance for doubtful accounts.

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 years ended December 31, 2021 and 2020, the Company wrote-down inventories of $179,222 and $971,719, respectively, which was recorded in cost of sales (see Note 4).

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, 2021 and 2020, management determined there were no impairments of the Company's property and equipment.

Intangible Assets

Amortizable finite-lived identifiable intangible assets consist of a trade name and customer relationships acquired in the acquisition of Activ, effective June 1, 2021 (See Note 3), and are stated at cost less accumulated amortization. The trade name and customer relationships are being amortized over a period of 10 years. The Company follows ASC 360 in accounting for finite-lived 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.

At December 31, 2021 and December 31, 2020, the Company had a trademark for $50,000 classified as an indefinite-lived intangible asset.

Goodwill

The Company tests goodwill for impairment annually on December 31, or more frequently if a triggering event occurs and it updates its test with information that becomes available through the end of the period reported. Goodwill impairment exists when the fair value of goodwill is less than its carrying value. The Company is its sole reporting unit. During the fourth quarter of 2021, the Company experienced a sustained decrease in its share price, and as of December 31, 2021, the Company's market capitalization was below the carrying value of the Company's net assets. Management concluded that this was an impairment triggering event, and concluded that there was goodwill impairment of $11,893,134 at December 31, 2021(See Note 6). No impairment of goodwill was recorded for the year ended December 31, 2020. Following the impairment, the Company had no remaining goodwill as of December 31, 2021.

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.

Concentrations

Revenue. During the year ended December 31, 2021, the Company had one customer that accounted for 49% of total revenue. During the year ended December 31, 2020, the Company had one customer that accounted for 49% of the Company's total revenue. No other customer accounted for more than 10% of revenue, during the years ended December 31, 2021 or 2020.

Accounts receivable. As of December 31, 2021, the Company had accounts receivable from one customer which comprised approximately 81% of its gross accounts receivable. As of December 31, 2020, the Company had accounts receivable from two customers which comprised approximately 50% and 48%, respectively of accounts receivable. No other customer accounted for more than 10% of accounts receivable as of December 31, 2021 or 2020.

Purchases from vendors. During the year ended December 31, 2021, the Company utilized one manufacturer for most its production and packaging of its clinical nutrition products. Total purchases from this manufacturer accounted for approximately 70% of all purchases. During the year ended December 31, 2020, the Company's largest vendor accounted for approximately 38% of all purchases. No other vendor accounted for more than 10% of purchases during the years ended December 31, 2021 or 2020.

Accounts payable. As of December 31, 2021, one vendor accounted for 46% of total accounts payable. As of December 31, 2020, the Company's largest two vendors accounted for 18% and 13% of the total accounts payable, respectively. No other vendor accounted for more than 10% of accounts payable as of December 31, 2021 or 2020.

Cash balances. 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 that hold such cash balances.

Advertising Costs

Advertising costs are expensed as incurred and are included in sales and marketing expense. Advertising costs aggregated approximately $161,833 and $44,429 for the years ended December 31, 2021 and 2020, respectively.

Research and Development Costs

Research and development costs consist primarily of fees paid to consultants and outside service providers, and other expenses relating to the acquisition, design, development and testing of the Company's Clinical Nutrition products. Research and development costs totaled $64,358 and $160,978 for the years ended December 31, 2021 and 2020, respectively.

Patent Costs

The Company is the owner of four issued domestic patents, one granted patent in Canada, and one pending patent application in 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, 2021, and 2020, patent costs were approximately $67,681 and $124,806, respectively, and are included in general and administrative costs in the statements of operations.

Stock-Based Compensation

The Company periodically issues stock options and restricted stock awards to employees and non-employees in non-capital raising transactions for services and for financing costs. 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. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

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.

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,	
	2021	**2020**
Warrants	485,067	2,132,758
Options	541,910	778,194
Unvested restricted common stock	202,671	30,000
	1,229,648	2,940,952

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 following table sets forth by level, within the fair value hierarchy, the Company's assets and liabilities at fair value as of December 31, 2021 and 2020:

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
U.S. Treasury securities	$ 4,995,623	$ -	$ -	$ 4,995,623
Total assets	$ 4,995,623	$ -	$ -	$ 4,995,623
Liabilities	$ -	$ -	$ -	$ -
Total liabilities	$ -	$ -	$ -	$ -

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets	$ -	$ -	$ -	$ -
Total assets	$ -	$ -	$ -	$ -
Liabilities				
Warrant liability	$ -	$ 25,978	$ -	$ 25,978
Total liabilities	$ -	$ 25,978	$ -	$ 25,978

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.

Recent Accounting Pronouncements

In September 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). 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 the Company 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.

In August 2020, the FASB issued 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) ("ASU 2020-06"). ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion models. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. This update simplifies the related settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective January 1, 2024 for the Company and the provisions of this update can be adopted using either the modified retrospective method or a fully retrospective method. Early adoption is permitted, but no earlier than January 1, 2021.

At December 31, 2020, the Company recorded a derivative liability of $25,978 related to 10,417 warrants issued in 2019 because the settlement provisions of the warrants contained language that the shares underlying the warrants are required to be registered. Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. ASU 2020-06 removed the requirement to consider if the warrants would be settled in registered shares, and accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $25,978 and a decrease in derivative warrant liability of $25,978 on January 1, 2021.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of ASU 2021-04 is not expected to have any impact on the Company's consolidated financial statement presentation or disclosures.

Other recent accounting pronouncements issued by the FASB, its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

3. Acquisition of Activ Nutritional, LLC

On June 1, 2021, the Company completed the acquisition of Activ Nutritional LLC ("Activ"). The acquisition was made pursuant to an equity purchase agreement dated May 18, 2021 between the Company, Adare Pharmaceuticals, Inc., ("Adare"), and Activ. The Company acquired all of the issued and outstanding equity of Activ from Adare for $26,000,000 in cash, subject to certain adjustments as provided in the equity purchase agreement.

Activ owns the Viactiv® line of supplement chews for bone health, immune health and other applications which are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target and Amazon. The Viactiv product lines are expected to become the Company's most prominent product lines for the foreseeable future.

The Company utilized the acquisition method of accounting for the acquisition in accordance with ASC 805, *Business Combinations*. The Company allocated the purchase price to Activ's tangible assets, identifiable intangible assets, and assumed liabilities at their estimated fair values as of the date of acquisition. The fair value of the intangible assets was estimated using the income approach, pursuant to which after-tax cash flows are discounted to present value based on projections and other available financial data. The cash flows were based on estimates used to value the acquisition, and the discount rates applied were benchmarked with reference to the implied rate of return from the transaction model, as well as the weighted average cost of capital. The valuation assumptions took into consideration the Company's estimates of customer attrition and revenue growth projections. The excess of the purchase price paid by the Company over the estimated fair value of identified tangible and intangible assets has been recorded as goodwill.

The following table summarizes the allocation of the fair value of the purchase consideration to the fair value of tangible assets, identifiable intangible assets, and assumed liabilities of Activ on the date of acquisition:

Fair value of consideration:	
Purchase price, as adjusted, paid in cash	$ 25,949,654
Allocation of the consideration to the fair value of assets acquired and liabilities assumed:	
Cash	$ 8,468
Accounts receivable	1,799,695
Inventories	613,063
Prepaids	49,025
Accounts payable	(313,731)
Net tangible assets	2,156,520
Trade names and trademarks	9,200,000
Customer relationships	2,700,000
Net identifiable intangible assets	11,900,000
Goodwill	11,893,134
Fair value of net assets acquired	$ 25,949,654

The goodwill is attributable to expected synergies resulting from integrating the Viactiv product lines into the Company's sales channels. The Company consolidated Activ's operations with the Company's operations commencing June 1, 2021, the closing date of the transaction. Activ's operations are included in the Company's Clinical Nutrition segment. The amount of revenue and net loss of Activ included in the Company's consolidated statements of operations during the year ended December 31, 2021, was $6,473,000 and $868,000, respectively.

Acquisition-related transaction costs (e.g., legal, due diligence, valuation, investment banking and other professional fees) are not included as a component of consideration transferred, but were expensed as incurred. During the year ended December 31, 2021, the Company incurred approximately $2,104,000 of acquisition-related costs, respectively, which are included as a line item in the Company's consolidated statements of operations.

Pro Forma Information

The following unaudited pro forma consolidated statement of operations for the year ended December 31, 2021 and 2020 is presented as if the acquisition of Activ had occurred on January 1, 2020, after giving effect to certain pro forma adjustments. The pro forma results of operations are presented for informational purposes only and are not indicative of the results of operations that would have been achieved if the acquisition had actually been consummated on January 1, 2020. These results are prepared in accordance with ASC 606.

	Unaudited Pro Forma December 31,	
	2021	**2020**
Revenue	$ 12,765,911	$ 13,820,092
Net loss	$ (22,171,583)	$ (10,757,277)
Net loss per share – basic and diluted	$ ($0.94)	$ ($0.75)

4. Inventories

Inventories consisted of the following:

	December 31,	
	2020	**2020**
Raw materials	$ 53,320	$ 218,307
Finished goods	314,371	166,665
Inventory	$ 367,691	$ 384,972

The Company's inventories are stated at the lower of cost or net realizable value on a FIFO basis.

For the years ended December 31, 2021 and 2020, the Company recorded inventory write-downs of $179,222 and $971,719, respectively, which are included in cost of sales.

5. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2021	2020
Leasehold improvements	$ 4,898	$ 103,255
Testing equipment	-	348,124
Furniture and fixtures	129,696	197,349
Computer equipment and software	111,469	68,460
Office equipment	1,642	9,835
	247,705	727,023
Less accumulated depreciation and amortization	(136,327)	(441,347)
	$ 111,378	$ 285,676

Depreciation expense consisted of the following for the years ended December 31, 2021 and 2020, respectively:

	Years Ended December 31,	
	2021	2020
Research and development expense	$ 38,106	$ 35,846
Sales and marketing expense	16,362	13,252
General and administrative expense	37,107	16,378
	$ 91,575	$ 65,476

6. Goodwill and Intangible Assets, Net

Intangible asset, net consisted of the following:

	December 31,	
	2021	2020
Trade name	$ 9,200,000	$ -
Customer relationships	2,700,000	-
Trademark	50,000	50,000
	11,950,000	50,000
Less accumulated amortization	(694,167)	-
	$ 11,255,833	$ 50,000

For the year ended December 31, 2021, amortization expense was $694,167. The expected future amortization expense for amortizable finite-lived intangible assets as of December 31, 2021 is as follows:

	Total
2022	$ 1,190,000
2023	1,190,000
2024	1,190,000
2025	1,190,000
2026	1,190,000
Thereafter	5,255,833
Total future expected amortization expense	$ 11,205,833

Goodwill:

The changes in the carrying amount of goodwill are as follows:

	As of December 31,	
	2021	2020
Beginning balance:	$ -	$ -
Acquisition (see Note 3)	11,893,134	-
Impairment	(11,893,134)	-
Ending balance:	$ -	$ -

In connection with its acquisition of Activ (see Note 3) the Company identified amortizable intangible assets consisting of trade names of $9,200,000 and customer lists of $2,700,000. The trade name and customer relationship are being amortized over their expected useful lives of 10 years.

As a result of the significant decrease in the Company's market capitalization during the fourth quarter of 2021, the Company evaluated the impact to assess whether there was an impairment triggering event requiring it to perform a goodwill impairment test. In connection with the impairment triggering event, the Company first evaluated the recoverability of its long-lived asset group containing trade name and customer relationships to determine whether any assets were impaired. The Company compared the undiscounted cash flows of its long-lived asset group containing trade name and customer relationships to the carrying value of the asset group. If the undiscounted cash flows were less than the assets carrying value, the asset would be impaired. As of December 31, 2021, the Company determined undiscounted cash flows related to the trade names and customer lists were more than the carrying value of the assets, and therefore these intangible assets were not impaired.

In connection with the impairment triggering event noted above, the Company next performed a goodwill impairment test as of December 31, 2021. As part of this impairment test, the Company used the income approach and utilized a substantial portion of the undiscounted cash flows forecast used to evaluate the long-lived asset group containing trade name and customer relationships above. However, the cash flow forecast was discounted to estimate fair value of the Company as sole reporting unit for the step one goodwill impairment test. The discount rate selected was 16% based on management's consideration of the related risk associated with the forecast. Based on the result, the discounted cash flows were less than the net carrying value of the Company's assets, and goodwill was determined to be impaired. Accordingly, the full amount of the Company's goodwill of $11,893,134 was written off as impaired during the fourth quarter of 2021.

These estimates and judgments used above may not be within the control of the Company and accordingly it is reasonably possible that the judgments and estimates could change in future periods.

7. Operating Leases

As of December 31, 2021, the Company leased a warehouse space in Ohio under an operating lease. The Company accounts for its lease under ASC 842, *Leases.* The Company determines whether a contract is, or contains, a lease at inception, and all leases greater than 12 months result in recognition of a right-of-use asset and an operating lease liability. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Leases with the duration of less than 12 months are not recognized on the balance sheet and are expensed on a straight-line basis over the lease term.

Lease cancellation

In October 2012, the Company entered into a lease for its corporate office and warehouse located in San Diego, California. The term of the lease, as amended, had a term through July 2023. On September 22, 2021, the Company entered into an agreement with the landlord to terminate the lease for this corporate office and warehouse space effective October 31, 2021. At September 22, 2021, the Company had recorded a right of use asset of $269,706, a lease deposit of $10,470, and an operating lease liability of $282,597, respectively, related to this lease. Pursuant to the termination agreement, the Company agreed to forfeit its security deposit, and pay the landlord an early termination fee of $108,527 before October 31, 2021 and vacate the premises before October 31, 2021, in exchange for a complete release. The Company vacated the leased space on October 29, 2021. At September 30, 2021, the Company accounted for the cancellation of the lease by writing off the right-of-use asset and the forfeited lease deposit from the consolidated balance sheet which resulted in an impairment expense of $280,176. Upon payment of the early termination fee of $108,527 in October 2021, the operating lease liability of approximately $270,000 was cancelled in full, which resulted in a gain on lease cancellation of $173,699. The net loss on the lease termination of $106,477 is presented on a separate line item on the accompanying consolidated statement of operations for the year ended December 31, 2021.

In July, 2021 the Company entered into a month-to-month lease for its primary corporate office space located in Houston, Texas, with lease payments of approximately $1,700 per month.

During the years ended December 31, 2021 and 2020, lease expense totaled approximately $148,826 and $45,000, respectively.

As of December 31, 2021, the Company's net right of use asset totaled $24,257. During the years ended December 31, 2021 and December 31, 2020, the Company recorded amortization of right-of-use asset of $124,627 and $79,328, respectively.

As of December 31, 2021, the Company's operating lease liabilities totaled $26,029. During the year ended December 31, 2021, the Company made payments of $148,826 towards the operating lease liability.

As of December 31, 2021, the weighted average remaining lease terms for operating leases are 1.17 years, and the weighted average discount rate for operating lease is 3.9%.

Future minimum lease payments under the leases are as follows:

Year ending	**Operating Leases**
2022	$ 22,843
2023	3,826
Total lease payments	26,669
Less: Imputed interest/present value discount	(641)
Present value of lease liabilities	26,028
Less Current portion	(22,221)
	$ 3,807

8. 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. The final payment due the former officer was made on June 15, 2021.

9. Warrant Liability

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. At December 31, 2020, the fair value of the derivative warrant liability was $25,978.

Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. ASU 2020-06 removed the requirement to consider if the warrants would be settled in registered shares, and accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $25,978 and a decrease in derivative warrant liability of $25,978 on January 1, 2021.

At December 31, 2020, the fair value of such warrant was determined to be $259,878 using the Black-Scholes option pricing model utilizing the following assumptions:

	Warrant Liability As of December 31, 2020
Stock price	2.49
Risk free interest rate	0.17%
Expected volatility	148%
Expected life in years	3.8
Expected dividend yield	0%
Number of warrants	10,417
Fair value of derivative warrant liability	25,978

For the year ended December 31, 2020, an increase in fair value of the warrants was determined to be approximately $12,655. There was no change in fair value of warrants during the year ended December 31, 2021.

10. Stockholders' Equity

Common Stock

The Company's common stock has a par value of $.001. As of December 31, 2021 and 2020, there were 250,000,000 shares authorized, and 24,426,993 and 15,170,628 shares of common stock outstanding.

January 2021 and February 2021 at the Market Offerings

On January 8, 2021, the Company entered into a sales agreement with Maxim Group LLC ("Maxim") pursuant to which the Company could sell up to $10,000,000 worth of shares of the Company's common stock in an "at the market" offering through Maxim (the "January 2021 1st ATM Offering"). The offer and sale of the shares was made pursuant to a shelf registration statement on Form S-3. The Company agreed to pay Maxim a commission equal to 3.0% of the aggregate gross proceeds from each sale of shares. On January 15, 2021, the Company completed the January 2021 1st ATM Offering, pursuant to which the Company sold an aggregate of 2,559,834 shares of its common stock and raised net proceeds (after deduction for sales commissions) of approximately $9,700,000.

On January 28, 2021, the Company entered into a sales agreement with Maxim pursuant to which the Company could sell up to $25,000,000 worth of shares of the Company's common stock in an "at the market" offering through Maxim (the "January 2021 2nd ATM Offering"). On February 10, 2021, the Company completed the January 2021 2nd ATM Offering, pursuant to which the Company sold an aggregate of 5,048,840 shares of its common stock and raised net proceeds (after deduction for sales commissions) of approximately $24,250,000.

The Company incurred costs related to these financings of approximately $327,000 which is reflected as a reduction to the proceeds from the shares issued. The net cash received from both offerings after all expenses was approximately $33,623,000.

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, 2019	**4,800,456**	**$ 2.28**	**4.91**
Granted	-	-	-
Forfeitures	-	-	-
Expirations	(10,830)	(9.00)	-
Exercised	(2,656,868)	(2.04)	-
December 31, 2020	**2,132,758**	**$ 2.40**	**3.81**
Granted			
Forfeitures			
Expirations			
Exercised	(1,647,691)	2.26	-
December 31, 2021, all exercisable	**485,067**	**2.71**	**2.71**

The exercise prices of warrants outstanding and exercisable as of December 31, 2021 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
160,108	$ 2.05
146,667	2.67
112,001	3.30
37,700	3.51
18,174	17.25
10,417	30.00
485,067	

During the year ended December 31, 2021, investors exercised warrants exercisable into 1,647,691 shares of common stock for total proceeds of approximately $3,568,415. The warrants were exercisable at $2.26 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 approximately $5,452,000. The warrants were exercisable at $2.05 per share.

As of December 31, 2021, the Company had an aggregate of 485,067 outstanding warrants to purchase shares of its common stock. The aggregate intrinsic value of warrants outstanding as of December 31, 2021 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, 2019	**493,750**	**13.56**	**3.64**
Granted	423,333	5.58	9.51
Forfeitures	(138,889)	-	-
Expirations	-	-	-
Exercised	-	-	-
December 31, 2020	**778,194**	**$ 9.48**	**6.38**
Granted	311,006	2.70	9.3
Forfeitures	(236,112)	-	-
Expirations	-	26.40	-
Exercised	-	-	-
December 31, 2021, outstanding	**853,088**	**$ 6.34**	**6.5**
December 31, 2021, exercisable	**549,910**	**$ 8.01**	**5.2**

The exercise prices of options outstanding and exercisable as of December 31, 2021 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
41,667	20,833	$ 0.91
41,667	41,667	1.48
50,000	-	1.61
66,668	8,344	1.76
5,000	5,000	1.91
41,667	41,667	2.33
1,667	1,667	2.46
16,667	12,501	3.25
152,671	-	3.95
208,333	191,962	6.00
104,167	104,167	12.00
1,041	1,041	13.80
112,500	112,500	15.00
853,088	**549,910**	

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, 2021, the Company granted options to purchase 311,006 shares of common stock to six employees and members of the Board of Directors with a grant date fair value determined to be $711,000 using a Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 111% to 119%, (ii) discount rate of 0.38% to 1.28% (iii) zero expected dividend yield, and (iv) expected life of 5.13-6.01 years. The options have an exercise price of $0.91 to $3.95 per share. Options for 202,671 vest ratably over three years, options for 87,501 shares vest on a quarterly basis over two years, and options for 20,834 shares vested immediately.

During the year ended December 31, 2020, the Company granted options to purchase 423,333 shares of common stock to the members of the Company's Board of Directors with a grant date fair value determined to be $1,033,510 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 ranging from $0.91 per share to $6.00 per share. The options vest on a quarterly basis over two years beginning three months after the grant date.

The Company computes stock price volatility over expected terms based on its historical common stock trading prices 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, 2021 and 2020, the Company recognized aggregate stock-compensation expense of approximately $601,000 and $495,000, respectively, related to the fair value of vested options.

As of December 31, 2021, the Company had an aggregate of 314,150 remaining unvested options outstanding, with a remaining fair value of approximately $284,388 to be amortized over an average of 5.2 years, weighted average exercise price of $8.01, and weighted average remaining life of 5.2 years. Based on the closing price of the Company's common stock on December 31, 2021 of $0.65, the aggregate intrinsic value of options outstanding as of December 31, 2021 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 8), 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.

Restricted Common Stock

Under the Company's 2018 Equity Incentive Plan, a total of 1,666,667 shares of the Company's common stock are available for grant to employees, directors and consultants of the Company. During the year ended December 31, 2021, the Company issued 244,338 shares of the Company's common stock under the plan, and at December 31, 2021, there was a balance of 1,422,329 shares available for grant.

In January 2021, the Company granted 152,671 shares of the Company's common stock to the Company's Chief Executive Officer ("CEO"). The shares vest on the first anniversary of the award. If the CEO's employment with the Company is terminated for any reason, any shares not then vested will be forfeited. Also effective in January 2021, the Company granted 41,667 shares of the Company's common stock to a consultant for services, with 4,167 of the shares vesting immediately and the balance of 37,500 shares vesting through August 15, 2021. In the event the consultant's service with the Company terminates, any shares not then vested will be forfeited. During the year ended December 31, 2021, the Company granted 50,000 shares of the Company's common stock with vesting terms to the Company's Chief Commercial Officer. The shares vest one third per year for three years on the anniversary of the award.

The total fair value of the 244,338 shares was determined to be approximately $743,000 based on the price per shares of the Company's common stock on the dates granted. The Company accounts for the share awards using the straight-line attribution or graded vesting method over the requisite service period provided that the amount of compensation cost recognized at any date is no less than the portion of the grant-date fair value of the award that is vested at that date. During the year ended December 31, 2021, total share-based expense recognized related to vested restricted shares totaled approximately $669,000. At December 31, 2021, there was approximately $63,000 of unvested compensation related to these awards that will be amortized over a remaining vesting period of 2.50 years.

The following table summarizes restricted common stock activity for the year ended December 31, 2021:

	Number of Shares	Fair value of shares
Non-vested shares, December 31, 2020	-	$ -
Granted	244,338	3.38
Vested	(41,667)	1.41
Forfeited	-	-
Non-vested shares, December 31, 2021	**202,671**	**$ 3.38**

11. Income Taxes

No federal tax provision has been provided for the years ended December 31, 2021 and 2020, 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, 2021 and 20120:

	Years Ended December 31,	
	2021	**2020**
U. S. federal statutory tax rate	(21.0)%	(21.0)%
State, net of federal benefit	(7.0)%	(7.0)%
Non-deductible goodwill impairment charge	-%	-%
	(28)%	(28.0)%
Change in valuation allowance	28%	28.0%
Effective tax rate	0.0%	0.0%

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, 2021 and 2020 are summarized below.

	December 31,	
	2021	**2020**
Deferred tax assets		
Net operating loss carryforwards	$ 8,329,000	$ 5,893,000
Stock-based compensation	1,637,000	1,362,000
Accrued expenses	12,000	12,000
Charitable contributions	3,000	-
Inventory reserves	137,000	-
Intangibles	39,000	106,000
Valuation allowance	(10,126,000)	(7,299,000)
Total deferred tax assets	31,000	74,000
Deferred tax liabilities		
Allowance for doubtful accounts	(4,000)	-
Operating lease right of use asset	(1,000)	(4,000)
Research and development credit	(13,000)	(13,000)
Depreciation	(13,000)	(57,000)
Total deferred tax liabilities	(31,000)	(74,000)
Deferred taxes, net	$	$

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, 2021, 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.

At December 31, 2021, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $34,006,000 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, 2021 and 2020 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, 2021, 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

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 approximately $96,000 in 2020 and approximately $51,000 in 2021, 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 approximately $22,174 and $20,000 in 2021 and 2020, respectively.

13. 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, 2021 and December 31, 2020 with respect to any such matters.

The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened legal proceeding against the Company that the Company believes could have a material adverse effect on its business, operating results, cash flows or financial condition.

Effective January 6, 2021, the Board of Directors appointed Bret Scholtes as President, Chief Executive Officer, and as a director of the Company. The Company and Mr. Scholtes entered into an employment agreement pursuant to which Mr. Scholtes' annual base salary is $400,000. The employment agreement provides that Mr. Scholtes shall have an annual target cash bonus of no less than $400,000 based on performance objectives determined by the Board of Directors.

Additionally, Mr. Scholtes shall be granted (i) stock options equal to 2% of the Company's issued and outstanding shares of common stock on the date of grant if the Company achieves certain specified performance objectives established by the Board of Directors for the Company's fiscal years ending December 31, 2021, and December 31, 2022, and (ii) additional stock options equal to either 2% or 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 January 6, 2021. If Mr. Scholtes' employment is terminated by the Company without cause, as defined under his employment agreement, if the term expires after a notice of non-renewal is delivered by the Company, or if Mr. Scholtes' employment is terminated following a change of control, as defined, Mr. Scholtes will be entitled to (a) twelve months' base salary, (b) the prorated portion of the any bonus, based on actual performance, and (c) base salary and benefits accrued through the date of termination.

NASDAQ Notice

On January 25, 2022, Guardion Health Sciences, Inc. (the "Company") received a written notice from the NASDAQ Stock Market LLC ("Nasdaq") that the Company has not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for a period of 30 consecutive business days. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The Notice has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is provided a compliance period of 180 calendar days from the date of the Notice, or until July 25, 2022, to regain compliance with the minimum closing bid price requirement. If the Company does not regain compliance during the compliance period ending July 25, 2022, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify for the second compliance period, the Company must (i) meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum closing bid price requirement and (ii) notify Nasdaq of its intent to cure the deficiency. The Company can achieve compliance with the minimum closing bid price requirement if, during either compliance period, the minimum closing bid price per share of the Company's common stock is at least $1.00 for a minimum of 10 consecutive business days. The Company anticipates that its shares of common stock will continue to be listed and traded on the Nasdaq Capital Market during the compliance period(s).

The Company plans to carefully assess potential actions to regain compliance. However, the Company may be unable to regain compliance with the minimum closing bid price requirement during the compliance period(s), in which case the Company anticipates Nasdaq would provide a notice to the Company that its shares of common stock are subject to delisting, and the Company's common shares would thereupon be delisted.

14. 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 the matter described below, there were no material subsequent events which affected, or could affect, the amounts or disclosures in the consolidated financial statements.

On February 18, 2022, the Company, entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company sold (i) 32,550,000 shares of common stock, (ii) Series A Warrants to purchase 37,000,000 shares of common stock, (iii) Series B Warrants to purchase 37,000,000 shares of common stock and (iv) Pre-Funded Warrants to purchase 4,450,000 shares of common stock. On February 23, 2022, the offering closed, and the net proceeds to the Company, after deducting offering expenses, were approximately $10 million. In the event that the Company fails to deliver shares by the required delivery date upon exercise of the warrants, the Company may be subject to cash penalties in an amount up to $20 per trading day for each $1,000 of warrant shares until such shares are delivered. In addition, if the warrant holder purchases shares in the market following the Company's failure to deliver shares upon exercise of the warrants, the Company will be required to cover the cost of any buy-ins and, at the option of the warrant holder, either reinstate the portion of the warrant for the shares that were not delivered or deliver the number of shares that should have been issued.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Delaware Certificate of Incorporation and amendment thereto (filed with the Company's Registration Statement on Form S-1 filed with the SEC on February 11, 2016 and incorporated herein by reference)
3.2	Certificate of Amendment to Certificate of Incorporation (filed with the Company's Current Report Form 8-K on February 1, 2019 and incorporated herein by reference)
3.3	Certificate of Amendment to Certificate of Incorporation (filed with the Company's Current Report on Form 8-K filed with the SEC on December 10, 2019 and incorporated herein by reference)
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	Amendment No. 1 to 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 February 14, 2022)
4.1*	Description of Securities
4.2	Form of Series A/B Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
4.4	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
4.5	Warrant Agency Agreement dated as of February 23, 2022, by and between Guardion Health Sciences, Inc., and V Stock Transfer, LLC (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
10.1+	Form of Indemnification Agreement (filed with the Company's Registration Statement on Form S-1 filed with the SEC on February 11, 2016 and incorporated herein by reference)
10.2	Intellectual Property Assignment Agreement with David W. Evans and VectorVision, Inc. dated as of September 29, 2017 (filed with the Company's Current Report on Form 8-K on October 5, 2017 and incorporated herein by reference)
10.3	Consulting Agreement with David W. Evans dated as of September 29, 2017 (filed with the Company's Current Report on Form 8-K on October 5, 2017 and incorporated herein by reference)
10.4+	Guardion Health Sciences, Inc. 2018 Equity Incentive Plan (filed with the Company's Definitive Proxy Statement on Schedule 14A on October 22, 2018 and incorporated herein by reference)
10.5	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)
10.6	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)
10.7+	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)
10.8	Equity Purchase Agreement, dated May 18, 2021, by and among the Company, Adare Pharmaceuticals, Inc., and Activ Nutritional, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 21, 2021)
10.9+	Employment Agreement by and between the Company and Jeffrey Benjamin dated July 29, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2021)
10.10+	Employment Agreement by and between the Company and Craig Sheehan dated June 1, 2021 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 16, 2021)
10.11	Lease Termination Agreement by and between the Company and Cal-Sorrento, Ltd. dated September 22, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 23, 2021)
10.12	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
10.13	Placement Agency Agreement dated as of February 18, 2022, by and among Guardion Health Sciences, Inc., Roth Capital Partners, LLC and Maxim Group LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
21.1*	List of Subsidiaries
23.1*	Consent of Weinberg & Company
24.1*	Power of Attorney (included on signature page hereto)
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File – the cover page of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 is formatted in Inline XBRL

* filed herewith

+ Indicates a management contract or any compensatory plan, contract or arrangement.

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 31st day of March 2022.

GUARDION HEALTH SCIENCES, INC.

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

POWER OF ATTORNEY

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 31, 2022
/s/ Jeffrey Benjamin Jeffrey Benjamin	Chief Accounting Officer (Principal Financial and Accounting Officer)	March 31, 2022
/s/ Craig Sheehan Craig Sheehan	Chief Commercial Officer	March 31, 2022
/s/ Robert N. Weingarten Robert N. Weingarten	Chairman of the Board of Directors	March 31, 2022
/s/ Mark Goldstone Mark Goldstone	Director	March 31, 2022
/s/ David W. Evans David W. Evans	Director	March 31, 2022
/s/ Donald A. Gagliano Donald A. Gagliano	Director	March 31, 2022
/s/ Michaela Griggs Michaela Griggs	Director	March 31, 2022

EXHIBIT 4.1

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

As of December 31, 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 the Company's Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the Company's Certificate of Incorporation, as amended (the "Certificate of Incorporation") and the Company's 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. The Company encourages you to read its Certificate of Incorporation, Bylaws, and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Capital Shares

The Company's 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 December 31, 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 December 31, 2021.

Voting Rights

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

Dividend Rights

Holders of the Company's Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Board of Directors (the "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 the Company has against the payment of dividends on Common Stock.

Liquidation Rights

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

Applicable Anti-Takeover Provisions

Set forth below is a summary of the provisions of the Company's 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").

Board of Director Vacancies

The Company's Bylaws authorize only its board of directors to fill vacant directorships. In addition, the number of directors constituting the Company's board of directors may be set only by the Board.

Ability of Stockholders to Call Special Meetings

The Company's Bylaws provide that stockholders can only call a special meeting if stockholders holding over 50% of all issued and outstanding shares of the Company entitled to vote at a meeting do so.

Advance Notice Requirements

The Company's 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

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

Exclusive Forum

In accordance with an exclusive forum provision set forth in the Company's 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 DGCL, or (d) any action asserting a claim governed by the internal affairs doctrine.

Listing

The Company's Common Stock is traded on the Nasdaq Capital Market under the trading symbol "GHSI".

Transfer Agent

The Company's transfer agent is VStock Transfer, LLC whose address is 18 Lafayette Pl., Woodmere, NY 11598.

EXHIBIT 21.1

LIST OF SUBSIDIARIES OF GUARDION HEALTH SCIENCES, INC.

Name	State or Other Jurisdiction of Incorporation
VectorVision Ocular Health, Inc.	Delaware
Transcranial Doppler Solutions, Inc.	Delaware
NutriGuard Formulations, Inc.	Delaware
Viactiv Nutrititionals, 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 and No. 333-255077) of Guardion Health Sciences, Inc. of our report dated March 31, 2022, with respect to the consolidated financial statements of Guardion Health Sciences, Inc. of December 31, 2021 and 2020, and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 31, 2022

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER OF GUARDION HEALTH SCIENCES, INC.
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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 31, 2022

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

EXHIBIT 31.2

CERTIFICATION OR PRINCIPAL FINANCIAL OFFICER OF GUARDION HEALTH SCIENCES, INC.
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Benjamin, 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 31, 2022

/s/ Jeffrey Benjamin
Jeffrey Benjamin
Chief Accounting Officer
(Principal Financial and 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

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Bret Scholtes and Jeffrey Benjamin, the Chief Executive Officer and Chief Accounting Officer, respectively, of Guardion Health Sciences, Inc. (the "Company"), hereby certify that based on the undersigned's knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2021 (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 31, 2022

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

March 31, 2022

/s/ Jeffrey Benjamin
Jeffrey Benjamin
Chief Accounting Officer
(Principal Financial and Accounting Officer)