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, 2022

OR

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

For the transition period from ____ to ____

Commission file number: 001-38861

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

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

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

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

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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, 2022, 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 $9.2 million based upon the closing price of the registrant's common stock of $7.25 on The Nasdaq Capital Market as of that date.

As of March 28, 2023, there were 1,267,340 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

Documents Incorporated by Reference:

Portions of the registrant's definitive proxy statement relating to its 2023 annual meeting of stockholders (the "2023 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2023 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2022 contains "forward-looking statements" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects, and other similar matters. These forward-looking statements are based on management's current expectations and assumptions about future events, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. These statements may be identified by words such as, "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning.

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

Other unknown or unpredictable factors that could also adversely affect our business, financial condition and results of operations may arise from time to time. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, the forward-looking statements discussed in this Annual Report on Form 10-K may not prove to be accurate. Accordingly, you should not place undue reliance on these forward-looking statements, which only reflect the views of the Company's management as of the date of this Annual Report on Form 10-K. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results or expectations, except as required by law. We qualify all of the information presented in this Annual Report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

RISK FACTOR SUMMARY

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

Risks Related to the Company's Business

- As the Company has incurred recurring losses and negative cash flows since its inception, there is no assurance that the Company will be able to reach and sustain profitability.
- The COVID-19 global pandemic has adversely impacted, and may continue to adversely impact the Company's business.
- Inflationary pressure and a potential recession may adversely impact the Company's business.
- The Company has limited experience in developing and marketing dietary supplements and medical foods and it may be unable to commercialize some of the products it develops or acquires.
- The Company's investment in new businesses and new products, services, and technologies is inherently risky, and could disrupt its current operations.
- The Company may not succeed in establishing and maintaining collaborative relationships, which may significantly limit its ability to develop and commercialize its products successfully, if at all.
- Competitors may develop 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 it unable to protect them, its competitive position may suffer.

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

- The Company may not realize the expected benefits of its acquisition of Activ, which may adversely affect the Company's business, financial condition, and results of operations.

- The Company may not be able to maintain or grow Activ's business as it expected.

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 nutritional medical foods and dietary supplements. These products are designed to support retail 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.

Our profile and focus fundamentally changed with the acquisition of Activ Nutritional, LLC ("Activ" or "Viactiv" as the context requires) in June 2021, the owner and distributor of the Viactiv® line of supplements for bone health and other applications. As a result of the Activ acquisition, our commercial efforts changed to its current focus on the development and marketing of science-based clinical nutrition products and supplements.

The acquisition and integration of the Viactiv line of products has changed our financial position, market profile and brand and operating focus. In order to leverage the Viactiv platform, the Company has searched for additional complementary business opportunities. Additionally, the Company is focusing on new product development that it can launch under the Viactiv brand and in the year ended December 31, 2022, the Company launched its new Omega Boost Gel Bites product.

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

- Brand awareness – Viactiv was initially launched by industry leaders Mead Johnson/Johnson & Johnson approximately twenty years ago, and we believe this history, along with the product's marketing campaigns, taste profile and receipt of consistently positive consumer reviews, have led to strong consumer awareness and acceptance. We are leveraging this strong consumer awareness to expand the Viactiv brand beyond calcium chews. We launched an Omega-3 product earlier this year called Omega Boost Gel Bites, and we are marketing it to a similar target audience as the calcium chews. This along with cross selling across products are important actions we are taking to take advantage of the Viactiv brand awareness to help us grow our business.

- Experienced management – As part of the Activ acquisition, we hired the senior executive responsible for the Viactiv brand at Adare Pharmaceuticals, Inc. ("Adare") as our Chief Commercial Officer. This senior executive was a member of the executive leadership team of Adare, and he has contributed strong sales, marketing and research and development skills and experiences to our leadership team. We have combined his skill set with other professionals on our team that had complementary skills, including manufacturing, logistics, financial management and medical education. Building out our team in this manner has helped us scale our capabilities and better exploit our collective industry experience.

- Established distribution – Viactiv's products are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target and Amazon. We added a direct-to-consumer eCommerce capability on our website viactiv.com earlier this year to expand our sales channels. The Viactiv calcium chews can now be purchased through any of these channels, and we subsequently added our ocular products to this platform. We are also working to leverage our distribution and supply networks to grow our Omega Boost Gel Bites product which is currently sold on our direct-to-consumer site as well as one online retailer. We are evaluating additional channel expansion for Omega Boost Gel Bites in addition to offering bundles with other GHSI products to our customers.

- Track record of financial performance – The Viactiv brand has a strong history of financial success both before and after our acquisition of the brand. Viactiv generated net revenues of approximately $10,640,000 in the year-ended December 31, 2022, and accounted for 96% of the Company's total revenues for the period. For the year ended December 31, 2021, on a pro forma basis and assuming Viactiv was owned by the Company for the entire year, our total revenues would have been $12,765,911 and the Viactiv products would have accounted for 96% of our pro forma total revenues for the period. Over time, we expect the acquisition of Viactiv to contribute increasing revenue and consistent operating margins, as well as a multitude of growth opportunities, to our Company.

Acquisition of Activ Nutritional, LLC

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

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

Recent Developments

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 will be 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.

November 2022 Securities Offering

On November 29, 2022, the Company, entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors (the "Investors"), pursuant to which the Company agreed to issue and sell, in a private placement (the "November 2022 Offering"), 495,000 shares of the Company's Series C Convertible Redeemable Preferred Stock, par value $0.001 per share and stated value of $10.00 per share (the "Series C Preferred Stock"), and 5,000 shares of the Company's Series D Redeemable Preferred Stock, par value $0.001 per share and stated value of $10.00 per share (the "Series D Preferred Stock"), which are collectively referred to herein as the "Preferred Stock", at an offering price of $9.50 per share, representing a 5% original issue discount to the stated value of $10.00 per share, for gross proceeds of $4,750,000 in the aggregate for the Offering, before the deduction of discounts, fees and offering expenses. The shares of Series C Preferred Stock were convertible, at a conversion price of $0.15768 ($7.884 as adjusted for the Reverse Stock Split) per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, par value $0.001 per share at the option of the holders and, in certain circumstances, mandatorily by the Company. The Purchase Agreement contained customary representations, warranties and agreements by the Company and customary conditions to closing. The November 2022 Offering closed on November 30, 2022.

Each Investor in the November 2022 Offering separately agreed, pursuant to a side letter (the "Side Letter"), to vote their respective shares of Preferred Stock on the Reverse Stock Split proposal at the special meeting of stockholders and to not transfer, offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of the shares of the Preferred Stock, unless and until the Reverse Stock Split has been approved by the Company's stockholders. Pursuant to the certificate of designation of the Series C Preferred Stock, the shares of Series C Preferred Stock had the right to vote on the Certificate of Amendment on an as-converted to Common Stock basis. In addition, pursuant to the Side Letter, the shares of Series D Preferred Stock were automatically voted in a manner that "mirrors" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that are not voted) and Series C Preferred Stock are voted on the Certificate of Amendment. The Certificate of Amendment required the approval of the majority of the votes associated with the Company's outstanding classes of stock entitled to vote on the proposal. Because the Series D Preferred Stock was automatically, and without further action of the purchaser, voted in a manner that "mirrors" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that are not voted) and Series C Preferred Stock are voted on the Reverse Stock Split, abstentions by common stockholders did not have any effect on the votes cast by the holders of the Series D Preferred Stock.

Pursuant to the Purchase Agreement, on November 29, 2022, the Company filed separate certificates of designation (each, a "Certificate of Designation") with the Secretary of State of the State of Delaware designating the rights, preferences and limitations of the shares of Series C Preferred Stock and Series D Preferred Stock, which provided, in particular, that the Preferred Stock would have no voting rights other than the right to vote on the Certificate of 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, provided that the Series D preferred stock contains a provision that limits the total voting power of a holder of Series D Preferred Stock to a maximum of 9.99% of the total voting power of the Company.

The holders of shares of Series C Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Series C Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of Common Stock at a conversion price of $0.15768 ($7.884 as adjusted for the Reverse Stock Split) per share. The conversion price was subject to adjustment pursuant to the Series C Preferred Stock Certificate of Designation for stock dividends and stock splits, subsequent rights offering, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the applicable Certificate of Designation). 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 commencing after the earlier of the receipt of stockholder approval of the Reverse Stock Split and 60 days after the closing of the issuances of the Preferred Stock, and until 90 days after such closing. The Company had 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 proceeds of the Offering were held in a third-party escrow account, along with the additional amount that would be necessary to fund the 105% redemption price, until the expiration of the redemption period for the Preferred Stock, as applicable, subject to the earlier payment to redeeming holders. Upon expiration of the redemption period, any proceeds remaining in the escrow account will be disbursed to the Company.

In connection with the Offering, the Company agreed to pay Roth Capital Partners, LLC, the Company's placement agent for the Offering (the "Placement Agent"), a financial advisory fee of $200,000 and to reimburse the Placement Agent for certain of its expenses, including legal costs, in an amount not to exceed $50,000. In addition, the Company agreed to pay the Placement Agent a cash fee equal to 5% of the gross proceeds received from any shares of Series C Preferred Stock that are ultimately converted into Common Stock.

All shares of Preferred Stock were fully redeemed as of February 8, 2023. The escrow account was closed upon payment of the last redemption on February 8, 2023. There was no balance remaining in the escrow account and therefore no money was returned to the Company.

Equity Distribution Agreement

On January 28, 2022, we entered into an Equity Distribution Agreement (the "Sales Agreement") with Maxim Group LLC, and Roth Capital Partners LLC as co-agents (collectively, the "Agents"), pursuant to which we were able to offer and sell, from time to time through the Agents, shares of our common stock having an aggregate offering price of up to $25,000,000 in one or more at-the-market offerings. As of March 1, 2023, we have not sold any shares of our common stock pursuant to the Sales Agreement. As a result of the February Offering (described below), we were restricted from utilizing the at-the-market offering for a period of 120 days, or through June 18, 2022.

February 2022 Securities Offering

On February 18, 2022, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which we issued and sold, in a best-efforts offering (the "February Offering"), (i) 651,000 units, priced at an offering price of $15.00 per unit, with each unit consisting of one share of common stock, one warrant to purchase one share of our common stock at an exercise price of $7.57 per share that expires on the fifth anniversary of the date of issuance ("Series A Warrant") and one warrant to purchase one share of common stock at an exercise price of $7.57 per share that expires on the eighteen month anniversary of the date of issuance ("Series B Warrant"), and (ii) 89,000 pre-funded units, priced at an offering price of $14.9995 per unit, with each unit consisting of one pre-funded warrant to purchase one share of common stock at an exercise price of $0.0001 per share that is exercisable at any time after issuance until exercised in full (a "Pre-Funded Warrant" and together with the Series A Warrants and Series B Warrants, the "Warrants"), one Series A Warrant and one Series B Warrant.

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

On February 23, 2022, we closed the February Offering, and issued (i) 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 net proceeds from the February Offering, after deducting the placement agent fees and estimated offering expenses payable by us were approximately $10.0 million. During the term of the Warrant, each warrant holder is entitled to certain rights as described in the Warrants, including the right to "cash out" the Warrant in the event of a fundamental transaction involving the Company, such as a change-in-control transaction or sale of substantially all of the Company's assets. Furthermore, in the event that the Company fails to deliver shares by the required delivery date upon exercise of the Warrants, the Company may be subject to cash penalties in an amount up to $20 per trading day for each $1,000 of warrant shares until such shares are delivered. In addition, if the warrant holder purchases shares in the market following the Company's failure to deliver shares upon exercise of the Warrants, the Company would be required to cover the cost of any buy-ins and, at the option of the warrant holder, either reinstate the portion of the Warrant for the shares that were not delivered or deliver the number of shares that should have been issued.

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

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

As a result of the November 2022 Offering and pursuant to the terms of the Warrant, on November 30, 2022 the exercise price for all of the Warrants was reduced to $7.884. Thereafter, as a result of the Reverse Stock Split and pursuant to the terms of the Warrants, the exercise price for all Warrants was reduced to $7.57 on January , 2023.

Product Offerings

Our product profile and focus fundamentally changed with the acquisition of Activ in June 2021, the owner and distributor of the Viactiv® line of supplements for bone health and other applications. For the year ended December 31, 2022, sales of the Viactiv line of supplements represented approximately 96% of our consolidated net sales versus 90% for the year ended December 31, 2021. The Viactiv line of supplements contains several flavored nutritional supplement products, but the milk chocolate and caramel flavored calcium chews constitute the main product category.

Viactiv was first introduced to the market over 20 years ago as a calcium-fortified soft chew intended to deliver clinical nutrition to women in a way that is enjoyable to taste and easy to consume. The chews are available in chocolate and caramel flavors, each delivering nutrition to help consumers maintain health goals, such as strong bones and immune support. The calcium chews contain 650mg of Calcium that deliver benefits of hard-to swallow pills with the great taste you expect from a gummy. Compared to the leading gummies, our calcium chews are one of the only ones with both Vitamin D and K1 to boost calcium absorption and help bone mineral density. Viactiv calcium chews are regulated in the U.S. as a dietary supplement.

In February 2022, we began the marketing of our Viactiv® Omega Boost Gel Bites product. The 1,200 mg Omega-3 gel bites are designed to provide total body support, including cardiovascular, brain, joint and eye health. The new dosage form is able to provide the potency of large, hard-to-swallow soft gels, in a great tasting chewable format that has ten times more Omega-3 than the leading fish oil gummies. The gel bite dosage form has been shown to have better absorption and fewer digestive issues than regular soft gel formulas, as well as no unpleasant fishy aftertaste and no sugar, which is associated with many other Omega-3 products. Viactiv Omega Boost Gel Bites are regulated in the U.S. as a dietary supplement.

GlaucoCetin, currently considered a dietary supplement, is a clinically supported, targeted nutrition. GlaucoCetin is designed specifically to provide nutrients to support mitochondrial function with additional antioxidants to reduce oxidative stress and increasing blood flow throughout the body, especially for enhanced eye support and ocular health. We market GlaucoCetin through direct-to-consumer strategies such as social media and paid search advertising.

We also sell Lumega-Z, our legacy medical food product that has a formula designed to replenish and restore the macular protective pigment, simultaneously delivering critical and essential nutrients to the eye.

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

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.

We distribute Lumega-Z and GlaucoCetin through E-commerce, in an online store that is operated at www.viactiv.com.

Prior Product Offerings

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

VectorVision: In September 2017, we acquired VectorVision, Inc. ("VectorVision"), a company that specialized in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision developed, manufactured and sold equipment and supplies for standardized vision testing for use by eye doctors in clinics, for researchers to use in clinical trials, for real-world vision evaluation, and industrial vision testing.

During December 2021, as part of management's comprehensive evaluation of our Company's business and in order to focus on those brands and lines of business that management believes provide the greatest growth opportunities, we determined to restructure the operations of our VectorVision business. We intend to explore various alternative ways to preserve, manage and exploit our intellectual property rights, including our U.S. patents, associated with the VectorVision technology, both domestically and internationally. As a result of this change to the VectorVision business strategy, management believes that it will be able to better focus its efforts and deploy capital resources to more growth-oriented brands and product lines, like Viactiv and Omega Boost, and other products in development, that it hopes to bring to market in 2023.

Competitive Advantage and Strategy

Dietary Supplements

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

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

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

The Viactiv calcium-fortified soft chews are formulated to deliver nutrition in a way that is enjoyable to taste and easy to consume. The calcium chews contain 650mg of Calcium that deliver benefits of hard-to swallow pills with the great taste you expect from a gummy. Compared to the leading gummies, our calcium chews contain 30% more calcium and are one of the only ones with both Vitamin D3 and K1 to boost calcium absorption and help bone mineral density.

The Viactiv Omega Boost Gel Bites were launched in 2022. The 1,200 mg Omega-3 gel bites are designed to provide total body support, including cardiovascular, brain, joint and eye health. The new dosage form is able to provide the potency of large, hard-to-swallow soft gels, in a great tasting chewable format that has ten times more Omega-3 than the leading fish oil gummies. The gel bite dosage form has been shown to have better absorption and fewer digestive issues than regular soft gel formulas. We believe the Viactiv brand and established distribution will make our Omega Boost Gel Bites sales and marketing functions more successful. Introducing this new product in 2022 expanded our portfolio beyond calcium chews which is an important aspect of our growth strategy. We believe the target audience for calcium will also be interested in purchasing our omega-3 supplements that we believe provide a preferred alternative to existing omega-3 soft gels and gummy products.

GlaucoCetin is clinically supported, targeted nutrition. GlaucoCetin is designed specifically to provide nutrients to support mitochondrial function with additional antioxidants to reduce oxidative stress and increasing blood flow throughout the body, especially for enhanced eye support and ocular health.

Medical Foods

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

Growth Strategy

We believe that developing new products, growing our established distribution and cost effectively marketing our products are the keys to growing our business. We have several innovation initiatives underway that are aimed at increasing the number of new products in our product portfolio and expanding our total addressable market, and we plan to grow our established distribution network. For example, we launched a new product named Viactiv® Omega Boost Gel Bites product earlier in 2022. The introduction of the Omega Boost Gel Bites product greatly expanded the total addressable market for Viactiv by expanding the brand into the established sizeable omega-3 market. We hope that our omega-3 product will distinguish itself from the competition over time.

Our current network includes many of the nation's largest retailers, including, among others, Walmart (retail and online), Target and Amazon. We expanded our sales channels for Viactiv during the year by launching a direct-to-consumer website. This new channel offers Viactiv customers an additional channel to purchase our products as well as offering customers with more customized offers and information. We are working to add additional retailers that sell our products and adding new sales channels. We are also focused on marketing initiatives that strengthen our brand and target consumers who would benefit most from our specific products.

Sales

Viactiv has traditionally sold the majority of its products through traditional retailers via the use of third party brokers. We have continued to utilize these brokers to sell the Viactiv products to retailers rather than employing an internal sales force. Online retailers have represented a smaller portion of sales, but we believe these sales can be meaningful and play an important role in our eCommerce strategy over time. In addition, we sell a limited amount of Viactiv products directly to consumers via our website, and plan to continue to invest in this channel to grow sales. While the footprint for our direct-to-consumer channel is currently small, we expect this channel to play an important role in our new product launches and growth.

Marketing – Digital

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

Marketing – Practitioners

Healthcare practitioners are important stakeholders for our products, especially Lumega-Z and GlaucoCetin. We have eliminated our direct sales approach that involved our sales representatives in favor of a more cost-effective approach to increase the awareness of our products with health care practitioners. This approach is designed to increase marketing reach through a combination of collaboration with industry-specific publishers, peer-to-peer promotion using key opinion leader clinicians, organic and paid search engine optimization and marketing, and other content-driven and educational approaches.

Domestic and International Expansion Strategy

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

Although we have decreased our focus on international expansion, we maintain relationships that we hope will lead to increased distribution of our existing products, intellectual property rights primarily associated with our VectorVision line of business and unique nutritional formulations in Asian markets.

Intellectual Property

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

Patents

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

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

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

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

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

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

(6) Chinese Patent No. ZL 2017800672763, titled "Method and Apparatus for Vision Acuity Testing," granted on June 7, 2022.*

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

(8) Japanese Patent No. 7039602, titled "Method and Apparatus for Vision Acuity Testing," granted on March 11, 2022.*

(9) Japanese Patent No. 7157070, titled "Method and Apparatus for Vision Acuity Testing," granted on October 11, 2022.*

(10) Korean Patent No. 10-2422480, titled "Method and Apparatus for Vision Acuity Testing," granted on July 14, 2022.*

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

Trademarks

We prominently display our trademarks on all Guardion and Viactiv products and believe that having distinctive trademarks is an important factor in the promotion and marketing our product offerings. We have acquired or are in the process of acquiring registered protection for the trademarks most critical to our business. We currently have twelve 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 five trademarks registered with the USPTO which are used in association with the Viactiv line of products.

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

Trademark Registrations/Applications

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

Trademark	Country	Registration No.	Reg Date	Owner
EPIQ-V	Philippines	4202100500186	10/29/2021	Guardion Health Sciences, Inc.
EPIQ-V	United States	6,429,847	07/20/2021	Guardion Health Sciences, Inc.
EPIQ-V	United States	6,449,526	08/10/2021	Guardion Health Sciences, Inc.
GLAUCOCETIN	United States	5,933,586	12/10/2019	Guardion Health Sciences, Inc.
GLAUCO-HEALTH	United States	5,092,549	11/29/2016	Guardion Health Sciences, Inc.
GUARDION	United States	5,025,658	08/23/2016	Guardion Health Sciences, Inc.
LUMEGA-Z	China	27151643	11/07/2018	Guardion Health Sciences, Inc.
LUMEGA-Z	United States	5,757,377	05/21/2019	Guardion Health Sciences, Inc.
MAPCAT SF	China	27151644	10/28/2018	Guardion Health Sciences, Inc.
MAPCAT SF	United States	4,997,319	07/12/2016	Guardion Health Sciences, Inc.
OMEGA BOOST	United States	6,958,987	1/17/202310/06/2021	Guardion Health Sciences, Inc.
OMEGA BOOST (stylized) 	United States	6,959,077	01/17/2023	Guardion Health Sciences, Inc.
VECTORVISION	China	27151642	02/07/2020	Guardion Health Sciences, Inc.
VECTORVISION	China	39703795	01/28/2021	Guardion Health Sciences, Inc.
VECTORVISION	China	48062177	07/14/2020	Guardion Health Sciences, Inc.
VECTORVISION	United States	4,341,403	05/28/2013	Guardion Health Sciences, Inc.
VIACTIV	Australia	IR13853061902404	10/15/2019	Activ Nutritional, LLC

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

Products Manufacturing and Sources and Availability of Raw Materials

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

Government Regulation

Dietary Supplement Regulation

The US Food and Drug Administration (FDA) has primary jurisdiction for the regulation of dietary supplements. The FDA regulates dietary supplements, such as Viactiv chews, as “dietary supplements” under the Federal Food, Drug, and Cosmetic Act (“FDCA”) as a distinct, sub-category of “food.” Dietary supplements must meet the requirements of applicable food laws and regulations. A “dietary supplement” is defined under the FDCA as “a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins, minerals, amino acids, herbs or other botanicals; a concentrate, metabolite, constituent, extract or combination of the ingredients listed above.” Dietary supplements are intended to enhance the diet and may not be represented as a conventional food or as the sole item of a meal or diet.

Dietary supplements do not require approval from the FDA before they are marketed. Except in the case of a "new dietary ingredient," where pre-market review for safety data and other information is required by law, a firm is not required to provide the FDA with the evidence it relies on to substantiate safety or effectiveness before marketing a supplement product.

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

Owners or responsible parties of any facilities at which dietary supplements are manufactured, packaged, labeled, or held for distribution must register the facility or facilities with FDA pursuant to the Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") before producing supplements. Manufacturers of dietary supplements also must follow current good manufacturing practice ("cGMP") regulations. Entities that manufacture, package, label or hold dietary supplement products must follow applicable cGMP regulations. These regulations focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements. We engage with contract manufacturers to manufacture our dietary supplements.

Companies are responsible for determining that the dietary supplements they manufacture or distribute are safe, and that any representations or claims made about them are substantiated by adequate evidence to show that the claims are not false or misleading. The Federal Trade Commission ("FTC") has the primary responsibility to regulate the advertising of foods, including dietary supplements. Under the FTC Act, all advertising claims, both express and implied, must be truthful, non-misleading, and substantiated. Claims about the health benefits of a product must meet the basic substantiation standard of "competent and reliable scientific evidence," generally randomize, 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, Twitter), and the internet.

Dietary supplements also are subject to the Nutrition, Labeling and Education Act, which regulates health claims, ingredient labeling, and nutrient content claims characterizing the level of a nutrient in a product. Dietary supplements may be intended to affect the structure or function of the human body. If the label of a dietary supplement contains such structure/function claims, the 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 such as 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 gathers material at trade shows and conferences and review company websites and social media accounts.

Healthcare Laws and Regulations

Stark Law

The Omnibus Budget Reconciliation Act of 1993 prohibits certain physician self-referrals. This law and its supporting regulations, which have been amended and expanded substantially, are commonly referred to as the "Stark Law," and prohibit a physician from making any referral of a Designated Health Service ("DHS") to an entity that furnishes or bills for DHS (a "DHS Entity") and with which the physician has a financial relationship, and prohibits DHS Entities from billing for any DHS that is referred, unless all of the requirements of a regulatory exception are met. Stark covered DHS include both outpatient prescription drugs and diagnostic testing that are reimbursable by Medicare or Medicaid. Many states have similar laws ("State Self-Referral Prohibitions"), some of which can apply to all payors and not just governmental payors.

At present, neither Lumega Z nor GlaucoCetin are outpatient prescription drugs nor are they reimbursable under any federal program. Further, we do not furnish any DHS to patients, nor bill any DHS to any federal program. We believe that the federal Stark Law is thus inapplicable. Further, we believe that State Self-Referral Prohibitions are unlikely to apply for similar reasons. To the extent that the products might become reimbursable under a federal program, or otherwise become covered under the Stark Law, we believe that the physicians who recommend our medical 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. While we believe that we are in material compliance with both federal and state AKS laws, the AKS laws present different levels of risks as to our sale of our medical foods, Lumega-Z and GlaucoCetin.

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

The Federal False Claims Act

The Federal False Claims Act provides for the imposition of extensive financial penalties (including treble damages and fines of over $22,000 for every false claim) if a provider submits false claims to any governmental health program either knowingly or in reckless disregard or in deliberate ignorance of the truth or falsity of the claims at issue. Liability under the False Claims Act can arise from patterns of deficient documentation, coding and billing, as well as for billing for services that are deemed not to have been medically necessary for the treatment of the patient. Many states have their own False Claims Acts as well.

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

State Regulatory Requirements

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

Other United States Regulatory Requirements

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

Foreign Regulatory Requirements

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

Employees

As of March 1, 2023, we, including our subsidiaries, had a total of 12 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-six (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. The Company had a net loss available to common shareholders of $15,863,812 for the year ended December 31, 2022 and a net loss of $24,745,009 for the year ended December 31, 2021. The Company had an accumulated deficit of $93,724,300 as of December 31, 2022. At December 31, 2022, the Company had cash and cash equivalents on hand of $10,655,490 and working capital of $14,307,051. Notwithstanding the net loss for 2022, management believes that its current cash balance is sufficient to fund operations for at least one year from the date the Company's 2022 financial statements are issued.

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

Even if profitability is achieved in the future, the Company may not be able to sustain profitability on a consistent basis. The Company expects to continue to incur substantial losses and negative cash flow from operations for the foreseeable future. The Company's financial statements for the year ended December 31, 2022 have been prepared assuming that the Company will continue as a going concern.

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

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

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

The COVID-19 global pandemic has 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.

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

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

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

Moreover, the Company had been experiencing supply chain constraints due to the COVID-19 pandemic. These constraints began in December 2021 and continued into the third quarter of 2022. These constraints impacted the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products and may impact the Company's ability to fulfill customer orders going forward which would have a material adverse effect on the Company's business and results of operations. The Company continues to experience challenges to meet customer demands, largely because of broad-based shortages in suppliers' labor which impact the availability of many critical components in the Company's supply chain and distribution. We are subject to, and paid in 2022, out-of-stock fees to certain retailers in the event that we are unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, the Company and its suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs, material costs and transportation challenges. The Company expects input cost inflation to continue at least throughout 2023.

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

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

The Company 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 expects to 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 conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, 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. More recently, the closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC) created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. 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 and could require us to delay or abandon clinical development plans. 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.

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

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

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

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

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

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

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

While the Company believes that these collaborative relationships help further validate its products, these relationships are not material to the Company because these relationships are not exclusive, there are many potential collaborative partners available, and the Company and each collaborator is free to enter into other collaborative relationships as needed.

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

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

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

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

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

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

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

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

Many large competitors have substantially greater financial, research and development, manufacturing, 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, the Company must develop more robust capabilities internally or collaborate with third parties that can perform these services. In the process of commercializing the Company's products, the Company may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations capable of successfully launching new products and generating sufficient product revenues. In addition, establishing such operations takes time and involves significant expense.

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

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

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

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

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

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

The Company may be unsuccessful in expanding its product distributions.

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

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

The Company has historically sold its products to customers outside the U.S. and may sell products outside of the United States in 2022 and beyond. As a result, the Company's business is exposed to risks inherent in international operations. These risks, which can vary substantially by location, include the following:

- governmental laws, regulations and policies adopted to manage national economic and macroeconomic conditions, such as increases in taxes, austerity measures that may impact consumer spending, monetary policies that may impact inflation rates, currency fluctuations and sustainability of resources;
- changes in environmental, health and safety regulations, such as the continued implementation of the European Union's Registration, Evaluation, 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. In determining the required quantities of its products and the manufacturing schedule, the Company must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between the Company's estimates and the actual amounts of products it requires. If the Company is unable to obtain from one or more of its vendors the needed materials or components that meet our specifications on commercially reasonable terms, or at all, the Company may not be able to meet the demand for its products. While the Company has not arranged for alternate suppliers, and it may be difficult to find alternate suppliers in a timely manner and on terms acceptable to the Company, the Company believes that there are alternative sources, suppliers and manufacturers available for its products in the event of a termination or a disagreement with any current vendor.

The Company has experienced supply chain constraints due to the COVID-19 pandemic. These constraints began in approximately December 2021 and have continued into the first quarter of 2022. These constraints impacted our ability the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products and may continue to impact its ability to fulfill customer orders going forward which would have a material adverse effect on the Company's business and results of operations. The Company is subject to out-of-stock fees to certain retailers in the event that the Company is unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, the Company and its suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs as well as transportation challenges. The Company expects input cost inflation to continue at least throughout 2023.

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, 2022 and 2021, the Company's billings were derived from a limited number of individual customers and distributors. During the years ended December 31, 2022 and 2021, the Company had one customer who accounted for approximately 57% and 49% of the Company's sales respectively No other customer accounted for more than 10% of sales in either year. Customers may stop purchasing the Company's products with little or no warning. Loss of customers may have an immediate adverse effect on the Company's financial results.

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

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

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

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

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

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

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

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

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

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

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

- the Company's competitors, many of which have substantially greater resources than the Company does and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate the Company's ability to make, use, and sell the Company's current and future products either in the United States or in international markets; and

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

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

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

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

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

Nasdaq has adopted new listing rules to become effective on the later of August 8, 2022 and the date a company files its proxy statement for its 2022 annual meeting of stockholders related to board diversity and disclosure, which requires all companies listed on Nasdaq's U.S. exchanges to publicly disclose consistent, transparent diversity statistics regarding their board of directors. Additionally, the rules require most Nasdaq-listed companies to have, or explain why they do not have, at least two diverse directors, including one who self-identifies as female and one who self-identifies as either an underrepresented minority or LGBTQ+.

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

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

The Company is regularly engaged in acquisition discussions with other companies and anticipate that one or more potential acquisition opportunities, including those that would be material or could involve businesses with operating characteristics that differ from the Company's existing business operations, may become available in the future. If and when appropriate acquisition opportunities become available, the Company intends to pursue them actively. Acquisitions involve a number of risks, including, but not limited to:

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

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

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

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

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

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

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

Risks Related to Government Regulations

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

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

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

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

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

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

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

Dietary supplements, such as Viactiv and 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 and future growth depend on the development, use and ultimate sale of products that are subject to FDA regulation. Under the FDCA and other laws, the Company is prohibited from promoting its nutritional products for treatment of a condition or disease. The Company's promotional materials and marketing activities must comply with FDCA, FTCA, and other applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the use of the Company's products outside of their intended use as supplements or foods (i.e., as a drug) or that make false or misleading statements. The FDA also could conclude that a performance claim is misleading if it determines that there are inadequate non-clinical and/or clinical data supporting the claim.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of the Company's sales and marketing activities may constitute the promotion of the Company's products for use as a drug in violation of applicable law, or that its promotional materials include false or misleading statements. The Company also faces the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that the Company discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations are typically expensive, disruptive, burdensome and generate negative publicity. If its promotional activities are found to be in violation of applicable law or if the Company agrees to a settlement in connection with an enforcement action, the Company 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, they are only available under the supervision of a physician. While not available in pharmacies, the Company is mindful that the act of physicians prescribing, particularly if conducted across state lines, could potentially be subject to certain pharmacy regulations. Each state has its own regulations concerning physician dispensing, restrictions on the corporate practice of medicine, anti-kickback and false claims. In addition, each state has a board of pharmacy that regulates the sale and distribution of drugs and other therapeutic agents. Some states require a physician to obtain a license to dispense prescription products. While the Company does not believe these pharmacy requirements are applicable, should a pharmacy board or medical board determine otherwise, there can be no assurance that the Company will be able to comply with the regulations of particular states into which the Company currently does business or may expand, or that we will be able to maintain compliance with the states in which we currently distribute our products.

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

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

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

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

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

Risks Related to the Company's Common Stock

We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness and otherwise maintain an effective system of internal control over financial reporting, it could result in us not preventing or detecting on a timely basis a material misstatement of the Company's financial statements.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. As further disclosed in "Item 9A. Controls and Procedures" of this Annual Report on Form 10-K, management had identified a material weakness specifically relating to deficiencies in its internal controls over the review process relating to third-party valuations. Outside of this subjective review process relating to valuations, no other deficiencies in internal controls were identified. The Company has taken actions to remediate the material weakness related to our internal control process of review contributing to financial reporting. We have made improvements to the design of the related controls, including standardized review procedures over third-party valuations. While these control deficiencies did not result in a misstatement to the consolidated financial statements, the material weakness could have resulted in a misstatement impacting account balances or disclosures that would have resulted in a material misstatement to the consolidated financial statements that would not have been prevented or detected on a timely basis.

Although we are implementing plans to remediate this material weakness, we cannot be certain of the success of the plans. If our remedial measures are insufficient to address the material weakness, or if one or more additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, or our disclosure controls and procedures are again determined to be ineffective, we may not be able to prevent or identify irregularities or ensure the fair and accurate presentation of our financial statements included in our periodic reports filed with the U.S. Securities and Exchange Commission. Additionally, the occurrence of, or failure to remediate, a material weakness and any future material weaknesses in our internal control over financial reporting or determination that our disclosure controls and procedures are ineffective may have other consequences that could materially and adversely affect our business, including an adverse impact on the market price of our common stock, potential actions or investigations by the U.S. Securities and Exchange Commission or other regulatory authorities, shareholder lawsuits, a loss of investor confidence and damage to our reputation.

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

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

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

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

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

The Company's stock price has fluctuated in the past, has been and may be volatile. The Company may incur rapid and substantial increases or decreases in its stock price in the foreseeable future that are unrelated to its operating performance or prospects. In addition, the recent outbreak of the novel strain of coronavirus (COVID-19) has caused broad stock market and industry fluctuations. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in the Company's common stock. The market price for the Company's common stock may be influenced by many factors, including the following:

- investor reaction to the Company's business strategy;
- the success of competitive products;
- the Company's continued compliance with the listing standards of Nasdaq;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to the Company's products;
- actions taken by regulatory agencies with respect to the Company's products, manufacturing process or sales and marketing terms;
- variations in the Company's financial results or those of companies that are perceived to be similar to the Company;
- the success of the Company's efforts to acquire or in-license additional products;
- developments concerning the Company's collaborations or partners;
- declines in the market prices of stocks generally;
- trading volume of the Company's common stock;
- sales of the Company's common stock by the Company or its stockholders;
- 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 short sellers of shares of common stock, known as a "short squeeze." These short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. While the Company has no reason to believe its shares would be the target of a short squeeze, there can be no assurance that the Company will not, in the future be subject to a short squeeze and you may lose a significant portion or all of your investment if you purchase the Company's shares at a rate that is significantly disconnected from its underlying value.

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

The Company has never paid any dividends to its common stockholders. The Company currently intends to retain any future earnings for funding growth and, therefore, does not expect to pay any cash dividends in the foreseeable future. If the Company determines that it will pay cash dividends to the holders of its common stock, it cannot assure that such cash dividends will be paid on a timely basis. The success of your investment in the Company will likely depend entirely upon any future appreciation. As a result, you will not receive any return on your investment prior to selling your shares in the Company and, for the other reasons discussed in this "Risk Factors" section, you may not receive any return on your investment even when you sell your shares in the Company.

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

The Company may require additional debt or equity financing to fund its operations, including, but not limited to, working capital. The Company's limited operating history since its recent acquisition of Activ, which fundamentally changed its business, 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 2. PROPERTIES

Our address is 2925 Richmond Avenue, Suite 1200, Houston, Texas 77098. Our corporate offices are rented on a month-to-month basis at a current rent of approximately $2,700 per month. We believe this facility will be adequate for our needs during the foreseeable future.

In connection with the VectorVision acquisition, we assumed a lease agreement for 5,000 square feet of office and warehouse space which commenced October 1, 2017 and continued through February 2023, at which point the lease expired and the Company is no longer in possession of 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 March 15, 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 it currently intends to retain future earnings, if any, to finance the expansion of its business, and the Company does not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on its common stock will be made by the Company's board of directors, in its discretion, and will depend on the Company's financial condition, results of operations, capital requirements and other factors that its board of directors considers significant.

ITEM 6. [RESERVED]

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

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

Overview

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

Our profile and focus fundamentally changed with the acquisition of Activ Nutritional, LLC ("Activ" or "Viactiv" as the context requires) in June 2021, the owner and distributor of the Viactiv® line of supplements for bone health and other applications. As a result of the Activ acquisition, our commercial efforts changed to its current focus on the development and marketing of science-based clinical nutrition and supplements.

The acquisition and integration of the Viactiv line of products has changed our financial position, market profile and brand and operating focus. In order to leverage the Viactiv platform, the Company has searched for additional complementary business opportunities. Additionally, the Company is focusing on new product development that it can launch under the Viactiv brand and in the year ended December 31, 2022, the Company launched its new Omega Boost Gel Bites product. Neither the operations nor the financial results for the twelve months ended December 31, 2022 are comparable to the twelve months ended December 31, 2021 since we acquired Activ on June 1, 2021.

We believe the Activ acquisition has added valuable attributes, that are helping us achieve our goals including (1) Viactiv's brand awareness and acceptance from the consumer; (2) experienced management; (3) established distribution networks and relationships; (4) product development potential; and (5) a long track record of financial performance.

- Brand awareness – Viactiv was initially launched by industry leaders Mead Johnson/Johnson & Johnson approximately twenty years ago, and we believe this history, along with the product's marketing campaigns, taste profile and receipt of consistently positive consumer reviews, have led to strong consumer awareness and acceptance. We are leveraging this strong consumer awareness to expand the Viactiv brand beyond calcium chews. We launched an Omega-3 product earlier this year called Omega Boost Gel Bites, and we are marketing it to a similar target audience as the calcium chews. This along with cross selling across products are important actions we are taking to take advantage of the Viactiv brand awareness to help us grow our business.

- Experienced management – As part of the Activ acquisition, we hired the senior executive responsible for the Viactiv brand at Adare Pharmaceuticals, Inc. ("Adare") as our Chief Commercial Officer. This senior executive was a member of the executive leadership team of Adare, and he has contributed strong sales, marketing and research and development skills and experiences to our leadership team. We have combined his skill set with other professionals on our team that had complementary skills, including manufacturing, logistics, financial management and medical education. Building out our team in this manner has helped us scale our capabilities and better exploit our collective industry experience.

- Established distribution – Viactiv's products are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target and Amazon. We added a direct-to-consumer eCommerce capability on our website viactiv.com earlier this year to expand our sales channels. The Viactiv calcium chews can now be purchased through any of these channels, and we subsequently added our ocular products to this platform. We are also working to leverage our distribution and supply networks to grow our Omega Boost Gel Bites product which is currently sold on our direct-to-consumer site as well as one online retailer. We are evaluating additional channel expansion for Omega Boost Gel Bites in addition to offering bundles with other GHSI products to our customers.

- Track record of financial performance – The Viactiv brand has a strong history of financial success both before and after our acquisition of the brand. Sales in the first nine months of 2022 were impacted by supply chain challenges that limited the inventory we were able to distribute for sale. Our results have also been adversely impacted by general economic conditions that have negatively affected the broader vitamin, mineral and supplement category at retail outlets. Viactiv generated net revenues of approximately $10,640,000 in 2022 which accounts for 96% of our total revenues in 2022. For the year ended December 31, 2021, on a pro forma basis, our total revenues would have been approximately $12,766,000 and the Viactiv products would have accounted for 94% of our pro forma total revenues for the year. Over time, we expect the acquisition of Viactiv to contribute increasing revenue and consistent operating margins and profitability, as well as a multitude of growth opportunities, to our Company.

Availability of Capital

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

The Company will continue to incur significant expenses related to the commercialization of its products and with respect to its efforts to build its infrastructure, expand its operations, and execute on its business plans. Even if profitability is achieved in the future, the Company may not be able to sustain profitability on a consistent basis. The Company expects to continue to incur substantial losses and negative cash flow from operations for the foreseeable future.

The Company does not have any credit facilities as a source of present or future funds. If the Company raises additional funds through the issuance of equity or convertible debt securities, the percentage ownership of the Company's stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting the ability to take specific actions, such as incurring additional debt, would increase expenses and may require that Company assets secure such debt.

Recent Developments

Reverse Stock Split

We held a special meeting of stockholders on January 5, 2023 (the "Meeting"), to consider and approve 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 (the "Proposal"). The primary reason for recommending the Proposal were to allow the Company's common stock to regain compliance with the minimum bid requirement of the Nasdaq Capital Market.

The Proposal was approved by the Company's stockholders at the Special Meeting and 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 be 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 that 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 common shares for rounding. Accordingly, all common shares, stock options, stock warrants and per share amounts in these consolidated financial statements have been adjusted retroactively to reflect the reverse stock splits as if the splits occurred at the beginning of the earliest period presented in this Annual Report.

On January 24, 2023, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") stating that because the Company's common stock had a closing bid price at or above $1.00 per share for a minimum of 10 consecutive trading days, the Company had regained compliance with the minimum bid price requirement of $1.00 per share follr continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2).

November 2022 Securities Offering

On November 29, 2022, the Company, entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a private placement (the "Offering"), 495,000 shares of the Company's Series C Convertible Redeemable Preferred Stock, par value $0.001 per share and stated value of $10.00 per share (the "Series C Preferred Stock"), and 5,000 shares of the Company's Series D Redeemable Preferred Stock, par value $0.001 per share and stated value of $10.00 per share (the "Series D Preferred Stock"), which are collectively referred to herein as the "Preferred Stock", at an offering price of $9.50 per share, representing a 5% original issue discount to the stated value of $10.00 per share, for gross proceeds of $4,750,000 in the aggregate for the Offering, before the deduction of discounts, fees and offering expenses. The shares of Series C Preferred Stock will be convertible, at a conversion price of $0.15768 ($7.884 as adjusted for the Reverse Stock Split) per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, par value $0.001 per share at the option of the holders and, in certain circumstances, mandatorily by the Company. The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The November 2022 Offering closed on November 30, 2022.

The Company held a special meeting of stockholders on January 5, 2023 to consider an amendment (the "Amendment") to the Company's Certificate of Incorporation, as amended, to authorize a reverse split of the Common Stock (the "Reverse Split"). Each Investor had separately agreed pursuant to a side letter (the "Side Letter") to vote their respective shares of Preferred Stock on the Reverse Split proposal at the special meeting of stockholders and to not transfer, offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of the shares of the Preferred Stock, unless and until the Reverse Split has been approved by the Company's stockholders. Pursuant to the certificate of designation of the Series C Preferred Stock, the shares of Series C Preferred Stock have the right to vote on such Amendment on an as-converted to Common Stock basis. In addition, pursuant to the Side Letter, the shares of Series D Preferred Stock shall automatically be voted in a manner that "mirrors" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that are not voted) and Series C Preferred Stock are voted on the Amendment. The Amendment requires the approval of the majority of the votes associated with the Company's outstanding classes of stock entitled to vote on the proposal. Because the Series D Preferred Stock will automatically and without further action of the purchaser be voted in a manner that "mirrors" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that are not voted) and Series C Preferred Stock are voted on the Reverse Split, abstentions by common stockholders did not have any effect on the votes cast by the holders of the Series D Preferred Stock.

Pursuant to the Purchase Agreement, on November 29, 2022, the Company filed separate certificates of designation (each, a "Certificate of Designation") with the Secretary of State of the State of Delaware designating the rights, preferences and limitations of the shares of Series C Preferred Stock and Series D Preferred Stock, which will provide, in particular, that the Preferred Stock will have 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 Split proposal, provided that the Series D preferred stock contains a provision that limits the total voting power of a holder of Series D preferred stock to a maximum of 9.99% of the total voting power of the Company.

The holders of shares of Series C Preferred Stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Series C Preferred Stock is convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of Common Stock at a conversion price of $0.15768 ($7.884 as adjusted for the Reverse Stock Split) per share. The conversion price can be adjusted pursuant to the Series C Preferred Stock Certificate of Designation for stock dividends and stock splits, subsequent rights offering, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the applicable Certificate of Designation). The holders of the Preferred Stock have the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares commencing after the earlier of the receipt of stockholder approval of the Reverse Split and 60 days after the closing of the issuances of the Preferred Stock, and until 90 days after such closing. 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 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 proceeds of the Offering were held in a third-party escrow account, along with the additional amount that would be necessary to fund the 105% redemption price, until the expiration of the redemption period for the Preferred Stock, as applicable, subject to the earlier payment to redeeming holders.

In connection with the Offering, the Company agreed to pay Roth Capital Partners, LLC, the Company's Placement Agent for the Offering (the "Placement Agent"), a financial advisory fee of $200,000 and to reimburse the Placement Agent for certain of its expenses, including legal costs, in an amount not to exceed $50,000. In addition, the Company agreed to pay the Placement Agent a cash fee equal to 5% of the gross proceeds received from any shares of Series C Preferred Stock that are ultimately converted into Common Stock.

As a result of the November 2022 Offering and pursuant to the terms of the Warrants, on November 30, 2022 the exercise price for all of the Warrants was reduced to $7.884. Thereafter, as a result of the Reverse Stock Split and pursuant to the terms of the Warrants, the exercise price for all Warrants was reduced to $7.57 on January 13, 2023.

As of February 8, 2023, no shares of Preferred Stock were outstanding, all investors were paid in full and the escrow account was closed. There were no conversions of the Preferred Stock into the Company's common stock. We have Restricted Cash on our December 31, 2022 balance sheet in the amount of $5,250,000, all of which was restricted for use to fund the redemption of this Preferred Stock.

Supply Chain Constraints; Inflationary Pressures

We experienced supply chain constraints due to the COVID-19 pandemic and its aftermath. These constraints began in approximately December 2021 and continued through approximately the third quarter of 2022. These constraints had impacted the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products and may continue to impact its ability to fulfill customer orders going forward which would have a material adverse effect on the Company's business and results of operations. The Company is subject to out-of-stock fees to certain retailers in the event that the Company is unable to adequately maintain certain inventory levels of our Viactiv products. The Company paid approximately $83,000 in such fees in 2022 to these retailers. Additionally, the Company and its suppliers are experiencing significant broad-based inflation of manufacturing and distribution costs as well as transportation challenges. The Company expects input cost inflation to continue at least throughout 2023.

Launch of Viactiv® Omega Boost Gel Bites

In February 2022, we began the marketing of our Viactiv® Omega Boost Gel Bites product, our first expansion of the Viactiv brand since we acquired the business in June 2021. The 1,200 mg Omega-3 gel bites are designed to provide total body support, including cardiovascular, brain, joint and eye health. The new dosage form is able to provide the potency of large, hard-to-swallow soft gels, in a great tasting chewable format that has ten times more Omega-3 than the leading fish oil gummies. The gel bite dosage form has been shown to have better absorption and fewer digestive issues than regular soft gel formulas, as well as no unpleasant fishy aftertaste and no sugar, which is associated with many other Omega-3 products. During the three months ended September 30, 2022, we announced interim results of an independent clinical study designed to evaluate the effectiveness of our new Viactiv Omega Boost Gel Bites at increasing Omega-3 saturation levels on red blood cells. Our interim clinical results showed a 50% improvement in Omega-3 levels in just 4 weeks of customer usage.

We hope that this new product will not only increase our revenues but also be the first of many new product launches over upcoming quarters. The Omega Boost Gel Bites also represent an expansion of the Viactiv brand beyond calcium products. Initial customer reaction has been positive as judged by online reviews. Although sales of our Omega Boost Gel Bites have been modest since its launch, we are optimistic about the potential of the product as we increase consumer awareness, receive additional clinical support for the efficacy of the product, refine our marketing activities and increase distribution.

Adding these products has enabled us to create additional value in multiple ways. We believe the Viactiv brand and established distribution will make our Omega Boost Gel Bites sales and marketing functions more successful. Introducing this new product in 2022 expanded our portfolio beyond calcium chews which is an important aspect of our growth strategy. The Viactiv brand has traditionally focused its marketing of calcium supplements to female purchasers at different life stages. We believe this target audience will also be interested in purchasing our omega-3 supplements that we believe provide a preferred alternative to existing omega-3 soft gels and gummy products.

The introduction of the Omega Boost Gel Bites product greatly expanded the total addressable market for Viactiv by expanding the brand into the established sizeable omega-3 market. We hope that our omega-3 product will distinguish itself from the competition over time.

We have also expanded our sales channels for Viactiv by launching a direct-to-consumer website. This new channel offers Viactiv customers an additional channel to purchase our products, but it also provides customers with more customized offers and information.

We plan to leverage the established distribution channels and marketing experience that Viactiv enjoys to our other products, which we hope will accelerate those products' revenue growth. Viactiv has traditionally distributed its calcium chews through traditional retailers with physical locations, online retailers and direct to consumer via our website. We launched our Omega Boost Gel Bites on the viactiv.com website, and we continue to add online retailers. We are currently evaluating whether to expand distribution to traditional retailers. Initial customer reaction to the Omega Boost Gel Bites has been positive as judged by online reviews, customer surveys and focus groups. While sales of our Omega Boost Gel Bites have been modest, we are optimistic about the product's potential as we increase consumer awareness, receive additional clinical support for the efficacy of the product, and refine our marketing activities.

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

During January 2022, we launched our new e-commerce venue through a Shopify store for our Viactiv line of products (which can be found at www.viactiv.com). The new e-commerce platform offers Viactiv customers the option of shopping via retail outlets (e.g., grocery, pharmacy, etc.) or online through those same retail websites or directly through our new branded website. We derived approximately 4% of our sales revenue from this channel during the year ended December 31, 2022. We hope to increase this revenue segment through a targeted marketing effort to attract existing and new customers through a digital marketing strategy which entails mobile optimization, performance marketing, and brand awareness.

Strategic Objectives, Goals and Strategies

Our ability to maximize stockholder value requires that we build a solid corporate foundation and demonstrate growth and commercial success on top of that foundation. We have taken a number of steps the last two years to strengthen our corporate foundation, including acquiring Viactiv, winding down and reevaluating Vector Vision, hiring key team members, launching a new product, strengthening our eCommerce capabilities and streamlining operations.

Our three primary objectives are:

- Demonstrate Commercial Success: We are focused on growing sales of our existing Viactiv product portfolio, growing sales of new products introduced in 2022 and positioning the other clinical nutrition products to maximize results. We have taken steps to address this objective during 2022 by launching the new Omega Boost Gel Bites, which adds a key product to our portfolio. New products are also important to reduce the risk of customer of supplier concentrations. We continue to work with our manufacturing partners to begin rebuilding inventories which were negatively impacted by the supply chain constraints we have experienced. Lack of inventory was the biggest impediment to our ability to grow sales of our calcium products in the first half of 2022, but we have made progress in rebuilding these stocks and re-stocking retailers during the second half of 2022. We have also communicated a price increase to our retail partners that was implemented during the year. Despite the operational improvements, our sales declined in the twelve months ended December 31, 2022. These sales declines are consistent with declines in the broader vitamin, mineral and supplement category at retail locations and were also the result of the continuing supply constraints we experienced during the six months ended December 31, 2022.

- Strengthen our Commercial Engine: We believe we need to effectively implement several strategies, including expanding our distribution within the sales channels, strengthening our Viactiv brand and related marketing, building our innovation pipeline and strengthening our team. During the year, we continued to discuss new distribution opportunities with new and existing customers as well as enhancing our direct-to-consumer capability on viactiv.com. We also advanced our marketing efforts by conducting consumer surveys and focus groups. We continue to monitor customer trends and identify opportunities for new product development.. As we enter 2023, we plan to focus our efforts on commercializing the Omega Boost Gel Bites that were introduced in 2022, and we will evaluate plans to launch another product in 2023. During the six months ended December 31, 2022, we strengthened our inventory levels in order to increase our marketing trials in an effort to get back to consistent selling levels with Amazon.com. We continue to pursue additional marketing strategies to increase the distribution of all Viactiv products across our existing sales channels.

- Strengthen our Clinical Nutrition Strategy: We are strengthening our Clinical Nutrition Strategy, by, among others, advancing clinical evidence regarding our existing and future products, partnering with specialty manufacturers and suppliers to leverage innovations, and working to increase awareness of our products within the healthcare community. During the twelve months ended December 31, 2022, we announced interim results of an independent clinical study designed to evaluate the effectiveness of new Viactiv Omega Boost Gel Bites at increasing Omega-3 saturation levels on red blood cells. Our interim clinical results showed a 50% improvement in Omega-3 levels in just 4 weeks of customer usage. Finally, we continue to meet with manufacturing partners to research the supply of science based ingredients and new formats that could be incorporated into our future products.

Evaluation of Strategic Alternatives

The Company is also evaluating alternative strategic paths focused on maximizing stockholder value, and we have hired a financial advisor to support this process. In March 2023, we retained Alantra, LLC ("Alantra") as the Company's exclusive financial advisor to implement a strategic review to evaluate alternatives to maximize stockholder value in the near-term, which could include, among other alternatives, a sale of the Company or the Viactiv brand, or a merger, acquisition, reverse acquisition, or other strategic transaction.

Our management team and Board of Directors believe that the current market valuation of the Company does not accurately reflect the potential value of the Company and the clinical nutrition platform and the brand that we are building. The Company is therefore exploring a diverse range of strategic options to help grow the Company and enhance stockholder value, including, among other things, a sale of the Company or Viactiv brand, merger, acquisition, reverse acquisition, or other strategic transaction. There can be no assurances, however, that this process will result in a transaction, or that if a transaction is completed, it will ultimately enhance stockholder value. There is no set timetable for the strategic review process and the Company does not intend to provide periodic updates until the Board of Directors makes a formal decision and determines that disclosure is appropriate and/or necessary under the circumstances.

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, 2022, we had one customer that accounted for 57% of total revenue. During the year ended December 31, 2021, we had one customers that accounted for 49% of total revenue, respectively. No other customer accounted for more than 10% of revenue during the years ended December 31, 2022 or 2021.

Accounts receivable

As of December 31, 2022, we had accounts receivable from one customer which comprised approximately 88% of accounts receivable. As of December 31, 2021, we had accounts receivable from one customer which comprised approximately 81% of accounts receivable. No other customer accounted for more than 10% of accounts receivable as of December 31, 2022 or 2021. The Company has no recent history of significant uncollectible accounts receivable from customers.

Purchases from vendors

During the years ended December 31, 2022 and 2021, we utilized one manufacturer for most our production and packaging of clinical nutrition products. Total purchases from this manufacturer accounted for approximately 48% and 70% of all purchases for the years ended December 31 2022 and 2021, respectively. No other vendor accounted for more than 10% of purchases during the years ended December 31, 2022 or 2021.

Accounts payable

As of December 31, 2022, one vendor accounted for 88% of total accounts payable. As of December 31, 2021, one vendor accounted for 46% of total accounts payable. No other vendor accounted for more than 10% of accounts payable as of December 31, 2022 or 2021.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

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

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

Inventories

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

Intangible Assets

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.

Goodwill

The Company tests goodwill for impairment annually on December 31, or more frequently if a triggering event occurs and it updates its test with information that becomes available through the end of the period reported. Goodwill impairment exists when the fair value of goodwill is less than its carrying value. The Company is its sole reporting unit.

Convertible 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.

Business Combinations

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

Stock-Based Compensation

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

Stock-based payments to officers, directors, consultants, contractors, and employees, which include grants of employee stock options, are recognized in the financial statements based on their fair values. Stock option grants, which are generally time or performance vested, are measured at the grant date fair value and charged to operations on a straight-line basis over the vesting period. The fair value of stock options is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the expected life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date and the estimated volatility of the common stock over the term of the equity award.

Recent 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 have been experiencing supply chain constraints due to the COVID-19 pandemic. These constraints began in approximately December 2021 and continued into the third quarter of 2022. These supply chain issues constrained our ability to obtain inventory to fulfill customer orders for our Viactiv brand products from approximately the third quarter of 2021 through the third quarter of 2022, and we have not experienced any disruptions since. We are subject to out-of-stock fees to certain retailers in the event that we are unable to adequately maintain certain inventory levels of our Viactiv products. Additionally, we and our suppliers are experiencing significant broad-based inflation pressures. We expect input cost inflation to continue at least throughout 2023.

Plan of Operations

General Overview

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

Our team is focused on building a strong foundation by developing a business model and infrastructure that is designed for long-term commercial success. This process will take time, but we continue to take important steps required to build a stronger company. Based on the availability of sufficient funding, we intend to increase our commercialization and business development activities, including engaging in new product development and further strategic transaction acquisitions, to capitalize on growth opportunities. We are also exploring, with the assistance of our financial advisor, a diverse range of strategic options to help grow the Company and enhance stockholder value, including, among other things, a sale of the Company or Viactiv brand, merger, acquisition, reverse acquisition, or other strategic transaction.

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

We are currently working on several initiatives that we believe will help achieve these long-term goals as described above under “Strategic Objectives, Goals and Strategies” and below.

Our growth initiatives are focused on increasing revenue and bringing compelling products to market under meaningful and differentiated brands that are supported by strong science. Management intends to focus on those products that possess the greatest chance for commercial success within a reasonable period of time and with a reasonable deployment of capital.

- We intend to improve our sales channels by increasing product commercialization through better access to sales channels and to leverage our collective experience, particularly from the Viactiv product distribution, to increase and improve the distribution of all of our products. We added a direct-to-consumer eCommerce capability on viactiv.com during 2022 to expand our sales channels. Our calcium chews can now be purchased through a number of sales channels, including stores owned by traditional retailers, websites of online retailers and directly from Viactiv at viactiv.com. We launched our Omega Boost Get Bites earlier in 2022 on the Viactiv direct-to-consumer site, and we added distribution of the product by adding it to certain online retailers during the year.

- We intend to enhance our product strategy by continuing to develop new products that increase our product breadth, like the Omega Boost Gel Bites. New products are an important component of our sales growth strategy, but they also diversify our customer base and supply chains. We also continue to critically evaluate our current product portfolio in order to improve or discontinue certain of our existing products. We are focused on products with differentiated formulations, product taste, compelling product formats, and competitive cost structures.

- We intend to improve our brand strategy by improving the management and exploitation of our brand portfolio particularly, by leveraging Viactiv’s strong consumer awareness and acceptance. Launching the Omega Boost Gel Bites was an important step to introducing new products to consumers aware of the Viactiv brand. This new product introduction also reinforced key attributes of the Viactiv brand, including consumer experience and product efficacy.

- We intend to strengthen our clinical nutrition strategy by continuing to advance clinical evidence regarding our products, working with manufacturers and suppliers to leverage our partner’s innovations and increasing awareness of our products and efforts within the healthcare community.

- We plan to expand our scientific work by improving the science that supports our products and drives our product development process and increasing clinical evidence regarding our products from established health care professionals. For example, during the twelve months ended December 31, 2022, we announced interim results of an independent clinical study designed to evaluate the effectiveness of new Viactiv Omega Boost Gel Bites at increasing Omega-3 saturation levels on red blood cells. Our interim clinical results showed a 50% improvement in Omega-3 levels in just 4 weeks of customer usage.

Results of Operations

Through December 31, 2022, we have primarily been engaged in product development, commercialization, completing the integration of Activ and raising capital. We have incurred and will continue to incur significant expenditures for the development of our products and intellectual property, which includes nutrition, medical foods and supplements. These products support healthcare professionals, their patients and consumers in achieving health goals. With the acquisition of the Viactiv brand and business effective June 1, 2021, and its successful integration into our operations since that date, we have established a significant baseline level of gross revenues. When comparing the Company’s financial performance for the years ended December 31, 2022 and December 31, 2021 below, consider that the Company only operated the Viactiv business for seven months in 2021 versus 12 months in 2022.

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

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

Comparison of Years Ended December 31, 2022 and 2021

	Years Ended December 31,			
	2022	2021	Change	
Revenue	$ 11,049,772	$ 7,233,118	$ 3,816,654	53%
Cost of goods sold	6,529,385	4,122,684	2,406,701	58%
Gross Profit	4,520,387	3,110,434	1,409,953	45%
Operating Expenses:				
Research and development	193,800	64,358	129,442	201%
Sales and marketing	2,069,660	2,324,569	(254,909)	(11%)
General and administrative	9,602,244	11,204,885	(1,602,641)	(14%)
Impairment of Intangible assets	10,065,833	-	10,065,833	
Impairment of Goodwill	-	11,893,134	(11,893,134)	
Acquisition transaction costs	-	2,103,680	(2,103,680)	
Loss on disposal of equipment	9,448	160,137	(150,689)	(94%)
Loss on lease termination, net	-	106,477	(106,477)	
Total Operating Expenses	21,940,985	27,857,240	(5,916,255)	(21%)
Loss from Operations	(17,420,598)	(24,746,806)	(7,326,208)	(30%)
Other Income (Expense):				
Change in fair value of warrant derivative liability	2,345,800	-	2,345,800	
Interest income	152,570	1,797	150,773	839%
Total other Income (Expense)	2,498,370	1,797	2,496,573	
Net loss	(14,922,228)	(24,745,009)	9,822,781	(40%)
Preferred stock deemed dividend	941,585	-	941,585	
Net Loss available to common stockholders	$ (15,863,813)	$ (24,745,009)	$ 8,881,196	(36%)

Revenue

For the year ended December 31, 2022, revenue from product sales was approximately $11,050,000 compared to revenue of approximately $7,233,000 for the year ended December 31, 2021, resulting in an increase of approximately $3,817,000 or 53%. The increase is primarily driven by the revenue of approximately $10,640,000 generated during the year ended December 31, 2022 by our Viactiv product line. In 2021 we owned the Viactiv product line for 7 months versus 12 months in 2022.

Cost of Goods Sold

For the year ended December 31, 2022, cost of goods sold was approximately $6,529,000 compared to cost of goods sold of approximately $4,123,000 for the year ended December 31, 2021, resulting in an increase of approximately $2,406,000 or 58%. This increase is primarily driven by the approximate $6,181,000 cost of sales related to our Viactiv product line.

Gross Profit

For the year ended December 31, 2022, gross profit was approximately $4,520,000 compared to gross profit of approximately $3,110,000 for the year ended December 31, 2021, resulting in an increase of approximately $1,410,000 or 45%. Gross profit represented 41% of revenues for the year ended December 31, 2022. Approximately $4,559,000 or 99% of the 2022 versus $2,991,000 or 96% of the 2021 gross profit was generated from the sale of the Viactiv products.

Research and Development

For the year ended December 31, 2022, research and development costs were approximately $194,000 compared to costs of approximately $64,000 for the year ended December 31, 2021, resulting in an increase of approximately $130,000 or 201%. Research and development costs during the year ended December 31, 2022 and 2021 consist primarily of clinical studies related to our clinical nutrition products.

Sales and Marketing

For the year ended December 31, 2022, sales and marketing expenses were approximately $2,070,000 compared to expenses of approximately $2,325,000 for the year ended December 31, 2021. The decrease in sales and marketing expenses of approximately $255,000 or 11% compared to the prior period was primarily due to the increased focus on targeted marketing spend related to our Viactiv line of products and increased fiscal discipline.

General and Administrative

For the year ended December 31, 2022, general and administrative expenses were approximately $9,602,000 compared to expenses of approximately $11,205,000 for the year ended December 31, 2021. The decrease of approximately $1,603,000 or 14% compared to the prior period. This decrease was primarily due to decreases in stock-based compensation of approximately $962,000, professional fees of approximately $775,000, consulting fees of approximately $719,000, rent of approximately $119,000, License and fees of approximately $97,000, Franchise and non-income related tax of approximately $75,000, computer and call center expense of approximately $54,000 and repairs and maintenance of approximately $51,000 offset by increases in amortization of intangibles of approximately $496,000, administrative and broker fees of approximately $263,000, legal fees of approximately $229,000, warehousing fees of approximately $150,000, shareholder meetings of approximately $65,000, payroll and benefits of approximately $61,000 recruitment fees of approximately $49,000 and dues and subscriptions of approximately $46,000.

Acquisition Transaction Costs

For the year ended December 31, 2021, acquisition transaction costs were approximately $2,104,000, all of which relate to our acquisition of Activ. We did not have any acquisition costs in 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 our consolidated statement of operations for the year ended December 31, 2022. For additional information, see Note 6 to the consolidated financial statements.

Impairment of Goodwill

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

Loss on Disposal of Fixed Assets

For the year ended December 31, 2022, loss on disposal of fixed assets was approximately $9,000 as compared to a loss of approximately $160,000 for the year ended December 31, 2021, a decrease of approximately $151,000 or 94%. The 2021 losses were attributable to the termination of our headquarters lease in San Diego, California, and disposal of related fixed assets.

Loss on Lease Termination

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

Change in Fair Value of Warrant Derivative Liability

For the year ended December 31, 2022, the gain on change in fair value of warrant derivative liabilities was approximately $2,346,000 as compared to $0 for the year ended December 31, 2021, an increase of approximately $2,346,000. The increase is due to the issuance of the Series A warrants and Series B warrants issued in the February Offering, and is based on the change in the fair value of the warrants from the issuance date to December 31, 2022, based on fluctuations in the Company's stock price, estimated lives, any adjustments to date, and the exercise price utilizing the Binomial Lattice model to calculate the fair value at each reporting date, as a noncash adjustment.

Interest Expense

There was no interest expense during the years ended December 31, 2022 and December 31, 2021.

Net Loss

For the year ended December 31, 2022, we incurred a net loss of approximately $14,922,000 compared to a net loss of approximately $24,745,000 for the year ended December 31, 2021. The decrease in net loss of approximately $9,823,000 or 36% for the year ended December 31, 2022 as compared to the year ended December 31, 2021 is primarily due to the 2021 charges to goodwill impairment of approximately $11,893,000, transaction costs associated with the 2021 acquisition of Activ of approximately $2,104,000, partially offset by the 2022 intangible asset impairment charge of approximately $10,066,000, the change in fair value of warrant liabilities of $2,345,000 and net reductions during 2022 in general and administrative costs as a result of our 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 is comprised of interest in the amount of $500,000, placement fees $250,000, legal fees $158,585, accounting fees $30,500 and escrow account fees $2,500. As the Company has an accumulated deficit balance, there is no overall impact to additional paid-in capital, as the deemed dividend is recorded as offsetting debit and credit entries to additional paid-in capital. Therefore, the amounts were not presented on the Statement of Stockholders' (Deficit) Equity.

Liquidity and Capital Resources

For the year ended December 31, 2022, we incurred a net loss of approximately $14,922,000 and used cash in operating activities of approximately $7,447,000. At December 31, 2022, we had cash and cash equivalents on hand of approximately $10,655,000 and working capital of approximately $14,307,000. Working Capital includes the sum of (current assets – restricted cash) – (current liabilities - the current portion of warrant derivative liabilities).

Notwithstanding the net loss for 2022, management believes that our current cash balance is sufficient to fund operations for in excess of one year from the date of the Company's 2022 financial statements are issued.

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

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

Sources and Uses of Cash

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

	Years Ended December 31,	
	2022	**2021**
Net cash used in operating activities	$ (7,446,812)	$ (10,644,416)
Net cash provided by (used in) investing activities	4,990,054	(31,011,401)
Net cash provided by financing activities	14,268,321	37,231,012
Net increase (decrease) in cash	$ 11,811,563	$ (4,424,805)

Operating Activities

Net cash used in operating activities was approximately $7,447,000 during the year ended December 31, 2022, as compared to approximately $10,644,000 used during the comparable prior year period. The change in operating activities stems primarily from our acquisition of the Viactiv business in 2021, the associated purchases of inventory and operating expense.

Investing Activities

Net cash provided by investing activities was approximately $4,990,000 for the year ended December 31, 2022 and the net cash used in investing activities was approximately $31,011,000 for the year ended December 31, 2021. For the year ended December 31, 2022, we purchased approximately $77,592,000 in U.S. Treasury Bills which was offset by sales and maturities of those U.S. Treasury Bills of approximately $82,587,000.

In 2021, we used cash of approximately $26,000,000 for the acquisition of Activ and $77,000 for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was approximately $14,268,000 for the year ended December 31, 2022 and consisted of the sale of common stock with net proceeds of approximately $8,835,000, the sale of preferred stock with net proceeds of approximately $4,308,000 and warrant exercises during the period with proceeds of approximately $1,134,000. Net cash provided by financing activities was approximately $37,231,000 for the year ended December 31, 2021 and consisted of the sale of common stock with net proceeds of approximately $33,663,000 and warrant exercises during the period with proceeds of approximately $3,568,000.

JOBS Act

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

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

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

PRINCIPAL COMMITMENTS

Appointment of CEO

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

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

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

None of the Company's executives were paid bonuses for the year ended December 31, 2022.

Office lease

In July, 2021, the Company entered into a month-to-month lease for its primary corporate office space located in Houston, Texas, with current lease payments of approximately $2,700 per month.

Trends, Events and Uncertainties

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found beginning on page F-1 of this Annual Report on From 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our Chief Executive Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management concluded that as of December 31, 2022, our disclosure controls and procedures were not effective due to a material weakness in our internal control over financial reporting described below.

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

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

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

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

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

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013).

Based on this evaluation, our Chief Executive Officer and our Chief Accounting Officer concluded that our internal controls over financial reporting were not effective as of December 31, 2022. Management has identified the following material weakness in the Company's internal control over financial reporting as of December 31, 2022:

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 this Annual Report on Form 10-K. 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. 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.

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

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

(c) Changes in Internal Control over Financial Reporting. There were no 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.

(d) Remediation of Material Weakness

Subsequent to September 30, 2022, the Company adopted additional internal controls wherein if the issuance of warrants or other derivative financial instruments, or any other complex transaction is contemplated, an accounting consultant will be engaged as to the financial statement impact that any such transaction may have, prior to consummation of the transaction.

ITEM 9B. OTHER INFORMATION

Not applicable.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

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, 2022 and 2021, 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, 2022 and 2021, 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
April 17, 2023

Guardion Health Sciences, Inc.
Consolidated Balance Sheets

	December 31,	
	2022	**2021**
Assets		
Current assets		
Cash and cash equivalents	$ 10,655,490	$ 4,093,927
Restricted cash	5,250,000	-
Short-term investments	-	4,995,623
Accounts receivable, net	1,924,353	1,411,567
Inventories, net	3,119,421	367,691
Prepaid expenses and other assets	687,933	1,200,376
Total current assets	**21,637,197**	**12,069,184**
Property and equipment, net	48,871	111,378
Intangible assets, net	-	11,255,833
Operating lease right-of-use asset, net	-	24,257
Total assets	**$ 21,686,068**	**$ 23,460,652**
Liabilities, Redeemable Preferred Stock, and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,518,052	$ 241,347
Accrued expenses	558,287	895,477
Operating lease liability - current	3,807	22,221
Warrant derivative liability – current	1,931,400	-
Total current liabilities	**4,011,546**	**1,159,045**
Warrant derivative liability – long-term	4,506,600	-
Operating lease liability – long-term	-	3,807
Total liabilities	**8,518,146**	**1,162,852**
Commitments and contingencies		
Redeemable preferred stock		
Series C convertible redeemable preferred stock, 495,000 shares issued and outstanding	5,197,500	-
Series D redeemable preferred stock, 5,000 shares issued and outstanding	52,500	-
Total redeemable preferred stock	5,250,000	-
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized		
Common stock, $0.001 par value; 250,000,000 shares authorized; 1,267,340 and 488,539 shares issued and outstanding at December 31, 2022 and December 31, 2021	1,267	489
Additional paid-in capital	101,640,955	101,099,383
Accumulated deficit	(93,724,300)	(78,802,072)
Total stockholders' equity	**7,917,922**	**22,297,800**
Total liabilities, redeemable preferred stock, and stockholders' equity	**$ 21,686,068**	**$ 23,460,652**

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2022	**2021**
Revenue		
Clinical nutrition	$ 11,031,053	$ 6,952,359
Other	18,719	280,758
Total revenue	11,049,772	7,233,118
Cost of goods sold		
Clinical nutrition	6,529,385	3,838,990
Other	-	283,694
Total cost of goods sold	6,529,385	4,122,684
Gross profit	4,520,387	3,110,434
Operating expenses		
Research and development	193,800	64,358
Sales and marketing	2,069,660	2,324,569
General and administrative	9,577,987	11,204,885
Impairment of intangible assets	10,065,833	-
Impairment of goodwill	-	11,893,134
Transaction costs related to acquisition	-	2,103,680
Impairment of right-of-use asset	24,257	-
Loss on lease termination		106,477
Loss on disposal of fixed assets	9,448	160,137
Total operating expenses	21,940,985	27,857,240
Loss from operations	(17,420,598)	(24,746,806)
Other income/(expense):		
Gain on change in fair value of warrant derivative liability	2,345,800	-
Interest income, net	152,570	1,797
Total other income (expense)	2,498,370	1,797
Net loss	**(14,922,228)**	**(24,745,009)**
Preferred stock deemed dividend	941,585	-
Net loss available to common stockholders	$ (15,863,813)	$ (24,745,009)
Net loss per common share – basic and diluted	$ (14.15)	$ (52.23)
Weighted average common shares outstanding – basic and diluted	1,121,000	473,772

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, 2020	303,413	$ 303	$ 62,598,291	$ (54,083,328)	$ 8,515,266
Cumulative effect adjustment from the impact of adoption of Accounting Standards Update (ASU) 2020-06 related to warrants (See Notes 2 and 8)	-	-	-	26,265	26,265
Common stock issued for cash, net of offering costs	152,173	152	33,662,444	-	33,662,596
Common stock issued upon exercise of warrants	32,953	33	3,568,382	-	3,568,415
Fair value of vested stock options	-	-	600,887	-	600,887
Fair value of vested restricted stock	-	-	669,379	-	669,379
Net loss	-	-	-	(24,745,009)	(24,745,009)
Balance at December 31, 2021	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

See accompanying notes to consolidated financial statements.

Guardion Health Sciences, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2022	**2021**
Operating Activities		
Net loss	$ (14,922,228)	$ (24,745,009)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,248,789	782,920
Impairment of intangible assets	10,065,833	-
Impairment of goodwill	-	11,893,134
Loss on lease termination, net	24,257	106,477
Loss on disposal of property and equipment	9,448	160,137
Allowance for accounts receivable	1,996	20,695
Inventory write-down	55,609	179,222
Operating lease right-of-use asset	-	124,628
Fair value of vested stock options	225,564	600,887
Fair value of common stock issued for services	82,266	669,379
Gain on change in fair value of warrant derivative liability	(2,345,800)	-
Changes in operating assets and liabilities:		
(Increase)/decrease:		
Accounts receivable	(94,286)	378,681
Inventories	(2,807,339)	451,122
Prepaid expenses and other	91,946	(971,420)
Increase/(decrease):		
Accounts payable	1,276,545	(680,697)
Accrued expenses	(337,190)	768,127
Operating lease liability	(22,222)	(233,741)
Payable to former officer	-	(148,958)
Net cash used in operating activities	(7,446,812)	(10,644,416)
Investing Activities		
Purchase of property and equipment	(5,569)	(74,592)
Purchase of U.S. Treasury Bills	(77,591,741)	(70,952,562)
Sale of U.S. Treasury Bills	82,587,364	65,956,939
Cash paid for acquisition, net of cash acquired	-	(25,941,186)
Net cash provided by (used in) investing activities	4,990,054	(31,011,401)
Financing Activities		
Proceeds from sale of common stock, net	8,834,899	33,662,597
Proceeds from sale of preferred stock, net	4,308,415	-
Proceeds from exercise of warrants	1,134,040	3,568,415
Repurchase of common stock to cover tax withholding on restricted stock units	(9,033)	-
Net cash provided by financing activities	14,268,321	37,231,012
Cash and cash equivalents and restricted cash:		
Net increase (decrease)	11,811,563	(4,424,805)
Balance at beginning of period	4,093,927	8,518,732
Balance at end of period	$ 15,905,490	$ 4,093,927
Supplemental disclosure of cash flow information:		
Cash paid for -		
Interest	$	$ -
Income taxes	$	$ -
Non-cash financing activities:		
To adjust warrant liability for adoption of ASU 2020-06	$ -	$ 26,265
Initial fair value of warrant derivative liabilities recognized in connection with issuance of common stock in February 2022	$ 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 nutrition, medical foods and dietary supplements. The Company offers a portfolio of science-based, clinically supported products and devices designed to support healthcare professionals and providers, and their patients and consumers. In June 2021, the Company acquired Activ Nutritional, LLC ("Activ"), the owner and distributor of the Viactiv® line of supplements for bone health and other applications (see Note 3). The Company was formed in 2009 as a California limited liability company under the name P4L Health Sciences, LLC, and in 2015 converted from a California limited liability company to a Delaware corporation, changing its name from Guardion Health Sciences, LLC to Guardion Health Sciences, Inc.

Liquidity

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. For the year ended December 31, 2022, the Company incurred a net loss of $14,922,228 and used cash in operating activities of $7,446,812. 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 net loss for 2022, management concluded that the Company will have adequate unrestricted cash available from the Company's cash and cash equivalents balance of $10,655,490 at December 31, 2022, 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 the Company's 2022 financial statements are issued.

The amount and timing of future cash requirements will depend, in part, on the Company's ability to ultimately achieve operating profitability. The Company expects to continue to incur net losses and negative operating cash flows in the near-term and will continue to incur significant expenses for the development, commercialization and distribution of its clinical nutrition products (including the Viactiv® product line), the development and commercialization of its diagnostics equipment, and the successful development and commercialization of any new products or product lines. The Company may also utilize cash to fund additional acquisitions.

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

COVID-19 and Inflation

COVID-19 and Supply Disruptions. The Company's financial results for the year ended December 31, 2022 have been affected by supply chain constraints due, in large part, to the COVID-19 pandemic and resulting labor shortages and increased wages experienced by the Company's suppliers. These constraints began in the fourth quarter of 2021 and continued throughout the first quarter of 2022 and had impacted the Company's ability to obtain inventory to fulfill customer orders for its Viactiv branded products on a timely basis. Additionally, the Company is subject to out-of-stock fees to certain retailers in the event that the Company is unable to adequately maintain certain inventory levels of its Viactiv products with such retailers. During 2022 the Company has seen some improvement in the inventory production cycle.

Inflation. The continuing impact of the COVID-19 pandemic, higher inflation, the actions by the Federal Reserve to address inflation, most notably dramatic increases in interest rates, and rising energy prices create uncertainty about the future economic environment which will continue to evolve and, we believe, has impacted the Company's business in 2022 and will continue to impact business in 2023. 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 Notice and Reverse Stock Split

On January 25, 2022, the Company received a written notice from the Nasdaq Stock Market LLC ("Nasdaq") that the Company had not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for a period of 30 consecutive business days. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(3)(A), the Company was provided a compliance period of 180 calendar days from the date of the notice, or until July 25, 2022, to regain compliance with the $1.00 minimum bid price requirement. The Company did not regain compliance during the compliance period ended July 25, 2022. Accordingly, the Company requested that Nasdaq grant the Company a second 180 calendar day period to regain compliance.

On July 26, 2022, the Company received a written notice from Nasdaq that the Company was granted a second 180 calendar day period, or until January 23, 2023, to regain compliance with the $1.00 minimum bid price requirement. Nasdaq's determination to grant the second compliance period was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. Previously, at the Company's Annual Meeting of Stockholders ("Annual Meeting") held on June 16, 2022, the proposal to grant discretionary authority to the Company's Board of Directors to amend the Company's Certificate of Incorporation, as amended, to combine outstanding shares of the Company's common stock into a lesser number of outstanding shares at a specific ratio within a range of no split to a maximum of a 1-for-30 split, with the exact ratio to be determined by the Board of Directors in its sole discretion (the "Reverse Stock Split") was not approved by the requisite vote of a majority of the Company's issued and outstanding shares. Although 63% of the stockholders represented at the Annual Meeting voted in favor of the Reverse Stock Split, more than 50% of the Company's issued and outstanding shares were required to vote in favor of the Reverse Stock Split. To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days prior to January 23, 2023.

We 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 "2023 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 2023 Reverse Stock Split. The 2023 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 2023 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 will be 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 that would be created as a result of the 2023 Reverse Stock Split was rounded up to the next whole share.

The Company's common stock will continue to trade on the Nasdaq Stock Market LLC under the existing symbol "GHSI", but the security has been assigned a new CUSIP number (40145Q500).

On January 24, 2023, Guardion Health Sciences, Inc. (the "Company") received a letter from The Nasdaq Stock Market LLC ("Nasdaq") stating that because the Company's common stock had a closing bid price at or above $1.00 per share for a minimum of 10 consecutive trading days, the Company had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2).

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The Company previously had two reportable segments, a Clinical Nutrition Segment and a Medical Devices Segment. During the fourth quarter of 2021, the Company announced it would be winding down the Medical Devices Segment, which accounted for approximately 4% of revenue in 2021. As a result, the Company no longer has any material revenues or expenses in the Medical Devices Segment, and accordingly, as of December 31, 2021, the Company is the sole reporting unit. At December 31, 2022, as there is only one reporting unit, all of the Company's prior period segment information has been eliminated.

Principles of Consolidation

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

Reverse Stock Splits

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

On January 6, 2023, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to effectuate the one-for-fifty (1:50) 2023 Reverse Stock Split of its common stock without any change to its par value (see Note 1). The authorized number of shares of common stock were not affected by the reverse stock split. The Company issued 35,281 additional common shares in connection with this reverse split as per the rounding provisions provided therein.

Accordingly, all common shares, stock options, stock warrants and per share amounts in these consolidated financial statements have been adjusted retroactively to reflect the reverse stock splits as if the splits occurred at the beginning of the earliest period presented in this Annual Report.

Use of Estimates

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

Revenue Recognition

The Company recognizes revenue in accordance with Financial Accounting Standard Board's ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*.

Revenue and costs of sales are recognized when control of the products transfers to our customer, which generally occurs upon delivery to the customer. The Company's performance obligations are satisfied at that time. The Company does not have any significant contracts with customers requiring performance beyond delivery, and contracts with customers contain no incentives or discounts that could cause revenue to be allocated or adjusted over time. Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer.

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

Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Historically the Company has not experienced any significant payment delays from customers.

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

Revenue by product:

	Years Ended December 31,	
	2022	2021
Clinical Nutrition	$ 11,031,053	$ 6,952,359
Other	18,719	280,758
	$ 11,049,772	$ 7,233,118

The Company's revenues earned during the years ended December 31, 2022 and 2021, are derived primarily from retail customers in North America.

Revenues by geographical areas:

	Years Ended December 31,	
	2022	2021
North America	$ 11,030,873	$ 7,052,645
Asia	-	158,738
Europe and Other	18,899	21,735
	$ 11,049,772	$ 7,233,118

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 of 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 of 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 $9,135,351 and $3,398,629 for the years ended December 31, 2022 and 2021, respectively. We operated the Activ business for 12 months of 2022 versus 7 months in 2021 from the date of acquisition.

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 $802,958 and $338,829 for the years ended December 31, 2022 and 2021, 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, 2022, $10,655,490 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 9). 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.

Investments

Short-term investments held by the Company as of December 31, 2021 consisted of a U.S. Treasury Bill, which was classified as held-to-maturity. The Company's U.S. Treasury Bill matured approximately 30 days from the date of the purchase. Unrealized gains and losses were not material. As of December 31, 2021, the carrying value of the Company's U.S. Treasury Bill approximates its fair value due to its short-term maturity. As of December 31, 2022, the Company held no short-term investments.

Accounts Receivable

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

At December 31, 2022 and 2021, the allowance for doubtful accounts was $1,996 and $20,695, 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. The Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. When evidence exists that the net realizable value of inventory is lower than its cost, the difference is recognized as a loss in the period in which it occurs. Once inventory has been written down, it creates a new cost basis for inventory that may not subsequently written up. For the years ended December 31, 2022 and 2021, the Company wrote-down inventories of $55,609 and $179,222, respectively, which was recorded in cost of sales (see Note 4).

Property and Equipment

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

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value at that time. At December 31, 2022 and 2021, management determined there were no impairments of the Company's property and equipment.

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.

Intangible Assets

The Company's amortizable finite-lived identifiable intangible assets consisted of a trade name and customer relationships acquired in the acquisition of Activ, effective June 1, 2021 (See Note 3), and were stated at cost less accumulated amortization. The trade name and customer relationships were being amortized over a period of 10 years. The Company follows ASC 360 in accounting for finite-lived intangible assets, which requires impairment losses to be recorded when indicators of impairment are present and the undiscounted cash flows estimated to be generated by the assets are less than the assets' carrying amounts. In addition, the Company's indefinite-lived intangible assets consisted of a $50,000 trademark asset. 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 6).

Goodwill

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

Leases

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

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 $1,618,199 and $161,833 for the years ended December 31, 2022 and 2021, 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 $193,800 and $64,358 for the years ended December 31, 2022 and 2021, respectively.

Patent Costs

The Company is the owner of four issued domestic patents, one granted patent 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, 2022, and 2021, patent costs were approximately $61,246 and $67,681, 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,	
	2022	**2021**
Warrants	1,526,701	9,701
Series C convertible redeemable preferred stock		-
Options	13,294	10,838
Unvested restricted common stock	667	4,053
	1,540,662	24,592

Fair Value of Financial Instruments

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

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

Level 2 – Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3 – Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The following table sets forth by level, within the fair value hierarchy, the Company's assets and liabilities at fair value as of December 31, 2022 and 2021:

	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

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

As of December 31, 2021, there was no warrant derivative liability. The following table provides a roll-forward of the warrant derivative liability measured at fair value on a recurring basis using unobservable level 3 inputs for the years ended December 31, 2022 as follows:

	2022
Warrant derivative liability	
Balance as of beginning of period – December 31, 2021	$ -
Fair value of warrant derivative liability recognized upon issuance of warrants in February 2022	8,783,800
Gain on change in fair value of warrant derivative liability	(2,345,800)
Balance as of end of period – December 31, 2022	$ 6,438,000

As of December 31, 2022, the Company's outstanding warrants were treated as derivative liabilities and changes in the fair value were recognized in earnings. 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 warrants based on the Company's historical volatility. 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 has one component. Therefore, the Company's Chief Executive Officer, who is also the CODM, makes decisions and manages the Company's operations as a single operating segment, which is conducting business as a plastic recycler. To date, the Company has not begun production and measures performance on a consolidated basis.

The Company previously had two reportable segments, a Clinical Nutrition Segment and a Medical Devices Segment. During the fourth quarter of 2021, the Company announced it would be winding down the Medical Devices Segment, which accounted for approximately 4% of revenue in 2021. As a result, the Company no longer has any material revenues or expenses in the Medical Devices Segment, and accordingly, as of December 31, 2021, the Company is the sole reporting unit. At December 31, 2022, as there is only one reporting unit, all of the Company's prior period segment information has been eliminated.

Concentrations

Revenue. During the year ended December 31, 2022, the Company had one customer that accounted for 57% of total revenue. During the year ended December 31, 2021, the Company had one customer that accounted for 49% of total revenue. No other customer accounted for more than 10% of revenue, during the years ended December 31, 2022 or 2021.

Accounts receivable. As of December 31, 2022, the Company had accounts receivable from one customer which comprised approximately 88% of its gross accounts receivable. As of December 31, 2021, the Company had accounts receivable from one customer which comprised approximately 81% of its gross accounts receivable. No other customer accounted for more than 10% of accounts receivable as of December 31, 2022 or 2021.

Purchases from vendors. During the years ended December 31, 2022 and 2021, the Company utilized one manufacturer for most its production and packaging of its clinical nutrition products. Total purchases from this manufacturer accounted for approximately 48% and 70% of all purchases, respectively. No other vendor accounted for more than 10% of purchases during the years ended December 31, 2022 or 2021.

Accounts payable. As of December 31, 2022, one vendor accounted for 88% of total accounts payable. As of December 31, 2021, one vendor accounted for 46% of total accounts payable. No other vendor accounted for more than 10% of accounts payable as of December 31, 2022 or 2021.

Recent Accounting Pronouncements

In September 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-13, Credit Losses – Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. As a smaller reporting company, ASU 2016-13 will be effective for the Company beginning January 1, 2023, with early adoption permitted. The Company is currently assessing the impact of adopting this standard on the Company's financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"). ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion models. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. This update simplifies the related settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective January 1, 2024 for the Company and the provisions of this update can be adopted using either the modified retrospective method or a fully retrospective method. Early adoption is permitted, but no earlier than January 1, 2021.

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

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. 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.

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. Acquisition of Activ Nutritional, LLC

On June 1, 2021, the Company completed the acquisition of Activ Nutritional LLC ("Activ"). The Company acquired all of the issued and outstanding equity of Activ from Adare Pharmaceuticals for $26,000,000 in cash, subject to certain adjustments. Activ owns the Viactiv® line of supplement chews for bone health, immune health and other applications which are currently marketed through many of the nation's largest retailers, including, among others, Walmart (retail and online), Target and Amazon. The Viactiv product lines have become the Company's most prominent product lines for the foreseeable future.

The Company utilized the acquisition method of accounting for the acquisition in accordance with ASC 805, *Business Combinations*, and allocated the purchase price to Activ's tangible assets, identifiable intangible assets, and assumed liabilities at their estimated fair values as of the date of acquisition. The fair value of the intangible assets was estimated using the income approach, and the excess of the purchase price paid by the Company over the estimated fair value of identified tangible and intangible assets was recorded as goodwill.

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

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

The Company consolidated Activ's operations with the Company's operations commencing June 1, 2021, the closing date of the transaction. The amount of revenue and net loss of Activ included in the Company's consolidated statements of operations during the year ended December 31, 2021, was $6,473,000 and $868,000, respectively.

During the year ended December 31, 2021, acquisition-related transaction costs (e.g., legal, due diligence, valuation, investment banking and other professional fees) of approximately $2,104,000 are not included as a component of consideration transferred but were expensed as incurred.

Pro Forma Information

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

	2021
Revenue	$ 12,765,911
Net loss	$ (22,171,583)
Net loss per share – basic and diluted	$ ($47.00)

4. Inventories

Inventories consisted of the following:

	December 31,	
	2022	2021
Raw materials	$ 49,637	$ 53,320
Finished goods	3,069,784	314,371
Inventories, net	$ 3,119,421	$ 367,691

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

For the years ended December 31, 2022 and 2021, the Company recorded inventory write-downs of $55,609 and $179,222, respectively, which are included in cost of sales.

5. Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2022	2021
Leasehold improvements	$ -	$ 4,898
Furniture and fixtures	110,016	129,696
Computer equipment and software	66,115	111,469
Office equipment	-	1,642
	176,131	247,705
Less accumulated depreciation and amortization	(127,260)	(136,327)
	$ 48,871	$ 111,378

Depreciation expense consisted of the following for the years ended December 31, 2022 and 2021, respectively:

	Years Ended December 31,	
	2022	2021
Research and development expense	$ -	$ 38,106
Sales and marketing expense	-	16,362
General and administrative expense	58,789	37,107
	$ 58,789	$ 91,575

6. Goodwill and Intangible Assets, Net

Intangible asset, net consisted of the following:

	December 31,	
	2022	2021
Trade name	$ -	$ 9,200,000
Customer relationships	-	2,700,000
Trademark	-	50,000
	-	11,950,000
Less accumulated amortization	-	(694,167)
	$ -	$ 11,255,833

In relation to the acquisition of Active in 2021 (see Note 3), the Company recorded trade names of $9,200,000 and customer relationships of $2,700,000 that were being amortized over their estimated useful lives of 10 years. 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 at December 31, 2022.

On December 31, 2022, as a result of the widespread delays and disruptions in the supply chain impacting the global economic environment, coupled with, a decline in the Company's market capitalization during 2022, the Company performed an impairment analysis of its intangible assets. In this analysis, the Company first evaluated the recoverability of its intangible assets by comparing the estimated future undiscounted cash flows of its intangible asset group to the carrying value of the asset group. The undiscounted cash flows were less than the intangible asset group's carrying value. As such, the Company determined the asset group's fair value to be nil and for the year ended December 31, 2022, recorded an impairment loss of $10,065,833 for the balance of the intangible assets.

Goodwill:

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

	As of December 31,	
	2022	2021
Beginning balance:	$ -	$ -
Acquisition (see Note 3)	-	11,893,134
Impairment	-	(11,893,134)
Ending balance:	$ -	$ -

In relation to the acquisition of Active (see Note 3) in 2021, the Company recorded goodwill of $11,893,134. As a result of a significant decrease in the Company's market capitalization during the fourth quarter of 2021, the Company evaluated the impact to assess whether there was an impairment triggering event requiring it to perform a goodwill impairment test. In connection with the impairment triggering event, the Company first evaluated the recoverability of its long-lived asset group containing trade name and customer relationships and determined the trade names and customer lists were not impaired at December 31, 2021. The Company next performed a goodwill impairment test as of December 31, 2021. As part of this impairment test, the Company used the income approach to estimate fair value of the Company as sole reporting unit for the step one goodwill impairment test. The discount rate selected was 16% based on management's consideration of the related risk associated with the forecast. Based on the result, the discounted cash flows were less than the net carrying value of the Company's assets, and goodwill was determined to be impaired. Accordingly, the full amount of the Company's goodwill of $11,893,134 was written off as impaired during the fourth quarter of 2021.

7. Operating Leases

In July, 2021, the Company entered into a month-to-month lease for its primary corporate office space located in Houston, Texas, with lease payments of approximately $2,200 per month. 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.

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, 2021, the balance of this lease's operating lease right of use asset was $24,257, and the related operating lease liability was $25,308. During the year ended December 31, 2022, the Company recorded an impairment of the operating lease right of use asset of $24,257, and made payments of $22,221 on the operating lease liability. At December 31, 2022, the balance of the operating lease liability was $3,807, which was paid off in February 2023.

Lease cancellation in 2021

In October 2012, the Company entered into a lease for its corporate office and warehouse located in San Diego, California. The term of the lease, as amended, had a term through July 2023. On September 22, 2021, the Company entered into an agreement with the landlord to terminate the lease for this corporate office and warehouse space effective October 31, 2021. The Company had recorded a right of use asset of $269,706, a lease deposit of $10,470, and an operating lease liability of $282,226, respectively, related to this lease. Pursuant to the termination agreement, the Company agreed to forfeit its security deposit, and pay the landlord an early termination fee of $108,527. The Company accounted for the cancellation of the lease by writing off the right-of-use asset and the forfeited lease deposit, cancelling the operating lease liability, and expensing the early termination fee, which resulted in recording a loss on lease cancellation of $106,477 for the year ended December 31, 2021.

During the years ended December 31, 2022 and 2021, lease expense totaled approximately $48,911 and $148,826, respectively.

As of December 31, 2022, the weighted average remaining lease terms for operating leases are 0.17 years, and the weighted average discount rate for operating lease is 3.9%.

Future minimum lease payments under the leases are as follows:

Year ending	Operating Leases
2023	3,826
Total lease payments	3,826
Less: Imputed interest/present value discount	(19)
Present value of lease liabilities	3,807
Less Current portion	(3,807)
	$ -

8. 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 10). Included in the February 2022 Offering were 740,000 warrants to purchase one share of the Company's common stock at an exercise price of $18.50 per share that expire on the fifth anniversary of the date of issuance ("Series A Warrant") and 740,000 warrants to purchase one share of the Company's common stock at an exercise price of $18.50 per share that expire on the 18 month anniversary of the date of issuance ("Series B Warrant").

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 9). The shares of Series C Preferred Stock are convertible at a conversion price of $7.88 per share into shares of the Company's common stock. Therefore, the exercise price relating to Series A Warrants and 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 clause to adjust the exercise price, based on circumstances not considered to be within the Company's control. The Company determined that the 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 Series B Warrants are not considered indexed to the Company's own stock and not eligible for an exception from derivative accounting. Accordingly, the Series A and 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 (see Note 13).

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

Below are the specific assumptions utilized:

	Series A Warrants		Series B Warrants	
	At Recognition	December 31, 2022	At Recognition	December 31, 2022
Common stock market price	$ 8.95	$ 7.26	$ 8.95	$ 7.26
Risk-free interest rate	1.89%	4.11%	1.37%	4.75%
Expected dividend yield	-	-	-	-
Expected term (in years)	5.00	4.15	1.50	0.65
Expected volatility	142.30%	131.20%	123.20%	104.50%

In January 2023, in conjunction with the completion of the Company's reverse stock split, the exercise price of the Series A and Series B warrants was adjusted to $7.55 per share of common stock, resulting in a loss on the change in fair value of $721,500.

On April 9, 2019, the Company issued 10,417 warrants (the "2019 Warrants") with an exercise price of $30.00 per share to the underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. At December 31, 2020, the fair value of the 2019 Warrants warrant liability was $25,978. Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. ASU 2020-06 removed the requirement to consider if the warrants would be settled in registered shares, and accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $25,978 and a decrease in derivative warrant liability of $25,978 on January 1, 2021.

9. Redeemable Preferred Stock (Temporary Equity)

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 have 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 is 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 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 classifies 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 is not solely within the Company's control. At December 31, 2022, the Series C Preferred stock and Series D Preferred Stock has been recorded at their redemption values of $5,197,500 and $52,500, respectively, which represents an increase of $941,585 from their initial carrying value of $4,308,415. The increase in the carrying value to the redemption value is recorded as a deemed dividend on the consolidated statements of operations and consolidated statements of stockholders' equity.

The shares of Series C Preferred Stock are 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 conversion price can be adjusted pursuant to the Series C Preferred Stock Certificate of Designation for stock dividends and stock splits, subsequent rights offering, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the applicable Certificate of Designation).

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 are 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 are voted on the Amendment. The Certificates of Designation for the Preferred Stock provides that the Preferred Stock have 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).

The holders of Series C Preferred Stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock.

In connection with the offering, the Company and the investors entered into a Registration Rights Agreement, pursuant to which the Company is required to file a registration statement with the Securities and Exchange Commission to register for resale the shares that are issued upon the potential conversion of shares of Preferred Stock. The registration statement is to be filed with the Securities and Exchange Commission on or before the later of 10 calendar days following the date of the shareholder meeting held on January 5, 2023, and the 70th calendar day following the date of the Registration Rights Agreement.

As of December 31, 2022, Series A and Series B preferred shares reflected on the balance sheet is reconciled on the following table:

	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, is held in an escrow account and presented as restricted cash on the consolidated balance sheets. Upon expiration of the redemption period, any proceeds remaining in the escrow account will be disbursed to the Company. The Preferred Stock was redeemed in full as of February 8, 2023, and the escrow account was closed.

10. ***Stockholders' Equity***

Common Stock

The Company's common stock has a par value of $.001. As of December 31, 2022 and 2021, there were 250,000,000 shares authorized, and 1,267,340 and 488,539 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 Series B Warrants are 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 effects a reverse stock split during the term of the Series A Warrants and Series B Warrants, the exercise price of such warrants following such reverse split will be subject to further adjustment in the event the trading price of our common stock following such reverse stock split is lower than the exercise price of such warrants. Also, subject to customary exceptions, the exercise price of the Series A 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. In such event, the exercise price of the Series A Warrants will 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 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 us, 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.

January 2021 and February 2021 at the Market Offerings

On January 8, 2021, the Company entered into a sales agreement with Maxim Group LLC ("Maxim") pursuant to which the Company could sell up to $10,000,000 worth of shares of the Company's common stock in an "at the market" offering through Maxim (the "January 2021 1st ATM Offering"). The offer and sale of the shares was made pursuant to a shelf registration statement on Form S-3. The Company agreed to pay Maxim a commission equal to 3.0% of the aggregate gross proceeds from each sale of shares. On January 15, 2021, the Company completed the January 2021 1st ATM Offering, pursuant to which the Company sold an aggregate of 51,197 shares of its common stock and raised net proceeds (after deduction for sales commissions) of approximately $9,700,000.

On January 28, 2021, the Company entered into a sales agreement with Maxim pursuant to which the Company could sell up to $25,000,000 worth of shares of the Company's common stock in an "at the market" offering through Maxim (the "January 2021 2nd ATM Offering"). On February 10, 2021, the Company completed the January 2021 2nd ATM Offering, pursuant to which the Company sold an aggregate of 100,977 shares of its common stock and raised net proceeds (after deduction for sales commissions) of approximately $24,250,000.

The Company incurred costs related to these financings of approximately $327,000, which is reflected as a reduction to the proceeds from the shares issued. The net cash received from both offerings after all expenses was approximately $33,663,000.

Warrants

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
December 31, 2020	**42,655**	**$ 120.00**	**3.81**
Granted	-	-	-
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	(32,954)	113.00	-
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, all exercisable	**1,526,701**	**8.67**	**2.39**

The exercise prices of warrants outstanding and exercisable as of December 31, 2022 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
1,517,000	$ 7.57
9,701	120.00
1,526,701	

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

During the year ended December 31, 2021, investors exercised warrants exercisable into 32,954 shares of common stock for total proceeds of approximately $3,568,415. The warrants were exercisable at $113.00 per share.

As of December 31, 2022, the Company had an aggregate of 1,526,701 outstanding warrants to purchase shares of its common stock. The aggregate intrinsic value of warrants outstanding as of December 31, 2022 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, 2020	**15,564**	**$ 474.00**	**6.38**
Granted	6,220	135.00	9.30
Forfeitures	(4,722)	-	-
Expirations	-	-	-
Exercised	-	-	-
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, outstanding	**13,294**	**217.05**	**6.80**
December 31, 2022, exercisable	**10,217**	**252.06**	**6.70**

The exercise prices of options outstanding and exercisable as of December 31, 2022 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
1,344	504	$ 7.35
841	629	45.50
1,002	334	80.50
1,008	756	88.00
840	840	116.70
336	336	162.33
3,058	1,953	197.70
3,862	3,862	300.00
1,003	1,003	750.00
13,294	**10,217**	

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

During the year ended December 31, 2022, the Company granted options to purchase an aggregate of 1,333 shares of common stock to each of the four independent members of the Board of Directors in connection with the compensation plan for such directors, with a grant date fair value of $7,793 using a Black-Scholes option pricing model based on the following assumptions: (i) a volatility rate of 146%, (ii) a discount rate of 3.35%, (iii) zero expected dividend yield, and (iv) an expected life of 3 years. The options have an exercise price of $7.50 per share. 167 of the options vested on June 30, 2022 and the remaining options vest pro-rata on a quarterly basis thereafter over two years, subject to continued service.

During the year ended December 31, 2021, the Company granted options to purchase 6,220 shares of common stock to six employees and independent members of the Board of Directors with a grant date fair value determined to be $711,000 using a Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 111% to 119%, (ii) discount rate of 0.38% to 1.28% (iii) zero expected dividend yield, and (iv) expected life of 5.13-6.01 years. The options have an exercise price of $45.50 to $197.50 per share. Options for 4,053 vest ratably over three years, options for 1,750 shares vest on a quarterly basis over two years, and options for 417 shares vested immediately.

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, 2022 and 2021, the Company recognized aggregate stock-compensation expense of approximately $226,000 and $601,000, respectively, related to the fair value of vested options.

As of December 31, 2022, the Company had an aggregate of 10,217 remaining unvested options outstanding, with a remaining fair value of approximately $284,388 to be amortized over an average of 5.2 years, weighted average exercise price of $8.01, and weighted average remaining life of 5.2 years. Based on the closing price of the Company's common stock on December 31, 2022 of $0.65, the aggregate intrinsic value of options outstanding as of December 31, 2022 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. During the year ended December 31, 2022, the Company issued 1,344 shares of the Company's common stock under the plan, and at December 31, 2022, there was a balance of 183,655 shares available for grant.

In January 2021, the Company granted 3,053 shares of the Company's common stock to the Company's Chief Executive Officer ("CEO"). The shares vested on the first anniversary of the award. Also effective in January 2021, the Company granted 833 shares of the Company's common stock to a consultant for services, with 83 of the shares vesting immediately and the balance of 750 shares vested on August 15, 2021. During the year ended December 31, 2021, the Company granted 1,000 shares of the Company's common stock with vesting terms to the Company's Chief Commercial Officer. The shares vest one third per year for three years on the anniversary of the award. There were no grants of Restricted Common Stock made during the year ended December 31, 2022.

The total fair value of the 1,344 shares was determined to be approximately $7,793 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, 2022, total share-based expense recognized related to vested restricted shares totaled approximately $82,266. At December 31, 2022, there was approximately $19,446 of unvested compensation related to these awards that will be amortized over a remaining vesting period of 1.50 years.

The following table summarizes restricted common stock activity for the year ended December 31, 2022:

	Number of Shares	Fair value per share
Non-vested shares, December 31, 2021	**4,054**	**$ 169.00**
Granted		
Vested	(3,387)	186.00
Forfeited		
Non-vested shares, December 31, 2022	**667**	**$ 80.50**

11. Income Taxes

No federal tax provision has been provided for the years ended December 31, 2022 and 2021, 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, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
U. S. federal statutory tax rate	(21.0)%	(21.0)%
State, net of federal benefit	(0.65)%	(7.0)%
Non-deductible goodwill impairment charge	-%	-%
	(21.65)%	(28.0)%
Change in valuation allowance	21.65%	28.0%
Effective tax rate	0.0%	0.0%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2022 and 2021 are summarized below.

	December 31,	
	2022	2021
Deferred tax assets		
Net operating loss carryforwards	$ 10,594,000	$ 8,329,000
Stock-based compensation	1,485,000	1,637,000
Accrued expenses	17,000	12,000
Charitable contributions	4,000	3,000
Inventory reserves	7,000	137,000
Intangibles	4,949,000	39,000
Valuation allowance	(16,546,000)	(10,126,000)
Total deferred tax assets	510,000	31,000
Deferred tax liabilities		
Unrealized gains/losses	(490,000)	-
Allowance for doubtful accounts		(4,000)
Operating lease right of use asset		(1,000)
Research and development credit	(10,000)	(13,000)
Depreciation	(10,000)	(13,000)
Total deferred tax liabilities	(510,000)	(31,000)
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, 2022, 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, 2022, the Company has available net operating loss carryforwards for federal income tax purposes of approximately $42,990,000 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, 2022 and 2021 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, 2022, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

12. 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, 2022 and December 31, 2021 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 January 6, 2021, the Board of Directors appointed Bret Scholtes as President, Chief Executive Officer, and as a director of the Company. The Company and Mr. Scholtes entered into an employment agreement pursuant to which Mr. Scholtes' annual base salary is $400,000. The employment agreement provides that Mr. Scholtes shall have an annual target cash bonus of no less than $400,000 based on performance objectives determined by the Board of Directors.

No executives were paid bonuses for the year ended December 31, 2022.

Additionally, Mr. Scholtes shall be granted (i) stock options equal to 2% of the Company's issued and outstanding shares of common stock on the date of grant if the Company achieves certain specified performance objectives established by the Board of Directors for the Company's fiscal years ended December 31, 2021, and December 31, 2022, and (ii) additional stock options equal to either 2% or 3% of the Company's issued and outstanding shares of common stock on the date of grant if the Company meets certain financial objectives during the first five years following January 6, 2021. If Mr. Scholtes' employment is terminated by the Company without cause, as defined under his employment agreement, if the term expires after a notice of non-renewal is delivered by the Company, or if Mr. Scholtes' employment is terminated following a change of control, as defined, Mr. Scholtes will be entitled to (a) twelve months' base salary, (b) the prorated portion of the any bonus, based on actual performance, and (c) base salary and benefits accrued through the date of termination.

NASDAQ Notice

On January 25, 2022, the Company received a written notice from the Nasdaq Stock Market LLC ("Nasdaq") that the Company had not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for a period of 30 consecutive business days. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(3)(A), the Company was provided a compliance period of 180 calendar days from the date of the notice, or until July 25, 2022, to regain compliance with the $1.00 minimum bid price requirement. The Company did not regain compliance during the compliance period ended July 25, 2022. Accordingly, the Company requested that Nasdaq grant the Company a second 180 calendar day period to regain compliance.

On July 26, 2022, the Company received a written notice from Nasdaq that the Company was granted a second 180 calendar day period, or until January 23, 2023, to regain compliance with the $1.00 minimum bid price requirement. Nasdaq's determination to grant the second compliance period was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

We 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 opens 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 will be 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. Further, the Series A and Series B warrants issued in connection with the February 2022 securities offering contain a provision which required that the exercise price of such warrants of $18.50 per share be adjusted to the volume weighted average price of the Company's common stock for the five trading days immediately following effectiveness of the Reverse Stock Split if such calculation resulted in an exercise price below the then-current exercise price. In accordance with this provision the Series A and Series B warrants have a current exercise price of $7.57. 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 common shares for rounding.

On January 24, 2023, Guardion Health Sciences, Inc. (the "Company") received a letter from The Nasdaq Stock Market LLC ("Nasdaq") stating that because the Company's common stock had a closing bid price at or above $1.00 per share for a minimum of 10 consecutive trading days, the Company had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2).

13. Restatement of Quarterly Consolidated Financial Statements (Unaudited)

As further described below, our unaudited consolidated financial statements covering the quarterly reporting periods during fiscal year 2022, consisting of the quarters ended March 31, 2022 , June 30, 2022, September 30, 2022 have been restated to reflect the correction of material errors.

Restatement Background

The need for the restatement arose out of the results of certain financial analysis the Company performed in the course of preparing for the audit of its December 31, 2022 consolidated financial statements. Upon reevaluation, the Series A and Series B Warrants issued in the February 2022 equity offering, it was determined that the Warrants contained a pricing reset feature that required the Warrants to be classified as a liability and marked to market at each reporting date as required under GAAP. Therefore, the Company recognized other income (expense) for the change in the fair value of the warrant liability at each reporting date.

Restatement Adjustments

The Company inadvertently did not classify the Warrants as a derivative liability, which led to accounting adjustments to correct the errors identified. The Company is providing restated quarterly and year-to-date unaudited consolidated financial information for interim periods occurring within the year ended December 31, 2022 in its audited financial statements for the year ended December 31, 2022. The following table summarizes the effect of the errors on the Company's consolidated balance sheets as of March 31, 2022, June 30, 2022, and September 30, 2022, and on the respective consolidated statements of operations and consolidated statements of cash flows.
The restated consolidated balance sheet line items for the first, second and third fiscal quarters of 2022 are as follows:

	March 31, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Total assets	$ 31,620,528	$ -	$ 31,620,528
Warrant derivative liability	-	11,466,300	11,466,300
Total liabilities	1,826,408	11,466,300	13,292,708
Additional paid-in capital	111,153,252	(8,783,800)	102,369,452
Accumulated deficit	(81,420,559)	(2,682,500)	(84,103,059)
Total stockholders' equity	29,794,120	(11,466,300)	18,327,820
Total liabilities and stockholders' equity	31,620,528	-	31,620,528

	June 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Total assets	$ 29,834,743	$ -	$ 29,834,743
Warrant derivative liability	-	6,108,700	6,108,700
Total liabilities	1,693,194	6,108,700	7,801,894
Additional paid-in capital	111,202,470	(8,783,800)	102,418,670
Accumulated deficit	(83,122,522)	2,675,100	(80,447,422)
Total stockholders' equity	28,141,549	(6,108,700)	22,032,849
Total liabilities and stockholders' equity	29,834,743	-	29,834,743

	September 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Total assets	$ 28,228,212	$ -	$ 28,228,212
Warrant derivative liability	-	5,235,500	5,235,500
Total liabilities	1,733,226	5,235,500	6,968,726
Additional paid-in capital	111,252,019	(8,783,800)	102,468,219
Accumulated deficit	(84,818,634)	3,548,300	(81,270,334)
Total stockholders' equity	26,494,986	(5,235,500)	21,259,486
Total liabilities and stockholders' equity	28,228,212	-	28,228,212

The restated line items of the consolidated statements of operations for the three months ended March 31, 2022, June 30, 2022, and September 30, 2022 are as follows:

	Three months ended March 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Revenue	$ 2,384,619	$ -	$ 2,384,619
Cost of goods sold and operating expenses	5,004,667	-	5,004,667
Change in fair value of warrant derivative liability	-	(2,682,500)	(2,682,500)
Total other income (expense):	1,561	(2,682,500)	(2,680,939)
Net loss	(2,618,487)	(2,682,500)	(5,300,987)
Net loss per common share – basic and diluted	(3.50)	(3.50)	(7.00)

	Three months ended June 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Revenue	$ 3,275,213	$ -	$ 3,275,213
Cost of goods sold and operating expenses	4,986,791	-	4,986,791
Change in fair value of warrant derivative liability	-	5,357,600	5,357,600
Total other income (expense):	9,615	5,357,600	5,367,215
Net loss	(1,701,963)	5,357,600	3,655,637
Net income (loss) per common share – basic and diluted	(1.50)	4.50	3.00

	Three months ended September 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Revenue	$ 2,663,550	$ -	$ 2,663,550
Cost of goods sold and operating expenses	4,402,944	-	4,402,944
Change in fair value of warrant derivative liability	-	873,200	873,200
Total other income (expense):	43,282	873,200	916,482
Net loss	(1,696,112)	873,200	(822,912)
Net loss per common share – basic and diluted	(1.50)	0.50	(0.50)

The restated line items of the consolidated statements of operations for the six months ended June 30, 2022; and the nine months ended September 30, 2022 are as follows:

	Six months ended June 30, 2022 (Unaudited)			Nine months ended September 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated	Originally Reported	Adjustment	Restated
Revenue	$ 5,659,832	$ -	$ 5,659,832	$ 8,323,382	$ -	$ 8,323,382
Cost of goods sold and operating expenses	9,991,458	-	9,991,458	14,394,402	-	14,394,402
Change in fair value of warrant derivative liability	-	2,675,100	2,675,100	-	3,548,300	3,548,300
Total other income (expense):	11,176	2,675,100	2,686,276	54,458	3,548,300	3,602,758
Net loss	(4,320,450)	2,675,100	(1,645,350)	(6,016,562)	3,548,300	(2,468,262)
Net loss per common share – basic and diluted	(4.50)	2.50	(1.50)	(5.50)	3.50	(2.50)

While the adjustments changed net loss and added a change in fair value of warrant derivative liability in the consolidated statements of cash flow statements, they did not have an impact on total net cash provided by operating activities, net cash used in investing activities, or net cash provided by (used in) financing activities for any of the applicable periods.

The restated line items of the consolidated statements of cash flows for the three months ended March 31, 2022; the six months ended June 30, 2022; and the nine months ended September 30, 2022 are as follows:

	Three months ended March 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Net Loss	$ (2,618,487)	$ (2,682,500)	$ (5,300,987)
Change in fair value of warrant derivative liability	-	2,682,500	2,682,500
Net cash used in operating activities	(2,226,473)	-	(2,226,473)
Non-cash financing activities:			
Issuance of warrant derivative liability	-	8,783,800	8,783,800

	Six months ended June 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Net Loss	$ (4,320,450)	$ 2,675,100	$ (1,645,350)
Change in fair value of warrant derivative liability	-	(2,675,100)	(2,675,100)
Net cash used in operating activities	(4,800,765)	-	(4,800,765)
Non-cash financing activities:			
Issuance of warrant derivative liability	-	8,783,800	8,783,800

	Nine months ended September 30, 2022 (Unaudited)		
	Originally Reported	Adjustment	Restated
Net Loss	$ (6,016,562)	$ 3,548,300	$ (2,468,262)
Change in fair value of warrant derivative liability	-	(3,548,300)	(3,548,300)
Net cash used in operating activities	(6,082,906)	-	(6,082,906)
Non-cash financing activities:			
Issuance of warrant derivative liability	-	8,783,800	8,783,800

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 10.3 to the Company's Current Report on Form 8-K filed with the SEC on August 19, 2019)
10.6	Warrant Agreement, including form of Series B Warrant, made as of October 30, 2019, between the Company and VStock (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 31, 2019)
10.7+	Employment Agreement, by and between the Company and Bret Scholtes (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 29, 2020)
10.8	Equity Purchase Agreement, dated May 18, 2021, by and among the Company, Adare Pharmaceuticals, Inc., and Activ Nutritional, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 21, 2021)
10.9+	Employment Agreement by and between the Company and Jeffrey Benjamin dated July 29, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2021)
10.10+	Employment Agreement by and between the Company and Craig Sheehan dated June 1, 2021 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 16, 2021)
10.11	Lease Termination Agreement by and between the Company and Cal-Sorrento, Ltd. dated September 22, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 23, 2021)
10.12	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
10.13	Placement Agency Agreement dated as of February 18, 2022, by and among Guardion Health Sciences, Inc., Roth Capital Partners, LLC and Maxim Group LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2022)
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)
21.1*	List of Subsidiaries
23.1*	Consent of Weinberg & Company
24.1*	Power of Attorney (included on signature page hereto)
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File – the cover page of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022 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 17th day of April 2023.

GUARDION HEALTH SCIENCES, INC.

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

POWER OF ATTORNEY

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

Signature	Title	Date
/s/ Bret Scholtes Bret Scholtes	CEO, President and Director (Principal Executive Officer)	April 17, 2023
/s/ Jeffrey Benjamin Jeffrey Benjamin	Chief Accounting Officer (Principal Financial and Accounting Officer)	April 17, 2023
/s/ Robert N. Weingarten Robert N. Weingarten	Chairman of the Board of Directors	April 17, 2023
/s/ Mark Goldstone Mark Goldstone	Director	April 17, 2023
/s/ Donald A. Gagliano Donald A. Gagliano	Director	April 17, 2023
/s/ Michaela Griggs Michaela Griggs	Director	April 17, 2023

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, 2022, Guardion Health Sciences, Inc. ("the Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")—our common stock, par value $0.001 per share ("Common Stock").

Description of Common Stock

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

Authorized Capital Shares

The Company's authorized capital shares consist of 250,000,000 shares of Common Stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). As of December 31, 2022, there were 1,267,340 shares of Common Stock issued and outstanding. There were also,495,000 shares of the Company's Series C Convertible Redeemable Preferred Stock, par value $0.001 per share and 5,000 shares of the Company's Series D Redeemable Preferred Stock, par value $0.001 per share outstanding at December 31, 2022.

Voting Rights

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

Dividend Rights

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

Liquidation Rights

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

Applicable Anti-Takeover Provisions

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

Board of Director Vacancies

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

Ability of Stockholders to Call Special Meetings

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

Advance Notice Requirements

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

Blank Check Preferred Stock

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

Exclusive Forum

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

Listing

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

Transfer Agent

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

EXHIBIT 21.1

LIST OF SUBSIDIARIES OF GUARDION HEALTH SCIENCES, INC.

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-1 (No. 333-232544, No. 333-234322 and No. 333-233067), Form S-3 (No. 333-248895), and Form S-8 (No. 333-231603 and No. 333-255077) of Guardion Health Sciences, Inc. of our report dated April 17, 2023, with respect to the consolidated financial statements of Guardion Health Sciences, Inc. as of December 31, 2022 and 2021, and for the years then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Weinberg & Company, P.A.
Los Angeles, California
April 17, 2023

EXHIBIT 31.1

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

I, Bret Scholtes, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: April 17, 2023

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

EXHIBIT 31.2

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

I, Jeffrey Benjamin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: April 17, 2023

/s/ Jeffrey Benjamin

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

EXHIBIT 32.1

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

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

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

April 17, 2023

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

April 17, 2023

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