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, 2023

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, Texas	**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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, 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 $9.9 million based upon the closing price of the registrant's common stock of $7.78 on The Nasdaq Capital Market as of that date.

As of March 15, 2024, there were 1,284,156 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

TABLE OF CONTENTS

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2023 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. The Company qualifies 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

- We have entered into a purchase agreement for the sale of all of the outstanding equity interests of Activ Nutritional, LLC ("Activ"), which owns the Viactiv brand and business.
- If the sale of Activ closes, we will be left with minimal operations as the Viactiv brand and business accounts for most of our revenue.
- The Board has approved a plan of dissolution which, if approved by the stockholders, will authorize us to liquidate and dissolve the Company.
- The Company has incurred recurring losses and negative cash flows since its inception and there is no assurance that the Company will be able to reach and sustain profitability.
- Inflationary pressure, interest rate concerns and a potential recession may adversely impact the Company's business.

- 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 or enhance 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 qualified 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 its unable to protect them, its competitive position may suffer.

- The Company relies on certain key employees who are vital to its ability to grow the business. Our inability to retain these individuals or hire new employees with the requisite skills for the positions may result in a reduced ability to operate the business.

- There may be breaches of the Company's information technology systems that materially damage business partner and customer relationships, curtail or otherwise adversely impact access to online stores and services, or subject the Company to significant reputational, financial, legal, and operational consequences.

- While the Company's operations and performance are focused on the United States, raw materials, including ingredients and packaging components utilized by its contract manufacturers, depend on global and regional economic conditions.

Risks Related to the Proposal to Approve the Transaction to Sell Activ

- Even if the sale of Activ does not close, our business may still be harmed by the loss of customers or employees as a result of our announcement of the transaction.

- The amount of net proceeds that the Company will receive from the sale of Activ is subject to uncertainties.

- The purchase agreement for the sale of Activ limits our ability to pursue alternative transactions and may cause other potential buyers to refrain from submitting bids.

- Doctor's Best, Inc. is financing its purchase of Activ and may not be able to secure the necessary cash to fund the purchase price at closing.

- The Company will not have any material assets following the consummation of the sale of Activ as the Viactiv brand and business accounts for most of our revenue.

Risks Related to the Plan of Dissolution

- If our stockholders do not approve the plan of dissolution, the Company would have limited assets with which to generate operating revenue and stockholders could face adverse tax consequences.
- We cannot determine the exact amount or timing of distributions to stockholders in connection with the potential dissolution of the Company.
- Our Board may abandon or delay the plan of dissolution in its sole discretion even if it is approved by our stockholders.
- If the Company is not dissolved, the SEC could classify the Company as a shell company and the Company could be delisted from Nasdaq.
- Our warrant holders could exercise their put rights under the Series A warrants, in which case the amount each stockholder would receive from a liquidating distribution would be reduced accordingly.

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 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 at all or on terms favorable to the Company.
- The Company may not be able to meet the continued listing requirements of the Nasdaq Stock Market and its stock may become delisted.

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., a Delaware corporation and its consolidated subsidiaries.

Overview

We develop and distribute clinically supported dietary supplements and medical foods. These products are designed to support consumers, healthcare professionals and providers, and their patients by supporting bone health, eye health, cardiovascular health, and brain health through nutrients such as Calcium, Vitamin D, Vitamin K, Carotenoids, and Omega-3s.

In June 2021, the Company acquired Activ Nutritional, LLC ("Activ" or "Viactiv" as the context requires), the owner and distributor of the Viactiv® line of supplements for bone health and other applications. The acquisition and integration of the Viactiv line of products changed our financial position, market profile and brand and operating focus, as more fully described below.

Recent Developments

Agreement to Sell Activ Nutritional, LLC

On January 30, 2024, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement") with Doctor's Best Inc., a Delaware corporation ("Doctor's Best"), for the sale of all of the outstanding equity interests of Activ for the aggregate cash consideration of $17.2 million, of which $1.7 million was placed in a third-party escrow account pursuant to the terms of the Purchase Agreement. Activ is a wholly-owned subsidiary of Viactiv Nutritionals, Inc ("Viactiv"), a Delaware corporation, and Viactiv is a wholly-owned subsidiary of the Company. The sale of Activ, as contemplated by the Purchase Agreement (the "Transaction"), is conditioned upon receiving approval from our stockholders, and such approval is also required under Delaware law as the sale of Activ, which owns the Viactiv® brand and business and accounted for 97.2% and 96.3% of our revenues during the years ended December 31, 2023, and 2022, respectively, constitutes a sale of substantially all of our assets and revenue-generating operations. The Transaction contemplated by the Purchase Agreement is the result of a broad review of strategic alternatives by our board of directors (the "Board"). The Board has determined that it is advisable and in the best interests of the Company and the Company's stockholders to approve the Transaction. In the event that the Transaction closes, the Company will be left with minimal operations.

Potential Dissolution

In the event that the Company's stockholders approve the Transaction and the Transaction closes, Additionally, the Board has determined that it is advisable and in the best interests of the Company and the Company's stockholders to approve a voluntary dissolution and liquidation of the Company (the "Dissolution") pursuant to a plan of dissolution (the "Plan of Dissolution"), which, if approved, will authorize the Company to liquidate and dissolve the Company in accordance with the Plan of Dissolution, but subject to the Company's ability to abandon or delay the Plan of Dissolution in the event that the Board determines that another transaction would be in the best interest of the Company's stockholders and further in accordance with the terms thereof. Assuming the approval of the Dissolution by the Company's stockholders, the decision of whether or not to proceed with the Dissolution and when to file the Certificate of Dissolution will be made by the Board in its sole discretion.

On March 15, 2024, the Company filed a Preliminary Proxy Statement with the United States Securities and Exchange Commission (the "SEC") in order to solicit the approval of the Company's stockholders in connection with the Transaction and the Dissolution.

Reverse Stock Split

The Company held a special meeting of stockholders on January 5, 2023 (the "Meeting"). At the Meeting, the Company's stockholders approved a proposal to amend the Company's Certificate of Incorporation to effect a reverse split of the Company's outstanding shares of common stock, par value $0.001, at a specific ratio, up to a maximum of a 1-for-100 split, with the exact ratio to be determined by the Company's board of directors in its sole discretion.

On January 5, 2023, the board of directors approved a one-for-fifty (1-for-50) reverse split of the Company's issued and outstanding shares of common stock (the "Reverse Stock Split"). On January 6, 2023, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation (the "Certificate of Amendment") to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 4:01 p.m. Eastern Time on January 6, 2023, and the Company's common stock began trading on a split-adjusted basis when the Nasdaq Stock Market opened on January 9, 2023.

When the Reverse Stock Split became effective, every 50 shares of the Company's issued and outstanding common stock were automatically combined, converted and changed into 1 share of the Company's common stock, without any change in the number of authorized shares or the par value per share. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of common stock and the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. Any fraction of a share of common stock created as a result of the Reverse Stock Split was rounded up to the next whole share. As a result, we issued an additional 35,281 shares of common stock for such rounding.

Product Offerings

For the year ended December 31, 2023, sales of the Viactiv line of supplements represented approximately 97.2% of our consolidated net sales versus 96.3% for the year ended December 31, 2022. 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 Product Line

In April 2022, the Viactiv product line was extended with the launch of Viactiv® Omega Boost Gel Bites, an omega-3 fish oil dietary supplement with a high level of DHA and EPA designed to compete in the growing omega-3 product segment. The 1200 mg omega-3 gel bite gummies are formulated to provide comprehensive body support, including cardiovascular, brain, joint, immune, hair, skin, nail and eye health. The dosage form provides the potency of large, hard-to-swallow soft gels, in a great tasting chewable format with significantly more omega-3 than the leading fish oil gummies. In a clinical study conducted at Western University of Health Sciences, participants who started omega-3 supplementation with Omega Boost saw a 50% average increase in their omega-3 levels in just 4 weeks compared with leading omega-3 brands as measured using the Omega Index test. In addition to superior absorption, the gel bite dosage form has been shown to have fewer digestive issues than regular soft gel formulas, as well as no unpleasant fishy aftertaste and no sugar, which is associated with many other omega-3 products. In 2023, we increased our digital advertising, social media, and retailer-specific support for Viactiv Omega Boost Gel Bites with messaging that focuses on clinically proven efficacy combined with taste advantages.

During the year ended December 31, 2023, the Company expanded on the launch of the Omega Boost Gel Bites product by executing a two-pronged approach to drive consumer awareness and trial of Omega Boost Gel Bites across the Amazon platform and the brand's website, and by introducing the product in conventional and specialty retailers.

Two new products will be added to the Viactiv product line in 2024. A clinically tested 600mg dose form of the Omega Boost Gel Bites product was introduced to the market in March 2024. The current 1200mg dose form of the Omega Boost Gel Bites product will be relaunched as a maximum formula to differentiate it to the 600mg offering. In addition to the innovation in the omega-3 segment, the Company will launch a magnesium citrate soft chew in April 2024. Both new Viactiv products will be available on viactiv.com and on the Amazon platform.

Ocular Product Line

We currently sell two ocular products. GlaucoCetin® is a dietary supplement in a capsule form designed specifically to provide nutrients to support mitochondrial function with additional antioxidants to help reduce oxidative stress and increase blood flow throughout the body for enhanced eye support and ocular health. We sell GlaucoCetin® on our website, guardionhealth.com and market it through direct-to-consumer strategies such as social media and paid search advertising. Lumega-Z®, our legacy medical food product has a formula designed to replenish and restore the macular protective pigment, simultaneously delivering critical and essential nutrients to the eye. As a medical food, Lumega-Z must be administered under the supervision of a physician or professional healthcare provider. The company sells Lumega-Z on our website, guardionhealth.com and uses a variety of marketing strategies to increase awareness of the brand among ophthalmologists and optometrists. We also market Lumega-Z through direct-to-consumer strategies. We recently changed the formulation of Lumega-Z from a liquid to a powder.

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 three groups; two treatment groups consisting of individuals with fine retinal drusen and a control group consisting of ocular normal individuals. The treatment groups were randomly assigned to either Lumega-Z or AREDS 2 (PreserVision™) soft gel supplements, the control group ocular normal individuals took no supplements. Each treatment 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.

Prior Product Offerings

In September 2017, we acquired VectorVision Ocular Health, 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, from Mr. David Evans.

As part of management's comprehensive evaluation of our Company's business following the acquisition of the Viactiv brand in June 2021, we determined to focus on the products that management believes provide the greatest growth opportunities.

On November 30, 2023, the Company sold all the outstanding capital stock of VectorVision to David Evans for a purchase price of $25,000 and recorded a gain of $129,930. The Company had previously terminated the operations of VectorVision as of December 31, 2021. David Evans was a director of the Company from September 2017 through June 2022.

Intellectual Property

Patents

We currently own and have exclusive rights to two U.S. patents, and one Canadian patent with respect to various products and product candidates.

Trademarks

We currently have eight trademarks registered with the United States Patent and Trademark Office ("USPTO"), all of which are used in association with the Guardion line of products. In addition, we have four trademarks registered with the USPTO which are used in association with the Viactiv line of products.

We also have seven trademarks currently registered in foreign jurisdictions for use with our Guardion line of products, and we have 19 registrations for the Viactiv trademark in a broad range of geographies.

Products Manufacturing and Sources and Availability of Raw Materials

We outsource the manufacturing of our medical food 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 (the "FDA") has primary jurisdiction for the regulation of dietary supplements. The FDA regulates dietary supplements, such as Viactiv calcium chews, Viactiv Omega Boost Gel Bites, and GlaucoCetin 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 company 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. Claims about the health benefits of a product must meet the basic substantiation standard of "competent and reliable scientific evidence," generally randomized, controlled, human clinical trials. 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, Instagram), 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 manufacturer must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim and 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 or professional healthcare provider 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 product to be a medical food. 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.

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 gather 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 food, Lumega-Z, 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.

At present, our products are not reimbursable under any federal program. Nevertheless, 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 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 become subject to 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 December 31, 2023, we had a total of nine 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.

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 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 of our common stock without any change to our par value.

On January 6, 2023, 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-fifty (1:50) 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. At December 31, 2023, the Company had cash and cash equivalents of $6,359,646 and working capital of $10,565,898. Management believes that the current cash balance and working capital resources are sufficient to fund operations for at least one year from the date the Company's 2023 financial statements are issued.

On January 30, 2024, the Company entered into the Purchase Agreement with Doctor's Best for the sale of all of the outstanding equity interests of Activ, which owns the Viactiv® brand and business and accounted for 97.2% and 96.3% of our revenues during the years ended December 31, 2023 and 2022, respectively, for the aggregate cash consideration of $17.2 million, of which $1.7 million was placed in a third-party escrow account pursuant to the terms of the Purchase Agreement. Additionally, the Board has determined that it is advisable and in the best interests of the Company and the Company's stockholders to approve a Plan of Dissolution, which, if approved, will authorize the Company to liquidate and dissolve the Company in accordance with the Plan of Dissolution, but subject to the Company's ability to abandon or delay the Plan of Dissolution in accordance with the terms thereof. Assuming the approval of the Dissolution by the Company's stockholders, the decision of whether or not to proceed with the Dissolution and when to file the Certificate of Dissolution will be made by the Board in its sole discretion. In the event that the Transaction closes, the Company will be left with minimal operations. Please see "*Risk Factors Relating to the Proposal to Approve the Transaction*" and "*Risk Factors Related to the Plan of Dissolution*" below.

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

While the impact of the COVID-19 pandemic on our business has largely abated, uncertainties continue in China, which is experiencing the ongoing effects of the pandemic and an economic slowdown. The effects of government agency actions and the Company's policies and those of third parties to combat future pandemics 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 Company may be negatively affected by the rate of inflation and its impact on the global economy.

Current inflation within the economy has resulted in increased interest rates and capital costs, contributed to supply shortages, increased the cost of living and labor, and other related items. As a result of inflation, which may continue, the Company may incur higher costs relating to the production of its products. Although the Company may take actions to counteract the impacts of inflation, if these actions are not effective it could have a material adverse effect on the Company's business, results of operations and financial condition. Additionally, higher future inflation or concerns of a recession could impact the demand for the Company's products.

A prolonged recession or a period of significant turmoil in the U.S. and international financial markets, could adversely affect the Company's business, liquidity and financial condition and its share price.

U.S. and international financial market disruptions such as the ones experienced in the last global financial crisis and the volatility experienced as a result of the COVID-19 pandemic, along with the possibility of a prolonged recession, may potentially affect various aspects of the Company's business, including the demand for its products, its counterparty credit risk and the ability of its customers, counterparties and others to establish or maintain their relationships with the Company. Volatility in the U.S. and other securities markets may also adversely affect the Company's share price.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflationary pressure, and interest rate changes, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the war between Russia and Ukraine, conflict in the Middle East, Houthi activity in the Red Sea that has disrupted a key global trade route, other terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers, and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Climate change and other sustainability matters could have an adverse impact on our business and results of operations.

Climate change resulting in the increased frequency and severity of natural disasters and other extreme weather conditions may adversely impact our business, results of operations, cash flows and financial condition. Specifically, the predicted physical effects of climate change may exacerbate challenges regarding the cost, quality and availability of ingredients and packaging materials, pose physical risks to the facilities of our key suppliers, disrupt our global supply chain or impact demand for our products. In addition, the increased concern over climate change is likely to continue to result in business risks, including additional legal and regulatory requirements intended to, among other things, reduce or mitigate the effects of climate change and may relate to, among other things, greenhouse gas emissions (e.g., carbon pricing), alternative energy policy and additional disclosure obligations. Such additional regulation may adversely affect our business, results of operations, cash flows and financial condition by increasing our compliance and contract manufacturing and supply chain costs and/or negatively impacting our reputation if we are unable to or are perceived (whether or not valid) not to satisfy such requirements or expectations. Achieving sustainability and social impact targets could require significant efforts from us and our stakeholders, such as our suppliers and other third parties. It could also require capital investment, additional expense (e.g., renewable energy costs) and the development of technology that may not currently exist. Any failure to achieve sustainability and social impact targets or the perception (whether or not valid) that we have failed to act responsibly with respect to such matters or to effectively respond to new or additional legal or regulatory requirements regarding climate change or other sustainability matters, could result in adverse publicity and increased litigation risk and adversely affect our business and reputation. There is also increased focus, including by governmental and non-governmental organizations, investors, customers, consumers, regulators, our employees and other stakeholders on these and other sustainability and social impact matters, including responsible sourcing, deforestation, animal welfare, labor, employment and human rights, the use of plastic, energy and water, the recyclability or recoverability of packaging, including single-use and other plastic packaging, and a growing demand for natural or organic products and ingredient transparency. Our reputation could be damaged if we do not (or are perceived not to) act responsibly with respect to sustainability matters, which could adversely affect our business, results of operations, cash flows and financial condition.

The Company has experience in developing dietary supplements and medical foods but 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. Extended timelines to secure raw materials combined with cost increases on ingredients, packaging and labor, and demand for higher retailer margins have created challenges to the development and commercialization of new products. No assurances can be made 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 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 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.

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 and contract manufacturers 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, distribution 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 qualified 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 requires robust capabilities internally in addition to collaboration with third parties that can perform these services. In the process of commercializing the Company's products, the Company may not be able to secure 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, this 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 may 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 the future. 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, Authorization 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. The Company is subject to the impact of changes to minimum order quantities and cost increases, including raw materials, labor and utilities incurred by its contract manufacturers. The Company experienced contract manufacturer related cost increases during the COVID-19 pandemic and from subsequent inflationary pressures in 2023. 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. It may be difficult to find alternate suppliers in a timely manner and on terms acceptable to the Company, however, 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.

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. The Company strives to comply with all applicable laws, internal policies, legal obligations, and industry codes of conduct relating to privacy, data security, cybersecurity and data protection. However, given that the scope, interpretation, and application of these laws and regulations are often uncertain and may be conflicting, it is possible that these obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules or our practices. In addition, 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, 2023 and 2022, the Company's billings were derived from a limited number of individual customers and distributors. During the years ended December 31, 2023 and 2022, the Company had one customer who accounted for approximately 50% and 57% of the Company's sales respectively. One other customer accounted for 13% of revenue during the year ended December 31, 2023. 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 retail customers and distributors rather than employing an internal sales force. The Company cannot make assurances that these brokers will be successful in selling its products to traditional retail customers or distributors. In addition, acceptance of the Company's products greatly benefits from physicians who understand and appreciate the benefits of Viactiv, Lumega-Z and GlaucoCetin and recommend them to their patients. The Company cannot make assurances 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 professionals, or if the Company fails to position its products as effective health remedies, 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 its 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, efficacy 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, efficacy 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 flow.

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 make assurances 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 make assurances 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 make assurances 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.

The Company relies on its executive leadership team to drive business growth and attract and retain quality employees. There is no assurance that the Company will be able to attract and retain quality executives and managers and integrate 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 listing rules related to board diversity and disclosure, which require all companies listed on Nasdaq's U.S. exchanges to publicly disclose consistent, transparent diversity statistics regarding their board of directors. Additionally, the rules 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.

Risk Factors Relating to the Proposal to Approve the Transaction to Sell Activ

If we fail to complete the Transaction, our business may be harmed

We cannot provide assurances that the Transaction will be completed. The closing of the Transaction is subject to a number of conditions, including but not limited to our obtaining stockholder approval of the Purchase Agreement and the absence of a material adverse effect on Activ's business. If the Transaction is terminated because (a) the Board fails to recommend the Purchase Agreement to our stockholders in a way that is not materially adverse to Doctor's Best or otherwise recommends a separate acquisition proposal, or (b) certain other triggering events occur, then we will be required to pay to Doctor's Best a termination fee of $688,000.

As a result of our announcement of the Transaction, third parties may be unwilling to enter into material agreements with us. New or existing customers and business partners may prefer to enter into agreements with our competitors who have not expressed an intention to sell their business because customers and business partners may perceive that such relationships with our competitors are likely to be more stable in the long-term. If we fail to complete the Transaction, the failure to maintain existing business relationships or enter into new ones could adversely affect our business, results of operations and financial condition. In addition, if the Transaction is not completed, the market price for our common stock may decline.

Our announcement of the Transaction may cause employees working for us to become concerned about the future of the business and lose focus or seek other employment.

In addition, if the Transaction is not completed, our directors, executive officers and other employees will have expended extensive time and effort and experienced significant distractions from their work during the pendency of the Transaction and we will have incurred significant third-party transaction costs, in each case, without any commensurate benefit, which may have a material and adverse effect on our stock price and results of operations.

If the Transaction is not completed, we may explore other potential transactions involving the Company, in whole or in part. The terms of an alternative transaction may be less favorable to us than the terms of the Transaction and there can be no assurance that we will be able to reach agreement with or complete an alternative transaction with another party.

The amount of net proceeds that we will receive from the Transaction is subject to uncertainties.

We will receive aggregate cash consideration of $17,200,000, subject to certain upward adjustments related to cash holdings and working capital in excess of a target of $3,677,000, certain downward adjustments related to indebtedness, unpaid transaction expenses, and working capital below a target of $3,677,000. However, there can be no assurance that our closing working capital will be at or above the target of $3,677,000. If the adjustment amount, as finally determined, is less than the estimated adjustment amount plus $100,000, Doctor's Best will receive from the escrow fund the amount of such shortfall. If the adjustment amount, as finally determined, equals or exceeds the estimated adjustment amount plus $100,000, Doctor's Best will pay us any excess in an amount not to exceed $225,000. The amount of our working capital at any given point in time is dependent upon a number of factors beyond our control. For example, the timing of cash payments for purchases and receipts for accounts receivable cannot be predicted precisely, our inventory levels vary according to customer orders and prepayments and accruals fluctuate throughout the year. We may also have unforeseen liabilities and expenses that must be satisfied from the after-tax net proceeds of the Transaction. As a result, the amount of the net proceeds from the Transaction is subject to substantial uncertainty, and it is possible that the net proceeds from the Transaction will be materially less than we expect. Additionally, if the adjustment amount, as finally determined, is less than the estimated adjustment amount plus $100,000, Doctor's Best will receive from the escrow fund the amount of such shortfall. If the adjustment amount, as finally determined, equals or exceeds the estimated adjustment amount plus $100,000, Doctor's Best will pay us any excess in an amount not to exceed $225,000. Further, the amount of any distribution from the proceeds of the Transaction may be reduced due to the option of the Series A Warrant holders to exercise their respective repurchase rights to cause the Company to repurchase such warrants from the holders for cash.

The Purchase Agreement limits our ability to pursue alternatives to the Transaction.

The Purchase Agreement contains provisions that make it more difficult for us to sell our business to any party other than Doctor's Best. These provisions include the prohibition on our ability to solicit competing proposals, the requirement that we pay a termination fee to Doctor's Best if the Purchase Agreement is terminated in specified circumstances, and Doctor's Best's right to be advised of competing proposals and to submit revised proposals for consideration. These provisions could discourage a third party that might have an interest in acquiring Activ from considering or proposing an alternative transaction and could make it more difficult for us to complete an alternative business combination transaction with another party.

If the Transaction is approved and consummated, Nasdaq may delist our shares from trading on its exchange, which could limit our stockholders' ability to make transactions in our shares and subject us to additional trading restrictions.

We are required to demonstrate compliance with Nasdaq's continued listing requirements in order to maintain the listing of our shares on Nasdaq. Such continued listing requirements for our shares include, among other things, having at least 300 shareholders, 500,000 publicly held shares and a market value of our listed publicly held shares of $1 million. In addition, a Nasdaq-listed company must meet at least one of the following standards: (i) stockholders equity of at least $2.5 million; (ii) market value of listed shares of at least $35 million; or (iii) net income from continuing operations of $500,000 in the latest fiscal year or in two of the last three fiscal years. We cannot assure you that our shares will be able to meet any of Nasdaq's continued listing requirements. If our shares do not meet the Nasdaq's continued listing requirements, Nasdaq may delist our shares from trading on its exchange, which could limit investors' ability to make transactions in our shares and subject us to additional trading restrictions.

If our shares do not meet Nasdaq's continued listing requirements, Nasdaq may delist our shares from trading on its exchange. If Nasdaq delists any of our shares from trading on its exchange and we are not able to list such shares on another approved national securities exchange, we expect that such shares could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including: (i) a limited availability of market quotations for our shares, (ii) reduced liquidity for our shares, (iii) a determination that our shares are "penny stocks" which will require brokers trading in our shares to adhere to more stringent rules, including being subject to the depository requirements of Rule 419 of the Securities Act, and possibly result in a reduced level of trading activity in the secondary trading market for our shares, (iv) a decreased ability to issue additional shares or obtain additional financing in the future, (v) a less attractive acquisition vehicle to a target business in connection with an initial business combination, (vi) our ability to complete an initial business combination with a target company contemplating a Nasdaq listing, and (vii) a limited amount of news and analyst coverage.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as covered securities. Our shares qualify as covered securities under such statute. If we were no longer listed on Nasdaq, our shares would not qualify as covered securities under such statute and we would be subject to regulation in each state in which we offer our shares.

If we are delisted from Nasdaq, but obtain a substitute listing for our common stock, it will likely be on a market with less liquidity, and therefore potentially experience more price volatility than our common stock 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 our common stock is delisted from Nasdaq, the value and liquidity of our common stock and warrants would likely be significantly adversely affected. A delisting of our common stock from Nasdaq could also adversely affect our ability to obtain financing for our operations and/or result in a loss of confidence by investors, employees and/or business partners.

Even if our stockholders approve the Transaction, Doctor's Best may be unable to secure the necessary cash to fund the purchase price.

Doctor's Best has represented to the Company in the Purchase Agreement that it will be able to fund the cash purchase price at closing. In order to mitigate any risk associated with Doctor's Best's ability to fund the closing purchase price, the Company and Doctor's Best agreed in the Purchase Agreement, among other things, that Doctor's Best would deliver (i) at signing, a consent of MUFG Union Bank to the transaction with MUFG Union Bank's approval of the draw to fund the purchase price (the "MUFG Consent") in a form satisfactory to the Company, and (ii) a weekly certificate during the interim period from the signing of the Purchase Agreement to the closing of the Transaction pursuant to which the Chief Financial Officer of Doctor's Best must certify that Doctor's Best has adequate capacity under its credit facility to fund the purchase price (the "Weekly Certificate"). Doctor's Best failed to deliver the MUFG Consent at signing but has since delivered a MUFG Consent on February 29, 2024. Doctor's Best failed to deliver the first Weekly Certificate when required but has complied with its obligations since that time.

Further, Doctor's Best has indicated to the Company's management and advisors that it may utilize cash from its parent-group entities in China in order to fund the purchase price. Approvals from or registration with appropriate government and regulatory authorities may be required with respect to remitting cash out of China and/or converting any cash from China into United States dollars. Doctor's Best is required to pay the cash purchase price at closing in order for the Transaction to be completed, subject to a thirty (30) day cure period. As a result of its potential financing uncertainty, if Doctor's Best is unable to obtain or utilize its financing options in the United States, its ability to pay the cash purchase price may be delayed or inhibited. Under the Purchase Agreement, if the Company terminates the Purchase Agreement due to Doctor's Best's failure to fund the cash purchase price at closing, then the parties are obligated to release $1,700,000, representing the full amount held in escrow, plus any interest and earnings accrued thereon, to the Company.

The Company will not have any material business assets following the consummation of the Transaction.

The Viactiv® brand and business accounted for 97.2 and 96.3% of our revenues during the years ended December 31, 2023 and 2022, respectively. As a result, the sale of Activ to Doctor's Best constitutes a sale of substantially all of our assets and revenue-generating operations. Following the consummation of the Transaction, the remaining business of the Company will not be material.

Risk Factors Related to the Plan of Dissolution

If our stockholders vote against the Plan of Dissolution proposal, our business could be harmed, and our stockholders could face adverse tax consequences.

If we do not obtain stockholder approval of the Plan of Dissolution proposal, we would have to continue its business operations despite the sale of substantially all of our assets and our announced Dissolution. Assuming the completion of the Transaction, our remaining business assets would not be material and as a result we would have limited assets with which to generate operating revenue and likely will have retained only those employees required to wind-up our corporate existence. Further, we do not intend to invest in another operating business following the closing of the Transaction. Further, our stockholders could incur an increased stockholder-level tax liability from any distribution made outside the Plan of Dissolution.

We cannot determine at this time the exact amount or timing of any distributions to stockholders because there are many factors, some of which are outside of our control, which could affect our ability to make such distributions in the future.

If the Transaction is approved, we expects to receive aggregate cash consideration of $17,200,000, subject to certain upward adjustments related to cash holdings and working capital in excess of a target of $3,677,000, certain downward adjustments related to indebtedness, unpaid transaction expenses, and working capital below a target of $3,677,000. However, there can be no assurance that our closing working capital will be at or above the target of $3,677,000. If the adjustment amount, as finally determined, is less than the estimated adjustment amount plus $100,000, Doctor's Best will receive from the escrow fund the amount of such shortfall. If the adjustment amount, as finally determined, equals or exceeds the estimated adjustment amount plus $100,000, Doctor's Best will pay us any excess in an amount not to exceed $225,000 (see the Risk Factor subsection entitled *The amount of net proceeds that we will receive from the Transaction is subject to uncertainties*).

Assuming the Plan of Dissolution is approved by stockholders, and subject to the possibility that the Board abandons or delays the effectiveness of the Plan of Dissolution in favor of a separate subsequent transaction involving the Company that the Board determines to be in the best interest of the Company and its stockholders, we plan to distribute, in an initial distribution (with potential subsequent distributions thereafter), a portion of the net proceeds from the Transaction, which may include a portion of the Company's other cash on its balance sheet, subject to the Company's obligations to warrant holders and a contingency reserve for remaining costs and liabilities, after the filing of the Certificate of Dissolution with the Delaware Secretary of State. The amount and timing of the distributions to stockholders will be determined by the Board in its sole discretion, subject to the provisions of the Plan of Dissolution. Subsequent distributions would be made in such amounts and at such times as determined by the Board in its sole discretion in accordance with the Plan of Dissolution. However, there can be no assurance as to the timing and amount of distributions to stockholders, even if all of our remaining assets are sold because there are many factors, some of which are outside of our control, that could affect our ability to make such distributions in the future. Further, the Board may, in its sole discretion, take into account the timing of liquidating distributions or potential transactions when determining whether to make a distribution to stockholders following the consummation of the Transaction, if approved. If the Board, in its sole discretion, determines to promptly proceed with liquidating the Company's assets pursuant to the Plan of Dissolution, if approved, then the Board may, in its sole discretion, elect not to proceed with initial distributions prior to such liquidating distributions due to the administrative costs and burdens involved. However, if the Board expects to engage in a potential transaction following the consummation of the Transaction, if approved, rather than proceeding with the dissolution of the Company, the Board may elect, in its sole discretion, to make interim distributions to the Company's stockholders.

If stockholders do not approve the Plan of Dissolution, the Company will seek to complete the Transaction, if the Transaction is approved by the stockholders and the other conditions to closing set forth in the Purchase Agreement are satisfied or waived. In that event, the Company will have transferred substantially all of its operating assets to Doctor's Best and will have limited operations and working capital resources to generate revenue. With limited operations and working capital resources with which to generate revenues and no Plan of Dissolution approved, The Company anticipates that it would use its cash to pay ongoing operating expenses, and the Board would determine whether to make any distributions to stockholders. The Board would have to evaluate the alternatives available to the Company, including, among other things, the possibility of investing the cash received from the Transaction in another operating business, engage in a reverse merger or recapitalization or other strategic transaction. In the event that we make a distribution outside of the Plan of Dissolution, our stockholders could incur an increased stockholder-level tax liability from such distribution (see the section entitled *Material United States Federal Income Tax Consequences to Company Stockholders*).

In addition, we will continue to incur claims, liabilities and expenses from operations (including various operating costs, salaries, directors and officers insurance, payroll and local taxes, legal and accounting fees, and miscellaneous office and operating expenses) as we seek to close the Transaction and effect the Dissolution. Our estimates regarding our expense levels may be inaccurate. Any unexpected claims, liabilities or expenses that arise prior to the liquidation and final dissolution of the Company or any claims, liabilities or expenses that exceed our estimates could leave us with less cash than is necessary to pay liabilities and expenses and would likely reduce the amount of cash available for ultimate distribution to our stockholders. Further, if cash to be received from the sale of our remaining assets is not adequate to provide for all of our obligations, liabilities, expenses and claims, we will not be able to distribute any amount at our stockholders. Further, the amount of any distribution from the proceeds of the Transaction may be reduced due to the option of the Series A Warrant holders to exercise their respective repurchase rights to cause the Company to repurchase such warrants from the holders for cash.

For the foregoing reasons, there can be no assurance as to the timing and amount of distributions to stockholders, even if all of our remaining asset are sold or otherwise disposed of; provided that the Company must complete the distribution of all of its properties and assets to its stockholders as provided in the Plan of Distribution as soon as practicable following the filing of the Certificate of Dissolution with the Delaware Secretary of State and in any event on or before the tenth anniversary of such filing.

Our Board may abandon or delay implementation of the Plan of Dissolution even if it is approved by our stockholders.

Our Board has adopted and approved a Plan of Dissolution for the Dissolution of the Company following the closing of the Transaction. Even if the Plan of Dissolution proposal is approved by our stockholders, the Board has reserved the right, in its sole discretion, to abandon or delay implementation of the Plan of Dissolution if as a result of the Plan of Dissolution (i) we would be insolvent or unable to pay our debts as they come due, (ii) we would have remaining liabilities in excess of the Company's remaining assets, (iii) we would otherwise be unable to satisfy in full all valid claims against the Company (iv) the Board determined to invest the cash received from the Transaction in another operating business, or (v) the Board abandons or delays the effectiveness of the Plan of Dissolution in favor of a separate subsequent transaction involving the Company that the Board determines to be in the best interest of the Company and its stockholders. Following completion of the Transaction, we will continue to exist as a public company until we are dissolved. The Board may also conclude either that its fiduciary obligations require it to pursue business opportunities that present themselves or that abandoning the Plan of Dissolution is otherwise in our best interests and the best interests of our stockholders. If the Board elects to pursue any alternative to the Plan of Dissolution, the value of our common stock may decline.

Our stock transfer books will close on the date we file the Certificate of Dissolution with the Secretary of State of the State of Delaware, after which it will not be possible for stockholders to trade our stock.

We will close our stock transfer books and discontinue recording transfers of our common stock at the close of business on the date we file the Certificate of Dissolution with the Secretary of State of the State of Delaware, which is referred to herein as the final record date. Thereafter, certificates representing shares of our common stock will not be assignable or transferable on our books. The proportionate interests of all of our stockholders will be fixed on the basis of their respective stock holdings at the close of business on the final record date, and, after the final record date, any distributions made by us shall be made solely to the stockholders of record at the close of business on the final record date.

We will continue to incur claims, liabilities and expenses and a delay in the consummation of the Transaction and/or Dissolution will reduce the amount available for distribution to stockholders.

Claims, liabilities and expenses from operations, such as operating costs, salaries, insurance, payroll and local taxes, legal, accounting and consulting fees and miscellaneous expenses, will continue to be incurred as we wind down. These expenses will reduce the amount of assets available for ultimate distribution to stockholders.

If the Company is not dissolved, the SEC could classify the Company as a shell company, which could result in certain negative consequences, including a delisting of our common stock on Nasdaq.

If the Plan of Dissolution is not approved and/or the Company is not dissolved, then the SEC could take the position that the Company is a shell company. Recently, the SEC has exercised heightened scrutiny in classifying companies as "shell companies" under Rule 405 of the Securities Act. This classification by the SEC would prohibit the Company from using Form S-3 "shelf registration" to register securities for public offerings until 12 months after it has ceased to be a shell company. Further, the Company would no longer be able to use Rule 144 for 12 months after it ceases to be a shell company, among other rules and regulations of which we would not be able to take advantage. Shell company status could dissuade certain parties from looking to acquire the Company in a change in control transaction in an effort to avoid SEC scrutiny and potentially onerous reporting requirements. In addition to the scrutiny and obligations the Company would have pursuant to federal securities laws and regulations as a result of such a classification by the SEC, we could be delisted from Nasdaq.

We are required to demonstrate compliance with Nasdaq's continued listing requirements in order to maintain the listing of our securities on Nasdaq. Such continued listing requirements for our securities include, among other things, having at least 300 shareholders, 500,000 publicly held shares and a market value of our listed publicly held securities of $1 million. We cannot assure you that our shares will be able to meet any of Nasdaq's continued listing requirements. If our securities do not meet the Nasdaq's continued listing requirements, including as a result of the Company's potential shell company status following the consummation of the Transaction, Nasdaq may delist our securities from trading on its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

If our securities do not meet Nasdaq's continued listing requirements, Nasdaq may delist our securities from trading on its exchange. If Nasdaq delists any of our securities from trading on its exchange and we are not able to list such securities on another approved national securities exchange, we expect that such securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including: (i) a limited availability of market quotations for our securities, (ii) reduced liquidity for our securities, (iii) a determination that our shares are "penny stocks" which will require brokers trading in our shares to adhere to more stringent rules, including being subject to the depository requirements of Rule 419 of the Securities Act, and possibly result in a reduced level of trading activity in the secondary trading market for our securities, (iv) a decreased ability to issue additional securities or obtain additional financing in the future, (v) a less attractive acquisition vehicle to a target business in connection with an initial business combination, (vi) our ability to complete an initial business combination with a target company contemplating a Nasdaq listing, including the Business Combination and (vii) a limited amount of news and analyst coverage.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as covered securities. Our shares qualify as covered securities under such statute. If we were no longer listed on Nasdaq, our securities would not qualify as covered securities under such statute and we would be subject to regulation in each state in which we offer our securities under each states respective "blue sky" securities laws.

If stockholders do not approve the Plan of Dissolution, the Company will still seek to complete the Transaction, if the Transaction is approved by the stockholders and the other conditions to closing set forth in the Purchase Agreement are satisfied or waived, in which case any distribution to our stockholders may be reduced or eliminated.

In the event that our stockholders do not approve the Plan of Dissolution, we will still seek to complete the Transaction, if the Transaction is approved by the stockholders and the other conditions to closing set forth in the Purchase Agreement are satisfied or waived. In that event, the Company will have transferred substantially all of its operating assets to Doctor's Best and will have limited operations and working capital resources to generate revenue and to fund its ongoing expenses. With limited assets with which to generate revenues and no Plan of Dissolution approved, the Company anticipates that it would use its cash to pay ongoing operating expenses, and the Board would determine whether to make any distributions to stockholders. The Board would have to evaluate the alternatives available to the Company, including, among other things, acquiring other businesses, investing the cash received from the Transaction in another operating business, or engaging in a subsequent reverse merger or recapitalization or similar transaction. In the event that we make a distribution outside of the Plan of Dissolution, our stockholders could incur an increased stockholder-level tax liability from such distribution.

If our warrant holders exercise their respective put rights triggered by the Transaction being deemed a fundamental transaction under our Series A Warrants, we will be obligated to pay such exercising holders' cash, which would reduce the amount each Company stockholder would receive from a liquidating distribution.

In connection with our February 2022 public offering, we issued the Series A Warrants to purchase shares of our common stock. Such warrants contain a provision which provides that in the event of a fundamental transaction, such as a change-in-control transaction or sale of all or substantially all of the Company's assets, the holder has the option, exercisable at any time concurrently with, or within 30 days after the consummation of the fundamental transaction, to cause the Company to repurchase such warrants from the holders for cash in an amount equal to the Black-Scholes value of such warrant calculated in accordance with the terms of the warrant.

We currently estimate that the liability to the Company associated with these warrants based on information currently available to the Company is approximately $5,100,000. That amount could increase or decrease based on a number of factors that are outside the control of the Company. Such factors include, among others, the trading and price volatility of our common stock, the number of warrant holders that may elect to exercise their warrants in accordance with their terms prior to the closing of the Transaction and forego their put rights, and the number of warrant holders that exercise their put rights in accordance with the terms of the warrants. To the extent that this obligation is triggered and exercised by the warrant holders, the Company would need to make such payments out of its available cash and/or the Transaction proceeds, and any such payments would reduce the amount each stockholder would be able to receive from any liquidating distributions.

Such warrant holders are also able to exercise their warrants in exchange for common stock of the Company. Any such exercise would decrease the aforementioned liability of the Company but would result in dilution to the common stock held by all other stockholders.

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 (as applicable);
- 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 GlaucoCetin, 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 to be a medical food, as that term is defined under the FDCA. While the Company believes Lumega-Z is a medical food, if the FDA determines Lumega-Z 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 depends 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 will 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® to be medical food and not a drug, it is 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

Please see "*Risk Factors Relating to the Proposal to Approve the Transaction*" and "*Risk Factors Related to the Plan of Dissolution*" above.

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. As a result of 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;
- the impact of a potential recession on the economy generally and the Company's customers;
- the impact of inflation generally and on the Company's products;
- 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. 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 to 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 has 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 and 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 acquisition of Activ, which fundamentally changed its business, may make 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 directors;
- raise sufficient funds in the capital markets to effectuate the Company's business plan;
- identify, acquire or successfully integrate any acquisition candidate or product; and
- identify or implement any particular strategic transaction designed to enhance stockholder value.

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.

We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our shareholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

Our Board of Directors is responsible for overseeing our risk management and strategy and cybersecurity is a critical element of this strategy. Management is responsible for the day-to-day administration of our risk management strategy and our cybersecurity policies, processes, and practices. We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our operations, business strategy, results of operations or financial condition. For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, refer to Part I, Item 1A. Risk Factors for additional information about cybersecurity risks and potential related impacts on our Company.

Cybersecurity Insurance and Internal Audits

The annual renewal of our cybersecurity insurance policy includes an internal audit of cybersecurity defense, response, recovery, and remediation protocols. The independent third-party audit is based on criteria designed to meet cybersecurity industry standards.

Employee Awareness and Compliance

Our IT policies including cybersecurity have been developed in conjunction with independent third parties that specialize in cybersecurity, cloud, and digital infrastructure. The policies include employee security awareness, employee onboarding and offboarding, incident response protocols, business continuity including backup protocols, and disaster recovery. Dedicated Company IT personnel supported by independent third-party cybersecurity resources are responsible for implementing and monitoring cybersecurity measures, conducting risk assessments, and ensuring compliance with regulatory requirements. The IT team regularly attends webinars providing cybersecurity training and industry updates to stay abreast of trends and apply learning throughout the Company.

We implement ongoing employee cybersecurity awareness programs across the Company. The programs include cybersecurity best practices, phishing simulation exercises and targeted communication campaigns. Mandatory annual cyber awareness employee training developed by a third-party specialist is conducted to enhance management's ability to detect and respond to cyber threats. The online training includes a system for scoring and reporting on the program's efficacy to enable improvements to be made to subsequent training modules.

Data Protection, Endpoint Management and Threat Intelligence

Encryption protocols have been implemented to safeguard sensitive data. They include the protection of data both at rest and during transmission. We manage access controls to restrict data acquisition and system entry to authorized personnel only and enforce compliance with pre-set permission levels via Microsoft systems. We work with a third-party IT resource with an endpoint management system to monitor and secure all endpoints within the Company's cloud-based network and invest in continuous threat intelligence resources and technologies to detect, analyze, and respond to emerging cyber threats.

Cyberattack Response

The Company's cyberattack response plan has been developed in conjunction with independent third parties that specialize in cybersecurity, cloud, and digital infrastructure. The plan includes incident response protocols, disaster recovery strategies, business continuity measures, stakeholder communication and SEC compliance reporting. Simulated cyberattacks are conducted to assess the efficacy of the cyberattack response plan and identify areas of potential risk. Regularly scheduled cybersecurity initiatives include penetration testing to proactively identify and address vulnerabilities in the Company's systems. Each penetration test is documented and reported. Post-test actions are implemented to drive continuous improvement across our systems.

Cybersecurity Governance

Cybersecurity is a key priority at the board level. Our Board of Directors provides governance of cyber-related risk management by establishing management and oversight expectations. The Board approves cybersecurity policies, including the annual cybersecurity insurance policy, and ensures regulatory compliance with the policies.

The Board of Directors facilitates ongoing information exchange, including updates on SEC requirements for reporting on cybersecurity risk management and improving and standardizing disclosures related to cybersecurity incidents. Management regularly updates the Board on IT matters, including cybersecurity.

ITEM 2. PROPERTIES

Our corporate 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 $3,000 per month. This facility will be adequate for the needs of the Company during the foreseeable future.

In connection with the operations of VectorVision, we had a lease agreement for 5,000 square feet of office and warehouse space which commenced October 1, 2017 and continued through February 2023, at which point the lease expired and the Company vacated the leased premises.

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 December 31, 2023, there were approximately 80 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 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.

Trading Arrangement

During the quarter ended December 31, 2023, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" as such term is defined in Item 408(a) of Regulation S-K. As of December 31, 2023, the Company did not have a "Rule 10b5-1 trading arrangement" in effect with respect to its securities.

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 dietary supplements and medical foods. The Company offers a portfolio of science-based, clinically supported products designed to support consumers, healthcare professionals and providers, and their patients by supporting bone health, eye health, cardiovascular health, and brain health through nutrients such as Calcium, Vitamin D, Vitamin K, Carotenoids, and Omega-3s.

In June 2021, the Company acquired Activ Nutritional, LLC ("Activ" or "Viactiv" as the context requires), the owner and distributor of the Viactiv® line of supplements for bone health and other applications. The acquisition and integration of the Viactiv line of products changed our financial position, market profile and brand and operating focus. The acquisition and integration of the Viactiv line of products changed our financial position, market profile and brand and operating focus, as more fully described below.

Recent Developments

Agreement to Sell Activ Nutritional, LLC

On January 30, 2024, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement") with Doctor's Best Inc., a Delaware corporation ("Doctor's Best"), for the sale of all of the outstanding equity interests of Activ for the aggregate cash consideration of $17.2 million, of which $1.7 million was placed in a third-party escrow account pursuant to the terms of the Purchase Agreement. Activ is a wholly-owned subsidiary of Viactiv Nutritionals, Inc ("Viactiv"), a Delaware corporation, and Viactiv is a wholly-owned subsidiary of the Company. The sale of Activ, as contemplated by the Purchase Agreement (the "Transaction"), is conditioned upon receiving approval from our stockholders, and such approval is also required under Delaware law as the sale of Activ, which owns the Viactiv® brand and business and accounted for 97.2% and 96.3% of our revenues during the years ended December 31, 2023, and 2022, respectively, constitutes a sale of substantially all of our assets and revenue-generating operations. The Transaction contemplated by the Purchase Agreement is the result of a broad review of strategic alternatives by our board of directors (the "Board"). The Board has determined that it is advisable and in the best interests of the Company and the Company's stockholders to approve the Transaction. In the event that the Transaction closes, the Company will be left with minimal operations.

Potential Dissolution

In the event that the Company's stockholders approve the Transaction and the Transaction closes, Additionally, the Board has determined that it is advisable and in the best interests of the Company and the Company's stockholders to approve a voluntary dissolution and liquidation of the Company (the "Dissolution") pursuant to a plan of dissolution (the "Plan of Dissolution"), which, if approved, will authorize the Company to liquidate and dissolve the Company in accordance with the Plan of Dissolution, but subject to the Company's ability to abandon or delay the Plan of Dissolution in the event that the Board determines that another transaction would be in the best interest of the Company's stockholders and further in accordance with the terms thereof. Assuming the approval of the Dissolution by the Company's stockholders, the decision of whether or not to proceed with the Dissolution and when to file the Certificate of Dissolution will be made by the Board in its sole discretion.

On March 15, 2024, the Company filed a Preliminary Proxy Statement with the United States Securities and Exchange Commission (the "SEC") in order to solicit the approval of the Company's stockholders in connection with the Transaction and the Dissolution.

Availability of Capital

We intend to complete the Transaction and the Dissolution as announced, in which case the Company will have no further need for capital. In the event that our stockholders do not approve the Plan of Dissolution, we will still seek to complete the Transaction, if the Transaction is approved by the stockholders and the other conditions to closing set forth in the Purchase Agreement are satisfied or waived. In that event, we will have transferred substantially all of our operating assets to Doctor's Best and will have limited operations and working capital resources to generate revenue and to fund our ongoing expenses. With limited assets with which to generate revenues and no Plan of Dissolution approved, we anticipate that we would use our cash to pay ongoing operating expenses, and the Company's Board of Directors would determine whether to make any distributions to stockholders. The alternatives available to the Company, may include, among other things, acquiring other businesses, investing the cash received from the Transaction in another operating business, or engaging in a subsequent reverse merger or recapitalization or similar transaction.

In the event that our stockholders do not approve the Plan of Dissolution but the Transaction is completed, the Company may 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.

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.

Concentration of Risk

As a result of the recent banking failures in the U.S. and abroad there has been a much-highlighted focus on what is being done to preserve capital. The Company's cash is held in a cash bank deposit program maintained by BMO Harris Bank ("BMO"), an FDIC-insured banking institution regulated by the Office of the Comptroller of the Currency ("OCC"). The Company's policy is to maintain its cash balances with financial institutions with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC") and/or by the Securities Investor Protection Corporation (the "SIPC"). The Company periodically has cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of $250,000 and $500,000, respectively. The Company has an overnight investment feature established with BMO whereby the Company's cash is swept into a Money Market Mutual Fund managed by Goldman Sachs Asset Management. This fund invests solely in high quality U.S. government issued securities. The Company has not experienced any losses to date resulting from this policy.

Revenue

During the year ended December 31, 2023, there was one customer that accounted for 50% of total revenue. During the year ended December 31, 2022, there was one customer that accounted for 57% of total revenue. One other customer accounted for 13% of revenue during the year ended December 31, 2023. No other customer accounted for more than 10% of total revenue for the year ended December 31, 2022.

Purchases from vendors

During the years ended December 31, 2023 and 2022, we utilized one manufacturer for most of the production and packaging of our clinical nutrition products. Total purchases from this manufacturer accounted for approximately 50% and 48% of all purchases for the years ended December 31 2023 and 2022, respectively. One other vendor accounted for 12% of purchases during the year ended December 31, 2023 however, no other vendor accounted for more than 10% for the year ended December 31, 2022.

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

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

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

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.

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 Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 — *Summary of Significant Accounting Policies* to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Recent Trends – Market Conditions

We, along with our suppliers, continue to experience significant broad-based inflation and labor cost pressures. We expect input cost inflation to continue through at least the remainder of 2024. The consequences of higher government deficits and debt, tighter monetary policy, and potentially higher long-term interest rates may result in a higher cost of capital for the business and an increase in our operating expenses. There are signs that unit volume consumption is softening in recent vitamins, minerals, and supplements syndicated industry data. We believe that the impact of inflation-based cost increases on consumers' purchasing power in combination with the implementation of higher retail prices across brands in the vitamins, minerals and supplements category is contributing to the softness.

Store traffic in the drug channel has declined due to a decrease in the number of people choosing to have a COVID- 19 shot. Lower footfall has reduced chainwide sales, including vitamins, minerals, and supplements. The legal cost of opioid settlements has also impacted drug retailers. In October 2023, Rite Aid filed for protection under Chapter 11 of the United States Bankruptcy Code and disclosed a restructuring plan which includes a phased approach to a significant store-closure program. We hope to identify new distribution opportunities to bridge any loss of distribution at Rite Aid and accelerate brand sales.

Plan of Operations

On January 30, 2024, the Company entered into the Purchase Agreement with Doctor's Best for the sale of all of the outstanding equity interests of Activ, which owns the Viactiv® brand and business and accounted for 97.2% and 96.3% of our revenues during the years ended December 31, 2023 and 2022, respectively, for the aggregate cash consideration of $17.2 million, of which $1.7 million was placed in a third-party escrow account pursuant to the terms of the Purchase Agreement. Additionally, the Board has determined that it is advisable and in the best interests of the Company and the Company's stockholders to approve a Plan of Dissolution, which, if approved, will authorize the Company to liquidate and dissolve the Company in accordance with the Plan of Dissolution, but subject to the Company's ability to abandon or delay the Plan of Dissolution in accordance with the terms thereof. Assuming the approval of the Dissolution by the Company's stockholders, the decision of whether or not to proceed with the Dissolution and when to file the Certificate of Dissolution will be made by the Board in its sole discretion. In the event that the Transaction closes, the Company will be left with minimal operations.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

	Years Ended December 31,			
	2023	2022	Change	
Revenue	$ 12,248,550	$ 11,049,772	$ 1,198,778	11%
Cost of goods sold	6,854,033	6,529,385	324,648	5%
Gross Profit	5,394,517	4,520,387	874,130	19%
Operating Expenses:				
Research and development	150,684	193,800	(43,116)	(22)%
Sales and marketing	1,704,680	2,069,660	(364,980)	(18)%
General and administrative	7,875,471	9,602,244	(1,726,773)	(18)%
Impairment of Intangible assets	-	10,065,833	(10,065,833)	(100)%
Loss on disposal of equipment	-	9,448	(9,448)	(100)%
Total Operating Expenses	9,730,834	21,940,985	(12,210,151)	(56)%
Loss from Operations	(4,336,317)	(17,420,598)	(13,084,281)	(75)%
Other Income (Expense):				
Change in fair value of warrant derivative liability	3,984,900	2,345,800	1,639,100	70%
Disposal of VectorVision subsidiary	129,930	-	129,930	-
Interest income	379,520	152,570	226,950	149%
Total other income	4,494,350	2,498,370	1,995,980	80%
Net income (loss)	158,033	(14,922,228)	15,080,261	101%
Preferred stock deemed dividend	-	941,585	(941,585)	(100)%
Net income (loss) available to common stockholders	$ 158,033	$ (15,863,813)	$ 16,021,846	101%

Revenue

For the year ended December 31, 2023, revenue from product sales was $12,248,550, as compared to revenue of $11,049,772 for the year ended December 31, 2022, reflecting an increase of $1,198,778, or 11%. The increase is primarily driven by the revenue of $11,907,867 generated during the year ended December 31, 2023, by e-commerce sales of our Viactiv product line.

Cost of Goods Sold

For the year ended December 31, 2023, cost of goods sold was $6,854,033, as compared to cost of goods sold of $6,529,385 for the year ended December 31, 2022, reflecting an increase of $324,648, or 5%. This increase was primarily driven by e-commerce sales related to our Viactiv product line.

Gross Profit

For the year ended December 31, 2023, gross profit was $5,394,517, as compared to gross profit of $4,520,387 for the year ended December 31, 2022, reflecting an increase of $874,130 or 19% driven by the increase of our e-commerce sales. Gross profit margin was 44% and 41% of revenues for the years ended December 31, 2023 and 2022, respectively. Approximately $5,313,785 or 99% of the 2023 versus $4,459,419 or 99% of the 2022 gross profit was generated from the sale of the Viactiv products.

Research and Development

For the year ended December 31, 2023, research and development costs were $150,684, as compared to research and development costs of $193,800 for the year ended December 31, 2022, reflecting a decrease of $43,116 or 22%. The decrease was primarily due to higher costs in 2022 for clinical studies that were not incurred in 2023. Research and development costs during the year, ended December 31, 2023, and 2022 consisted primarily of clinical studies related to the Company's clinical nutrition products.

Sales and Marketing

For the year ended December 31, 2023, sales and marketing expenses were $1,704,680, as compared to sales and marketing expenses of $2,069,660 for the year ended December 31, 2022. The decrease in sales and marketing expenses of $364,980, or 18%, in 2023 as compared to 2022 was primarily due to the increased focus on targeted marketing expenditures related to the Company's Viactiv line of products and increased fiscal discipline.

General and Administrative

For the year ended December 31, 2023, general and administrative expenses were $7,875,471, as compared to general and administrative expenses of $9,602,244 for the year ended December 31, 2022. The decrease of approximately $1,726,773, or 18%, compared to 2022 was primarily due to decreases in amortization of intangibles of $1,190,000, stock-based compensation of $295,645, consulting fees of $257,416, other professional fees of $201,917 and insurance expense of $132,881 offset by increases in legal fees of $217,507 and franchise tax expense of $196,838.

Disposal of VectorVision

During the year ended December 31, 2023, the Company sold all the outstanding capital stock of its wholly-owned subsidiary, VectorVision, and recorded a gain of $129,930.

Transaction Costs Related to Pending Disposition

For the year ended December 31, 2023, transaction costs related to pending dispositions were approximately $395,000, all of which relate to the potential sale of the Company's wholly-owned subsidiary, Activ Nutritional LLC, the owner of the Viactiv brand and business. We did not have any transaction costs related to pending dispositions in 2022.

Impairment of Intangible Assets

On December 31, 2022, as a result of the widespread delays and disruptions in the supply chain impacting the global economic environment during 2022, the Company performed an impairment analysis of its intangible assets and determined its intangible assets to be fully impaired. As a result, the Company wrote-down the full $10,065,833 remaining value of the intangible assets as of December 31, 2022 through an impairment loss recognized on the consolidated statement of operations for the year ended December 31, 2022.

Change in Fair Value of Warrant Derivative Liability

For the year ended December 31, 2023, the change in fair value of warrant derivative liabilities was $3,984,900 as compared to $2,345,800 for the year ended December 31, 2022, a decrease of $1,639,100.

Net Income/Loss

For the year ended December 31, 2023, the Company generated net income of $158,033 compared to a net loss of $14,922,228 for the year ended December 31, 2022. The change of $15,080,261 for the year ended December 31, 2023 as compared to the year ended December 31, 2022 is primarily due to the 2022 intangible asset impairment charge of $10,065,833, the decrease in change in fair value of warrant liabilities of $1,639,100 and net reductions during 2023 of $1,726,773 in general and administrative costs as a result of cost-cutting initiatives.

Preferred Stock Deemed Dividend

As a result of the offering on November 29, 2022, the issuance of the Preferred Stock triggered a deemed dividend of approximately $942,000 which reduced the income available to common stockholders. The $942,000 was comprised of interest in the amount of $500,000, placement fees of $250,000, legal fees of $158,585, accounting fees of $30,500 and escrow agent fees $2,500. As the Company has an accumulated deficit balance, there was no overall impact to additional paid-in capital, as the deemed dividend was recorded as offsetting debit and credit entries to additional paid-in capital. Therefore, the amounts were not presented on the statement of stockholders' equity.

Liquidity and Capital Resources

For the year ended December 31, 2023, the Company generated net income of $158,033 and used cash in operating activities of approximately $4,369,885. At December 31, 2023, the Company had cash and cash equivalents on hand of $6,359,646 and working capital of $10,565,898.

Considering the cash and cash equivalents on hand at December 31, 2023, management believes that the Company has the ability to fund operations in excess of one year from the date the Company's 2023 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.

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:

	December 31,	
	2023	**2022**
Net cash used in operating activities	$ (4,369,885)	$ (7,446,812)
Net cash provided by investing activities	16,138	4,990,054
Net cash provided by (used in) financing activities	(5,192,097)	14,268,321
Net increase (decrease) in cash	$ (9,545,844)	$ 11,811,563

Operating Activities

Net cash used in operating activities was $4,369,885 during the year ended December 31, 2023 as compared to $7,446,812 used in operating activities during the year ended December 31, 2022. The reduction in cash used in operating activities was primarily a result of inventory purchases in 2022 and the management of operating expenses in 2023.

Investing Activities

Net cash provided by investing activities was $16,138 for the year ended December 31, 2023, as compared to $4,990,054 for the year ended December 31, 2022.

Financing Activities

Net cash used in financing activities was $5,192,097 for the year ended December 31, 2023 and consisted of the repayment in full to the holders of the Preferred Stock of $5,250,000, offset by $57,903 of proceeds from the exercise of warrants. Net cash provided by financing activities was $14,268,321 for the year ended December 31, 2022 and consisted of the sale of common stock with net proceeds of $8,834,899, the sale of preferred stock with net proceeds of $4,308,415 and warrant exercises with proceeds of approximately $1,134,040.

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

Executives

On May 27, 2023, the Board of Directors accepted the resignation of Bret Scholtes, the Company's President and Chief Executive Officer, effective as of June 9, 2023. Mr. Scholtes also resigned from the Board, effective as of June 10, 2023. In connection with Mr. Scholtes' resignation from the Board, the Board of Directors approved a reduction in the size of the Board to four directors.

On June 19, 2023, the Board of Directors appointed Jan Hall as the Company's President and Chief Executive Officer, replacing Mr. Scholtes. The Company and Ms. Hall entered into an employment agreement pursuant to which Ms. Halls' annual base salary is $370,000 and provides that Ms. Hall shall have an annual target cash bonus of no less than her base salary based on performance objectives determined by the Compensation Committee of the Board of Directors. With respect to the 2023 performance period, Ms. Hall's annual bonus will be equal to either (i) her full target bonus, prorated based on a period commencing on June 19, 2023, or (ii) in the event there is a change in control of the Company that is consummated on or before March 31, 2024, $200,000, subject to remaining employed through the payment of her bonus (which may be up to 90 days following the change in control), compliance with her restrictive covenants, her execution and non-revocation of a general release of claims against the Company, and if requested, entering into any offer letter, restrictive covenant agreement and/or employment agreement with the buyer after being offered an opportunity to negotiate such agreements in good faith; provided, however, that in no event will she be entitled to both payments with respect to the 2023 performance period. In the event the Company terminates Ms. Hall's employment without cause, she resigns for good reason or her employment is terminated by the Company following a change in control of the Company, subject to executing and not revoking a general release of claims against the Company and complying with her restrictive covenants, she will be entitled to (a) nine months of salary continuation, which is to be increased to twelve months if the qualifying termination of her employment occurs on or after June 19, 2024; (b) any unpaid annual bonus for the year prior to the year in which the termination of her employment occurs; (c) a prorated bonus for the year in which the termination of her employment occurs, based on actual performance; and (d) any salary earned and vested benefits accrued prior to Ms. Hall's termination of employment.

On July 25, 2023, Jeffrey Benjamin, the Chief Accounting Officer and the Principal Financial Officer of the Company, provided the Company with notice of his resignation from his position as Chief Accounting Officer, which became effective July 25, 2023, and as an employee of the Company effective as of August 4, 2023.

On July 25, 2023, the Board of Directors approved the appointment of Katie Cox to replace Jeffrey Benjamin as the Company's Chief Accounting Officer at an annual base salary of $225,000. Ms. Cox will also be eligible to participate in the Company's benefit programs as may be offered from time to time to other similarly situated employees. Prior to her appointment as Chief Accounting Officer, Ms. Cox served as the Company's Head of Financial Planning and Analysis since June 2022. On May 18, 2023, Ms. Cox entered into a Retention Agreement with the Company, pursuant to which Ms. Cox will be entitled to receive a bonus of $50,000, which will be paid to Ms. Cox within 30 days immediately following a Change of Control Transaction (as such term is defined in the Retention Agreement). In addition, and subject to the satisfaction of certain conditions set forth in the Retention Agreement, in the event that a Change of Control Transaction is not consummated prior to December 31, 2023, Ms. Cox will be eligible to receive a retention bonus of $50,000, which if not otherwise forfeited, will be paid on December 31, 2023. Pursuant to the Retention Agreement, in the event that the Company terminates Ms. Cox's employment without Cause (as such term is defined in the Retention Agreement), the Company shall continue to pay her Base Salary for a period of 6 months thereafter.

On June 1, 2023, the Company entered into a Bonus Agreement with its Chief Commercial Officer, Craig Sheehan. Pursuant to the 2023 Bonus Agreement, Mr. Sheehan will be eligible to receive a bonus of up to $200,000 during 2023. Mr. Sheehan will be paid the first tranche of the 2023 Bonus in the amount of $50,000 on July 15, 2023 and will be paid the remaining portion of the 2023 Bonus on the earlier of December 31, 2023 or within thirty days following the closing date of a change in control of the Company, or a sale of the Company's Viactiv brand and/or Activ Nutritional, LLC, a wholly-owned subsidiary of the Company, provided, in each case, that he (i) remains employed as a full-time employee of the Company and in good standing through the applicable payment (unless the Company terminates his employment without cause prior to such date), and (ii) has satisfied all of the terms of the 2023 Bonus Agreement and his employment agreement with the Company dated June 1, 2021.

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 Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

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, 2023, our disclosure controls and procedures were effective

We had previously determined that as of December 31, 2022, our disclosure controls and procedures were not effective due to a material weakness in our internal control over financial reporting as described below.

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:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

(2) 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

(3) 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, 2023.

Material Weakness in the Company's Internal Control over Financial Reporting as of December 31, 2022:

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Subsequent to filing our Form 10-Q for the third quarter ended September 30, 2022 and as a result of additional analysis performed in preparation for the December 31, 2022 audit, management became aware that the Company did not maintain effective controls over the preparation and review of accounting for complex financial transactions, mainly due to the lack of adequate technical expertise to ensure the proper application, at inception, of ASC 815-15 *Embedded Derivatives* related to certain stock warrants issued in the quarterly period ended March 31, 2022, and the subsequent impact on the quarterly periods ended June 30, 2022, and September 30, 2022. This resulted in an error in our interim consolidated quarterly financial statements as originally reported in our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2022, June 30, 2022, and September 30, 2022, which in turn required a restatement of our interim consolidated financial data for those periods within the Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Management determined that this control deficiency constituted a material weakness in internal control over financial reporting as of March 31, 2022, June 30, 2022, and September 30, 2022.

Remediation of Material Weakness

During the year ended December 31, 2023, management designed and implemented the following measures to remediate the material weakness related to the identification and accounting for complex financial transactions, mainly due to the lack of adequate technical expertise to ensure proper application, as described in the preceding paragraph. As part of the remediation process, the Company established a policy to engage a qualified accounting consultant to review and analyze the financial impact for complex financial transactions on a quarterly basis, or when any significant unusual transaction has been entered into, to determine the proper accounting treatment with respect to the Company's financial statements.

The associated controls related to the mitigation of the material weakness described above have been in operation for a sufficient period of time for management to be able to conclude that these controls are operating effectively. Accordingly, as of December 31, 2023, management believes that the measures designed and implemented during the year ended December 31, 2023 with respect to the identification and accounting for complex financial transactions are effective, which were applied with respect to the preparation of the interim financial statements included in Quarterly Reports on Form 10-Q prepared and filed during 2023, are effective, and that the material weakness is considered fully remediated.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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.

(d) Changes in Internal Control over Financial Reporting. There were no other 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 will be disclosed in an amendment to this Form 10-K that will be filed on or before April 30, 2024.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be disclosed in an amendment to this Form 10-K that will be filed on or before April 30, 2024.

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

The information required by this item will be disclosed in an amendment to this Form 10-K that will be filed on or before April 30, 2024.

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

The information required by this item will be disclosed in an amendment to this Form 10-K that will be filed on or before April 30, 2024.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be disclosed in an amendment to this Form 10-K that will be filed on or before April 30, 2024.

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
Index

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, 2023 and 2022, 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, 2023 and 2022, 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 28, 2024

Guardion Health Sciences, Inc.
Consolidated Balance Sheets

	December 31,	
	2023	**2022**
Assets		
Current assets		
Cash and cash equivalents	$ 6,359,646	$ 10,655,490
Restricted cash	-	5,250,000
Accounts receivable, net	2,274,394	1,924,353
Inventories	2,677,112	3,119,421
Prepaid expenses and other current assets	573,780	687,933
Total current assets	**11,884,932**	**21,637,197**
Property and equipment, net	33,245	48,871
Total assets	**$ 11,918,177**	**$ 21,686,068**
Liabilities, Redeemable Preferred Stock, and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 614,122	$ 1,518,052
Accrued expenses	704,912	558,287
Operating lease liability - current	-	3,807
Warrant derivative liability – current	-	1,931,400
Total current liabilities	**1,319,034**	**4,011,546**
Warrant derivative liability – long-term	2,453,100	4,506,600
Total liabilities	**3,772,134**	**8,518,146**
Commitments and contingencies		
Redeemable preferred stock		
Series C convertible redeemable preferred stock, 495,000 shares issued and outstanding at December 31, 2022	-	5,197,500
Series D redeemable preferred stock, 5,000 shares issued and outstanding at December 31, 2022	-	52,500
Total redeemable preferred stock	-	5,250,000
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized		
Common stock, $0.001 par value; 250,000,000 shares authorized; 1,275,239 shares and 1,267,340 shares issued and outstanding on December 31, 2023 and 2022, respectively	1,275	1,267
Additional paid-in capital	101,711,035	101,640,955
Accumulated deficit	(93,566,267)	(93,724,300)
Total stockholders' equity	**8,146,043**	**7,917,922**
Total liabilities, redeemable preferred stock, and stockholders' equity	**$ 11,918,177**	**$ 21,686,068**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Consolidated Statements of Operations

	December 31,	
	2023	**2022**
Revenue		
Nutritional supplements	$ 11,907,867	$ 10,640,119
Ocular products	340,683	409,653
Total revenue	12,248,550	11,049,772
Cost of goods sold		
Nutritional supplements	6,594,082	6,171,641
Ocular products	259,951	357,744
Total cost of goods sold	6,854,033	6,529,385
Gross profit	5,394,517	4,520,387
Operating expenses		
Research and development	150,684	193,800
Sales and marketing	1,704,680	2,069,660
General and administrative	7,480,925	9,577,987
Transaction costs related to pending disposition of business	394,546	-
Impairment of intangible assets	-	10,065,833
Impairment of right-of-use asset	-	24,257
Loss on disposal of fixed assets	-	9,448
Total operating expenses	9,730,834	21,940,985
Loss from operations	(4,336,317)	(17,420,598)
Other income (expense):		
Change in fair value of warrant derivative liability	3,984,900	2,345,800
Gain on disposal of VectorVision subsidiary	129,930	-
Interest income, net	379,520	152,570
Total other income (expense)	4,494,350	2,498,370
Net income (loss)	**158,033**	**(14,922,228)**
Preferred stock deemed dividend	-	941,585
Net income (loss) available to common stockholders	$ 158,033	$ (15,863,813)
Net income (loss) per common share – basic and diluted	$ 0.12	$ (14.15)
Weighted average common shares outstanding – basic and diluted	1,270,846	1,121,000

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, 2021	488,539	$ 489	$ 101,099,383	$ (78,802,072)	$ 22,297,800
Common stock issued for cash, net of offering costs	651,000	651	8,834,247	-	8,834,898
Recognition of fair value of warrant derivative liabilities issued in connection with issuance of common stock	-	-	(8,783,800)	-	(8,783,800)
Common stock issued upon exercise of warrants	89,000	89	1,133,951	-	1,134,040
Preferred stock deemed dividend	-	-	(941,585)		(941,585)
Fair value of vested stock options	-	-	225,564	-	225,564
Issuance of common stock for services	-	-	82,266	-	82,266
Issuance of common stock – vested restricted stock units	4,220	4	(4)	-	-
Repurchase of common stock to cover income tax withholding on vested restricted stock units	(743)	(1)	(9,032)	-	(9,033)
Shares issued in connection with reverse split due to rounding	35,324	35	(35)	-	-
Net Loss	-	-	-	(14,922,228)	(14,922,228)
Balance at December 31, 2022	1,267,340	1,267	101,640,955	(93,724,300)	7,917,922
Fair value of vested stock options	-	-	(2,921)	-	(2,921)
Fair value of vested restricted stock	250	-	15,105	-	15,105
Common stock issued upon exercise of warrants	7,649	8	57,895	-	57,903
Net Income	-	-	-	158,033	158,033
Balance at December 31, 2023	1,275,239	$ 1,275	$ 101,711,035	$ (93,566,267)	$ 8,146,043

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Consolidated Statements of Cash Flows

	December 31,	
	2023	**2022**
Operating Activities		
Net income (loss)	$ 158,033	$ (14,922,228)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	19,418	1,248,789
Gain on disposal of VectorVision subsidiary	(129,930)	
Impairment of intangible assets	-	10,065,833
Loss on lease termination, net	-	24,257
Loss on disposal of property and equipment	-	9,448
Allowance for accounts receivable	1,840	1,996
Inventory write-down	126,650	55,609
Fair value of vested stock options	(2,921)	225,564
Fair value of common stock issued for services	15,105	82,266
Change in fair value of warrant derivative liability	(3,984,900)	(2,345,800)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Accounts receivable	(351,880)	(94,286)
Inventories	315,659	(2,807,339)
Prepaid expenses and other	114,153	91,946
Increase (decrease) in:		
Accounts payable	(903,930)	1,276,545
Accrued expenses	256,625	(337,190)
Operating lease liability	(3,807)	(22,222)
Net cash used in operating activities	(4,369,885)	(7,446,812)
Investing Activities		
Purchase of property and equipment	(3,792)	(5,569)
Net proceeds from disposal of VectorVision subsidiary	19,930	
Purchase of U.S. Treasury Bills	-	(77,591,741)
Sale of U.S. Treasury Bills	-	82,587,364
Net cash provided by investing activities	16,138	4,990,054
Financing Activities		
Proceeds from sale of common stock, net	-	8,834,899
Proceeds from sale of preferred stock, net	-	4,308,415
Proceeds from exercise of warrants	57,903	1,134,040
Repurchase of common stock to cover tax withholding on restricted stock units	-	(9,033)
Redemption of preferred stock	(5,250,000)	-
Net cash provided by (used in) financing activities	(5,192,097)	14,268,321
Cash and cash equivalents and restricted cash:		
Net increase (decrease)	(9,545,844)	11,811,563
Balance at beginning of period	15,905,490	4,093,927
Balance at end of period	$ 6,359,646	$ 15,905,490
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash financing activities:		
Settlement of liabilities related to sale of VectorVision subsidiary	$ 110,000	$
Recognition of initial warrant derivative liability	$ -	$ 8,783,800

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

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, 2023, the Company recorded a decrease in cash of $9,545,844, comprised primarily of cash used in operating activities of $4,369,885 and cash used in financing activities of $5,192,097. The Company's management evaluated whether there are conditions or events considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued.

Notwithstanding the decrease in cash for 2023, management concluded that the Company will have adequate unrestricted cash available from the Company's cash and cash equivalents balance of $6,359,646 at December 31, 2023, so that it is probable that the Company will be able to fund its current operating plan and meet all of its obligations due within one year from the date that the Company's 2023 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), and the successful development and commercialization of any new products or product lines.

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.

The continuing impact of the actions by the Federal Reserve to address inflation, most notably increases in interest rates, rising energy prices and increasing labor costs create uncertainty about the future economic environment which will continue to evolve and, we believe, has impacted the Company's business in 2023 and will continue to impact business in 2024. The implications of higher government deficits and debt, tighter monetary policy, and potentially higher long-term interest rates may drive a higher cost of capital for the business.

Nasdaq Listing and Reverse Stock Splits

The Company's common stock is traded on the Nasdaq Capital Market ("Nasdaq") under the symbol "GHSI".

On March 1, 2021, the Company effectuated a 1-for-6 reverse split of its outstanding shares of common stock. Subsequently, on January 6, 2023, the Company effectuated a 1-for-50 reverse split of its outstanding shares of common stock. The Company effected these reverse stock splits to remain in compliance with the $1.00 minimum bid price requirement of Nasdaq. However, there can be no assurances that the Company will be able to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq over time, or that it will be successful in maintaining compliance with any of the other continued listing requirements of Nasdaq.

The authorized number of shares of common stock and the par value per share were not affected by these reverse stock splits, and no fractional shares were issued in connection with these reverse stock splits.

All common shares, stock options, stock warrants and per share amounts presented herein have been adjusted retroactively to reflect the reverse stock splits for all periods presented.

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").

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Activ Nutritionals, Inc., and NutriGuard Formulations, Inc., All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's 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 realizability of deferred tax assets and the related valuation allowance, 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 Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers.

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.

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

In certain circumstances, returns of products are allowed. Due to the insignificant amount of historical returns, the stand-alone nature of our products, and our assessment of performance obligations and transaction pricing for our sales contracts the Company does not currently maintain a contract asset or liability balance for obligations. The Company assesses its contracts and the reasonableness of our conclusions on a quarterly basis.

Revenue by product:

	December 31,	
	2023	**2022**
Nutritional supplements	$ 11,907,867	$ 10,640,119
Ocular products	340,683	390,934
Other	-	18,719
	$ 12,248,550	$ 11,049,772

The Company's revenues during the years ended December 31, 2023 and 2022 are derived primarily from retail customers in North America.

Revenues by geographical areas:

	December 31,	
	2023	2022
North America	$ 12,248,550	$ 11,030,873
Europe and Other	-	18,899
	$ 12,248,550	$ 11,049,772

Third-Party Outsourcing

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. Substantially all the Company's products are shipped through the third-party fulfillment center to the customer. 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.

The Company outsources the production of substantially all its products with a third-party that manufactures and packages the finished products under a product supply agreement.

Costs incurred related to third-party outsourcing, which includes manufacturing, order processing and fulfillment, customer invoicing, collections and warehousing, were $7,135,910 and $9,135,351 for the years ended December 31, 2023 and 2022, respectively.

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.

Shipping Costs

Shipping costs associated with product distribution after manufacture are included as part of cost of goods sold. Shipping and handling expense totaled $537,887 and $802,958 for the years ended December 31, 2023 and 2022, respectively.

Cash and cash equivalents

Cash and cash equivalents consist of funds deposited with BMO Harris Bank ("BMO"), a major established high quality financial institution in short-term (original maturity of generally 60 days or less) liquid investments in money market deposit accounts. Cash equivalents are classified as Level 1 in the GAAP valuation hierarchy and are valued using the net asset value ("NAV") per share of the money market fund. The Company has an overnight investment feature established with BMO whereby the Company's cash is swept into a Money Market Mutual Fund managed by Goldman Sachs Asset Management. This fund invests solely in high quality U.S. government issued securities. As of December 31, 2023, $6,359,646 included in cash and cash equivalents was held in the Goldman Sachs Financial Square Government Institutional Fund, a fund that is not insured by the Federal Deposit Insurance Corporation (the "FDIC").

The Company's policy is to maintain its cash balances with financial institutions with high credit ratings and in accounts insured by the FDIC and/or the Securities Investor Protection Corporation (the "SIPC"). The Company periodically has cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of $250,000 and $500,000, respectively. 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 institution that holds such cash balances. The Company has not experienced any losses to date resulting from this policy.

Restricted Cash

At December 31, 2022, $5,250,000 is held in escrow to fund the redemption of the Company's redeemable Preferred Stock (See Note 8). The holders of the Preferred Stock had a period of 90 days from the date the shares were issued in November 2022 to redeem them. All of the shares were redeemed and all investors were paid in full as of February 2023.

Accounts Receivable

Accounts receivable are recorded at the invoiced amounts. Management evaluates the collectability of its trade accounts receivable and determines an allowance for potential credit losses 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, 2023 and 2022, the allowance for potential credit losses was $1,840 and $1,996, respectively.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. At each balance sheet date, the Company evaluates its inventories for estimated obsolescence or diminution in 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 be written up. For the years ended December 31, 2023 and 2022, the Company wrote-down inventories by $126,650 and $55,609, respectively, which was recorded in cost of sales (see Note 3).

Property and Equipment

Property and equipment, net are stated at historical cost less accumulated depreciation and amortization. Additions, and improvements, that substantially extend the useful life of an asset are capitalized, while expenditures for repairs and maintenance 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, 2023 and 2022, management determined there were no impairments of the Company's property and equipment.

Intangible Assets

At December 31, 2022, the Company's intangible assets consisted of amortizable finite-lived identifiable trade name, customer relationships, and indefinite lived trademark. 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, 2022, management, with the assistance of a third-party valuation expert, performed an impairment analysis of the Company's intangible assets, and concluded that the fair value of the intangible assets was less than carrying value, and recorded an impairment loss of $10,065,833 (see Note 5).

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.

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. As of December 31, 2023, the Company did not have any lease obligations.

Redeemable Preferred Stock

Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

Accounting for Warrants

The Company evaluates all of its financial instruments, including issued warrants, to determine if such instruments are liability classified, pursuant to ASC 480, Distinguishing Liabilities from Equity ("ASC 480") or derivatives or contain features that qualify as embedded derivatives pursuant to ASC 815, Derivatives and Hedging ("ASC 815"). The classification of instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

The Company determined that the warrants issued in connection with the February 2022 securities offering do not meet the criteria for equity classification and must be recorded as liabilities. Liability classified warrants are measured at fair value at inception and at each reporting date, with changes in fair value recognized in the statements of operations in the period of change.

Advertising Costs

Advertising costs are expensed as incurred and are included in sales and marketing expense. Advertising costs aggregated approximately $1,448,308 and $1,618,199 for the years ended December 31, 2023 and 2022, 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 $150,684 and $193,800 for the years ended December 31, 2023 and 2022, respectively.

Patent Costs

The Company is the owner of four issued domestic patents, and five international patents, one granted in Canada, one granted in China, one pending patent application in Hong Kong, two granted patents in Japan and one granted patent in South Korea. 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, 2023 and 2022, patent costs were approximately $50,684 and $61,246, 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,	
	2023	**2022**
Warrants	786,701	1,526,701
Options	20,577	13,294
Unvested restricted common stock	334	667
	807,612	1,540,662

Fair Value of Financial Instruments

Accounting standards require certain assets and liabilities to be reported at fair value in 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, 2023 and 2022:

	December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets	$ -	$ -	$ -	$ -
Total assets	$ -	$ -	$ -	$ -
Liabilities				
Warrant derivative liability	$ -	$ -	$ 2,453,100	$ 2,453,100
Total liabilities	$ -	$ -	$ 2,453,100	$ 2,453,100

	December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Total assets	$ -	$ -	$ -	$ -
	$ -	$ -	$ -	$ -
Liabilities	$ -	$ -	$ -	$ -
Warrant derivative liability	-	-	6,438,000	$ 6,438,000
Total liabilities	$ -	$ -	$ 6,438,000	$ 6,438,000

The change in Level 3 liabilities measured at fair value for the years ended December 31, 2023 and 2022 were as follows:

Warrant derivative liability

Balance - December 31, 2021	$ -
Fair value of warrant derivative liability recognized upon issuance of warrants in February 2022	8,783,800
Change in fair value of warrant derivative liability	(2,345,800)
Balance - December 31, 2022	6,438,000
Change in fair value of warrant derivative liability	(3,984,900)
Balance - December 31, 2023	$ 2,453,100

As of December 31, 2023, the Company's outstanding warrants were treated as derivative liabilities and changes in the fair value were recognized in the statement of operations. The estimated fair value of the warrants is determined using Level 3 inputs. Inherent in a binomial lattice model are assumptions related to expected probability of event occurrence, including stock splits, stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock underlying the warrants based on the historical trading volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the Company's historical rate, which the Company anticipates remaining at zero.

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.

Segment Information

Under ASC 280, Segment Reporting, operating segments are defined as components of an enterprise where discrete financial information is available that is evaluated regularly by the chief operating decision maker ("CODM"), in deciding how to allocate resources and in assessing performance. The Company's operation segment consists of one component, and the Company's Chief Executive Officer, who is also the CODM, makes decisions and manages the Company's operations as a single operating segment.

Concentrations

Revenue. During the year ended December 31, 2023, the Company had one customer that accounted for 50% of total revenue and one customer that accounted for 13% of total revenue. During the year ended December 31, 2022, the Company had one customer that accounted for 57% of total revenue. No other customer accounted for more than 10% of revenue for the years ending December 31, 2023 or 2022.

Accounts receivable. As of December 31, 2023, the Company had accounts receivable from one customer which comprised approximately 57% of its gross accounts receivable. As of December 31, 2022, the Company had accounts receivable from one customer, which comprised approximately 88% of its gross accounts receivable. One other customer accounted for approximately 18% of accounts receivable as of December 31, 2023. No other customer accounted for more than 10% of accounts receivable as of December 31, 2023 or 2022.

Purchases from vendors. During the years ended December 31, 2023 and 2022, the Company utilized one manufacturer for most of its production and packaging of its clinical nutrition products, with total purchases from this manufacturer accounted for approximately 50% and 48% of all purchases, respectively. One other vendor accounting for 12% of purchases during the year ended December 31, 2023; however, no other vendor accounted for more than 10% of purchases for the year ended December 31, 2023 or 2022.

Accounts payable. As of December 31, 2023, one vendor accounted for 91% of total accounts payable. As of December 31, 2022, one vendor accounted for 88% of total accounts payable. No other vendor accounted for more than 10% of accounts payable as of December 31, 2023 or 2022.

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 adopted ASU 2016-03 effective January 1, 2023, and there was no material impact on the Company's financial position, results of operations and cash flows.

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. The Company adopted ASU 2021-04 effective January 1, 2022. The adoption of ASU 2021-04 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

In July 2023, the FASB issued ASU 2023-03, Presentation of Financial Statements (Topic 205), Income Statement — Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation — Stock Compensation (Topic 718) Presentation of Financial Statements ("ASU 2023-03"). ASU 2023-03 amends the FASB Accounting Standards Codification to include Amendments to SEC Paragraphs pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and SEC Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 — General Revision of Regulation SX: Income or Loss Applicable to Common Stock. As ASU 2023-03 did not provide any new guidance, there was no transition or effective date associated with its adoption. Accordingly, the Company adopted ASU 2023-03 immediately upon its issuance. The adoption of ASU 2023-03 did not have any impact on the Company's consolidated financial statement presentation or related disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expense categories that are regularly provided to the chief operating decision maker and included in each reported measure of a segment's profit or loss. The update also requires all annual disclosures about a reportable segment's profit or loss and assets to be provided in interim periods and for entities with a single reportable segment to provide all the disclosures required by ASC 280, Segment Reporting, including the significant segment expense disclosures. This standard will be effective for the Company on January 1, 2024 and interim periods beginning in fiscal year 2025, with early adoption permitted. The updates required by this standard should be applied retrospectively to all periods presented in the financial statements. The Company does not expect this standard to have a material impact on its results of operations, financial position or cash flows.

Other recent accounting pronouncements and guidance 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. Inventories

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value and consisted of the following:

	December 31,	
	2023	**2022**
Raw materials	$ 35,404	$ 49,637
Finished products	2,641,708	3,069,784
Inventories	$ 2,677,112	$ 3,119,421

4. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2023	**2022**
Furniture and fixtures	111,670	110,016
Computer equipment and software	68,253	66,115
	179,923	176,131
Less accumulated depreciation and amortization	(146,678)	(127,260)
	$ 33,245	$ 48,871

For the years ended December 31, 2023 and 2022, depreciation expense was $19,418 and $58,789, respectively, and is included in general and administrative expense.

5. Intangible Assets, Net

As of and during the year ended December 31, 2023, the Company had no intangible asserts.

At December 31, 2022, the Company's intangible assets consisted of amortizable finite-lived identifiable trade name, customer relationships, and indefinite lived trademark. For the year ended December 31, 2022, amortization was $1,190,000, resulting in a balance of intangible assets, net of amortization, of $10,065,833 before an annual impairment analysis. On December 31, 2022, the Company performed an impairment analysis of its intangible assets and determined the asset group's fair value to be zero and therefore recorded an impairment loss of $10,065,833 for the balance of the intangible assets.

6. Operating Leases

The Company leases its corporate office space located in Houston, Texas, with lease payments of approximately $3,000 per month under a month-to-month 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.

During the years ended December 31, 2023 and 2022, lease expense totaled $38,139 and $48,911, respectively.

As of December 31, 2022, the Company also leased a warehouse space in Ohio under an operating lease that expired in February 2023. At December 31, 2022, the Company recorded an impairment of the operating lease right of use asset of $24,257. At December 31, 2022, the balance of the operating lease liability was $3,807, which was paid off in February 2023.

7. Warrant Derivative Liability

On February 18, 2022, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company issued and sold shares of the Company's common stock and warrants to purchase shares of the Company's common stock (the "February 2022 Offering") (see Note 9). Included in the February 2022 Offering were 740,000 common stock purchase warrants at an exercise price of $18.50 per share that expire on the fifth anniversary of the date of issuance (the "Series A Warrants") and 740,000 common stock purchase warrants at an exercise price of $18.50 per share that expire on the 18 month anniversary of the date of issuance (the "Series B Warrants"). The Series A Warrants expire in February 2027 and the Series B Warrants expired in August 2023.

The Series A Warrants and Series B Warrants contain certain anti-dilution provisions, including a down round provision. On November 29, 2022, the Company issued and sold shares of the Company's Series C Convertible Redeemable Preferred Stock and Series D Redeemable Preferred Stock (see Note 8). The shares of Series C Preferred Stock were convertible at a conversion price of $7.88 per share into shares of the Company's common stock. Therefore, the exercise price for the to Series A Warrants and the Series B Warrants was adjusted downward from $18.50 per share to $7.88 per share on November 30, 2022 to equal the Series C Convertible Redeemable Preferred Stock conversion price.

In addition, the Series A Warrants and Series B Warrants contained a provision which requires the exercise price of such warrants to be adjusted to the volume weighted average price of the Company's common stock for the five trading days immediately following effectiveness of a reverse stock split if such calculation results in an exercise price below the then-current exercise price. The Company determined that this provision represented a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40, and thus the Series A Warrants and the Series B Warrants are not considered indexed to the Company's own stock and not eligible for an exception from derivative accounting. In January 2023, in conjunction with the completion of the Company's reverse stock split (see Note 1), the exercise price of the Series A Warrants and the Series B Warrants was adjusted to $7.57 per share of common stock.

The Series A Warrants and the Series B Warrants were classified as a derivative liability, with an initial fair value of $8,783,800 recorded upon issuance in February 2022. During the year ended December 31, 2022, the fair value of the warrant liability decreased by $2,345,800, and at December 31, 2022, the fair value of the warrant liability was $6,438,000. During the year ended December 31, 2023, the fair value of the warrant liability decreased by $3,984,900, and at December 31, 2023, the fair value of the warrant liability was $2,453,100.

Changes in the fair value of the warrant liabilities, until they are either exercised or expire are recognized as other income (loss) in the Company's consolidated statements of operations.

Below are the specific assumptions utilized:

Series A Warrants

	December 31, 2023	December 31, 2022	February 18, 2022 (Date Issued)
Common stock market price	$ 5.34	$ 7.26	$ 8.95
Risk-free interest rate	4.10%	4.11%	1.89%
Expected dividend yield	-	-	-
Expected term (in years)	3.15	4.15	5.00
Expected volatility	97.60%	131.20%	142.30%
Fair value of warrant liability	$ 2,453,100	$ 4,506,600	$ 5,768,300

Series B Warrants

	August 24, 2023 (Date Expired)	December 31, 2022	February 18, 2022 (Date Issued)
Common stock market price	$ 7.47	$ 7.26	$ 8.95
Risk-free interest rate	-	4.75%	1.37%
Expected dividend yield	-	-	-
Expected term (in years)	-	0.65	1.50
Expected volatility	-	104.50%	123.20%
Fair value of warrant liability	$ -	$ 1,931,400	$ 3,015,500

During 2023, Series B Warrants were exercised into 7,649 shares of common stock were for cash proceeds of $57,903. The remainder of the 732,351 Series B Warrants expired on August 24, 2023. On the expiration date, the derivative liability related to the Series B Warrants was reduced to a fair value of zero, with such change being recorded as part of the change in fair value of the warrant derivative liability included in the statement of operations.

8. Redeemable Preferred Stock (Temporary Equity, redeemed February 2023)

On November 29, 2022, the Company issued and sold, in a private placement, 495,000 shares of the Company's Series C Convertible Redeemable Preferred Stock (the "Series C Preferred Stock"), and 5,000 shares of the Company's Series D Redeemable Preferred Stock (the "Series D Preferred Stock," and together with the Series C Preferred Stock, the "Preferred Stock"), at an offering price of $9.50 per share, representing a 5% original issue discount ("OID) to the stated value of $10.00 per share, for gross proceeds of $4,750,000, and net proceeds of $4,308,415 after the deduction of fees and offering expenses.

The holders of the Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares through February 27, 2023, which was 90 days from the issue date of the Preferred Stock. The Company has the option to redeem the Preferred Stock for cash at 105% of the stated value commencing after receipt of stockholder approval of the reverse stock split, subject to the rights of the holders of Series C Preferred Stock to convert their shares of Series C Preferred Stock into common stock prior to such redemption. The Company classified the Preferred Stock outside of permanent equity (as temporary equity within the mezzanine section between liabilities and equity on the consolidated balance sheets) since the redemption of such shares was not solely within the Company's control. At December 31, 2022, the Series C Preferred stock and Series D Preferred Stock had been recorded at their redemption values of $5,197,500 and $52,500, respectively, which represented an increase of $941,585 from their initial carrying value of $4,308,415. The increase in the carrying value to the redemption value was recorded as a deemed dividend on the consolidated statements of operations and consolidated statements of stockholders' equity.

The shares of Series C Preferred Stock were convertible, at a conversion price of $7.88 per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, at the option of the holders and, in certain circumstances, by the Company.

The Series C Preferred Stock had the right to vote on an amendment (the "Amendment") to the Company's Articles of Incorporation, as amended, to authorize a reverse split of the Common Stock on an as-converted to common stock basis. The shares of the Series D Preferred Stock were automatically voted in a manner that "mirrored" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that were not voted) and Series C Preferred Stock were voted on the Amendment. The Certificates of Designation for the Preferred Stock provided that the Preferred Stock had no voting rights other than the right to vote on the Amendment and as a class on certain other specified matters, and, with respect to the Series D Certificate of Designation, the right to cast 1,000,000 votes per share of Series D Preferred Stock on the reverse stock split proposal. The Amendment required the approval of the majority of the votes associated with the Company's outstanding stock entitled to vote on the proposal. On January 5, 2023, the Amendment to authorize a reverse split of the Common Stock was approved at a special meeting of shareholders. Following the meeting, the Board of Directors approved a one-for-fifty (1-for-50) reverse split of the Company's issued and outstanding shares of common stock (see Note 1).

As of December 31, 2022, the Series C and Series D preferred shares reflected on the balance sheet were reconciled as follows:

	Series C Preferred Stock	Series D Preferred Stock
Gross Proceeds	$ 4,702,500	$ 47,500
Less:		
Preferred stock issuance costs	(437,169)	(4,416)
Plus:		
Accretion of carrying value to redemption value	932,169	9,416
Preferred stock subject to possible redemption	$ 5,197,500	$ 52,500

At December 31, 2022, $4,750,000 in gross proceeds from the issuance of the Preferred Stock, plus $500,000 additional amount necessary to fund the 105% redemption price, was held in an escrow account and presented as restricted cash on the consolidated balance sheets. The Preferred Stock was redeemed in full as of February 8, 2023, and the escrow account was closed.

9. *Stockholders' Equity*

Common Stock

The Company's common stock has a par value of $.001. As of December 31, 2023 and 2022, there were 250,000,000 shares authorized, and 1,275,239 and 1,267,340 shares of common stock outstanding.

February 2022 Offering

On February 18, 2022, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company issued and sold, (i) 651,000 units, at $15.00 per unit, with each unit consisting of one share of the Company's common stock, one warrant to purchase one share of the Company's common stock at an exercise price of $18.50 per share that expires on the fifth anniversary of the date of issuance ("Series A Warrant") and one warrant to purchase one share of the Company's common stock at an exercise price of $18.50 per share that expires on the 18 month anniversary of the date of issuance ("Series B Warrant"), and (ii) 89,000 pre-funded units, at $14.995 per unit, with each unit consisting of one pre-funded warrant to purchase one share of the Company's common stock at an exercise price of $0.005 per share (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 (collectively, the "February 2022 Offering").

The exercise prices of the Series A Warrants and the Series B Warrants were subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock. In addition, in the event the Company effected a reverse stock split during the term of the Series A Warrants and the Series B Warrants, the exercise price of such warrants following such reverse split was be subject to further adjustment in the event the trading price of the Company's common stock following such reverse stock split was lower than the exercise price of such warrants. Also, subject to customary exceptions, the exercise price of the Series A Warrants and the Series B Warrants is subject to adjustment in the event of issuances of the Company's common stock or common stock equivalents at a price below the exercise price of the Series A Warrants and the Series B Warrants. In such event, the exercise price of the Series A Warrants and the Series B Warrants would be reduced to the price of the securities issued in such transactions. In the event of a fundamental transaction, such as a change-in-control transaction or sale of substantially all of the Company's assets, the holder of a warrant shall have the option, exercisable at any time concurrently with, or within 30 days after, the consummation of the fundamental transaction, to cause the Company to purchase such warrant from the holder for cash in an amount equal to the Black-Scholes option value of such warrant calculated in accordance with the terms of the warrant.

On February 18, 2022, the Company entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Roth Capital Partners LLC ("Roth") and Maxim Group LLC, as co agents (collectively, the "Agents"), pursuant to which the Company paid the Agents an aggregate fee equal to 7.0% of the gross proceeds from the units sold in the February 2022 Offering and reimbursed the Agents $100,000 for expenses incurred in connection with the February 2022 Offering. In addition, the Company issued warrants (the "Placement Agent Warrants") to Roth to purchase up to 37,000 shares of the Company's common stock exercisable at an exercise price of $7.57 per share. The Placement Agent Warrants were immediately exercisable and expire on the fifth anniversary of the date of the issuance.

On February 23, 2022, the Company closed the February 2022 Offering, and issued (i) 651,000 shares of common stock, (ii) Series A Warrants to purchase 740,000 shares of common stock, (iii) Series B Warrants to purchase 740,000 shares of common stock, and (iv) Pre-Funded Warrants to purchase 89,000 shares of common stock. The gross proceeds from the February 2022 Offering were $11,100,000 and the net proceeds, after deducting the placement agent fees and offering expenses payable by the Company, were approximately $9,969,000. Included in the net proceeds was approximately $1,134,000 from the exercise of the 89,000 Pre-Funded Warrants.

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, 2021	**9,701**	**$ 120.00**	**2.71**
Granted	1,606,000	7.57	2.40
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	(89,000)	-	-
December 31, 2022	**1,526,701**	**8.67**	**2.39**
Granted	-	-	-
Forfeitures	-	-	-
Expirations	(732,351)	7.57	-
Exercised	(7,649)	-	-
December 31, 2023, all exercisable	**786,701**	**$ 8.96**	**3.12**

The exercise prices of warrants outstanding and exercisable as of December 31, 2023 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
777,000	$ 7.57
9,701	120.00
786,701	

During the year ended December 31, 2023, investors exercised 7,649 Series B Warrants at $7.57 per share and received 7,649 shares of common stock, reflecting total cash proceeds of $57,903. In addition, the remaining 732,351 Series B Warrants expired on August 24, 2023.

During the year ended December 31, 2022, investors exercised warrants exercisable at $15.00 per share into 89,000 shares of common stock for total proceeds of approximately $1,334,555.

As of December 31, 2023, the aggregate intrinsic value of warrants outstanding as of December 31, 2023 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, 2021	**17,062**	**$ 317.00**	**6.50**
Granted	1,333	7.50	9.50
Forfeitures	(2,014)	-	-
Expirations	(3,087)	-	-
Exercised	-	-	-
December 31, 2022	**13,294**	**217.05**	**6.80**
Granted	11,336	6.22	8.80
Forfeitures	(595)	197.70	-
Expirations	(3,458)	-	-
Exercised	-	-	-
December 31, 2023, outstanding	**20,577**	**$ 77.72**	**7.60**
December 31, 2023, exercisable	**11,735**	**$ 129.48**	**6.80**

The exercise prices of options outstanding and exercisable as of December 31, 2023 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
10,000	2,500	$ 6.01
1,344	1,344	7.35
1,344	336	7.78
841	841	45.50
1,002	668	80.50
1,008	1,008	88.00
840	840	116.70
336	336	162.33
3,862	3,862	300.00
20,577	**11,735**	

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 years ended December 31, 2023 and 2022, the Company granted options to purchase an aggregate of 1,336 and 1,333 shares, respectively, of common stock to the independent members of the Company's Board of Directors in connection with the compensation plan for such directors, with a grant date fair values of $8,454 and $7,793, respectively, using a Black-Scholes option pricing model based on the following assumptions: (i) a volatility rate of 146% and 146%, respectively, (ii) a discount rate of 3.81% and 3.35%, respectively, (iii) zero expected dividend yield, and (iv) an expected life of 3 years. The options have an exercise price of $7.78 and $7.35 per share, respectively. The options vest on a quarterly basis over two years from the grant date, with the first tranche vesting on September 30, 2023.

During the year ended December 31, 2023, the Company granted options to purchase 10,000 shares of common stock to the Company's new Chief Executive Officer ("CEO") with a grant date fair value of $65,000 using a Black-Scholes option-pricing model based on the following assumptions: (i) a volatility rate of 146%, (ii) a discount rate of 3.80%, (iii) zero expected dividend yield, and (iv) an expected life of 6 years. The options vest on a quarterly basis over two years from issuance, with the first tranche vesting on September 30, 2023.

The Company's former Chief Executive Officer resigned effective June 9, 2023. All options issued to the former Chief Executive Officer that were not vested at the time of resignation were forfeited. Compensation expense previously recorded related to the unvested options was reversed, resulting in a reduction of stock compensation expense of $92,412 during the year ended December 31, 2023.

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, 2023 and 2022, the Company recognized aggregate stock-compensation expense of $(2,920) and $226,000, respectively, related to the fair value of vested options, net of the impact of forfeitures.

As of December 31, 2023, the Company had an aggregate of 8,842 remaining unvested options outstanding, with a remaining fair value of approximately $136,000 to be amortized over an average of 4.75 years, a weighted average exercise price of $9.03, and a weighted average remaining life of 4.9 years. Based on the closing price of the Company's common stock on December 29, 2023 (the last trading day of the year) of $5.34, the aggregate intrinsic value of options outstanding as of December 31, 2023 was zero.

Restricted Common Stock

Under the Company's 2018 Equity Incentive Plan, a total of 200,000 shares of the Company's common stock are available for grant to employees, directors, and consultants of the Company. No shares were issued under the plan during the year ended December 31, 2023. During the year ended December 31, 2022, the Company issued 1,000 shares of the Company's common stock under the plan, and at December 31, 2023, there was a balance of 183,655 shares available for grant.

The total fair value of the 1,000 shares was determined to be approximately $80,500 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, 2023, total share-based expense recognized related to vested restricted shares totaled approximately $15,000. At December 31, 2023, there was approximately $4,000 of unvested compensation related to these awards that will be amortized over a remaining vesting period of 0.50 years.

The following table summarizes restricted common stock activity for the year ended December 31, 2023:

	Number of Shares	Fair value per share
Non-vested shares, December 31, 2022	**667**	**$ 80.50**
Granted		
Vested	(333)	80.50
Forfeited		
Non-vested shares, December 31, 2023	**334**	**$ 80.50**

10. Income Taxes

No federal tax provision has been provided for the years ended December 31, 2023 and 2022 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, 2023 and 2022:

	Years Ended December 31,	
	2023	2022
U. S. federal statutory tax rate	(21.0)%	(21.0)%
State, net of federal benefit	1.52%	(0.65)%
Non-deductible expenses	(1.17)%	-%
	(20.65)%	(21.65)%
Valuation allowance	20.65%	21.65%
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, 2023 and 2022 are summarized below.

	December 31,	
	2023	2022
Deferred tax assets		
Net operating loss carryforwards	$ 11,792,000	$ 10,594,000
Stock-based compensation	1,485,000	1,485,000
Accrued expenses	55,000	17,000
Charitable contributions	4,000	4,000
Inventory reserves	2,000	7,000
Intangibles	5,022,000	4,949,000
Valuation allowance	(16,972,000)	(16,546,000)
Total deferred tax assets	1,388,000	510,000
Deferred tax liabilities		
Unrealized gains/losses	(1,381,000)	(490,000)
Allowance for doubtful accounts	-	-
Operating lease right of use asset	-	-
Research and development credit	-	(10,000)
Depreciation	(7,000)	(10,000)
Total deferred tax liabilities	(1,388,000)	(510,000)
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, 2023, 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, 2023, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $48,310,000 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, 2023 and 2022 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, 2023, 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.

11. Sale of VectorVision

On November 30, 2023, the Company sold all the outstanding capital stock of its wholly-owned subsidiary VectorVision Ocular Health, Inc. ("VectorVision"), to David Evans for $25,000 and recorded a gain of $129,930. The Company acquired VectorVision, which specialized in visual acuity testing, from David Evans in 2017, and had previously terminated the operations of VectorVision as of December 31, 2021. David Evans was a director of the Company from September 2017 through June 2022.

12. 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, 2023 and 2022 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.

On May 27, 2023, the Board of Directors accepted the resignation of Bret Scholtes, the Company's President and Chief Executive Officer, effective as of June 9, 2023. Mr. Scholtes also resigned from the Board of Directors, effective as of June 10, 2023. In connection with Mr. Scholtes' resignation from the Board of Directors, the Board of Directors approved a reduction in the size of the Board of Directors to four directors.

On June 19, 2023, the Board of Directors appointed Jan Hall as the Company's President and Chief Executive Officer, replacing Mr. Scholtes. The Company and Ms. Hall entered into an employment agreement pursuant to which Ms. Halls' annual base salary was $370,000. The employment agreement provides that Ms. Hall shall have an annual target cash bonus of no less than her base salary based on performance objectives determined by the Compensation Committee of the Board of Directors.

During the year ended December 31, 2023, two executives were paid bonuses, consisting of $200,000 to Craig Sheehan, Chief Operations Officer and $50,000 to Katie Cox, Chief Accounting Officer as retention bonuses in the event of a sale of the Company's Activ Nutritional LLC subsidiary, which owns the Viactiv brand and business.

Subsequent Event

Pending Disposition

On January 30, 2024, the Company, Viactiv Nutritionals, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Viactiv"), and Activ Nutritional LLC, a Delaware limited liability corporation, which is wholly-owned by Viactiv ("Activ"), entered into an Equity Purchase Agreement (the "Agreement") with Doctor's Best Inc., a Delaware corporation ("Doctor's Best"), on the other hand. Pursuant to the Agreement, Doctor's Best agreed to acquire all of the outstanding equity interests of Activ from Viactiv (the "Transaction") for aggregate cash consideration to the Company of $17,200,000 (the "Base Purchase Price"), with $1,700,000 of the Base Purchase Price being placed in a third-party escrow account pursuant to the terms of the Agreement, and the Base Purchase Price being subject to adjustment as provided in the Agreement based upon the working capital of Activ at the time of closing (the "Closing"). Doctor's Best is a wholly-owned subsidiary of Kingdomway USA Corp. ("Kingdomway"), the U.S. subsidiary holding company of Xiamen Kingdomway Group Company ("XKDW"), which is listed on the Shenzhen Stock Exchange.

The Agreement contains customary representations, warranties and covenants regarding the parties thereto. The Closing is subject to the satisfaction or waiver of certain customary closing conditions, including, but not limited to, the approval of the transaction by the requisite vote of the Company's stockholders. The Agreement also contains customary termination provisions and mutual indemnification obligations.

The Series A Warrant agreement (see Note 7) contains a cash settlement provision whereby the holders of the warrants can elect to settle the warrants for cash based on the Black-Scholes value of the warrant, upon the occurrence of certain fundamental transactions, as defined, such as a change of control, or the sale or disposition of all or substantially all of the Company's assets. Management believes that the pending disposition described above, if consummated, would meet the definition of a fundamental transaction and would result in the Company being acquired to purchase the Series A Warrants from the holders by cash payment equal to the Black-Scholes value of the Series A warrants.

Management currently estimates that the liability to the Company associated with these warrants based on information currently available to the Company is approximately $5,100,000. That amount could increase or decrease based on a number of factors that are outside the control of the Company. Such factors include, among others, the trading and price volatility of the Company's common stock, the number of warrant holders that may elect to exercise their warrants in accordance with their terms prior to the closing of the Transaction and forego their put rights, and the number of warrant holders that exercise their put rights in accordance with the terms of the warrants. To the extent that this obligation is triggered and exercised by the warrant holders, the Company would need to make such payments out of the its available cash and/or the Transaction proceeds, and any such payments will reduce the amount each Company stockholder would be able to receive from any liquidating distributions.

In the event that the Company's stockholders approve transaction and the transaction closes, the Company would be left with minimal operations. The Board of Directors has determined that it is advisable and in the best interests of the Company and the its stockholders to approve a voluntary dissolution and liquidation of the Company pursuant to a Plan of Liquidation and Dissolution, which, if approved, would authorize the Company to liquidate and dissolve in accordance with its terms, but such decision would be subject to the Company's ability to abandon or delay the Plan of Dissolution in the event that the Board of Directors determines that another transaction would be in the best interests of the Company's stockholders. Assuming the approval of the Plan of Liquidation and Dissolution by the Company's stockholders, the decision of whether or not to proceed with the dissolution and when to file the Certificate of Dissolution will be made by the Board of Directors in its sole discretion.

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)
3.6	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on January 6, 2023)
3.7	Certificate of Designation of Series C Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 2, 2022)
3.8	Certificate of Designation of Series D Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on December 2, 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 10.1 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)
10.14+	Amendment to the 2018 Equity Incentive Plan (incorporated by reference to Appendix A of the Company's definitive proxy statement on Schedule 14A filed with the SEC on April 21, 2022)
10.15	Form of Securities Purchase Agreement dated November 29, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 2, 2022)
10.16	Form of Registration Rights Agreement dated November 29, 2022 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on December 2, 2022)
10.17	Form of Side Letter dated November 29, 2022 (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on December 2, 2022)
10.18+	Employment Agreement by and between the Company and Janet Hall dated May 28, 2023 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 30, 2023)
10.19+	Bonus Agreement by and between the Company and Craig Sheehan dated June 1, 2023 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 5, 2023)
10.20+	Retention Agreement dated as of May 18, 2023 by and between Guardion Health Sciences, Inc. and Katherine Cox (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on July 31, 2023)
10.21+	Employment Agreement dated as of September 21, 2023 by and between Guardion Health Sciences, Inc. and Katie Cox (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 26, 2023)
10.22	Equity Purchase Agreement by and among Doctor's Best Inc., Activ Nutritional, LLC, Viactiv Nutritionals, Inc. and Guardion Health Sciences, Inc. dated as of January 30, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 31, 2024)
21.1*	List of Subsidiaries
23.1*	Consent of Weinberg & Company, P.A.
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
97.1*	Guardion Health Sciences, Inc. Clawback Policy
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, 2023 is formatted in Inline XBRL

* Filed herewith
**Furnished 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 28th day of March 2024.

GUARDION HEALTH SCIENCES, INC.

/s/ Jan Hall
Jan Hall
President and 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/ Jan Hall Jan Hall	President and Chief Executive Officer (Principal Executive Officer)	March 28, 2024
/s/ Katie Cox Katie Cox	Chief Accounting Officer (Principal Financial and Accounting Officer)	March 28, 2024
/s/ Robert N. Weingarten Robert N. Weingarten	Chairman of the Board of Directors	March 28, 2024
/s/ Mark Goldstone Mark Goldstone	Director	March 28, 2024
/s/ Donald A. Gagliano Donald A. Gagliano	Director	March 28, 2024
/s/ Michaela Griggs Michaela Griggs	Director	March 28, 2024

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, 2023, 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. As of December 31, 2023, there were 1,275,239 shares of Common Stock issued and outstanding.

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 of 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
NutriGuard Formulations, Inc.	Delaware
Viactiv Nutritionals, Inc.	Delaware

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-231603 and No. 333-255077) of Guardion Health Sciences, Inc. of our report dated March 28, 2024, with respect to the consolidated financial statements of Guardion Health Sciences, Inc. as of December 31, 2023 and 2022, and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 28, 2024

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, Jan Hall, 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 28, 2024

/s/ Jan Hall
Jan Hall
President and 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, Katie Cox, 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 28, 2024

/s/ Katie Cox
Katie Cox
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, Jan Hall and Katie Cox, 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, 2023 (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 28, 2024

/s/ Jan Hall
Jan Hall
President and Chief Executive Officer
(Principal Executive Officer)

March 28, 2024

/s/ Katie Cox
Katie Cox
Chief Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

GUARDION HEALTH SCIENCES, INC.

COMPENSATION RECOUPMENT POLICY

I. Purpose and Scope

The Board believes that it is in the best interests of Guardion Health Sciences, Inc. (the "**Company**") and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this compensation recoupment policy (the "**Policy**"), which provides for the recovery of erroneously awarded incentive compensation from the Company's executive officers in the event of a Triggering Event (as defined below).

II. Administration

This Policy is designed to comply with Section 10D of the Exchange Act, Rule 10D-1, Nasdaq Listing Rule 5608and other regulations, rules and guidance of the Securities and Exchange Commission (the "**SEC**") thereunder, and related securities regulations and regulations of the stock exchange or association on which Company's common shares are listed. This Policy shall be administered by the Compensation Committee of the Board (the "**Committee**").

Any determinations made by the Committee shall be final and binding. In addition, the Company shall file all disclosures with respect to this Policy in accordance with Rule 10D of the Exchange Act and Rule 10D-1 promulgated by the SEC thereunder, including the disclosures required by the applicable SEC regulations, and with the disclosure required by any rules or standards adopted by the national securities exchange on which the Company's securities are listed. The Committee hereby has the power and authority to enforce the terms and conditions of this Policy and to use any and all of the Company's resources it deems appropriate to recoup any excess Incentive Compensation subject to this Policy.

III. Covered Executives

This Policy applies to the Company's current and former Covered Executives, as determined by the Committee in accordance with Section 10D of the Exchange Act, Rule 10D-1 promulgated by the SEC thereunder and the listing standards of the national securities exchange on which the Company's securities are listed.

IV. Event That Triggers Recoupment Under This Policy

The Board or Committee will be required to recoup any excess Incentive Compensation "received" by any Covered Executive during the three (3) completed fiscal years (together with any intermittent stub fiscal year period(s) of less than nine (9) months resulting from Company's transition to different fiscal year measurement dates) immediately preceding the date the Company is deemed (as determined pursuant to the immediately following sentence) to be required to prepare an accounting restatement of its financial statements (the "**Three-Year Recovery Period**") irrespective of any fault, misconduct or responsibility of such Covered Executive for the accounting restatement of the Company's financial statements. For purposes of immediately preceding sentence, the Company is deemed to be required to prepare an accounting restatement of its financial statements on the earlier of: (A) the date upon which the Board or Committee, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Covered Accounting Restatement; or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare Covered Accounting Restatement (a "**Triggering Event**").

V. Excess Incentive Compensation: Amount Subject to Recovery

The amount of Incentive Compensation to be recovered shall be the excess of the Incentive Compensation "received" by the Covered Executive over the amount of Incentive Compensation which would have been received by the Covered Executive had the amount of such Incentive Compensation been calculated based on the restated amounts, as determined by the Committee. For purposes of this Policy, Incentive Compensation shall be deemed "received", either wholly or in part, in the fiscal year during which any applicable Financial Reporting Measure is attained (or with respect to, or based on, the achievement of any Financial Reporting Measure which such Incentive Compensation was granted, earned or vested, as applicable), even if the payment, vesting or grant of such Incentive Compensation occurs after the end of such fiscal year. Amounts required to be recouped under this Policy will be calculated on a pre-tax basis.

It is specifically understood that, to the extent that the impact of the accounting restatement on the amount of Incentive Compensation received cannot be calculated directly from the information in the accounting restatement (e.g., if such restatement's impact on the Company's share price is not clear), then such excess amount of Incentive Compensation shall be determined based on the Committee's reasonable estimate of the effect of the accounting restatement on the share price or total shareholder return upon which the Incentive Compensation was received. The Company shall maintain documentation for the determination of such excess amount and provide such documentation to the Nasdaq Stock Market ("**Nasdaq**") as may be required.

VI. Method of Recovery

The Committee will determine, in its sole discretion, the methods for recovering excess Incentive Compensation hereunder, which methods may include, without limitation:

a. requiring reimbursement of cash Incentive Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;

c. offsetting the recouped amount from any compensation otherwise owed or to be owed by the Company to the Covered Executive to the extent applicable;

d. cancelling outstanding vested or unvested equity awards; and/or

e. taking any other remedial and recovery action permitted by law, as determined by the Committee.

VII. Impracticability

The Committee shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Committee in accordance with Rule 10D-1 of the Exchange Act and the listing standards of the stock exchange or association on which the Company's securities are listed. It is specifically understood that recovery will only be deemed impractical if: (A) the direct expense paid to a third party to assist in enforcing the policy would exceed the amount to be recovered (before concluding that it would be impracticable to recover any amount of erroneously awarded Incentive Compensation based on expense of enforcement, the Committee shall make a reasonable attempt to recover such erroneously awarded Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the stock exchange or association on which the Company's common shares are trading); (B) recovery would violate home country law where that law was adopted prior to the November 28, 2022 (before concluding that it would be impracticable to recover any amount of erroneously awarded Incentive Compensation based on violation of home country law, the Committee shall obtain an opinion of home country counsel, acceptable to the applicable stock exchange or association on which Company's common shares are trading, that recovery would result in such a violation, and must provide such opinion to Nasdaq as may be required); or (C) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a), and the regulations promulgated thereunder.

VIII. Other Recoupment Rights; Acknowledgement

The Committee may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company. The Company shall provide notice and seek written acknowledgement of this Policy from each Covered Executive; *provided*, that the failure to provide such notice or obtain such acknowledgement shall have no impact on the applicability or enforceability of this Policy.

IX. No Indemnification or Company-Paid Insurance

The Company shall not indemnify any Covered Executives against the loss of any excess Incentive Compensation. In addition, the Company will be prohibited from paying or reimbursing a Covered Executive for premiums of any third-party insurance purchased to fund any potential recovery obligations.

X. Amendment and Termination; Interpretation

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect and comply with further regulations, rules and guidance of the SEC, and rules of the stock exchange or association on which Company's common shares are listed. The Board may terminate this Policy at any time. The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. This Policy is designed and intended be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1 and other regulations, rules and guidance of the SEC thereunder, and related securities regulations and regulations of the stock exchange or association on which Company's common shares are listed. To the extent of any inconsistency between this Policy and such regulations, rules and guidance, such regulations, rules and guidance shall control and this Policy shall be deemed amended to incorporate such regulations, rules and guidance unless the Board or the Committee shall expressly determine otherwise. This Policy shall be applicable, binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives, to the fullest extent of the law.

XI. Definitions

For purposes of this Policy, the following terms shall have the following meanings:

1. "**Board**" means the Board of Directors of the Company.

2. "**Company**" means Guardion Health Sciences, Inc.

3. A "**Covered Accounting Restatement**" is any accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws. A Covered Accounting Restatement includes any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as "Big R" restatements), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as "little r" restatements). A Covered Accounting Restatement does not include an out-of-period adjustment when the error is immaterial to the previously issued financial statements, and the correction of the error is also immaterial to the current period; retrospective application of a change in accounting principle; retrospective revision to reportable segment information due to a change in the structure of an issuer's internal organization; retrospective reclassification due to a discontinued operation; retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; and retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

4. "**Covered Executive**" means any person who:

    a. Has received applicable Incentive Compensation:

        i. During the Three-Year Recovery Period; and
        ii. After beginning service as an Executive Officer; and

    b. Has served as an Executive Officer at any time during the performance period for such Incentive Compensation.

5. "**Effective Date**" means the date the Policy is adopted by the Board.

6. "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

7. "**Executive Officer(s)**" means an "executive officer" as defined in Exchange Act Rule 10D-1(d), and includes any person who is the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the issuer in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company (with any executive officers of the Company's parent(s) or subsidiaries being deemed Covered Executives of the Company if they perform such policy making functions for the Company). All executive officers of the Company identified by the Board pursuant to 17 CFR 229.401(b) shall be deemed "Executive Officers."

8. "**Financial Reporting Measure(s)**" means any measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, including share price and total shareholder return, and also including, but not limited to, financial reporting measures such as "non-GAAP financial measures" for purposes of Exchange Act Regulation G and 17 CFR 229.10, as well other measures, metrics and ratios that are not non-GAAP measures, like same store sales. Financial Reporting Measures may or may not be included in a filing with the SEC, and may be presented outside the Company's financial statements, such as in Management's Discussion and Analysis of Financial Conditions and Results of Operations or the performance graph. Financial Reporting Measures include, without limitation:

    a. Company share price
    b. Total shareholder return
    c. Revenue
    d. Operating profitability
    e. Net income
    f. Earnings before interest, taxes, depreciation, and amortization (EBITDA)
    g. Liquidity measures such as working capital or operating cash flow
    h. Return measures such as return on invested capital or return on assets
    i. Earnings measures such as earnings per share

9. "**Incentive Compensation**" means any compensation which (A) was approved, awarded or granted to, or earned by a Covered Executive while the Company has a class of securities listed on a national securities exchange or a national securities association, and (B) approved, awarded or granted to, or earned by the Covered Executive following on or after the Effective Date (including any award under any long-term or short-term incentive compensation plan of the Company, including any other short-term or long-term cash or equity incentive award or any other payment) that, in each case, is granted, earned, or vested based wholly or in part upon the attainment of any Financial Reporting Measure (i.e., any measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, including share price and total shareholder return). Incentive Compensation may include (but is not limited to) any of the following:

    a. Annual bonuses and other short- and long-term cash incentives
    b. Stock options
    c. Stock appreciation rights
    d. Restricted shares
    e. Restricted share units
    f. Performance shares
    g. Performance units