UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

For the transition period from _____ to _____

Commission file number 000-30415

ZIVO BIOSCIENCE, INC.

(Exact name of Registrant as specified in its charter)

Nevada	**87-0699977**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
21 East Long Lake Road, Suite 100 Bloomfield Hills, MI	**48304**
(Address of principal executive offices)	(Zip Code)

(248) 452 9866
(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, $0.001 par value per share	**ZIVO**	**OTCQB**
Warrants to Purchase Common Stock, $0.001 par value per share	**ZIVOW**	**OTC Pink**

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 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 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 ☒

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant based upon the June 30, 2023 price at which the common equity was last sold was approximately $17.3 million. The number of outstanding shares of the registrant's common stock as of March 12, 2024 was 2,777,639.

Documents Incorporated by Reference

Portions of the Company's proxy statement for the Annual Meeting of the Stockholders to be held June 11, 2024 are incorporated by reference into Part III of this report. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023. Additionally, portions of the Annual Report are incorporated by reference in this Form 10-K in response to Items within part II.

FORM 10-K
ZIVO BIOSCIENCE, INC. AND SUBSIDIARIES INDEX

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this Annual Report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve known and unknown risks, uncertainties and other factors which may cause our or our industry's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to statements regarding:

- our ability to continue as a going concern and our history of losses;
- our ability to obtain additional financing;
- our relatively new business model and lack of revenues;
- our ability to prosecute, maintain or enforce our intellectual property rights;
- disputes or other developments relating to proprietary rights and claims of infringement;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the implementation of our business model and strategic plans for our business and technology;
- the successful development of our production capabilities;
- the successful development of our sales and marketing capabilities;
- the potential markets for our products and our ability to serve those markets;
- the rate and degree of market acceptance of our products and any future products;
- our ability to retain key management personnel;
- regulatory developments and our compliance with applicable laws;
- our liquidity; and
- other factors described in the "Risk Factors" section of this Annual Report on From 10-K

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential," "targets," "intends," and similar expressions intended to identify forward looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this report to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. We qualify all of our forward-looking statements by these cautionary statements.

You should refer to the section entitled "Risk Factors" of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. No forward-looking statement is a guarantee of future performance.

You should read this Annual Report on Form 10-K and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this Annual Report on Form 10-K and the documents we incorporate by reference herein represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, we undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

Item 1. Business.

Unless we state otherwise or the context otherwise requires, references in this Annual Report on Form 10-K to "we," "our," "us," "ZIVO," "the Registrant" or "the Company" refer to Zivo Bioscience, Inc., a Nevada corporation, and its subsidiaries.

Overview

We are a research and development company operating in both the biotech and agtech sectors, with an intellectual property portfolio comprised of proprietary algal and bacterial strains, biologically active molecules and complexes, production techniques, cultivation techniques and patented or patent-pending inventions for applications in human and animal health.

We believe that our proprietary algal culture and materials derived therefrom show promise in benefiting both animal and human health, primarily through inflammation-modulating and immune-boosting properties. Overall, our efforts have been centered around two potential value-creating initiatives; the first being the identification of bioactive extracts or novel bioactive molecules from our proprietary algal culture to treat various diseases, and second, the utilization of our proprietary algal culture in its whole form as a food product to leverage its nutritional value. In the first quarter of 2022, we reformulated our biotech and agtech businesses around these two concepts. We reviewed the market potential (scale and profit) and the technical and business risks associated with each of the opportunities we had been working on and developed a focused strategy for each business.

Available Information.

We maintain an internet website at https://ir.zivobioscience.com. We make available on or through our website, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practical after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. We do not intend the address of our website to be an active link or to otherwise incorporate the contents of our website into this Annual Report.

Biotech (Therapeutic) Business Strategy

Our strategy is to develop bioactive extracts, fractions, and molecules derived from our proprietary algal culture, targeting human and animal diseases, such as poultry coccidiosis, bovine mastitis, human cholesterol, and canine osteoarthritis. As part of our therapeutic strategy, we will continue to seek strategic partners for late-stage development, regulatory preparation and commercialization of our products in key global markets.

We seek to partner with established animal health companies and create value through licensing or other commercial arrangements, while accelerating final product development and mitigating market introduction risk.

After identification and study of active materials obtained from our proprietary algal culture and assessing their potential treatment applications, we have identified an effective product candidate for treating coccidiosis in broiler chickens. The focus on coccidiosis is driven by the potential to rapidly generate significant revenue, primarily due to the widespread prevalence of coccidiosis as a global issue in the poultry industry and the lack of effective and innovative, non-antibiotic alternatives for fighting the disease. Additionally, the clinical testing cycle for chickens is comparatively shorter than that for other species.

The coccidiosis market within the global animal health sector is currently saturated with predominantly antibiotic- or ionophore-based products and marginally effective vaccines. What we believe distinguishes Zivo's product candidate from available treatments is its innovative non-antibiotic method of action. As an immune modulator, ZIVO's product candidate augments the chicken's immune system to combat the effects of the coccidiosis causing parasite and other pathogens. We believe that unlike established treatments, our novel non-antibiotic technology addresses both industry and consumer concerns related to residual antibiotics and chemicals in the global food supply.

We expect that this departure from the conventional products that have dominated the market for the past six decades will provide us with a strategic advantage in this market. We aim to bring much-needed innovation to an area that has experienced limited advancements, potentially offering a disruptive and effective solution for treating coccidiosis in broiler chickens. Our emphasis on a non-antibiotic approach aligns with evolving industry-wide expectations and supports a commitment to providing safer and more sustainable solutions in animal health.

Coccidiosis Product Candidate

In numerous prior studies, ZIVO's offering has demonstrated multiple benefits, including:

- Minimized or eliminated the negative effects of coccidiosis on the digestive health in broiler chickens by numerous measures of gut health and overall well-being;
- Reduced the incidence of Campylobacter, Salmonella, E. coli, and Clostridium perfringens, all significant sources of food-borne illness, in the digestive tract of broiler chickens in the absence of antibiotics or other antimicrobial compounds; and
- Reduced mortality.

The predominant treatment for coccidiosis in the poultry industry, in-feed anticoccidial drugs, targets the Eimeria parasite directly and requires constant use over the lifespan of the animal for efficacy and can over time result in the development of resistant Eimeria strains. Other treatment strategies, such as vaccines, require several weeks for immunity to manifest, which can significantly impact growth potential. Often, several treatment products are used in combination, increasing costs in an industry already facing heavy inflationary pressures. As a result, the poultry industry is actively searching for a novel solution.

We believe our treatment alternative represents an innovative new product class that aims to strengthen the immune system of chickens through multiple complementary immune pathways to afford a rapid, robust, and effective response to disease-causing pathogens without the adverse effects associated with traditional antimicrobial drugs and chemicals.

Agtech (Nutrition) Business Strategy

For the nutrition side of our business, we have developed our proprietary algal culture to be commercially viable as a nutritional product. The dry, powdered form contains over 50% protein, is an excellent source of other essential vitamins and nutrients and has little odor and a mild taste compared with other algae products. As we reviewed our nutrition business early this year, we were very satisfied with the nature of the product; however, we identified gaps in customer acquisition and in scale-up technology preventing us from growing our proprietary algae in quantities to sufficiently meet the potential demand. We have, therefore, focused our nutrition strategy on developing a cost effective, commercial-scale growing technology.

In 2021, we initiated a long-term collaboration, commencing a development agreement with Grupo Alimenta, a well-established family-run Peruvian agricultural conglomerate. A combined Grupo Alimenta and ZIVO team has dedicated their efforts to perfecting the cultivation process and constructing commercial-scale algae ponds using ZIVO's proprietary cultivation process and pond design. By early 2023, the team successfully had demonstrated the continuous production of high-quality dried algae at the production site in Peru (Alimenta Algae SAC), and the facility passed food safety and cGMP audits, conducted independently by local, Peruvian state, and a reputable and FDA certified 3rd party company, to meet all requirements to produce and import food products into the United States via the FDA Foreign Supplier Verification Program. Subsequently, focus shifted to commercial production and increased production volumes. Plans are to complete build-out at Alimenta Algae to reach full capacity in late 2025, with capability to produce roughly 100,000 kg per year.

A significant milestone in this partnership is the transition from the development agreement to a commercial agreement. Under a contract manufacturing arrangement, Alimenta is set to make essential investments in the Peru site to facilitate production scale-up. In turn, ZIVO, through its ZIVOLife, LLC subsidiary ("ZIVOLife"), commits to purchasing the entire output from that facility. We believe this collaborative effort marks a pivotal step in advancing our shared goals in the algae production venture.

In June 2023, ZIVOLife commenced commercial shipments of our dried green algae powder intended for human consumption as a food or food ingredient. Through a global distribution agreement, ZWorldwide, Inc., based in Miami, has taken on the role of selling the Peruvian-grown product under the brand name Zivolife™. The primary market focus for the product's introduction is the North American green powder food market. ZWorldwide, functioning as a marketing and distribution company, is actively retailing the Zivolife™ product directly to consumers through its online platform at www.zivo.life. At this stage, our product volumes remain relatively low and are anticipated to be constrained as we complete the scale-up process with our contract manufacturing partner in Peru. This strategic approach is designed to ensure a controlled expansion of our presence in the market, balancing demand considerations with maintaining product quality and process discipline. The offtake agreement with ZWorldwide, Inc. includes provisions to purchase all ZIVOLife production through 2024 and at least 24,000 kg per year for a minimum of five years.

Additional Indications

Pending additional funding, ZIVO may also pursue the following indications:

Biotech (Therapeutic):

- **Bovine Mastitis**: ZIVO intends to continue development of a treatment for bovine mastitis based on previous successful proof of concept studies using active materials derived from its proprietary algal culture.
- **Canine Joint Health**: Studies have indicated a potential chondroprotective effect when a compound fraction from ZIVO's algal culture was introduced into *ex vivo* canine joint tissues.
- **Human Immune Modulation**: Early *in vitro* studies involving human immune cells and *in vivo* studies performed in non-clinical species have indicated that one of the isolated and characterized biologically active molecules in the Company's portfolio may serve as an immune modulator with potential application in multiple disease situations.

Agtech (Nutrition):

- **Companion Animal Food Ingredient**: The self-affirmed GRAS process was completed for ZIVO algal biomass in late 2018 and updated in May 2023 to validate its suitability as a safe product for human consumption as an ingredient in foods and beverages. We plan to leverage this work into viable food and nutritional supplements for companion animals.
- **Skin Health**: ZIVO is developing its algal biomass as a skin health ingredient, with topical skin product testing started in the third quarter of 2020, and clinical efficacy claim studies planned for ingestible and topical products.
- **NDI (New Dietary Ingredient)**: The algal biomass may also be sold as a dietary supplement or dietary ingredient in a dietary supplement, in which case it needs to notified to the FDA prior to sales. The notification package includes studies and reports that support its record of safe human consumption, its safe manufacture, and marketing claims. ZIVO's GRAS study and cGMP audit record with Alimenta Algae may be leveraged for this work.

Our Market Opportunity

Biotech (Therapeutic)

Livestock and Companion Animal Health

The annual market sizes for vaccines, phytogenics and eubiotics in the animal health market as a whole were approximately $9.2 billion in 2020, $753.0 million in 2020, and $3.9 billion in 2019, respectively. During the same time period, the annual market sizes for drugs, vaccines & feed additives and supplements in the companion animal market were approximately $11.8 billion in 2020 and $637.6 million in 2019, respectively.

Poultry Gut Health

Coccidiosis, a parasitic disease of the intestinal tract, is one of the largest health and animal welfare problems facing poultry flocks. Consumer and regulatory pressures have created what we believe to be an opportunity to develop and market an alternative to various additives routinely mixed into chicken feed. The Company is developing a product candidate expected to boost immune response, thereby combatting a broad range of infective pathogens, with the goal of simultaneously improving feed conversion, productivity, and overall bird health.

Bovine Mastitis

Bovine mastitis, or inflammation of the udder, can halt milk production and may result in unsaleable milk. The U.S. cow herd averaged 9.4 million cows in 2018 and U.S. milk production hit 217.6 billion pounds in 2018. Bovine mastitis affects approximately 1.5 million out of the 9 million dairy cows in the U.S. on an annual basis, and the average loss per cow per year in milk output is 846 pounds. Current treatments are primarily antibiotic-based, which require a holding period and disposal of milk during that holding period.

Canine Joint Health

Osteoarthritis (OA) is one of the most common ailments among pet dogs, with prevalence believed to be greater than 20%. The U.S. is expected to hold the largest share of the global market for veterinary pain management due to the vast pet population in the region, increasing animal healthcare expenditure, large number of hospitals and clinics, growing pool of veterinarians, and high prevalence of diseases causing pain. According to IBISWorld, the U.S. veterinary services market showed a solid, steady increase in consumer spending over the past few years.

Human Immune Modification

Immune-related and infectious diseases represent a vast range of health issues affecting millions of humans. New applications in pharma, food and nutraceuticals are continually introduced into this growing market. The annual market sizes for the antibiotics, eubiotics, autoimmune, and the antidiabetic markets were approximately $40.0 billion in 2020, $37.9 billion in 2019, $110.0 billion in 2017 and $48.8 billion in 2018, respectively. Beyond arthritis, there are more than 80 types of clinically different autoimmune diseases. Many major pharmaceutical and biopharmaceutical companies have extensive licensing and development programs focused on autoimmune/anti-inflammatory R&D. The rise in strategic alliances by discovery stage R&D companies like ZIVO is one of the latest trends that may gain traction in the autoimmune and anti-inflammatory therapeutics market in the coming years.

Agtech (Nutrition)

Human Functional Food Ingredients

The market for healthy foods, health foods, vegan and vegetarian food products continues to gain traction in the US and worldwide, especially as consumers look for healthful and nutritional ingredients to improve overall health and immune response. The drive toward plant-based proteins, microbiome-enhancing natural foods, food/beverage ingredients and dietary supplements continues to expand.

Clinical Development and Regulatory Pathway

Clinical Experience, Future Development and Clinical Trial Plans

Our product candidates are at different stages of development for different applications. Accordingly, the various regulatory processes required for the various applications are at different stages of completion. With respect to human food applications, we have completed the FDA's self-affirmed Generally Regarded as Safe ("GRAS") process for our dried algal biomass which allows for product commercialization with a consumption limit of up to nine grams per day.

Beyond use of the dried algal biomass in human food in the U.S. with nutritional claims, ZIVO has not yet received the required approvals for commercialization for any product form or application. To date, however, we have performed a number of studies required by regulatory bodies including bench top and pre-clinical tests (which include animal testing, performance, and other tests) for various product forms and applications pertinent to qualified health claims and structure/function claims. As described below, the Company intends to perform additional testing of its products in connection with obtaining the requisite regulatory approvals.

Poultry Gut Health

We are actively developing a product candidate targeting poultry gut health. We have conducted 21 clinical trials to date, most recently in October of 2023. The early studies focused on determining the general effects of various product candidates, while the more recent studies have been focused on optimizing a single lead product candidate including study of dosage levels, interactions with vaccines and various product formulations.

In late 2022, a third party performed a four-month study on behalf of a potential partner company, which included a 42-day coccidiosis trial in broiler chickens. That study evaluating the Company's novel immune-modulating biologic for treating coccidiosis in broiler chickens produced questionable results due to a high disease burden among tested chickens.

The most recent 42-day coccidiosis challenge study found health benefits including a statistically significant reduction in intestinal damage caused by the Eimeria parasite compared with untreated control birds. This improvement in intestinal health following parasite exposure was on par with the market-leading commercial ionophore. We believe that this reduction in intestinal damage enables poultry farms to optimize feed utilization as measured by the Feed Conversion Ratio (FCR), which is the primary driver of profitability. Similar to the outcomes related to intestinal damage, our product also resulted in statistically significant improvement in FCR compared with untreated controls. These results were not statistically different from the market-leading commercial ionophore.

ZIVO's approach for developing our coccidiosis product candidate as feed additives enables us to generate products that boost the immune response and reduce the effects of disease, while maintaining a single regulatory relationship, which is with the U.S. Department of Agriculture (USDA).

We recently announced receipt of a letter from the USDA's Center for Veterinary Biologics (CVB) affirming that the agency has claimed jurisdiction for reviewing our immune-modulating biologic for treating coccidiosis in broiler chickens. This important jurisdictional announcement de-risks our regulatory path and opens the door to further discussions with the CVB on the final product development plan, regulatory strategy, and data requirements for licensure. This was a significant milestone as USDA approval is likely to provide a favorable timeline to approval relative to the alternative involving the FDA.

Potential Additional Indications

Following development of our initial product candidate for poultry gut health, the Company intends to continue to pursue the below indications:

Biotech:

Product	Stage of Development and/or Regulatory Status to Date	Next Steps
Bovine Mastitis	The Company has conducted multiple *in vitro* and *ex vivo* experiments as well as four clinical trials to determine general effects and to evaluate product modalities and methods of administration. These studies include two (2) multianalyte *in vivo* studies of mastitis-inducing pathogens, most recently *staph aureus.* *Discovery Stage, pre-GMP, pre-GLP*	The Company expects to conduct three or more small studies to validate a product candidate previously validated in poultry, among other similar candidates and to make refinements to same before offering to potential licensees.
Canine Joint Health	The Company has conducted multiple *in vitro* inflammatory experiments, followed by two *in vivo* trials with mice, and two *ex vivo* experiments using canine hip joint tissue. *Discovery Stage, pre-GMP, pre-GLP*	Additional *ex vivo* experiments are necessary to gauge effectiveness of product candidate, to be followed by two *in vivo* studies to determine dosage and tolerance, likely followed by one or more validation studies on behalf of prospective licensees.
Human Immune Modulation	The Company has conducted six *in vitro* experiments using human immune cells attenuated by proprietary TLR4 inhibitor.	The Company has additional testing planned, beginning with repeated *in vitro* testing of different dosages and purities.
Agtech:		
Algal biomass for human consumption	The Company completed the self-affirmed GRAS in November 2018, and the dossier was updated to current FDA standards and Zivo production methods in May 2023. No clinical testing is required for commercialization.	Zivolife™ met safe human consumption requirements and sales began in June 2023. ZIVO continues to review its GRAS status to be current with new FDA regulations and to complete studies supporting increases in the allowable daily intake (ADI). In addition, ZIVO is looking into regulatory requirements to sell Zivolife™ outside United States
Biomass for supporting skin health / anti-aging	The Company is planning several investigations to establish definitive support for the mechanism of action associated with skin health / anti-aging. Support for the indication is a prerequisite to the human new dietary ingredient (NDI) application. Topical skin product testing began in 2020.	The Company is planning additional studies to support skin health/anti-aging. Pending the outcome of these tests, we expect to notify the Food and Drug Administration about these ingredients and our intent to market according to Section 413(d) of the FD&C Act, 21 U.S.C. 350b(d).

Competition and Functional Equivalents

Biotech (Therapeutic)

Our industries are all very competitive and subject to rapid and significant innovation and change. In addition to companies cultivating and creating homeopathic and natural remedies, our potential competitors and functional equivalents include large pharmaceutical and biopharmaceutical companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Key competitive factors affecting our products' commercial success will include efficacy, safety, tolerability, reliability and price.

Poultry Gut Health: Conventional poultry production typically involves the use of ionophores and other anticoccidial compounds, some of which are produced by HuvePharma, Elanco, Zoetis, and Phibro, among others. No Antibiotics Ever (NAE) poultry production, relies on effective and economically sound alternatives, such as vaccines and antimicrobial chemicals, as well as product candidates offered by ZIVO.

Bovine Mastitis: Branded antibiotic solutions include ToDay™ and Masti-Clear; homeopathic solutions include Amoxi-Mast™; topical and salve solutions include Germicidal teat dips, Fight Bac™ teat disinfectant spray, and Sterosol™ Pre/Post Teat Dip. Vaccine and antimicrobial solutions include Lysigin and Spectramast LC™.

Canine Joint Health: The global veterinary pain management drugs market is segmented into opioids, agonists, local anesthetics, NSAIDs (Non-steroidal Anti-Inflammatory Drugs), Disease-modifying Osteoarthritis Drugs (DMOAD) and others. The key players of the global veterinary pain management drugs market are Boehringer Ingelheim, Zoetis, Inc., Merck Animal Health, Elanco, Bayer AG, Vetoquinol S.A., Ceva Sante Animale, Virbac Group, Norbrook Laboratories Ltd, and Dechra Pharmaceuticals.

Human Immune Modulation: Several companies have TLR4 inhibitors currently in development. Eritoran (Eisai Research Institute of Boston, Andover, MA) and Resatorvid (TAK-242; Takeda Pharmaceutical Company) appear to be the lead candidates. Their mechanism of action (MOA) is cited as inhibition of the production of lipopolysaccharide (LPS)-induced inflammatory mediators by binding to the intracellular domain of TLR4. Eritoran has reached the clinical trial stage.

Agtech (Nutrition)

Human Food and Food Ingredient: As an algae powder, we believe that our primary competition will come from other established microalgae and green powder food and nutraceutical businesses like Earthrise, Cyanotech, and AG1. As an ingredient in other foods, ZIVO sees innovators in food technology such as DSM, Cognis, ConAgra, Cargill and Nestle, each of which has active M&A efforts, a large scientific staff and a generous R&D budget to develop supplements and ingredients for a wide range of applications, as potential competitors or potential partners.

Skin Health & Anti-Aging: There are a multitude of topical treatments and dietary supplements marketed for skin health and/or anti-aging applications, including premium multi-collagen peptides capsules such as, Well Roots Biotin Rich Plus Collagen, Heliocare Skin Care Dietary Supplement, CoQ10 Supplement, Vitamin C, Peptan®, Verisol®, and Pure Gold Collagen®.

Material Agreements

CEO Note and Warrants

On April 3, 2023, the Company entered into a Subscription Agreement (the "Subscription Agreement") with the Company's Chief Executive Officer (the "Subscriber"), pursuant to which the Company, in a private placement (the "Private Placement"), agreed to issue and sell to the Subscriber a 10% promissory note with a principal amount of $1 million (the "Payne Note") and a warrant (the "Payne Warrant") to purchase 65,000 shares of the Company's common stock, par value $0.001 per share ("Common Stock"). The Company had the ability to prepay all or a portion of the outstanding Payne Note principal and accrued and unpaid interest without any prepayment fee.

Each warrant is exercisable for a period of three years from issuance at a per-share exercise price equal to $17.46. The exercise price and number of the shares of our Common Stock issuable upon exercising the Payne Warrant will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization, or similar transaction, as described therein.

The Warrants are exercisable commencing on the date of issuance and expires on the three year anniversary of the issuance date. The exercise price and number of the shares of our common stock issuable upon exercising the Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein.

Placement Agent Agreement

On June 30, 2023, the Company entered into a placement agency agreement (the "Placement Agent Agreement") with Maxim Group LLC (the "Placement Agent") pursuant to which the Company engaged Maxim as the placement agent in connection with the Offerings. The Placement Agent agreed to use its reasonable best efforts to arrange for the sale of the Shares, Warrants and Pre-Funded Warrants (collectively, the "Securities"). The Company agreed to pay the Placement Agent a placement agent fee in cash equal to 7.0% of the gross proceeds from the sale of the Securities. The Company also agreed to reimburse the Placement Agent for certain of its expenses in an aggregate amount up to $105,000, or up to $40,000 in the event that there is not a closing of the Offerings. The Placement Agent Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

Distribution Agreement

In September 2022, the Company through its ZIVOLife LLC subsidiary entered into a Marketing , Sales, and Distribution Agreement ("Distribution Agreement") with ZWorldwide, Inc., based in Miami, Florida. ZWorldwide has taken on the role of selling the Peruvian-grown product under the brand name Zivolife™. The primary market focus for the product's introduction is the North American green powder food market. ZWorldwide, functioning as a direct-to-consumer marketing company, is actively retailing the Zivolife™ product directly to consumers through its online platform at www.zivo.life. This agreement grants ZWorldwide exclusive worldwide rights to the Zivolife product as a food or food additive for human use.

On July 26, 2023, the parties amended the Distribution Agreement to include purchase commitments from ZWorldwide for ZIVOLife product including that ZWorldwide would purchase the entire supply of Zivolife produced in the first 18 months. And, subject to certain capacity limitations, ZWorldwide has committed to purchasing at least 2,000 kilograms of our product per month through August 31, 2028. The parties further agreed to mutual approval of certain capacity improvements beyond a minimum amount.

Supply Agreement

In July 2023, the Company through it ZIVOLife LLC subsidiary and Alimenta Algae SA, a Peruvian company, signed a binding Contract Manufacturing Term Sheet (the "Term Sheet"). This binding Term Sheet defines certain operating agreements between the parties while the parties negotiate a definitive contract manufacturing agreement. The Term Sheet includes a limited license for Alimenta to manufacture the Company's dried green algae nutritional product known as Zivolife™. ZIVOLife committed to purchase all of the Zivolife™ product produced by Alimenta at the site subject to certain capacity growth and overall limitations. Alimenta agreed to secure financing necessary to fund the expansion of cultivation and process capacity. The Term Sheet terminated all existing development agreements between the Parties.

Securities Purchase Agreement

On July 5, 2023, the Company, closed on a Securities Purchase Agreement dated June 30, 2023 (the "Purchase Agreement") with a single institutional investor (the "Investor"), pursuant to which the Investor agreed to purchase from the Company, in a registered direct offering (the "Registered Offering"), (i) an aggregate of 171,666 shares of the Company's Class A Common Stock, par value $0.001 per share at a price of $16.02 per share, (ii) an aggregate of 78,021 pre-funded warrants to purchase 78,021 shares of Common Stock, at an offering price of $16.0194 per pre-funded warrant at an exercise price of $0.0006 per share, with a term of exercise of five years (collectively, the "Registered Offering Securities"). The gross proceeds to the Company from the Registered Offering and concurrent private placement described below were approximately $4,000,000 (before deducting the placement agent's fees and other offering expenses paid by the Company in the amount of $364,997).

Subscription Agreement

On November 16, 2023, the Company entered into a Subscription Agreement (the "Subscription Agreement") with the HEP Investments, LLC, a significant shareholder of the Company, (the "Subscriber"), pursuant to which the Company, in a private placement (the "Private Placement"), agreed to issue and sell to the Subscriber a 10% promissory note with a principal amount of $150,000 (the "Note"). The Note bears interest at a fixed rate of 10% per annum and requires us to repay the principal and accrued and unpaid interest thereon on May 16, 2024 (the "Maturity Date"), with an option to extend the Maturity Date an additional six months. There is no penalty on prepayment of the Note. On December 5, 2023, the Company repaid the principal in full along with all accrued interest to that date.

Intellectual Property

Protection of our intellectual property is a strategic priority for our business. We rely on a combination of patents, trademarks, copyrights, trade secrets as well as nondisclosure and assignment of invention agreements, material transfer agreements, confidentiality agreements and other measures to protect our intellectual property and other proprietary rights.

Patents and Proprietary Rights

ZIVO Algal Products & Derivatives

We have rights in certain granted patents, patent application publications and trademarks. With respect to patents and trademarks, we have secured patent and federal trademark registrations in the USPTO, including the below:

- U.S. Patent No. 7,807,622 issued October 5, 2010, relates to our proprietary complex algal culture. The title of the patent is: "Composition and use of phyto-percolate for treatment of disease." This invention relates generally to a method of preparation of a phyto-percolate that is derived from freshwater mixture including algae. The invention further relates to the potential use of the phyto-percolate in a variety of disease states. This patent was filed on November 30, 2006 and has a term of 20 years from the earliest claimed filing date.
- U. S. Patent No. 8,586,053 issued November 19, 2013, relates to our proprietary algal culture. The title of the patent is: "Composition and Use of Phytopercolate for Treatment of Disease." This invention relates generally to a method of preparation of a phyto-percolate that is derived from fresh water mixture including algae. The invention further relates to the use of the phyto-percolate in a variety of disease states. The phyto-percolate is believed to contain an activity that induces the reduction of soluble and insoluble fibrin. Further, the phyto-percolate is believed to reduce oxidative stress in the body. The patent was filed on April 20, 2006 and has a term of 20 years from the earliest claimed filing date.
- U.S. Patent No. 8,791,060 issued July 29, 2014, relates to our proprietary culture. Title of the patent is the same: "Composition and Use of Phytopercolate for Treatment of disease." This invention relates generally to a method of preparation of a phyto- percolate that is derived from fresh water mixture including algae. The invention further describes proteolytic activity. The patent was filed on October 4, 2010 and has a term of 20 years from the earliest claimed filing date.
- U.S. Patent No. 9,486,005 issued November 8, 2016, relates to our proprietary culture. Title of the patent is: "Agents and Mechanisms for Treating Hypercholesterolemia." This invention relates generally to a method of treating hypercholesterolemia in mammals, by administering an effective amount of microbial fermentation product and regulating genes involved in lipoprotein metabolism.
- U.S. Patent No. 10,161,928, issued December 25, 2018, relates to a panel for monitoring levels of biomarkers. Title of the patient is: "Wellness Panel." This invention relates generally to an assay having at least one inflammation monitoring test, at least one oxidative stress monitoring test, and at least one antioxidant activity monitoring test. A method of monitoring an individual's health, by collecting a sample from the individual applying the sample to an assay panel performing at least one inflammation monitoring test, at least one oxidative stress monitoring test, and at least one antioxidant activity monitoring test in the panel, and determining levels of biomarkers related to inflammation, oxidative stress, and antioxidant activity and therefore providing information regarding the individual's relative health and/or risk of developing one or more disease.
- U.S. Patent No. 10,166,270, issued January 1, 2019, relates to disclosing a composition and method for effecting various cytokines and NF-KB. Title of the patent is: Composition and Method for Affecting Cytokines and NF-KB." This invention relates generally to administering an effective amount of a phyto-percolate composition to an individual. In various exemplary embodiments, the composition is claimed to be useful for the effective treatment of inflammation, cancer, and/or various infections including HIV by regulation of various interleukins, such as IL-10 and Il-2, and of transcription factors including NF-KB.

- U.S. Patent No. 10,232,028, issued March 19, 2019, relates to isolates and fractions from a phyto-percolate and methods for affecting various cytokines by administering an effective amount of one or more of said isolates or fractions to an animal. In various exemplary embodiments, the isolates are useful for the treatment of bovine, canine and swine infection or inflammation, including bovine mastitis, by regulation of TNF-a, lactoferrin, INF-y, IL-B, serum amyloid-A (SAA), IL-6 and/or B-defensin associated with infection or an immune response generally.

- U.S. Patent 10,765,732 issued September 8, 2020, title: Compounds and Methods for Affecting Cytokines. relates isolates and fractions from a phyto-percolate and methods for affecting various cytokines by administering an effective amount of one or more of said isolates or fractions to an animal. In various exemplary embodiments, the isolates are useful for the treatment of bovine, canine and swine infection or inflammation, including bovine mastitis.

- U.S. Patent 10,842,179 issued on November 24, 2020, titled: Agents and Mechanisms for Treating Hypercholesterolemia relates to methods of treating hypercholesterolemia in mammals using a microbial fermentation and the regulation of genes involved in lipoprotein metabolism. A related European family member, EP2538951, was also granted on April 22, 2020.

- U.S. Patent 11,065,287 issued on July 20, 2021, titled: Methods of Modulating Immune and Inflammatory Responses Via Administration of an Algal Biomass relates to algal biomass and supernatant derived from at least one species of algae exhibits anti-inflammatory and immune response modulating properties. Methods of reducing the symptoms of or treating a condition or disease in an animal, including bovine mastitis and Bovine Respiratory Disease Complex, and the pain and discomfort caused by osteoarthritis, injury or overexertion or muscle and connective tissue strains, A related Brazilian family member, BR112017017599, was also granted on November 16th, 2021.

- Canadian Patent CA3014897 issued on December 29, 2020, titled: Nutritional Support for Animals Via Administration of an Algal Derived Supplement relates to an algal biomass and supernatant derived from at least one species of algae exhibits the ability to maintain general health in humans and non-human animals and promote a healthy immune system in them. Food, feed and nutritional supplements comprising an algal biomass or supernatant derived from at least one species of algae are described. Methods of maintaining general health or promoting a healthy immune system in humans and non-human animals comprises administering to the animal in need thereof an algal biomass or supernatant derived from at least one species of algae, or an extract, derivative or homeopathic compound derived from the algae species, biomass or supernatant, or a composition thereof.

- Canadian Patent CA2631773 issued on April 26, 2022, titled Composition and Use of Phyto-Percolate for Treatment of Disease relates to generally to a method of preparation of phyto-percolate that is derived from fresh water mixture including algae. The phyto-percolate is believed to contain an enzyme having proteolytic activity. The invention further relates to the use of the phyto-percolate in a variety of disease states.

- European Patent 2538951 issued on April 22, 2020, titled Agents and Mechanisms for Preventing Hypercholesterolemia relates to the extractions from algae. In particular, the present inventor relates to cholesterol-lowering extractions from algae and extractions that have the ability to favorably shift HDL.LDL profile in mammals.

- U.S. Patent 11,806,375 B2 issued on November 7, 2023; Nutritional Support for Animals Via Administration of an Algal Derived Supplement relates to an algal biomass and supernatant derived from at least one species of algae exhibits the ability to maintain general health in humans and non-human animals and promote a healthy immune system in them. Food, feed and nutritional supplements comprising an algal biomass or supernatant derived from at least one species of algae are described. Methods of maintaining general health or promoting a healthy immune system in humans and non-human animals comprises administering to the animal in need thereof an algal biomass or supernatant derived from at least one species of algae, or an extract, derivative or homeopathic compound derived from the algae species, biomass or supernatant, or a composition thereof.

- European Patent 3258948 issued on December 6, 2023 titled Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry relates to an algal biomass used as a natural ingredient in poultry feed reverses the detrimental effects of coccidiosis and necrotic enteritis in poultry. Algal biomass augmented poultry feed was shown to improve feed conversion rates, reduce mortality rates, and reduce intestinal lesion scores. In various embodiments, the algal biomass comprises at least one species of klebsormidium. In various aspects, the algal biomass may be obtaining by continuously cultivating at least one species of klebsormidium in raceway ponds, separating the plant material and spray drying to obtain the algal biomass.

- European Patent 3897188 issued on November 29, 2023, titled Methods of Modulating Immune Response and Inflammatory Response Via Administration of Algal Biomass relates to methods of modulating immune responses and inflammatory responses in animals and in particular relates to an algal biomass having anti-inflammatory and autoimmune modulating properties and methods of treating bovine mastitis and other diseases in animals by administering same.

Patents

The term of individual patents and patent applications will depend upon the legal term of the patents in the countries in which they are obtained. In most countries, the patent term is 20 years from the date of filing of the patent application (or parent application, if applicable). For example, if an international Patent Cooperation Treaty ("PCT") application is filed, any patent issuing from the PCT application in a specific country expires 20 years from the filing date of the PCT application. In the United States, using the Paris Convention route, if a patent was in force on June 8, 1995, or issued on an application that was filed before June 8, 1995, that patent will have a term that is the greater of 20 years from the filing date, or 17 years from the date of issue.

Under the Hatch-Waxman Act, the term of a patent that covers an FDA-approved drug or biological product may also be eligible for patent term extension ("PTE"). PTE permits restoration of a portion of the patent term of a U.S. patent as compensation for the patent term lost during product development and the FDA regulatory review process if approval of the application for the product is the first permitted commercial marketing of a drug or biological product containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of an investigational new drug (IND) and the submission date of a biological license application ("BLA") plus the time between the submission date of a BLA and the approval of that application. The Hatch-Waxman Act permits a PTE for only one patent applicable to an approved drug, and the maximum period of restoration is five years beyond the expiration of the patent. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and a patent can only be extended once, and thus, even if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions may be available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a BLA, we expect to apply for PTEs for patents covering our therapeutic candidates and products and their methods of use.

The following patent filings are pertinent to the operation of the ZIVO business:

Application Name	Country	Application No.	Status
Agents and Method for improving Gut Health	US	17/465,457	Under Prosecution; Published April 28, 2022
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	US	17/415,221	Under Prosecution; Notice of Publication March 10, 2022
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	Brazil	12021012229	Under Prosecution
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	Canada	3124190	Under Prosecution
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	Hong Kong	62022046143	Under Prosecution
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	Mexico	MX/a/a2021/007359	Under Prosecution
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	Peru	1048-2021	Under Prosecution
Algal Feed Ingredient for Controlling Coccidiosis and Necrotic Enteritis in Poultry	Thailand	2101003721	Under Prosecution

Application Name	Country	Application No.	Status
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (Complete)	US	17/576,237	Under Prosecution; published July 21, 2022
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Australia	202209715	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Canada	3,204,145	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	New Zealand	801560	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Japan	2023-542922	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Russia	2023118590	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	China	202280010396.0	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Brazil	BR 11 2023 014244 0	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Europe	22743011.3	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Mexico	MX/a/2023/008373	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	Peru	2054-2023	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (**Complete**)	South Africa	2023/069858	Under Prosecution
Algoriphagus SP, Bosea SP, Brevundimonas SP, Desulfovibrio SP, Microbacterium SP, Sphingomonas SP, and Variovorax SP for Use in Disease Prevention and Treatment (Simplified)	US	17/576,444	Under Prosecution; Published July 21, 2022

Application Name	Country	Application No.	Status
Brevundimonas SP for Use in Disease Prevention	US	PCT 18/077,132	National Stage Deadline June 7, 2024
Composition and Method For Affecting Cytokines and NF-κB	Brazil	BR 11 2012 011678 9	Under Prosecution
Dietary Supplements, Food Ingredients and Foods Comprising High-Protein Algal Biomass	Mexico	MX/a/2019/010670	Under Prosecution
Dietary Supplements, Food Ingredients and Foods Comprising High-Protein Algal Biomass	Peru	1820-2019	Under Prosecution
Dietary Supplements, Food Ingredients and Foods Comprising High-Protein Algal Biomass	Thailand	190105502	Under Prosecution
Dietary Supplements, Food Ingredients and Foods Comprising High-Protein Algal Biomass	China	201880030155	Under Prosecution
Dietary Supplements, Food Ingredients and Foods Comprising High-Protein Algal Biomass	Hong Kong	62020009617	Under Prosecution
Dietary Supplements, Food, Ingredients and Foods Comprising High-Protein Algal Biomass	Europe	18763110.5	Under Prosecution
Enhancement of Vaccine Efficacy Via Biomass and/or Related Material in Animal Feed	US	17/367,193	Under Prosecution; Published March 3, 2022; National Stage Deadline December 26, 2022
Enhancement of Vaccine Efficacy Via Biomass and/or Related Material in Animal Feed	Europe	22182898.1	Under Prosecution
Enhancement of Vaccine Efficacy Via Biomass and/or Related Material in Animal Feed	Brazil	BR 102022013331.0	Under Prosecution
Enhancement of Vaccine Efficacy Via Biomass and/or Related Material in Animal Feed	China	202210757383.1	Under Prosecution
Enhancement of Vaccine Efficacy Via Biomass and/or Related Material in Animal Feed	India	202244038199	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	US	17/358,878	Under Prosecution; Published January 20, 2022
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Austria	2021296916	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Brazil	112022026479.8	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Canada	3182630	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	China	202180050311.7	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Europe	218288421	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Japan	2022-580155	Under Prosecution

Application Name	Country	Application No.	Status
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Mexico	Mx/a/2023/000158	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	New Zealand	795393	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Peru	00344-2022-DIN	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	Russia	2022133478	Under Prosecution
Immune Priming To Accelerate/Enhance Immune Response Through Administration of Natural Immune Modulator	South Africa	2022-13483	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	US	17/587,582	Under Prosecution; Published August 4, 2022
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	New Zealand	801882	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Australia	2022213400	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Japan	2023-546076	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Russia	2023118986	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Brazil	BR 11 2023 0149223	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Canada	3,205,544	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	China	202280012094.7	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Europe	22746711.5	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Mexico	MX/a/2023/008874	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	Peru	002229-2023/DIN	Under Prosecution
Maturation of Immune and Metabolic Processes via Algal Biomass and/or Related Material Administered to Animals	South Africa	2023/07227	Under Prosecution

Application Name	Country	Application No.	Status
Method of Modulating Immune Response and Inflammatory Response Via Administration Algal Biomass	Brazil	BR 1120170175991	Under Prosecution
Methods of Modulating Immune Response and Inflammatory Response Via Administration of Algal Biomass	Hong Kong	18108238.5	Under Prosecution
Methods of Modulating Immune Response and Inflammatory Response Via Administration of Algal Biomass	Canada	3,011,687	Under Prosecution
Natural Feed Composition Derived from Fresh Water Algal Cultures for the Promotion of Animal Growth	US	17/410,016	Under Prosecution; Published July 28, 2022
Natural Feed Composition Derived from Fresh Water Algal Cultures for the Promotion of Animal Growth	Brazil	BR 112023001466-2	Under Prosecution
Natural Feed Composition Derived from Fresh Water Algal Cultures for the Promotion of Animal Growth	Russia	2023100901	Under Prosecution
Natural Feed Composition Derived from Fresh Water Algal Cultures for the Promotion of Animal Growth	China	202180064154.5	Under Prosecution
Natural Feed Composition Derived from Fresh Water Algal Cultures for the Promotion of Animal Growth	Mexico	MX/a/2023/001221	Under Prosecution
Natural Feed Composition Derived from Fresh Water Algal Cultures for the Promotion of Animal Growth	Europe	21848954	Under Prosecution
Nutritional Support for Animals Via Administration of an Algal Derived Supplement	Europe	17753729.7	Under Prosecution
Nutritional Support for Animals Via Administration of an Algal Derived Supplement	Mexico	MX/a/2018/009818	Under Prosecution
Nutritional Support for Animals Via Administration of an Algal Derived Supplement	Hong Kong	19,125,173	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	US	17/358,953	Under Prosecution; Published February 24, 2022
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Australia	202129453	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Brazil	112022026461-5	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Canada	3,182,236	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	China	417764600	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Europe	2182917.9	Under Prosecution

Application Name	Country	Application No.	Status
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Japan	TBD	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Mexico	Mx/a/2023/000166	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	New Zealand	795328	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Peru	003043-2022-DIN	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	Russia	2022133470	Under Prosecution
Positive Latency Effects on Coccidiosis Prevention and Treatment via Animal Feed	South Africa	2022/13479	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	US	17/400,790	Under Prosecution; Published February 17, 2022
The Use of Variovorax Microbes as a Coccidiostat	Canada	3,187,128	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Australia	202136515	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Peru	000249-2023/DIN	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Brazil	BR 112023001738-6	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Russia	2023101488	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	South Africa	2023/00973	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Japan	2023-509572	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	China	202180055783.1	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Europe	21856718.8	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	Mexico	MX/a/2023/001775	Under Prosecution
The Use of Variovorax Microbes as a Coccidiostat	New Zealand	796429	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	US	17/320,706	Under Prosecution; Published November 18, 2021
Use of TLR4 Modulator in the Treatment of Coccidiosis	Australia	2021271805	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	Brazil	BR 11 2022 022083 9	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	Canada	3177327	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	China	202180034578.7	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	Europe	21805132.4	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	Japan	2022-560562	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	Mexico	MX/a/2022/04213	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	New Zealand	793737	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	Russia	2022128942	Under Prosecution
Use of TLR4 Modulator in the Treatment of Coccidiosis	South Africa	2022/11691	Under Prosecution

The following trademark filings are pertinent to the operation of ZIVO's business:

Trademark	Filing Date	Application No.	Country	Status
ZIVO	7/22/2022	97/516,573	US	Under Prosecution
ZIVO	7/30/2020	48512762 (Class 29)	CN	Issued
ZIVO	7/30/2020	48512762 (Class 5)	CN	Issued
ZIVO	7/30/2020	48512744 (Class 31)	CN	Issued
ZIVO Bioscience	1/18/2023	97/759,042	US	Under Prosecution
ZIVO Bioscience and Device	7/30/2020	48512743 (Class 5)	CN	Issued
ZIVO Bioscience and Device	7/30/2020	48512742 (Class 29)	CN	Issued
ZIVO Bioscience and Device	7/30/2020	48512741 (Class 31)	CN	Issued

Trade Secrets

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect such intellectual property and proprietary information by generally requiring our employees, consultants, contractors, scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements upon the commencement of their employment or engagement as the case may be. Our agreements with our employees prohibit them from providing us with any intellectual property or proprietary information of third parties. We also generally require confidentiality agreements or material transfer agreements with third parties that receive or have access to our confidential information, data or other materials. Notwithstanding the foregoing, there can be no assurance that our employees and third parties that have access to our confidential proprietary information will abide by the terms of their agreements. Despite the measures that we take to protect our intellectual property and confidential information, unauthorized third parties may copy aspects of our products or obtain and use our proprietary information.

Government Regulation

Overview

Biotech

As a discovery-stage licensor, we do not intend to fund and oversee the final regulatory approvals and commercialization processes of our product candidates, as we expect these to be borne by the licensee in all cases.

Agtech

As the licensor of food technology, and producer of culture inoculum for cultivation, ZIVO and its licensed growers must furnish to customers algae based products that are compliant with all food standards and FDA regulations. In all cases, the compliance efforts involve GRAS affirmation and ZIVO has already obtained self-affirmed GRAS status for human use.

Food Ingredient - Human

The food ingredient industry is regulated by several federal agencies. Anything that is introduced into food or beverages, whether to prevent spoilage, optimize processing or to enhance its nutritive value, must meet standards set and enforced rigorously by the FDA and USDA.

GRAS (Generally Regarded as Safe)

The FDA requires that ingredients introduced into human foods and beverages are safe and are manufactured in a consistent manner that guarantees consumer safety. The standard that the Company must meet for food ingredient safety is GRAS (Generally Recognized As Safe). The Company opted to self-affirm GRAS status for its algal biomass, and upon completion in November 2018, and updated in 2023, of the self-affirmation process, the algae biomass may be used as a food ingredient. To sell as a dietary supplement, the Company may submit the self-affirmed GRAS report to the FDA in expectation the agency will respond to the Company noting "no questions" concerning our data.

In 2016, ZIVO contracted the Burdock Group to assist the Company in the compliance process, and to help with the process with the FDA. Further, the Company retained the New York law firm of Ullman Shapiro Ullman LLP, now part of Rivkin-Radler LLP, to advise in the compliance process. In Q1-2023, ZIVO worked with EAS Consulting to update its GRAS dossier to current production methods and FDA regulations.

Foreign Supplier Verification Process (FSVP) and Current Good Manufacturing Practice Compliance

To sell food products in the United States, food must be produced in compliance with FDA 21 CFR 117 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food), which covers the standards necessary to consistently make a food product that is safe for human consumption. If the food manufacturer is outside the United States, then compliance with 21 CFR 117 is assured through the FDA Foreign Supplier Verification Program.

The Company, working with our contract manufacturer, Alimenta Algae in Peru, completed all the requirements to import and sell our algae product in the United States. Alimenta Algae passed (annual recurring) food safety and cGMP audits conducted by with Peruvian local and state regulatory authorities. In addition, the Alimenta Algae passed a separate food safety audit conducted by a reputable and FDA certified company, which was required to obtain ability to import food products into the United States via FDA-FSVP. Zivo and Alimenta Algae employed a independent consultant to review all facility food production processes and final product safety in accordance with 21 CFR 117. After the verification process and audits were completed, the consulting company now serves as the FSVP importer of record on all commercial product imported for sale in the U.S.

Dietary Supplements

Dietary supplements, which include vitamins, minerals, nutritive substances, and natural products that are standalone products (“nutraceuticals”) fall under the jurisdiction of the FDA and must comply with the Dietary Supplement Health Education Act (“DSHEA”) legislation passed in 1994 and updated several times since, along with the Food Safety Modernization Act of 2011.

NDI Application

As human dietary supplement applications are being readied for market launch, the Company is required to file a New Dietary Ingredient (NDI) Notification. The standard applied to NDI Notifications is “reasonable expectation of safety” for intended use as a supplement. As part of the notification process, ZIVO would be required to conduct at least one human study, and possibly two, in support of any potential health benefits or claims. These studies can run concurrently but should not be conducted by the same clinical research organization. To date, ZIVO has not run these studies. One such study may be the same dose tolerance study planned to increase the maximum allowable consumption limit as discussed above.

Skin Care and Topical Uses

The US Congress is contemplating the implementation of a statute requiring all skin care and cosmetics production to follow cGMP. If this legislation is passed the Company will need to ensure that it and any contract manufacturers are certified to be cGMP compliant.

Structure/Function Claims

The Company is marketing with structure/function claims based on the known composition of product and published studies linking that algal biomass and its nutritional components to various health claims, for example the ability to maintain a healthy immune response or a beneficial anti-inflammatory response. This is the most basic of FDA standards and essentially means that as long as cGMP standards are met, a study has been conducted and in-process toxicology reports are available, the Company is able to market its product.

The market reality is that nutraceutical and supplement makers won’t take on the product unless its chemical makeup is generally described, the plant or animal is properly classified (in this case, algae), the manufacturing process is free of health hazards, and cGMP protocols are observed, all of which the Company intends to meet or exceed.

USP Certification

The DSHEA regulations also require that a safe dosage is established for any vitamin, mineral or dietary supplement, whether it is natural or synthetic in composition. The United States Pharmacopeia ("USP") is the official pharmacopeia of the United States. USP establishes written (documentary) and physical (reference) standards for medicines, food ingredients, dietary supplement products and ingredients.

These standards are used by regulatory agencies and manufacturers help to ensure that these products are of the appropriate identity, as well as strength, quality, purity, and consistency. The Company will endeavor to adhere to the most basic USP standard in order to maintain speed to market. It or its licensees will then consider the USP Verified products designation.

Feed Ingredients & Supplements - Companion Animals

Although state and AAFCO officials regulate companion animal feeds, treats and supplements, the supervision and standards are largely handled by the FDA and the CVM on a national level. We currently do not have approval to sell companion animal feed ingredients since we must first develop the specie-specific safety and health data required to do so. Companion animal products are aimed primarily at dogs and horses. We believe that a single safety/tox study and a separate dose/benefit study per animal applications will be sufficient. As with humans, we would seek to obtain a GRAS affirmation.

To clarify, an "application" is a single ingredient in a single formulation and a single claim for a single animal species. Therefore, a dietary supplement derived from the Company's algal biomass, intended as a joint health supplement for adult dogs, constitutes a single application. That single application requires its own studies before any dog treat manufacturer would consider licensing or purchasing the Company's material. Any change to the claims (e.g. more energy, shinier coat, etc.) or the target specie requires a new study. This is the current state of regulation, and it holds true for all human and animal applications.

Employees

As of December 31, 2023 we had 8 full-time employees, consisting of clinical development, product development, regulatory, manufacturing, quality, finance, administration and managers. We also regularly use independent contractors across the organization. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated under the laws of the State of Nevada on March 28, 1983, under the name of "L. Peck Enterprises, Inc." On May 27, 1999, we changed our name to "Western Glory Hole, Inc." From 1990 until October 2003, we had no business operations; we were in the development stage and were seeking profitable business opportunities. On October 30, 2003, we acquired 100% of the outstanding shares of Health Enhancement Corporation ("HEC") in exchange for 112,500 of our shares, making HEC our wholly-owned subsidiary. In connection with this transaction, we changed our name to Health Enhancement Products, Inc. On October 14, 2014, at the annual meeting of the stockholders of the Company, a proposal was passed to change the name of the Company from Health Enhancement Products, Inc. to Zivo Bioscience, Inc. On October 30, 2014, the Financial Industry Regulatory Authority approved the name Zivo Bioscience, Inc. for trading purposes and the symbol changed to ZIVO effective November 10, 2014.

Item 1A. Risk Factors.

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this Annual Report. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.

Risks Relating to Our Business

Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations.

The health of the global economy, the credit markets and the financial services industry in particular, as well as the stability of the social fabric of our society, affects our business and operating results. For example, the credit and financial markets may be adversely affected by the current conflicts between Russia and Ukraine, Israel and Hamas, and measures taken in response thereto. If the credit markets are not favorable, we may be unable to raise additional financing when needed or on favorable terms. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions, such as recent supply chain disruptions, labor shortages and persistent inflation may adversely impact our suppliers' ability to provide our manufacturer with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

The Company is exposed to risks of political instability and changes in government policies, laws and regulations in Peru.

The Company's contract manufacturer for our algae products is located in the Republic of Peru, and may be adversely affected in varying degrees by political instability, government regulations relating to agriculture and foreign investment therein, and the policies of other nations in respect of Peru. Any changes in regulations or shifts in political conditions are beyond the Company's control and may adversely affect the Company's business. New laws, regulations and requirements may be retroactive in their effect and implementation. The Company's operations may be affected in varying degrees by government regulations, including those with respect to restrictions on production, price controls, export controls, income taxes, expropriation of property, employment, land use, water use, and environmental legislation.

Since December 2022, Peru has experienced an increased level of civil unrest and political protests. Civil unrest has led to disruptions in the ability of foreign nationals to travel to and from Peru. The Company continues to closely monitor the situation and its potential impact on Company operations.

We have incurred, and may continue to incur increased costs and demands upon management as a result of being a public company.

As a public company in the United States, quoted on the OTCQB, we incur significant legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and OTCQB, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board, on committees of our Board or as members of senior management.

We have a history of operating losses, and we may not be able to achieve or sustain profitability. In addition, we may be unable to continue as a going concern.

We have incurred net losses during each of our fiscal years since our inception. Our net loss for the year ended December 31, 2023 was approximately $7.8 million and our accumulated deficit totaled approximately $123.6 million as of December 31, 2023. We do not know whether or when we will become profitable, if ever. We currently expect operating losses and negative cash flows to continue for at least the next several years.

Our ability to generate sufficient revenue to achieve profitability depends on our ability, either alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our product candidates.

Our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our auditor's report for the year ended December 31, 2023 contains an explanatory paragraph that we have incurred significant losses since our inception and we expect that we will continue to incur losses as we aim to successfully execute our business plan and will be dependent on additional public or private financings, collaborations or licensing arrangements with strategic partners, or additional credit lines or other debt financing sources to fund continuing operations. Based on our cash balances, recurring losses since inception and our existing capital resources to fund our planned operations for a twelve-month period, there is substantial doubt about our ability to continue as a going concern. As noted below, we will need to obtain additional funding from equity or debt financings, which may require us to agree to burdensome covenants, grant security interests in our assets, enter into collaboration and licensing arrangements that require us to relinquish commercial rights, or grant licenses on terms that are not favorable. No assurance can be given at this time as to whether we will be able to achieve our fundraising objectives, regardless of the terms. If adequate funds are not available, the Company may be required to reduce operating expenses, delay or reduce the scope of its product development programs, obtain funds through arrangements with others that may require the Company to relinquish rights to certain of its technologies or products that the Company would otherwise seek to develop or commercialize itself, or cease operations.

We will require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our planned research, development and product commercialization efforts. In addition, we will require additional financing to achieve our goals and our failure to do so could adversely affect our commercialization efforts. We anticipate that our expenses will increase substantially if and as we:

- continue our development process for our product candidates;
- seek to maintain, protect and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

If we were to experience any delays or encounter issues with any of the above, it could further increase the costs associated with the above. Further, the net operating losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Our production of algae involves an agricultural process, subject to such risks as weather, disease, contamination, supply chain interruption, and water availability.

The production of our proprietary algae strain involves complex agricultural systems with inherent risks including weather, disease and contamination. These risks are unpredictable, and the efficient and effective cultivation of algae requires consistent light, warm temperatures, low rainfall and proper chemical balance in a very nutrient rich environment.

If the chemical composition of a pond changes from its required balance, unusually high levels of contamination due to the growth of unwanted organisms or other biological problems may occur and would result in a loss of harvestable output. These often arise without warning and sometimes there are few or no clear indicators as to appropriate remediation or corrective measures. However, environmental factors cannot be controlled in an open-air environment, therefore, we cannot, and do not attempt to, provide any form of assurance with regard to our systems, processes, location, or cost-effectiveness. In the event that our growers need to take steps to correct any chemical imbalance or contamination of their ponds, including by re-inoculating the ponds, such measures may not be effective and could interrupt production. To the extent that our production is negatively impacted by environmental factors, we may be unable to fill large orders for one or more months until such time that production improves.

We rely on third parties to grow our proprietary algae strains and conduct research, and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not currently, and do not expect to in the future, independently conduct any aspects of the growth of our proprietary algae strains, research and monitoring and management of our ongoing preclinical and clinical programs. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time unless otherwise stated in contractual agreements. If we need to enter into alternative arrangements, our commercialization activities or our therapeutic candidate development activities may be delayed or suspended. Our reliance on these third parties for research and development activities, reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols.

Any of these events could lead to delays in the development of our product candidates, including delays in our trials, or failure to obtain regulatory approval for our product candidates, or it could impact our ability to successfully commercialize our current product candidates.

Because our ZIVO algae is currently produced by only one grower, the loss of this grower would have a material adverse impact on our operating results and cash flows.

Currently, only one facility grows our ZIVO algae. Any termination of a business relationship with, or a significant sustained reduction in business received from this grower could delay our production efforts and could have a material adverse effect on our operating results and cash flows. We must materially increase the number of our growers and if we cannot, it will adversely impact our financial condition and our business.

Because our algae product is marketed and distributed by only one distributor, the loss of this distributor would have an adverse effect on near term revenue generation and cash flows.

Currently only one distributor markets and sells our ZIVO algae as Zivolife™, and the distributor has worldwide exclusivity as long as the agreement terms are met. Any termination of a business relationship with, or a significant sustained reduction in business and offtake from this distributor could delay could have a material adverse effect on our operating results and cash flows. ZIVO currently does not have internal sales, marketing and distribution capability for our products and the cost of establishing and maintaining such an organization may exceed the benefit of doing so.

Failure to proportionally advance both our manufacturing capacity and distribution networks could adversely affect our operating results, and near-term and long-term growth plans.

We are attempting to launch a new product, in a new market, utilizing new cultivation processes. As such, we face challenges in managing both the growth of supply from our contract manufacturer and demand from our distribution partner. Each partner faces independent challenges in meeting their contractual objectives, such as financing constraints, market conditions, and scaling of production and distribution networks. If either of these partners fails to meet their contractual objectives on the scheduled timelines, it may adversely affect the other partner and us. For example, if capacity outstrips demand, our grower may have trouble profitably maintaining the capacity. Conversely, if demand outstrips supply, our distributor may not have sufficient product to sell. In either scenario our operating results and near-term and long-term growth plans could be adversely affected.

If we fail to attract and keep our Chief Executive Officer and Chief Financial Officer, senior management and key scientific personnel, we may be unable to successfully develop our therapeutic candidates, conduct our clinical trials and commercialize our therapeutic candidates.

We are highly dependent on the members of our executive team, including our Chief Executive Officer and Chief Financial Officer, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are “at will” employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

If we are unable to enter into agreements with third parties to market and sell our product candidates, if approved, we may be unable to generate any revenues.

We currently do not have internal sales, marketing and distribution capability for our products and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. In order to market any products that may be eligible for commercialization, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have limited prior experience in the marketing, sale or distribution of approved products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our therapeutic candidates.

Because the results of preclinical studies and clinical trials are not necessarily predictive of future results, we can provide no assurances that our other product candidates will have favorable results in future studies or trials.

Positive results from preclinical studies or clinical trials should not be relied on as evidence that later or larger-scale studies or trials will succeed. Even if our product candidates achieve positive results in early-stage preclinical studies or clinical trials, there is no guarantee that the efficacy of any product candidate shown in early studies will be replicated or maintained in future studies and/or larger populations. Similarly, favorable safety and tolerability data seen in short-term studies might not be replicated in studies of longer duration and/or larger populations. If any product candidate demonstrates insufficient safety or efficacy in any preclinical study or clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that product candidate.

Further, data obtained from clinical trials are susceptible to varying interpretations. If we delay or abandon our efforts to develop any of our product candidates, we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

Development of certain of our products involves a lengthy and expensive process, with uncertain outcomes. We may, and our current or future licensees may, incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product.

We may, and our current or future licensees may, experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our products, including:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the failure to successfully complete pre-clinical testing requirements required by the FDA and international organizations;
- delays may occur in reaching, or failing to reach, agreement on acceptable clinical trial contracts with third parties or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- the cost of clinical trials of our products may be greater than we anticipate;
- delays or difficulties in obtaining an FDA No Objection letter for human consumption of our algal biomass; and

If we are required to conduct additional clinical trials or other testing of our biotech product candidates under development or algal biomass beyond those that we contemplate, if we are unable to successfully complete clinical trials of our product candidates under development or algal biomass or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may, or our existing or future licensees may:

- not obtain marketing approval at all;
- be delayed in obtaining marketing approvals in a jurisdiction; or
- be subject to additional post-marketing testing requirements.

Increased regulatory scrutiny of nutritional supplements as well as new regulations that are being adopted in some of our markets with respect to nutritional supplements could result in more restrictive regulations and harm our results if our supplements or advertising activities are found to violate existing or new regulations or if we are not able to effect necessary changes to our products in a timely and efficient manner to respond to new regulations.

There has been an increasing movement in the United States and other markets to increase the regulation of dietary supplements, which could impose additional restrictions or requirements on us and increase the cost of doing business. On February 11, 2019, the FDA issued a statement from then FDA Commissioner, Dr. Scott Gottlieb, regarding the agency's efforts to strengthen the regulation of dietary supplements. The FDA will be prioritizing and focusing resources on misbranded products bearing unproven claims to treat, cure, or mitigate disease. Commissioner Gottlieb established a Dietary Supplement Working Group tasked with reviewing the agency's organizational structure, process, procedures, and practices to identify opportunities to modernize the oversight of dietary supplements. Additionally, on December 21, 2015, the FDA created the Office of Dietary Supplements ("ODSP"). The creation of this new office elevates the FDA's program from its previous status as a division under the Office of Nutrition and Dietary Supplements. ODSP will continue to monitor the safety of dietary supplements.

In August 2016, the FDA published its revised draft guidance on Dietary Supplements: New Dietary Ingredient Notifications and Related Issues. If a company sells a dietary supplement containing an ingredient that FDA considers either not a dietary ingredient or a new dietary ingredient ("NDI") that needs an NDI notification, the agency may threaten or initiate enforcement against such company. For example, it might send a warning letter that can trigger consumer lawsuits, demand a product recall, or even work with the Department of Justice to bring a criminal action. Our operations could be harmed if new guidance or regulations require us to reformulate products or effect new registrations, if regulatory authorities make determinations that any of our products do not comply with applicable regulatory requirements, if the cost of complying with regulatory requirements increases materially, or if we are not able to effect necessary changes to our products in a timely and efficient manner to respond to new regulations. In addition, our operations could be harmed if governmental laws or regulations are enacted that restrict the ability of companies to market or distribute nutritional supplements or impose additional burdens or requirements on nutritional supplement companies.

The growth of our agtech sector depends in part on market acceptance of products that contain our algae.

The success of our nutrition business involves the use of our algal biomass in various animal and human products. There can be no assurance regarding the successful distribution and market acceptance of products containing our algae. The expenses or losses associated with lack of market acceptance of our products could harm our ability to find or maintain new licensees for these products.

If our computer systems are hacked, or we experience any other cybersecurity incident, we may face a disruption to our operations, a compromise or corruption of our confidential information and/or damage to our business relationships, all of which could negatively impact our business, results of operations or financial condition.

We rely on information technology networks and systems, including the Internet, to process, transmit and store electronic information, and to manage or support a variety of business processes and activities. Additionally, we collect and store certain data, including proprietary business information, and may have access to confidential or personal information in certain of our businesses that is subject to privacy and security laws and regulations. These technology networks and systems may be susceptible to damage, disruptions or shutdowns due to failures during the process of upgrading or replacing software, databases or components; power outages; telecommunications or system failures; terrorist attacks; natural disasters; employee error or malfeasance; server or cloud provider breaches; and computer viruses or cyberattacks. Cybersecurity threats and incidents can range from uncoordinated individual attempts to gain unauthorized access to information technology networks and systems to more sophisticated and targeted measures, known as advanced persistent threats, directed at us, our products, customers and/or our third-party service providers. It is possible a security breach could result in theft of trade secrets or other intellectual property or disclosure of confidential customer, supplier or employee information. Should we be unable to prevent security breaches or other damage to our information technology systems, disruptions could have an adverse effect on our operations, as well as expose us to costly litigation, liability or penalties under privacy laws, increased cybersecurity protection costs, reputational damage, and product failure.

The animal health industry is highly competitive.

The animal health industry is highly competitive. Our competitors include standalone animal health businesses, the animal health businesses of large pharmaceutical companies, specialty animal health businesses and companies that mainly produce generic products. We believe many of our competitors are conducting R&D activities in areas served by our products and in areas in which we are developing products. Several new start-up companies also compete in the animal health industry. We also face competition from manufacturers of drugs globally, as well as producers of nutritional health products. These competitors may have access to greater financial, marketing, technical and other resources. As a result, they may be able to devote more resources to developing, manufacturing, marketing and selling their products, initiating or withstanding substantial price competition or more readily taking advantage of acquisitions or other opportunities.

Competitive pressure could arise from, among other things, more favorable safety and efficacy product profiles, limited demand growth or a significant number of additional competitive products being introduced into a particular market, price reductions by competitors, the ability of competitors to capitalize on their economies of scale, the ability of competitors to produce or otherwise procure animal health products at lower costs than us and the ability of competitors to access more or newer technology than us.

Our R&D relies on evaluations of animals, which may become subject to bans, additional restrictive regulations or increased attention from activism movements.

We are required to evaluate the effect of our product candidates in animals. Animal testing in certain industries has been the subject of controversy and adverse publicity. Some organizations and individuals have attempted to ban animal testing or encourage the adoption of new regulations applicable to animal testing. To the extent that the activities of such organizations and individuals are successful, our R&D, and by extension our business, financial condition and results of operations, could be materially adversely affected. In addition, negative publicity about us or our industry could harm our reputation. For example, farm animal producers may experience decreased demand for their products or reputational harm as a result of evolving consumer views of animal rights, nutrition, health-related or other concerns. Any reputational harm to the farm animal industry may also extend to companies in related industries, including our Company. Adverse consumer views related to the use of one or more of our product candidates in farm animals also may result in a decrease in the use of such products and could have a material adverse effect on our operating results and financial condition.

Use of social media could give rise to liability or reputational harm.

We and our employees use social media to communicate externally. There is risk that the use of social media by us or our employees to communicate about our product candidates or business may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock.

Risks Relating to Our Intellectual Property

We may not be able to protect our proprietary algae cultures and bioactive compounds in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property of our products. Patents might not be issued or granted with respect to our patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our products or any future products, or fail to otherwise provide us with any competitive advantage. As such, we do not know the degree of future protection that we will have on our products, if any, and a failure to obtain adequate intellectual property protection with respect to our products could have a material adverse impact on our business.

Patent protection may not be available for some of the therapeutic candidates or products we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed.

Claims of intellectual property infringement by or against us could seriously harm our businesses.

From time to time, we may be forced to respond to or prosecute intellectual property infringement claims to defend or protect our rights. These claims, regardless of merit, may consume valuable management time, result in costly litigation or cause product shipment delays. Any of these factors could seriously harm our business and operating results. We may have to enter into royalty or licensing agreements with third parties who claim infringement. These royalty or licensing agreements, if available, may be costly to us. If we are unable to enter into royalty or licensing agreements with satisfactory terms, our business could suffer.

Risks Related to Our Common Stock

Our Common Stock has been delisted by Nasdaq, which may affect liquidity.

The Company's common stock was suspended from trading and delisted from the Nasdaq Capital Market on November 27, 2023. Beginning November 27, 2023, the Company's common stock had been trading over the counter on the OTC Markets' Pink Sheets, and since January 26, 2024 the Company's common stock has been trading over the counter on the OTCQB® market tier, an electronic quotation service operated by OTC Markets Group Inc., under its current trading symbol ZIVO. Similarly, since November 27, 2023, the Company's warrants are traded over the counter on the OTC Markets' Pink Sheets market tier under its current trading symbol ZIVOW.

Our shares of common stock are thinly traded. If an active market for our common stock with meaningful trading volume does not develop or is not maintained, the market price of our common stock may decline materially and you may not be able to sell your shares.

The market price and trading volume of our securities may be volatile and may be affected by economic conditions beyond our control, which could lead to losses for stockholders.

The market price and trading volume of our securities is likely to be volatile. Some specific factors that could negatively affect the price of our securities or result in fluctuations in its price and trading volume include:

- results of trials of our product candidates;
- results of trials of our competitors' products;
- regulatory actions with respect to our therapeutic candidates or products or our competitors' products;
- actual or anticipated fluctuations in our quarterly operating results or those of our competitors;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- issuances by us of debt or equity securities;
- litigation involving our Company, including stockholder litigation; investigations or audits by regulators into the operations of our company; or proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- trading volume of our common stock;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biotech or agtech stocks;
- influence of retail investors and/or social media on our common stock, such as a massive short squeeze rally; and
- conditions in the U.S. financial markets or changes in general economic conditions.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2023, our largest shareholder, HEP Investments, LLC ("HEP" or "HEP Investments"), beneficially owns approximately 18.0% of our Common Stock. Therefore, HEP Investments will have the ability to influence us through this ownership position. This stockholder may be able to determine all matters requiring stockholder approval, including elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that an individual may believe are in the stockholders' best interest.

Our management has identified certain internal control deficiencies, which management believes constitute material weaknesses. Our failure to establish and maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common stock.

We review and update our internal controls, disclosure controls and procedures, and corporate governance policies as our Company continues to evolve. In addition, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("***SOX***") and management is required to report annually on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we are no longer a "smaller reporting company" as defined by applicable SEC rules.

Our management's evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2023 concluded that our controls were not effective, due to material weaknesses resulting from an ineffective overall control environment. The material weaknesses stem primarily from our small size and include the inability to (i) maintain appropriately designed information technology general controls in the areas of user access, vendor management controls, and segregation of duties, including controls over the recording of journal entries, related to certain information technology systems that support the Company's financial reporting process; and (ii) design and maintain effective controls over complex accounting areas and related disclosures including income tax , stock-based compensation, and deferred research and development obligations - participation agreements. Specifically, management did not identify controls over the review of the tax provision, including the valuation analysis relating to deferred tax assets, considerations for uncertain tax positions, the preparation of income tax footnote and required disclosures and selecting and applying accounting policies, proper review of the financial statements and the application of GAAP relating to the accounting and classification of deferred research and development obligations - participation agreements. Management did not identify controls over the review of stock-based compensation, including the valuation of options granted under the Company's equity-based compensation plans.

Such shortcomings could have an adverse effect on our business and financial results. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively affect the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The effect of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board and as executive officers.

Subject to limitations on liquidity, the Company is planning to take steps to remediate these material weaknesses. However, we cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies.

As a smaller reporting company, we are subject to scaled disclosure requirements that may make it more challenging for investors to analyze our results of operations and financial prospects.

Currently, we are a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act. As a "smaller reporting company," we are able to provide simplified executive compensation disclosures in our filings and have certain other decreased disclosure obligations in our filings with the SEC, including being required to provide only two years of audited financial statements in annual reports. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects.

Furthermore, we are a non-accelerated filer as defined by Rule 12b-2 of the Exchange Act, and, as such, are not required to provide an auditor attestation of management's assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404(b) of the Sarbanes-Oxley Act. Because we are not required to, and have not, had our auditor's provide an attestation of our management's assessment of internal control over financial reporting, a material weakness in internal controls may remain undetected for a longer period.

Our annual and quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to annual and quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our product candidates, products or future development programs;
- if any of our product candidates receives regulatory approval, the level of underlying demand for these product candidates and wholesalers' buying patterns;
- addition or termination of trials or funding support;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our products or those of our competitors;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of clinical studies for our therapeutic candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

If our annual or quarterly operating results fall below the expectations of investors or securities analysts, the price of our securities could decline substantially. Furthermore, any annual or quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that annual and quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional funds through debt or equity financing could be dilutive and may cause the market price of our common stock to decline.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic collaborations or partnerships, or marketing, distribution or licensing arrangements with third parties, we may be required to limit valuable rights to our intellectual property, technologies, therapeutic candidates or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our therapeutic candidates.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell our common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell our common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

We are at risk of litigation.

We may become party to litigation from time to time in the ordinary course of business which could adversely affect our business. Should any litigation in which we become involved be determined against us, such a decision could adversely affect our ability to continue operating and the market price for our shares and could use significant resources. Even if we are involved in litigation and win, litigation can redirect significant company resources.

Item 1B. Unresolved Staff Comments.

Not required for smaller reporting companies.

Item 1C. Cybersecurity.

Risk Management and Strategy

Many aspects of our business are dependent upon our computer systems, devices, and networks to collect, process, and store data necessary to conduct many aspects of our business, including the analysis of our products, the maintenance of our intellectual property, the recording and reporting of commercial and financial information, and payroll. We rely on standard operating systems and software from established and reliable third parties to provide security including Microsoft 365, QuickBooks, and Paylocity. The Company does not have in-house information technology personnel. Management makes concerted efforts to select third-party software providers with a demonstrated track-record of effectively addressing cyber-security concerns. In event of a cyber-security incident, we would rely upon these providers. In light of the Company's current size and relatively low cyber-risk profile, management believes that reliance upon experienced third-party providers is the most prudent and cost-effective course.

To date, risks from cybersecurity threats or incidents have not materially affected our company. However, the sophistication of and risks from cybersecurity threats and incidents continues to increase, and the preventative actions that we have taken and continue to take to reduce the risk of cybersecurity threats and incidents and protect our systems and information may not successfully protect against all cybersecurity threats and incidents. For more information on how cybersecurity risk could materially affect our company's business strategy, results of operations, or financial condition, please refer to Item 1A Risk Factors.

Governance

Our board stays informed on data privacy and information security issues and vulnerabilities that may be applicable to the Company. We outsource most aspects of our information technology management and these third party providers are available to address any cybersecurity issues that may arise.

Item 2. Properties.

The Company's principal executive office is located at 21 East Long Lake Road, Suite 100, Bloomfield Hills, MI 48304 in a facility where we lease roughly 4,800 square feet. We believe that our existing facilities are adequate for our current needs. If we determine that additional or new facilities are needed in the future, we believe that sufficient options would be available to us on commercially reasonable terms. We also lease a laboratory and office (roughly 2,700 square feet) at 608 Danley Drive, Unit #1, Fort Myers, FL 33907.

Item 3. Legal Proceedings.

On April 13, 2022, AEGLE Partners, 2 LLC ("AEGLE") initiated an arbitration in Michigan against the Company with the American Arbitration Association. AEGLE asserted claims related to a certain Supply Chain Consulting Agreement entered into between AEGLE and the Company in 2019 (as amended from time to time, the "Supply Chain Consulting Agreement"), and a disagreement between AEGLE and the Company regarding whether AEGLE was entitled to payment of certain fees and warrants pursuant to the Supply Chain Consulting Agreement. AEGLE's complaint sought, among other things, three times the payment of such alleged fees and warrants and recovery of AEGLE's costs and expenses. On April 20, 2023, the Company and AEGLE settled the pending arbitration matter for $13,000.

Additionally, the Company may be subject to various claims, complaints, and legal actions that arise from time to time in the normal course of business. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on the Company's business, financial position, results of operations, or cash flows.

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

Our common stock is quoted on OTCBQ under the symbol "ZIVO". Our public warrants are quoted on OTC Markets' Pink Sheets under the symbol ZIVOW.

Holders

As of March 14, 2024, there were approximately 209 holders of record of our common stock. The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations, or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have not paid any cash dividends on our common stock since our inception and do not anticipate paying any cash dividends in the foreseeable future. We plan to retain our earnings, if any, to provide funds for the expansion of our business.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains certain forward-looking statements that involve risk and uncertainties. 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 set forth under the section titled "Risk Factors," and other documents we file with the SEC. Historical results are not necessarily indicative of future results.

Overview

We have put in place a business model in which we may derive future income from licensing and selling natural bioactive ingredients including algal biomass and products that may be derived from or are initially based on the algal biomass. We expect that these planned new products will likely be sold or licensed to much larger, better-financed human and animal pharma companies, and to food, dietary supplement, and skin care manufacturers. The anticipated income streams are to be generated from a) sales of algal biomass or extracts thereof, and b) license payments in the form of royalties and / or other contractual payments for licensed natural bioactive ingredients. Our manufacturing strategy is to create contract manufacturers for our non-licensed products which products will be sold by us to food distributors and retailers, animal food, dietary supplement, and medical food processors and/or name-brand marketers. Further, we expect to license our bioactive fractions and molecules as lead compounds or templates for synthetic variants intended for therapeutic applications.

Financial Overview

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs for personnel in functions not directly associated with research and development activities, professional fees and consultant expenses, and other overhead spending. Personnel related costs include cash compensation, benefits, and stock-based compensation expenses. Professional fees and consultant expenses consist primarily of legal fees relating to corporate matters, intellectual property costs, professional fees for consultants assisting with regulatory, and financial matters. Other overhead spending includes cost to support information technology, rent, insurances, public company listing, and supplies.

We anticipate that our general and administrative expenses will significantly increase in the future to support our continued research and development activities, potential commercialization of our product candidates, hiring of additional personnel, legal and professional services, and other public company related costs.

Research and Development

Research and development expenses are incurred in developing our product candidates, compensation and benefits for research and development employees, including stock-based compensation, research related overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, costs related to regulatory operations, fees paid to research consultants and other outside expenses. Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to significantly increase over the next several years as we continue to develop product candidates targeting additional pharma and algal biomass applications. These additional activities will increase the need to conduct preclinical testing and clinical trials and will depend on the duration, costs and timing to complete our preclinical programs and clinical trials.

Interest Expense

Interest expense primarily consists of interest costs related to our convertible notes and for interest on short term debt, as discussed in detail below.

Other Income

Other income consists of proceeds derived from activity outside of normal operating activity, including amortization of debt discounts where appropriate.

Results of Operations

Comparison of Year Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the year ended December 31, 2023 and 2022:

	Year ended December 31,	
	2023	2022
Total revenue	$ 27,650	$ -
Total cost of goods sold	(16,040)	$ -
Gross margin	$ 11,610	
Costs and expenses:		
General and administrative	5,897,594	6,491,704
Research and development	1,377,028	2,240,270
Total costs and expenses	$ 7,274,622	$ 8,731,974
Loss from operations	$ (7,263,012)	$ (8,731,974)
Total interest and other (expense), net	(514,172)	$ (13,319)
Net loss	$ (7,777,184)	$ (8,745,293)

Revenue

During the year ended December 31, 2023, the Company recorded commercial revenue relating to sales of the Company's dried algal biomass product as a human food or food ingredient. The $27,650 for the year ending December 31, 2023 is an increase over the $0 in revenue in the prior year. The $27,650 increase is the result of product volume sold in the year ended December 31, 2023, versus no recorded product volume or revenue in the year ended December 31, 2022.

Costs of Goods Sold

Cost of goods sold for the year ended December 31, 2023 was $16,040. This is $16,040 higher than the same period last year, attributable to product volume as no product was shipped in the comparable prior year period.

General and Administrative Expenses

General and administrative expenses were $5.9 million for the 12 months ended December 31, 2023, which is about $600,000 lower than the approximately $6.5 million for the comparable prior period, explained by the following changes: a decrease of $270,000 in labor expense ($750,000 non-cash decrease due to stock options issued to employees partially offset by a roughly $480,000 increase in cash compensation and benefits), and a decrease in overhead expense of $330,000 ($820,000 decrease in directors fees, $290,000 decrease in consultant expense, partially offset by an increase of $260,000 in accounting, increase of $430,000 in legal, and increase in other overhead of $90,000). The increases in accounting and legal fees versus the prior year period were largely the result of legal and accounting fees incurred in capital raising efforts in 2023.

Research and Development Expenses

For the 12 months ended December 31, 2023, we incurred $1.4 million in net R&D expenses, as compared to $2.2 million for the comparable period in 2022.

Of these costs in 2023, $1.2 million is for salary and other internal costs, a decrease of approximately $325,000 from the prior year. The decrease is primarily explained by lower stock related compensation costs of $260,000 and lower travel expense by $30,000. Third party research and development spending of $856,000 was $610,000 lower than the prior year due to fewer third-party research studies and the end of our development program in our nutrition business. For the year ending December 31, 2023, the Company recognized a reduction in gross research and development spending of roughly $700,000 to account for the amortization of the spending obligation created through the complete funding of the Participation Agreements, roughly $70,000 lower than the amount research and development was reduced in 2022. (See *Note 8: Deferred R&D Obligations - Participation Agreements*)

	December 31, 2023	December 31, 2022
Labor and other internal expenses	$ 1,222,280	$ 1,582,628
External research expenses	856,080	1,431,667
Total gross R&D expenses	$ 2,078,360	$ 3,014,295
Less contra-expense for amortization of deferred R&D obligation - Participation Agreements	(701,332)	(774,025)
Net R&D expenses	$ 1,377,028	$ 2,240,270

Subject to the availability of funding, we expect our R&D costs to grow as we work to complete the research in the development of natural bioactive compounds for use as dietary supplements and food ingredients, as well as biologics for medicinal and pharmaceutical applications in humans and animals. The Company's scientific efforts presently are focused on the licensing products for healthy immune response in livestock and growing of our proprietary algal culture in commercial scale facilities.

Liquidity and Capital Resources

Historical Capital Resources

As of December 31, 2023, our principal source of liquidity consisted of cash deposits of 274,380. We expect to continue to incur significant expenses and increasing operating and net losses for the foreseeable future until and unless we generate an adequate level of revenue from potential commercial sales to cover expenses.

We anticipate that our expenses will increase substantially as we develop and seek to commercialize our product candidates and continue to pursue pre-clinical and clinical trials, seek regulatory approvals, manufacture product candidates, hire additional staff, add operational, financial and management systems and continue to operate as a public company.

Our source of cash to date has been proceeds from the issuances of notes, common stock with and without warrants and unsecured loans, and the entry into Participation Agreements, the terms of which are further described below. See also "*Funding Requirements and Outlook*" below.

Unsecured Loans

From January 1, 2022 to December 31, 2023, the Company received gross proceeds of $2,384,200 in unsecured loans. As of December 31, 2023, no principal and accrued interest remained outstanding under such loans.

Private Placements

In the year ending December 31, 2023, we entered into Subscription Agreements with accredited investors pursuant to which we, in private placements, issued and sold an aggregate of 734,682 shares of common stock for gross proceeds in the amount of $4,640,000.

Funding Requirements and Outlook

At December 31, 2023, we had $274,380 in cash deposits.

Management has noted the existence of substantial doubt about our ability to continue as a going concern. Additionally, our independent registered public accounting firm included explanatory paragraphs in the reports on our financial statements as of and for the years ended December 31, 2023, noting the existence of substantial doubt about our ability to continue as a going concern. Our existing cash is not sufficient to fund our operating expenses through at least twelve months from the date of this filing. To continue to fund operations, we will need to secure additional funding through public or private equity or debt financings, through collaborations or partnerships with other companies or other sources. We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital when needed could compromise our ability to execute on our business plan. If we are unable to raise additional funds, or if our anticipated operating results are not achieved, we believe planned expenditures may need to be reduced in order to extend the time period that existing resources can fund our operations. If we are unable to obtain the necessary capital, it may have a material adverse effect on our operations and the development of our technology, or we may have to cease operations altogether.

Our material cash requirements relate to the funding of our ongoing product development. See "*Item 1-Business-Clinical Development and Regulatory Pathway-Clinical Experience, Future Development and Clinical Trial Plans*" in this Report for a discussion of design, development, pre-clinical and clinical activities that we may conduct in the future, including expected cash expenditures required for some of those activities, to the extent we are able to estimate such costs.

The development of our product candidates is subject to numerous uncertainties, and we could use our cash resources sooner than we expect. Additionally, the process of development is costly, and the timing of progress in pre-clinical tests and clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving further regulatory approvals and achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Cash Flows

Cash Flows from Operating Activities. During the 12 months ended December 31, 2023, our operating activities used $5.8 million in cash, a decrease of cash used of roughly $1.3 million from the comparable prior period. The approximate $1.3 million decrease in cash used by operating activities was primarily attributable to the following (all of which are approximated): a $900,000 decrease in net loss, a decrease in non-cash expenses of $1.3 million (explained by a decrease of stock issued for services of $1.8 million, higher debt discount amortization of $(440,000), and lower amortization of deferred R&D obligations of $(70,000)), and changes is assets and liabilities of $1.7 million (mostly explained by an increase in accrued liabilities for unpaid bonus payments to certain employees of $940,000, an increase in accounts payable of $720,000 including $170,000 in overdue board of directors fees and $570,000 in legal and accounting professional services).

Cash Flows from Investing Activities. During the 12 months ended December 31, 2023 and 2022, there were no investing activities.

Cash Flows from Financing Activities. During the 12 months ended December 31, 2023, we generated $4.3 million in cash from financing activities; a private placement of stock and warrants in July 2023 in the amount of $3.6 million, and several private placements of common stock in December 2023 totaling $640,000, compared to zero provided in the prior year.

We estimate that we would require approximately $5 million in cash over the next 12 months in order to fund our basic operations, excluding our R&D initiatives. Based on this cash requirement, we have a near-term need for additional funding to continue to develop our products and intellectual property. Historically, we have had substantial difficulty raising funds from external sources. If we are unable to raise the required capital, we will be forced to curtail our business operations, including our R&D activities. The following table shows a summary of our cash flows for the periods indicated:

	Twelve months ended December 31,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (5,799,893)	$ (7,102,612)
Investing activities	-	-
Financing activities	4,275,010	-
Net increase (decrease) in cash and cash equivalents	$ (1,524,883)	$ (7,102,612)

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Fair Value of Financial Instruments

We account for fair value measurements of assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring or nonrecurring basis adhering to the Financial Accounting Standards Board ("FASB") fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the Company at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

As of December 31, 2023 and December 31, 2022, fair values of cash, prepaid, other assets, accounts payable and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. We elected to account for the convertible notes while they were outstanding on a fair value basis under ASC 825 to comprehensively value and streamline the accounting for the embedded conversion options. The fair value of these convertible notes were based on both the fair value of our common stock, discount associated with the embedded redemption features, and cash flow models discounted at current implied market rates evidenced in recent arms-length transactions representing expected returns by market participants for similar instruments and are based on Level 3 inputs.

Complex Financial Instruments

We evaluate all conversion and redemption features contained in a debt instrument to determine if there are any embedded derivatives that require separation from the host debt instrument. An embedded derivative that requires separation is bifurcated from its host debt instrument and a corresponding discount to the host debt instrument is recorded. The discount is amortized and recorded to interest expense over the term of the host debt instrument using the straight-line method which approximates the effective interest method. The separated embedded derivative is accounted for separately on a fair market value basis. We record the fair value changes of a separated embedded derivative at each reporting period in the consolidated statements of comprehensive loss as a fair value change in derivative and warrant liabilities.

Stock-Based Compensation

We account for share-based compensation in accordance with the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 718, Compensation - Stock Compensation. Accordingly, compensation costs related to equity instruments granted are recognized at the grant-date fair value. The Company records forfeitures when they occur. Share-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718.

Recent Accounting Pronouncements

See "*Note 3 - Summary of Significant Accounting Policies*" in this Report regarding the impact of certain recent accounting pronouncements on our financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

Reference is made to the Consolidated Financial Statements, the Reports thereon, and the Notes thereto, commencing on page F-1 of this report, which Consolidated Financial Statements, Reports, Notes and data are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Incorporated by reference to "*Proposal No. 2 - Ratification of Independent Registered Public Accounting Firm*" in the Registrant's 2023 Proxy Statement to be filed within 120 days after the Registrant's fiscal year end.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and to ensure that information required to be disclosed is accumulated and communicated to management, including our principal executive and financial officers, to allow timely decisions regarding disclosure. The Chief Executive Officer and the Chief Financial Officer, as our principal financial and accounting officer, have reviewed the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K and, based on their evaluation, have concluded that the disclosure controls and procedures were not effective as of such date due to material weaknesses in internal control over financial reporting, described below.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer 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.

Because of its inherent limitations, internal control over financial reporting may not detect or prevent misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management utilized the criteria established in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023. As previously reported, we identified material weaknesses that continued to exist at December 31, 2023. In addition, in connection with the audit of our consolidated financial statements for the year ended December 31, 2023, we identified additional material weaknesses in internal control over financial reporting, as described below.

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 our annual or interim financial statements will not be prevented or detected on a timely basis.

Material Weaknesses in Internal Control Over Financial Reporting

Management has determined that the Company had the following material weaknesses in its internal control over financial reporting.

Control Environment, Risk Assessment, and Monitoring

Management did not design and maintain appropriate entity-level controls impacting the control environment, risk assessment procedures, and monitoring activities to prevent or detect material misstatements to the consolidated financial statements. These deficiencies were attributed to: (i) lack of structure and responsibility, insufficient number of qualified resources, and inadequate oversight and accountability over the performance of controls, (ii) ineffective identification and assessment or risks impacting internal control over financial reporting, and (iii) ineffective evaluation and determination as to whether the components of internal control were present and functioning.

Control Activities and Information and Communication

These material weaknesses contributed to the following additional material weaknesses within certain business processes and the information technology environment:

- Management did not design and maintain appropriate information technology general controls in the areas of user access, vendor management controls, and segregation of duties, including controls over the recording and review of journal entries, related to certain information technology systems that support the Company's financial reporting process.
- Management did not design, implement, and retain appropriate documentation of formal accounting policies, procedures, and controls across substantially all of the company's business processes over; (i) the financial reporting process, including management review controls over key disclosures and financial statement support schedules, (ii) the monthly financial close process, including journal entries and account reconciliations and (iii) the completeness and accuracy of information used by control owners in the operation of certain controls, to achieve timely, complete, accurate financial accounting, reporting.
- Management did not design and implement controls over the accounting, classification, and application of United States Generally Accounting Principles ("US GAAP") relating to income taxes, stock-based compensation, and deferred research and development obligations - participation agreements accounting. Specifically:
- Management did not identify controls over the review of the tax provision, including the valuation analysis related to deferred tax assets, considerations for uncertain tax positions, the preparation of the income tax footnote and required disclosures and selecting and applying accounting policies;
- Management did not identify controls over the accounting and classification of deferred research and development obligations - participation agreements; and
- Management did not identify controls over the valuation of stock-based compensation for option awards to employees and members of the board of directors.

Based on the assessment and identification of the material weaknesses described above, management has concluded that, as of December 31, 2023, our internal control over financial reporting was not effective and could lead to a material misstatement of account balances or disclosures. Accordingly, management has concluded that these control deficiencies constitute material weaknesses.

However, after giving full consideration to these material weaknesses, and the additional analyses and other procedures that we performed to ensure that our consolidated financial statements included in this Annual Report on Form 10-K were prepared in accordance with U.S. GAAP, our management has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with U.S. GAAP.

Remediation

Management has been implementing and continues to implement measures designed to ensure that control deficiencies contributing to the material weaknesses are remediated, such that these controls are designed, implemented, and operating effectively. The remediation actions include:

- Developing a training program and educating control owners concerning the principles of the Internal Control - Integrated Framework (2013) issued by COSO;
- Implementing a risk assessment process by which management identifies risks of misstatement related to all account balances;
- Developing internal controls documentation, including comprehensive accounting policies and procedures over financial processes and related disclosures;

- Enhancing policies and procedures to retain adequate documentary evidence for certain management review controls over certain business processes including precision of review and evidence of review procedures performed to demonstrate effective operation of such controls;
- Engaging outside resources for complex accounting matters and drafting and retaining position papers for all complex, non-recurring transactions;
- Developing monitoring activities and protocols that will allow us to timely assess the design and the operating effectiveness of controls over financial reporting and make necessary changes to the design of controls, if any
- Segregating key functions within our financial and information technology processes supporting our internal controls over financial reporting;
- Reassessing and formalizing the design of certain accounting and information technology policies relating to security and change management controls, including user access reviews, including assessing the need for implementing a more robust information technology system;
- Continuing to enhance and formalize our accounting, business operations, and information technology policies, procedures, and controls to achieve complete, accurate, and timely financial accounting, reporting and disclosures.

Changes in Internal Control Over Financial Reporting

Except for the material weaknesses discussed above, there was no other change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Incorporated by reference to "*Proposal No. 1 - Election of Directors - Management," "Information with Respect to the Board of Directors," and "Management"* in the Registrant's 2024 Proxy Statement to be filed within 120 days after the Registrant's fiscal year end.

Item 11. Executive Compensation

Incorporated by reference to "*Executive Compensation*" in the Registrant's 2024 Proxy Statement to be filed within 120 days after the Registrant's fiscal year end.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Incorporated by reference to "*Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters*" in the Registrant's 2024 Proxy Statement to be filed within 120 days after the Registrant's fiscal year end.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Incorporated by reference to "*Certain Relationships and Related Transactions*" *and "Proposal No. 1 - Election of Directors"*in the Registrant's 2024 Proxy Statement to be filed within 120 days after the Registrant's fiscal year end.

Item 14. Principal Accountant Fees and Services

Incorporated by reference to "*Proposal No. 2 - Ratification of Independent Registered Public Accounting Firm"* in the Registrant's 2024 Proxy Statement to be filed within 120 days after the Registrant's fiscal year end. Information about aggregate fees billed to us by our principal accountant, BDO USA, P.C. (PCAOB ID No. 243) will be included under the caption "Independent Auditor Fees" in the 2024 Proxy Statement, and that information is incorporated by reference herein.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) (1) (2) Financial Statements.

Financial Statements begin on page F-1 of this report.

All schedules have been omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or Notes thereto.

(3) Exhibits.

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
3.1	Articles of Incorporation of the Registrant as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 22, 2011)
3.2	Certificate of Amendment to Articles of Incorporation dated October 16, 2014 (incorporated by reference to Exhibit 3.12 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2014)
3.3	Certificate to Amendment dated May 28, 2021 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 8-K filed on June 2, 2021)
3.4	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 17, 2010)
3.5	Second Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 7, 2022)
4.2*	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K filed on April 22, 2022)
4.3	Form of Representative's Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 2, 2021)
4.4	Form of Common Stock Purchase Warrant by and between the Registrant and Direct Transfer LLC (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on June 2, 2021)
4.5	Warrant Agency Agreement (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1/A filed on May 26, 2021)
10.1+	2019 Omnibus Long-Term Incentive Plan (incorporated by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K filed on March 26, 2020)
10.1.1+	Stock Option Grant Notice for 2019 Omnibus Long-Term Incentive Plan (incorporated by reference to Exhibit 10.37 of the Registrant's Annual Report on Form 10-K filed on March 26, 2020)
10.2+	2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on February 16, 2022)
10.3	Supply Chain Agreement with Aegle Partners 2 LLC, dated February 27, 2019 (incorporated by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form S-1/A filed on May 26, 2021)
10.3.1	First Amendment to Supply Chain Agreement with Aegle Partners 2 LLC, dated September 14, 2019 (incorporated by reference to Exhibit 10.39 to the Registrant's Registration Statement on Form S-1/A filed on May 26, 2021)
10.3.2	Second Amendment to Supply Chain Agreement with Aegle Partners 2 LLC, dated November 24, 2020 (incorporated by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-1/A filed on May 26, 2021)

10.4+	Employment Agreement, dated as of February 15, 2022, by and between John Payne and the Company (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 16, 2022)
10.5+	Letter Agreement between Keith Marchiando and Zivo Bioscience, Inc., dated January 1, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 7, 2021)
10.6	Form of Paulson Convertible Note (incorporated by reference to Exhibit 10.45 to the Registrant's Registration Statement on Form S-1/A filed on May 26, 2021)
10.7	Form of Shapiro Convertible Note (incorporated by reference to Exhibit 10.46 to the Registrant's Registration Statement on Form S-1/A filed on May 26, 2021)
10.8*	Zivo Bioscience, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q filed with the Securities and Exchange Commission on November 15, 2021)
10. 9	Stock Option Grant Notice and Agreement to Zivo Bioscience, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 filed with the Securities and Exchange Commission on November 15, 2021)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of BDO USA, P.C.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1*	Certification of the Principal Executive Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of the Principal Financial Officer pursuant to 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 (formatted as Inline XBRL and contained in Exhibit 101)

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* Filed herewith.

** Furnished herewith.

\+ Indicates a management contract or compensatory plan.

† Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

Item 16. Form 10-K Summary.

None.

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.

ZIVO BIOSCIENCE, INC.

Date: March 15, 2024

By: */s/ Keith R. Marchiando*
Keith R. Marchiando
Chief Financial Officer, and Secretary

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

By: */s/ John B. Payne*
John B. Payne,
Chief Executive Officer, President and Director
March 15, 2024

By: */s/ Keith R. Marchiando*
Keith R. Marchiando
Chief Financial Officer, and Secretary
March 15, 2024

By: */s/ Christopher D. Maggiore*
Christopher D. Maggiore,
Director
March 15, 2024

By: */s/ Nola E. Masterson*
Nola E. Masterson,
Director
March 15, 2024

By: */s/ Alison A. Cornell*
Alison A. Cornell,
Director
March 15, 2024

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Zivo Bioscience, Inc.
Bloomfield Hills, Michigan

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Zivo Bioscience, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity (deficit), 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 at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Private Placement Warrants

As discussed in Note 5 to the consolidated financial statements, the Company completed a private placement whereby the Company issued warrants to purchase 65,000 shares of the Company's common stock, and as discussed in Note 9 to the consolidated financial statements, the Company completed a registered direct offering whereby the Company issued pre-funded warrants to purchase 78,021 shares of common stock, Series A Warrants to purchase 249,688 shares of common stock, and Series B Warrants to purchase 249,688 shares of common stock (collectively, the "Private Placement Warrants"). The Company determined that the Private Placement Warrants should be classified as equity.

We identified the assessment of the accounting treatment for Private Placement Warrants as equity or liability as a critical audit matter. The principal considerations that led to this determination was the complexity in assessing the warrant features, which requires management to make significant judgments in the interpretation of the terms of the agreements and the application of the appropriate accounting guidance. Auditing the Company's application of appropriate accounting guidance for the Private Placement Warrants required challenging and complex auditor judgment due to the nature and extent of audit effort required, including the extent of specialized skills and knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Inspecting the agreements and evaluating the completeness and accuracy of the contract terms included in the Company's technical accounting analyses and testing management's application of the relevant accounting guidance, including the balance sheet classification and disclosures.
- Utilizing professionals with specialized knowledge and skills in the relevant technical accounting guidance to assist in: (i) evaluating the relevant contract terms of the warrant issuances in relation to the appropriate accounting guidance, and (ii) assessing the appropriateness of conclusions reached by the Company.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2022.

Troy, Michigan

March 15, 2024

ZIVO BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash	$ 274,380	$ 1,799,263
Accounts receivable	3,735	-
Prepaid expenses	147,262	102,416
Total current assets	$ 425,377	$ 1,901,679
PROPERTY AND EQUIPMENT, NET	-	-
OTHER ASSETS:		
Operating lease - right of use asset	98,280	189,282
Security deposit	32,058	32,058
Total other assets	130,338	221,340
TOTAL ASSETS	$ 555,715	$ 2,123,019
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT):		
CURRENT LIABILITIES:		
Accounts payable	$ 993,090	$ 490,670
Accounts payable – related party	172,670	-
Current portion of long-term operating lease	106,342	99,259
Convertible debentures payable	240,000	240,000
Deferred R&D obligations - participation agreements	-	525,904
Deferred R&D obligations - participation agreements related parties	-	175,427
Accrued interest	100,686	98,286
Accrued liabilities – employee bonus	1,148,770	398,176
Total current liabilities	$ 2,761,558	$ 2,027,722
LONG TERM LIABILITIES:		
Long-term operating lease, net of current portion	-	105,919
Total long-term liabilities	-	105,919
TOTAL LIABILITIES	$ 2,761,558	$ 2,133,641
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' (DEFICIT):		
Common stock, $0.001 par value, 25,000,000 and 25,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 2,382,356 and 1,569,943 issued and outstanding at December 31, 2023, and December 31, 2022, respectively (a)	$ 2,383	$ 1,570
Additional paid-in capital [(a)]	121,373,488	115,792,338
Accumulated deficit [(a)]	(123,581,714)	(115,804,530)
Total stockholders' (deficit)	$ (2,205,843)	$ (10,622)
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT)	$ 555,715	$ 2,123,019

(a) Results have been adjusted for the 1-6 Reverse Split in October 2023. See Note 9, "Stockholders' Equity (Deficit)" for details regarding the stock split.

The accompanying notes are an integral part of these consolidated financial statements.

ZIVO BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the year ended December 31, 2023	For the year ended December 31, 2022
REVENUE:		
Product revenue	$ 27,650	$ -
Total Revenues	$ 27,650	$ -
COST OF GOODS SOLD		
Product costs	16,040	-
Total Cost of Goods Sold	16,040	-
GROSS MARGIN	11,610	-
COSTS AND EXPENSES:		
General and administrative	5,897,594	6,491,704
Research and development	1,377,028	2,240,270
Total Costs and Expenses	$ 7,274,622	$ 8,731,974
LOSS FROM OPERATIONS	$ (7,263,012)	$ (8,731,974)
OTHER (EXPENSE):		
Amortization of debt discount	(439,594)	-
Interest expense - related parties	(50,785)	-
Interest expense – other	(23,793)	(13,319)
Total Other Expense	$ (514,172)	$ (13,319)
NET LOSS	$ (7,777,184)	$ (8,745,293)
BASIC AND DILUTED LOSS PER SHARE	$ (4.60)	$ (5.57)[(a)]
WEIGHTED AVERAGE BASIC AND DILUTED SHARES OUTSTANDING	1,690,009	1,569,943[(a)]

(a) Results have been adjusted for the 1-6 Reverse Split in October 2023. See Note 9, “Stockholders’ Equity (Deficit)” for details regarding the stock split.

The accompanying notes are an integral part of these consolidated financial statements.

ZIVO BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE PERIOD JANUARY 1, 2022 THROUGH DECEMBER 31, 2023

	Common Stock		Additional Paid in	Accumulated	
	Shares [a]	Amount [a]	Capital [a]	Deficit	Total
Balance, January 1, 2022	1,569,943	$ 1,570	$ 113,099,876	$ (107,059,237)	$ 6,042,209
Employee and director equity-based compensation	-	-	2,692,462	-	2,692,462
Net loss for the twelve months ended December 31, 2022	-	-	-	(8,745,293)	(8,745,293)
Balance, December 31, 2022	1,569,943	$ 1,570	$ 115,792,338	$ (115,804,530)	$ (10,622)

	Common Stock		Additional Paid in	Accumulated	
	Shares [a]	Amount [a]	Capital [a]	Deficit	Total
Balance, January 1, 2023	1,569,943	$ 1,570	$ 115,792,338	$ (115,804,530)	$ (10,622)
Employee and director equity-based compensation	-	-	867,359	-	867,359
Private offering issuance of stock and warrants, net of issuance costs	171,666	172	3,634,791	-	3,634,963
Debt discount for related party loan warrants	-	-	439,594	-	439,594
Fractional Shares from Split	(290)	-	-	-	-
Common stock issued on prefunded warrant exercise	78,021	78	(31)	-	47
Private sales of common stock – other	125,324	125	154,875	-	155,000
Private sales of common stock – related party	437,692	438	484,562	-	485,000
Net loss for the twelve months ended December 31, 2023	-	-	-	(7,777,184)	(7,777,184)
Balance, December 31, 2023	2,382,356	$ 2,383	$ 121,373,488	$ (123,581,714)	$ (2,205,843)

(a) Results have been adjusted for the 1-6 Reverse Split in October 2023. See Note 9, "Stockholders' Equity (Deficit)" for details regarding the stock split.

The accompanying notes are an integral part of these consolidated financial statements.

ZIVO BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
Cash flows from operating activities:		
Net Loss	$ (7,777,184)	$ (8,745,293)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization on debt discount	439,594	-
Employee and director equity-based compensation expense	867,359	2,692,462
Non-cash lease expense	91,002	79,637
Amortization of deferred R&D obligations - participation agreements	(701,332)	(774,025)
Changes in assets and liabilities:		
Prepaid expenses	(44,846)	(44,338)
Security deposits	-	(29,058)
Accounts payable	502,420	(163,663)
Accounts payable – related party	172,670	-
Accounts receivable	(3,735)	-
Lease liabilities	(98,835)	(51,695)
Accrued liabilities	752,994	(66,639)
Net cash (used) in operating activities	$ (5,799,893)	$ (7,102,612)
Cash flows from investing activities:		
Net cash (used) in investing activities	$ -	$ -
Cash Flow from Financing Activities:		
Proceeds of loans payable, other	$ 605,600	$ 628,600
Payment of loans payable, other	(605,600)	(628,600)
Proceeds of loans payable, related party	1,150,000	-
Payment of loans payable, related party	(1,150,000)	-
Proceeds from private placement of registered securities, net	3,634,963	-
Exercise of common stock warrants	47	-
Proceeds from direct sale of common stock, related party	485,000	-
Proceeds from direct sales of common stock	155,000	-
Net cash provided by financing activities	$ 4,275,010	$ -
Decrease in cash	$ (1,524,883)	$ (7,102,612
Cash at beginning of period	1,799,263	8,901,875
Cash at end of period	$ 274,380	$ 1,799,263
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 72,178	$ 10,920
Income taxes	$ -	$ -

The accompanying notes are an integral part of these consolidated financial statements.

Supplemental Schedule of Non-Cash Investing and Financing Activities:

For the Year Ended December 31, 2023:

During the year ended December 31, 2023, the Company had no non-cash investing or financing transactions.

For the Year Ended December 31, 2022:

During the year ended December 31, 2022, the Company had no non-cash financing transactions.

During the year ended December 31, 2022, the Company had non-cash investing activities in the amount of $241,694 related to ROU assets obtained in exchange for ROU liabilities.

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 - DESCRIPTION OF BUSINESS

The business model of Zivo Bioscience, Inc. and its subsidiaries (Health Enhancement Corporation, HEPI Pharmaceuticals, Inc., Zivo Bioscience, LLC, Wellmetrix, LLC, WellMetris, LLC, Zivo Biologic, Inc., ZIVOLife, LLC, and Zivo Zoologic, Inc. (collectively the "Company")) is to derive future income from licensing and selling natural bioactive ingredients derived from their proprietary algae cultures to animal, human and dietary supplement and medical food manufacturers.

NOTE 2 - BASIS OF PRESENTATION

Going Concern

The Company has incurred net losses since inception, experienced negative cash flows from operations for the year ended December 31, 2023 and has an accumulated deficit of $123.6 million. The Company has historically financed its operations primarily through the issuance of common stock, warrants, and debt.

The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There can be no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis.

The Company intends to fund ongoing activities by utilizing its current cash on hand and by raising additional capital through equity or debt financings. There can be no assurance that the Company will be successful in raising that additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

These factors 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. The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business; no adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

Stock Split

On October 26, 2023, the Company effected a 1-for-6 reverse stock split of its common stock and proportionately decreased the number of authorized shares of common stock. All share, per share, options, and warrants information has been retroactively adjusted to reflect the reverse split. The shares of common stock retain a par value of $0.001 per share

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of Zivo Bioscience, Inc. and its wholly-owned subsidiaries, Health Enhancement Corporation, HEPI Pharmaceuticals, Inc., Wellmetrix, LLC, Wellmetris, LLC, Zivo Bioscience, LLC, Zivo Biologic, Inc., ZIVOLife, LLC, and Zivo Zoologic, Inc. All significant intercompany transactions and accounts have been eliminated in consolidation.

Accounting Estimates

The Company's consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America, which require management to make 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 amount of revenues and expenses during the reporting period. Due to the inherent uncertainty involved in making estimates, actual results could differ from those estimates. Management uses its best judgment in valuing these estimates and may, as warranted, solicit external professional advice and other assumptions believed to be reasonable.

Cash

For the purpose of the statements of cash flows, cash equivalents include time deposits, certificates of deposit and all highly liquid debt instruments with original maturities of three months or less. The Company maintains cash and cash equivalents balances at financial institutions and are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. At times, balances in certain bank accounts may exceed the FDIC insured limits. At December 31, 2023 and 2022, the Company did not have any cash equivalents.

Leases

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, *Leases*, requires the recognition of a right-of-use ("ROU") asset and a corresponding lease liability on the balance sheet. ROU assets represent the right to use an underlying asset over the lease term and lease liabilities represent the obligation to make lease payments resulting from the lease agreement. ROU assets and lease liabilities are recognized on commencement of the lease agreement.

ROU assets are included within operating lease right-of-use assets, and the corresponding operating lease liabilities are recorded as current portion of long-term operating lease, and within long-term liabilities as long-term operating lease, net of current portion on the Company's Consolidated Balance Sheets as of December 31, 2023 and 2022.

Lease assets and lease liabilities are recognized based on the present value of lease payments over the lease term at commencement date. Generally, we do not consider any additional renewal periods to be reasonably certain of being exercised, as comparable locations could generally be identified within the same trade areas for comparable lease rates. Because the Company's leases do not provide an implicit rate of return, the Company used its incremental borrowing rate in determining the present value of lease payments. We have elected the practical expedient not to separate lease and nonlease components for all of our building leases.

Revenue Recognition

Revenue is recognized in accordance with ASC 606, which utilizes five steps to determine whether revenue can be recognized and to what extent: (i) identify the contract with a customer; (ii) identify the performance obligation(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) determine the recognition period. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, *Revenue from Contracts with Customers*, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied when control of the product is transferred according to agreed shipping terms, and revenue is recognized at that single point in time.

Significant judgments exercised by management include the identification of performance obligations, and whether such promised goods or services are considered distinct. The Company evaluates promised goods or services on a contract-by-contract basis to determine whether each promise represents a good or service that is distinct or has the same pattern of transfer as other promises. A promised good or service is considered distinct if the customer can benefit from the good or service independently of other goods/services either in the contract or that can be obtained elsewhere, without regard to contract exclusivity, and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contact. If the good or service is not considered distinct, the Company combines such promises and accounts for them as a single combined performance obligation.

Research and Development

Research and development ("R&D") costs are expensed as incurred. The Company's R&D costs, including internal expenses, consist of clinical study expenses as it relates to the therapeutic (biotech) business and the development and growing of algae as it relates to the nutrition (agtech) business. External clinical studies expenses were approximately $900,000 and $1.4 million for the years ended December 31, 2023 and 2022, respectively. Internal expenses, composed of staff salaries compose approximately $1.2 million and $1.5 million for the years ended December 31, 2023 and 2022, respectively. These costs were offset by the amortization of the R&D obligation of $701,332 and $774,025 for the years ending December 31, 2023 and 2022, respectively; of which, $175,427 and $193,160, for the years ended December 31, 2023 and 2022, respectively were attributable to related parties (see "*Note 8 - Deferred R&D Obligations - Participation Agreements*").

Income Taxes

The Company follows the authoritative guidance for accounting for income taxes. Deferred income taxes are determined using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The tax effects of temporary differences that gave rise to the deferred tax assets and deferred tax liabilities at December 31, 2023 and 2022 were primarily attributable to net operating loss carry forwards. Since the Company has a history of losses, and it is more likely than not that some portion or all of the deferred tax assets will not be realized, a full valuation allowance has been established. In addition, utilization of net operating loss carry-forwards is subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code. The annual limitation may result in the expiration of net operating loss carry-forwards before utilization.

Stock Based Compensation

The Company accounts for stock-based compensation in accordance with FASB ASC 718, *Compensation - Stock Compensation.* Under the provisions of FASB ASC 718, stock-based compensation cost is estimated at the grant date based on the award's fair value and is recognized as expense over the requisite service period. The Company, from time to time, issues common stock or grants common stock options to its employees, consultants and board members. At the date of grant, the Company determines the fair value of the stock option award and recognizes compensation expense over the requisite service period. Issuances of common stock are valued at the closing market price on the date of issuance and the fair value of any stock option or warrant awards is calculated using the Black Scholes option pricing model and employing the simplified term method as the Company does not have a historical basis to determine the term. The Company records forfeiture of options when they occur.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions, including the expected stock price volatility. In considering the expected term of the options, the Company employs the simplified method. The Company uses this method as it does not have a history of option exercises to establish a robust estimated term based on experience. The simplified term is used for the determination of expected volatility as well as the identification of the risk free rate.

Income (Loss) Per Share

Basic loss per share is computed by dividing the Company's net loss by the weighted average number of shares of common stock outstanding during the period presented. Diluted loss per share is based on the treasury stock method and includes the effect from potential issuance of common stock such as shares issuable pursuant to the exercise of options and warrants and conversions of debentures. Potentially dilutive securities as of December 31, 2023, consisted of 8,746 shares of common stock from convertible debentures and related accrued interest and 1,459,881 shares of common stock underlying outstanding options and warrants. Potentially dilutive securities as of December 31, 2022, consisted of 8,924 shares of common stock from convertible debentures and related accrued interest and 1,044,600 shares of common stock underlying outstanding options and warrants. For 2023 and 2022, diluted and basic weighted average shares were the same, as potentially dilutive shares are anti-dilutive.

Segment Reporting

The company reports all financial results as one segment. The Company's Chief Executive Officer, who is considered to be the chief operating decision maker (CODM), reviews financial information presented on a consolidated basis, accompanied by information about operations for purposes of making operating decisions and assessing financial performance. The Company operates solely in the United States.

Warrants

The Company accounts for warrants issued on June 2, 2021 in connection with a public offering of commons stock and common stock warrants, and traded on the OTC Pink under the symbol ZIVOW, ("Public Warrants") and Private Placement Warrants issued in July 2023, see *Note 9 – STOCKHOLDERS' EQUITY (DEFICIT)*, (collectively "Warrants") as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the Warrants and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815-40, Contracts in Entity's Own Equity ("ASC 815-40"). The assessment considers whether the Warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815-40, including whether the Warrants are indexed to the Company's own stock and whether the events where holders of the warrants could potentially require net cash settlement are within the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. The fair value of Warrants is estimated using Black Scholes modeling. Inputs under the model include the Company's Common Share price, the risk-free interest rate, the expected term, the volatility, and the dividend rate. Warrants that are determined to require liability classifications are measured at fair value upon issuance and are subsequently remeasured to their then fair value at each subsequent reporting period with changes in fair value recorded in current earnings. Warrants that are determined to require equity classifications measured at fair value upon issuance and are not subsequently remeasured unless they are required to be reclassified.

Fair Value of Financial Instruments

We account for fair value measurements of assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring or nonrecurring basis adhering to the Financial Accounting Standards Board ("FASB") fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the Company at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

As of December 31, 2023 and 2022, fair values of cash, prepaid expenses, accounts receivable,, other assets, accounts payable, accrued expenses, and other liabilities approximated their carrying values because of the short-term nature of these assets or liabilities. As of December 31, 2023 and 2022 the fair value of the convertible notes approximated their carrying value. We elected to account for the convertible notes while they were outstanding on a fair value basis under ASC 825 to comprehensively value and streamline the accounting for the embedded conversion options. The fair value of these convertible notes were based on both the fair value of our common stock, discount associated with the embedded redemption features, and cash flow models discounted at current implied market rates evidenced in recent arms-length transactions representing expected returns by market participants for similar instruments and are based on Level 3 inputs.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents. The Company has historically maintained cash balances at financial institutions which exceed the current FDIC limit of $250,000 at times during the year.

The Company has not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such account.

Recently Adopted Accounting Standards

In June 2016, the FASB issued Accounting Standard Update ("ASU") 2016-13, *Measurement of Credit Losses on Financial Instruments (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The standard is effective for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company adopted this ASU beginning January 1, 2023. The Company has determined there is no impact of this standard on its financial statements.

In August 2020, the FASB 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") to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. The Company adopted ASU 2020-06 effective January 1, 2023, using the modified retrospective approach. The adoption of AASU 2020-06 did not have an impact on any amounts recorded the Company's consolidated financial statements. In addition, the adoption requires the use of the if-converted method for all convertible notes in the diluted net income (loss) per share calculation and the inclusion of the effect of potential share settlement of the convertible notes, if the effect is more dilutive. There was no impact to diluted earnings per share for the year ended December 31, 2023, as the convertible debentures were not in the money during the period.

NOTE 4 - LEASES

On December 17, 2020, the Company entered into a 25 ½ month lease agreement for a facility that contains office, warehouse, lab and R&D space in Ft. Myer, Florida. The lease agreement commenced on December 17, 2020 and ends on January 31, 2023. The lease agreement provided for a total rent of $54,993 over the period. Occupancy of the property commenced on December 17, 2020, and there was a 6-week rent holiday and a commencement date of February 1, 2021. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Rent is $3,291 per month from January 15, 2021 to January 31, 2022 and $1,154 from February 1, 2022 to January 31, 2023. On June 5, 2022, the Company exercised an option to extend the lease through December 31, 2024. The lease extension rent is $2,261 per month for calendar year 2023, and $2,300 per month for calendar year 2024, and totals an additional rent obligation of $54,743 of rent over the extension period.

On January 14, 2022, the Company entered into a 34-month sublease agreement for a 4,843 square-foot office in Bloomfield Hills, Michigan. The Company moved its headquarters to this location. The agreement commenced on January 29, 2022 and ends on November 30, 2024. The agreement provided for a total rent of $232,464. Occupancy of the property commenced on January 29, 2022, there was a three-month rent holiday with a rent commencement date of April 29, 2022. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Rent is $7,265 per month from commencement to November 30, 2022, $7,466 from November 30, 2022 to November 30, 2023, and $7,668 from November 30, 2023 to the lease end date.

The balances for our operating lease where we are the lessee are presented as follows within our consolidated balance sheet:

Operating leases:

Assets:	**December 31, 2023**	**December 31, 2022**
Operating lease right-of-use asset	$ 98,280	$ 189,282
Liabilities:		
Current portion of long-term operating lease	$ 106,342	$ 99,259
Long-term operating lease, net of current portion	-	105,919
	$ 106,342	$ 205,178

The components of lease expense are as follows within our consolidated statement of operations:

	For the Year ended	
	December 31, 2023	December 31, 2022
Operating lease expense	$ 108,942	$ 102,249

Other information related to leases where we are the lessee is as follows:

	For the Year ended	
	December 31, 2023	December 31, 2022
Weighted-average remaining lease term:		
Operating leases	0.94 Years	1.94 Years
Discount rate:		
Operating leases	11.00%	11.00%

Supplemental cash flow information related to leases where we are the lessee is as follows:

	For the Year ended	
	December 31, 2023	December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:	$ 116,209	$ 74,307
Non-cash investment in ROU asset	-	241,694

As of December 31, 2023, the maturities of our operating lease liability are as follows:

Year Ended:	Operating Lease
December 31, 2024	112,407
Total minimum lease payments	$ 112,407
Less: Interest	(9,471)
Present value of lease obligations	$ 102,936
Less: Current portion	102,936
Long-term portion of lease obligations	$ -

NOTE 5 - LOAN PAYABLE, RELATED PARTIES

Payne Bridge Loan

On April 3, 2023, the Company entered into a Subscription Agreement (the "Subscription Agreement") with the Company's Chief Executive Officer (the "Subscriber"), pursuant to which the Company, in a private placement (the "Private Placement"), agreed to issue and sell to the Subscriber a 10% promissory note with a principal amount of $1 million (the "Payne Note") and a warrant (the "Payne Warrant") to purchase 65,000 shares of the Company's common stock, par value $0.001 per share ("Common Stock"). The Company had the ability to prepay all or a portion of the outstanding Payne Note principal and accrued and unpaid interest without any prepayment fee.

Each warrant is exercisable for a period of three years from issuance at a per-share exercise price equal to $17.46. The exercise price and number of the shares of our Common Stock issuable upon exercising the Payne Warrant will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization, or similar transaction, as described therein.

The allocation of fair value between the Payne Note and the Payne Warrant was recorded at the issuance date using a relative fair value allocation method. The Company determined the fair value of the Payne Warrants as of April 3, 2023 using the Black-Scholes option pricing model and applying the following assumptions as of April 3, 20233 not adjusted for the subsequent 1-6 Stock Split in October 2023:

Fair value of common stock	$ 3.11
Expected term (in years)	3
Risk-free interest rate	3.73%
Dividend yield	-
Volatility	99.89%

As a result, $439,594 or the proceeds were allocated to the Payne Warrant and the debt discount. The Payne Warrant, which qualified for the derivatives scope exception, met equity classification, and were recognized as a component of permanent stockholders' equity within additional paid-in-capital and as a debt discount on the consolidated balance sheet.

The Payne Note matured on October 2, 2023, and bore interest at an annual rate of 10.0%. The debt discount was amortized using the effective interest rate method over the term of the Payne Note. The effective interest rate on the Payne Note, including the amortization of the discount was 49.0% as of October 2, 2023. In the year ended December 31, 2023, the Company recorded $489,594 of interest expense related to the Note, which included $439,594 of non-cash amortization of the loan discount. The Payne Note was satisfied in full on October 2, 2023.

HEP Investments, LLC

On November 16, 2023, the Company entered into a Subscription Agreement (the "Subscription Agreement") with the HEP Investments, LLC a greater than 10% shareholder of the Company (the "November Subscriber"), pursuant to which the Company, in a private placement (the "Private Placement"), agreed to issue and sell to the November Subscriber a 10% promissory note with a principal amount of $150,000 (the "November Note"). The Company had the ability to prepay all or a portion of the outstanding November Note principal and accrued and unpaid interest without any prepayment fee.

On December 5, 2023 the Company repaid the principal in full and $784 of accrued interest to satisfy the November Note in full.

As of December 31, 2023, there were no Loans Payable to related parties.

NOTE 6 - CONVERTIBLE DEBT

The Company has $240,000 of outstanding convertible debentures. The debentures carry 1% per annum interest rate which is accrued until maturity. The original maturity dates have passed and the lender allows for rolling 30-day extensions until notice is given by the lender to the Company to the contrary. As of December 31, 2023, that agreement is still in place.

NOTE 7 - NOTE PAYABLE

Short Term Loans

On February 14, 2023, the Company entered into a short-term, unsecured loan agreement to finance a portion of the Company's directors' and officers', and employment practices liability insurance premiums. The note in the amount of $605,600 carries an 8.4% annual percentage rate and will be paid down equal monthly payments of $69,666, which payment began March 10, 2023. The loan was fully paid off, and there was no remaining principal balance as of December 31, 2023.

On February 21, 2022, the Company entered into a short-term, unsecured loan agreement to finance a portion of the Company's directors' and officers' insurance premiums. The note in the amount of $628,600 carried a 4.15% annual percentage rate and was paid down in nine equal payments of $71,058 beginning in March 2022. The loan was fully paid off, and there was no remaining principal balance as of December 31, 2022.

NOTE 8 - DEFERRED R&D OBLIGATIONS - PARTICIPATION AGREEMENTS

The Company entered into twenty-one (21) License Co-Development Participation Agreements (the "Participation Agreements") with certain investors ("Participants") for aggregate proceeds of $2,985,000. The Participation Agreements provide for the issuance of warrants to such Participants and allows the Participants to participate in the fees (the "Fees") from licensing or selling bioactive ingredients or molecules derived from ZIVO's algae cultures. Specifically, ZIVO has agreed to provide to the Participants a 44.78% "Revenue Share" of all license fees generated by ZIVO from any licensee (See the Table below).

According to the terms of the Agreements, and pursuant to ASC 730-20-25 the Company has bifurcated the proceeds of $2,985,000 as follows: 1) the 17,712 warrants sold were attributed a value of $953,897 based on the Black Scholes pricing model using the following assumptions: volatilities ranging from 129.13% to 154.26%; annual rate of dividends 0%; discount rates ranging from 0.26% to 0.87%, and recorded as Additional Paid In Capital; 2) the remaining $2,031,103 was recorded as Deferred R&D Obligation - Participation Agreements. Since the Company believes there is an obligation to perform pursuant to ASC 730-20-25, the Deferred R&D Obligation will be amortized ratably based on expenses incurred as the Company develops the technology for bioactive ingredients or molecules (including its TLR4 Inhibitor molecule) derived from the Company's algae cultures. In the year ending December 31, 2023, the Company recognized $701,332 as a contra R&D expense related to personnel and third-party expenses to develop the subject technology. $175,427 of this total contra R&D expense was attributed to deferred R&D obligations funded by a related party. As of December 31, 2023, the R&D obligation has been fully amortized, and no balance remains. In the prior year ending December 31, 2022, the Company recognized $774,025 as a contra R&D expense related to personnel and third-party expenses to develop the subject technology. $193,610 of this total contra R&D expense was attributed to deferred R&D obligations funded by a related party. As of December 31, 2022, the remaining R&D obligation was $701,332, of which $175,427 was attributed to a related party.

The Participation Agreements allow the Company the option to buy back the right, title and interest in the Revenue Share for an amount equal to the amount funded plus a forty percent (40%) premium, if the option is exercised less than 18 months following execution, and for either forty (40%) or fifty percent (50%) if the option is exercised more than 18 months following execution. Pursuant to the terms of twelve of the Participation Agreements, the Company may not exercise its option until it has paid the Participants a revenue share equal to a minimum of thirty percent (30%) of the amount such Participant's total payment amount. Pursuant to the terms of one of the Participation Agreements, the Company may not exercise its option until it has paid the Participant a revenue share equal to a minimum of one hundred forty percent (140%) of such Participant's total payment amount. Five of the Participation Agreements have no minimum threshold payment. Once this minimum threshold is met, the Company may exercise its option by delivering written notice to a Participant of its intent to exercise the option, along with repayment terms of the amount funded, which may be paid, in the Company's sole discretion, in one lump sum or in four (4) equal quarterly payments. If the Company does not make such quarterly payments timely for any quarter, then the Company shall pay the prorated Revenue Share amount, retroactive on the entire remaining balance owed, that would have been earned during such quarter until the default payments have been made and the payment schedule is no longer in default. See below a summary of the Participation Agreements:

Agreement #	Date of Funding	Amount Funded	Warrants	Term	Exercise Price	Revenue Share	Minimum Payment Threshold	Buy-back Premium % pre-18 mos.	Buy-back Premium % post 18 mos.
1	April 13, 2020	$ 100,000	625	5 Years	$ 57.60	1.500%	$ -	40%	40%
2	April 13, 2020	150,000	937	5 Years	57.60	2.250%	-	40%	40%
3	April 13, 2020	150,000	937	5 Years	57.60	2.250%	-	40%	40%
4	May 7, 2020	250,000	1,562	5 Years	57.60	3.750%	-	40%	40%
5	June 1, 2020	275,000	1,718	5 Years	52.80	4.125%	82,500	40%	50%
6	June 3, 2020	225,000	1,406	5 Years	52.80	3.375%	67,500	40%	50%
7	July 8, 2020	100,000	625	5 Years	57.60	1.500%	30,000	40%	50%
8	Aug. 24, 2020	125,000	781	5 Years	57.60	1.875%	37,500	40%	50%
9	Sept. 14, 2020	150,000	937	5 Years	57.60	2.250%	45,000	40%	50%
10	Sept.15, 2020	50,000	312	5 Years	57.60	0.750%	15,000	40%	50%
11	Sept.15, 2020	50,000	312	5 Years	57.60	0.750%	15,000	40%	50%
12	Sept.25, 2020	300,000	937	5 Years	57.60	4.500%	420,000	40%	50%
13	Oct. 8, 2020	500,000	3,125	5 Years	57.60	7.500%	150,000	40%	40%
14	Oct. 4, 2020	100,000	625	5 Years	57.60	1.500%	40,000	40%	50%
15	Oct. 4, 2020	250,000	1,562	5 Years	57.60	3.750%	-	40%	40%
16	Oct. 9, 2020	50,000	312	5 Years	57.60	0.750%	15,000	40%	40%
17	Dec. 16, 2020	10,000	62	5 Years	57.60	0.150%	17,000	40%	50%
18	Jan. 22, 2021	40,000	250	5 Years	67.20	0.600%	12,000	40%	50%
19	Jan. 25, 2021	40,000	250	5 Years	67.20	0.600%	12,000	40%	50%
20	Jan. 27, 2021	25,000	156	5 Years	67.20	0.375%	12,000	40%	50%
21	May 14,2021	45,000	281	5 Years	62.40	0.675%	13,500	40%	50%
		$ 2,985,000	17,712			44.775%	$ 984,000		

Certain of the Participation Agreements are owned by related parties. Participation Agreement numbers 8, 14, and 19 totaling $265,000 are owned by HEP Investments, Participation Agreement 21 in the amount of $45,000 is owned by MKY MTS LLC an entity controlled by the owners of HEP Investments, and Participation Agreement 13 in the amount of $500,000 is owned by an investment company owned by a significant shareholder Mark Strome ("Strome").

NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT)

June 2023 Registered Direct Offering and 2023 Private Placement Warrants

On July 5, 2023, the Company, closed on a Securities Purchase Agreement dated June 30, 2023 (the "Purchase Agreement") with a single institutional investor (the "Investor"), pursuant to which the Investor agreed to purchase from the Company, in a registered direct offering (the "Registered Offering"), (i) an aggregate of 171,666 shares of the Company's Class A Common Stock, par value $0.001 per share at a price of $16.02 per share, (ii) an aggregate of 78,021 pre-funded warrants to purchase 78,021 shares of Common Stock, at an offering price of $16.0194 per pre-funded warrant at an exercise price of $0.0006 per share, with a term of exercise of five years (collectively, the "Registered Offering Securities"). The gross proceeds to the Company from the Registered Offering and concurrent private placement described below were approximately $4,000,000 (before deducting the placement agent's fees and other offering expenses paid by the Company approximately $365,000).

As additional consideration for the purchase of the Private Placement Securities, we agreed to issue to the Investors Series A Warrants to purchase 249,688 shares of common stock at an exercise price of $16.80 per share, and Series B Warrants to purchase 249,688 shares of common stock at an exercise price of $16.80 per share (collectively, the "Private Placement Warrants"). The exercise price of the Private Placement Warrants is $16.80 per share, however, is subject to adjustment 100% of the highest VWAP during the period beginning on the trading day immediately preceding a public announcement of an applicable fundamental transaction and ending within 30 trading days following the fundamental transaction. In such event, the Investor shall have the right to receive, for each Private Placement Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, at the option of the Investor, the number of Shares of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of Shares for which this Private Placement Warrant is exercisable. Further, if the Company is given any choice as to the securities, cash or property to be received in a fundamental transaction, then the Investor shall be given the same choice as to the alternate consideration it receives upon any exercise of these Private Placement Warrants following such fundamental transaction.

All the pre-funded warrants associated with the Registered Offering and the Series A and Series B warrants have been classified and accounted for under the equity method. The net proceeds of the offering, including the fair value assigned to the Private Placement Warrants were recorded as a component of stockholders' equity within additional paid-in-capital.

Recapitalization - Reverse Stock Split

On October 26, 2023, the Company filed a certificate of amendment to its articles of incorporation with the Secretary of State of the State, of Nevada (the "Certificate of Amendment"), to (i) effectuate a reverse stock split (the "Reverse Stock Split") of its issued and outstanding shares of common stock and treasury shares on a 1-for-6 basis and (ii) decrease the number of total authorized shares of common stock of the Company from 150,000,000 to 25,000,000 shares.

As of the Effective Time, every 6 shares of issued and outstanding common stock were converted into one share of common stock. No fractional shares were issued in connection with the Reverse Stock Split. Instead, a holder of record of old common stock as of immediately prior to the Effective Time who would otherwise have been entitled to a fraction of a share was entitled to receive cash in lieu thereof.

The Company's transfer agent, Issuer Direct Corporation, acted as the exchange agent for the Reverse Stock Split. The Reverse Stock Split did not alter the par value of the Company's common stock or modify any voting rights or other terms of the common Stock. In addition, pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under all of the Company's outstanding stock options and warrants to purchase shares of common Stock, and the number of shares authorized and reserved for issuance pursuant to the Company's equity incentive plan will be reduced proportionately.

All issued and outstanding common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of common stock. A proportionate adjustment was also made to the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans to reflect the Reverse Stock Split.

Board of Directors Fees

On July 28, 2022, our Board of Directors awarded options pursuant to the Non-Employee Director Compensation Policy. The Board granted to each of the three non-employee directors $50,000 in value of common stock options. The Company used the Black Scholes option pricing model to determine the number of shares that would derive a value of $50,000 for each non-employee director. The Black Scholes pricing model used the following assumptions: term of 5.31 years; volatility 120.99%; annual rate of dividends 0%; discount rate 2.69%. The model yielded an award grant of 7,896 total options, 2,632 for each of the three non-employee directors.

On December 16, 2022, our Board of Directors awarded options to each of the three non-employee directors of $10,000 in value of common stock options. The Company used the Black Scholes option pricing model to determine the number of shares that would derive a value of $10,000 for each non-employee director. The Black Scholes pricing model used the following assumptions: term of 5 years; volatility 116.42%; annual rate of dividends 0%; discount rate 3.61%. The model yielded an award grant of 2,121 total options, 707 for each of the three non-employee directors. The options vested immediately upon issuance.

On December 19, 2022, our Board of Directors appointed Ms. Alison Cornell as lead independent director. In recognition of that appointment the Board of Directors awarded to Ms. Cornell $300,000 in value of common stock options. The Company used the Black Scholes option pricing model to determine the number of shares that would derive a value of $300,000 for the lead independent director. The Black Scholes pricing model used the following assumptions: term of 5 years; volatility 116.47%; annual rate of dividends 0%; discount rate 3.70%. The model yielded an award grant of 23,240 total options. The options vested immediately upon issuance.

On June 12, 2023, our Board of Directors awarded options pursuant to the Non-Employee Director Compensation Policy. The Board granted to each of the three non-employee directors $50,000 in value of common stock options. The Company used the Black Scholes option pricing model to determine the number of shares that would derive a value of $50,000 for each non-employee director. The Black Scholes pricing model used the following assumptions: term of 5.31 years; volatility 112.25%; annual rate of dividends 0%; discount rate 3.88%. The model yielded an award grant of 10,878 total options, 3,626 for each of the three non-employee directors.

The Company recorded directors' fees of $337,682 and $1,155,722 for the years ended December 31, 2023 and 2022, respectively, representing the cash fees paid or accrued and the expense associated with the common stock options described above. As of December 31, 2023 the Company had unpaid directors' fees accrued in the amount of $172,670. There were no unpaid directors' fees as of December 31, 2022.

Stock Issuances

During the month of December 2023, the Company issued 563,016 shares of common stock for proceeds of $640,000 to various investors in private placements. Included in those amounts were issuances of 437,692 shares of common stock for proceeds of $485,000 to two related parties.

Stock Based Compensation

During 2023, options were granted to the directors of the Company, and during 2022 options were granted to the employees and directors of the Company. As a result of these and continued vesting of prior grants, the Company recorded expenses of approximately $870,000 during the year ended December 31, 2023, of which approximately $230,000 of this expense was for R&D and $640,000 was attributed to G&A. During the year ending December 31, 2022 the Company recorded expenses of approximately $2.7 million, of which approximately $500,000 of this expense was for R&D and $2.2 million was attributed to G&A.

The fair value of options was estimated on the date of grant using the Black-Scholes option-pricing model based on the following weighted average assumptions:

Year Ended December 31,

	2023	2022
Expected volatility	112.28%	116.42% to 130.18%
Expected dividends	0%	0%
Expected term	5.31 years	5 to 5.75 years
Risk free rate	3.88%	1.88 to 3.70%

On February 22, 2022, the Board of directors granted options under its 2021 equity incentive plan (the "2021 Plan") to purchase 28,747 shares of common stock to certain employees of the Company. The options have a term of ten years and vest over three years. The options were valued at $493,536 using the Black Scholes pricing model relying on the following assumptions: simplified term of 5.75 years; volatility 130.18%; annual rate of dividends 0%; discount rate 1.88%.

On August 29, 2022, the Board of directors granted options under its 2021 equity incentive plan (the "2021 Plan") to purchase 28,831 shares of common stock to certain employees of the Company. The options have a term of ten years and vest over three years. The options were valued at $590,896 using the Black Scholes pricing model relying on the following assumptions: simplified term of 5.75 years; volatility 121.19%; annual rate of dividends 0%; discount rate 3.25%.

On December 16, 2022, the Board of directors granted options under its 2021 equity incentive plan (the "2021 Plan") to purchase 31,836 shares of common stock to the Chief Executive Officer of the Company. The options have a term of ten years and vested immediately upon issuance. The options were valued at $450,000 using the Black Scholes pricing model relying on the following assumptions: simplified term of 5.0 years; volatility 116.41%; annual rate of dividends 0%; discount rate 3.6%.

Stock Warrants Exercised

During the twelve months ended December 31, 2023, the Prefunded Warrants in connection with the Securities Purchase Agreement dated June 30, 2023 were exercised on a cash basis. The Company received $47 in exchange for the issuance of 78,021 shares of common stock. See *NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) - June 2023 Registered Direct Offering and 2023 Private Placement Warrants.*

2021 Equity Incentive Plan

On October 12, 2021, after approval from the stockholders at the Company's 2021 annual meeting of stockholders, the Company adopted the 2021 Plan for the purpose of enhancing the Company's ability to attract and retain highly qualified directors, officers, key employees and other persons and to motivate such persons to improve the business results and earnings of the Company by providing an opportunity to acquire or increase a direct proprietary interest in the operations and future success of the Company. The 2021 Plan is administered by the compensation committee of the Board who will, amongst other duties, have full power and authority to take all actions and to make all determinations required or provided for under the 2021 Plan. Pursuant to the 2021 Plan, the Company may grant options, share appreciation rights, restricted shares, restricted share units, unrestricted shares and dividend equivalent rights. The 2021 Plan has a duration of 10 years.

Subject to adjustment as described in the 2021 Plan, the aggregate number of shares of common stock available for issuance under the 2021 Plan is initially set at 166,666 shares; this number is automatically increased each January 1st by an amount equal to 5% of the number of common stock shares outstanding at that date. As of December 31, 2023, 232,101 options have been issued under the 2021 Plan, and 91,559 shares remained available for issuance.

2019 Omnibus Long-Term Incentive Plan

Prior to the adoption of the 2021 Equity Incentive Plan, the Company maintained a 2019 Omnibus Long-Term Incentive Plan (the "2019 Plan"). Following the approval by the shareholders of the 2021 Equity Incentive Plan, no additional awards have been or will be made under the 2019 Plan. As of December 31, 2023, 130,203 stock options had been issued under the 2019 Plan with terms between 5 years and 10 years, of which 60,414 remained outstanding.

Common Stock Options

A summary of the status of the Company's options issued under the Company's equity incentive plans is presented below. As of December 31, 2023 there is no intrinsic value in any of the Company's outstanding options as the market price of the Company's common stock is in all cases lower than the exercise price of options.

	December 31, 2023		December 31, 2022	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, beginning of year	281,637	$ 36.29	286,838	$ 44.28
Forfeited	-	-	(127,872)	40.88
Issued	10,878	16.74	122,671	22.40
Outstanding, end of period	292,515	$ 35.56	281,637	$ 36.29

Options outstanding and exercisable by price range as of December 31, 2023 were as follows:

Outstanding Options			Exercisable Options		
Range of Exercise Price	Number	Average Weighted Remaining Contractual Life in Years	Range of Exercise Price	Number	Weighted Average Exercise Price
$ 12.00-17.99	68,075	9.05	$ 12.00-17.99	68,075	$ 16.58
18.00-23.99	36,727	8.65	18.00-23.99	22,312	22.94
24.00-29.99	8,885	7.78	24.00-29.99	8,885	$ 26.88
30.00-35.99	118,414	7.89	30.00-35.99	92,875	33.00
48.00-53.99	1,041	1.54	48.00-53.99	1,041	52.80
54.00-59.99	4,166	1.63	54.00-59.99	4,166	57.60
66.00-71.99	27,083	6.80	66.00-71.99	19,271	67.20
72.00-77.99	28,124	1.14	72.00-77.99	28,124	76.80
	292,515	7.39		244,749	$ 35.52

Common Stock Warrants - Private

A summary of the status of the Company's private warrants is presented below.

	December 31, 2023		December 31, 2022	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Outstanding, beginning of year	267,013	$ 47.10	425,606	$ 45.42
Issued	642,397	14.83	-	-
Exercised	(78,021)	0.00	-	-
Cancelled	-	-	-	-
Expired	(159,941)	47.53	(158,593)	42.60
Outstanding, end of period	671,448	$ 21.59	267,013	$ 47.10

Unregistered warrants outstanding and exercisable by price range as of December 31, 2023 were as follows:

Outstanding Warrants			Exercisable Warrants		
Range of	Number	Average Weighted Remaining Contractual Life in Years	Exercise Price	Number	Weighted Average Exercise Price
$ 12.00-17.99	564,376	2.93	$ 12.00-17.99	564,376	16.88
30.00.35.99	36,800	2.42	30.00.35.99	36,800	33.00
36.00-41.99	5,309	0.74	36.00-41.99	5,309	38.40
48.00-53.99	24,650	0.67	48.00-53.99	24,650	48.61
54.00-55.99	38,543	1.70	54.00-55.99	38,543	57.60
60.00-65.99	281	2.37	60.00-65.99	281	62.40
66.00-71.99	656	2.07	66.00-71.99	656	67.20
84.00-89.99	833	0.99	84.00-89.99	833	86.40
	671,448	2.72		671,448	$ 21.59

Common Stock Warrants - Public

A summary of the status of the Company's public warrants is presented below:

	December 31, 2023		December 31, 2022	
	Number of Registered Warrants	Weighted Average Exercise Price	Number of Registered Warrants	Weighted Average Exercise Price
Outstanding, beginning of year	495,917	$ 33.00	495,917	$ 33.00
Issued	-	-	-	-
Exercised	-	-	-	-
Cancelled	-	-	-	-
Expired	-	-	-	-
Outstanding, end of period	495,917	$ 33.00	495,917	$ 33.00

Registered warrants outstanding and exercisable by price range as of December 31, 2023, were as follows:

Outstanding Registered Warrants			Exercisable Registered Warrants		
Exercise Price	Number	Average Weighted Remaining Contractual Life in Years	Exercise Price	Number	Weighted Average Exercise Price
$ 33.00	495,917	2.4	$ 33.00	495,917	33.00

NOTE 10 - COMMITMENTS AND CONTINGENCIES

Alimenta Supply Agreement

In July 2023, the Company through it ZIVOLife LLC subsidiary and Alimenta Algae SAC, a Peruvian company, signed a binding Contract Manufacturing Term Sheet (the "Term Sheet"). This binding Term Sheet commits ZIVOLife to purchase all of the Zivolife™ product produced by Alimenta at the site subject to certain capacity growth plans and overall capacity limitations. The purchase commitment will end on August 31, 2028. During the year ended December 31, 2023, the Company purchased $16,040 of product subject to this agreement. There were no purchases under this agreement in the year ended December 31, 2022.

Legal Contingencies

On April 13, 2022, AEGLE Partners, 2 LLC ("AEGLE") initiated an arbitration in Michigan against the Company with the American Arbitration Association. AEGLE asserted claims related to a certain Supply Chain Consulting Agreement entered into between AEGLE and the Company in 2019 (as amended from time to time, the "Supply Chain Consulting Agreement"), and a disagreement between AEGLE and the Company regarding whether AEGLE was entitled to payment of certain fees and warrants pursuant to the Supply Chain Consulting Agreement. AEGLE's complaint sought, among other things, three times the payment of such alleged fees and warrants and recovery of AEGLE's costs and expenses. On April 20, 2023, the Company and AEGLE settled the pending arbitration matter for $13,000.

We may become a party to litigation in the normal course of business. In the opinion of management, there are no legal matters involving us that would have a material adverse effect upon our financial condition, results of operation or cash flows.

NOTE 11 - RELATED PARTY TRANSACTIONS

Loan Payable - Related Party

See "*Note 5 - Loan Payable, Related Parties*" for disclosure of loans payable to related parties.

Employment Agreement

The company presently has in place employment agreements with the Chief Executive Officer and the Chief Financial Officer.

Building Lease

In January 2022 the Company terminated its agreement for the rental of its office space from M&M Keego Center LLC, an entity controlled by an immediate family member of a principal shareholder.

Stock Issuances

During the month of December 2023, the Company issued 437,692 shares of common stock for proceeds of $485,000 to two related parties.

NOTE 12 - INCOME TAXES

The following table presents the components of net loss before income taxes:

	Years Ended December 31,	
	2023	**2022**
Domestic	$ (7,777,184)	$ (8,745,293)
(Loss) before provision for income taxes	(7,777,184)	(8,745,293)

There was no income tax for the years ended December 31, 2023 and December 31, 2022. The Company's tax expense differs from the "statutory" tax expense for the years ended December 31, 2023, and 2022 as noted below:

	For the Years Ended December 31,			
	2023		**2022**	
Income tax (benefit) / Expense at federal statutory rate	$(1,633,209)	21.0%	$(1,836,512)	21.0%
Apportioned state income taxes	(95,082)	1.2%	(131,407)	1.5%
Stock based compensation	89,502	(1.2)%	297,653	(3.3)%
Rate change	46,848	(0.6)%	(31,180)	0.3%
Return to provision adjustments	5,968	(0.1)%	(1,515)	0.0%
Other non-deductible items	1,195	0.0%	-	0.0%
Change in valuation allowance	1,584,778	(20.3)%	1,702,961	(19.5)%
Total income tax provision	$ -	0.0%	$ -	0.0%

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards. The tax effects of significant items comprising the Company's deferred taxes were as follows:

	For the Years Ended December 31,	
	2023	**2022**
Deferred tax assets/(liabilities)		
Federal net operating loss carryforwards	$ 8,703,105	$ 7,606,833
State net operating loss carryforwards	130,413	74,353
Stock based compensation	2,665,017	2,738,159
Section 174 research and experimental expenditures	623,902	374,926
Accrued compensation	254,637	-
Operating leases	1,973	-
Total deferred tax assets	12,379,047	10,794,271
Other deferred tax liabilities	(178)	(180)
Total deferred tax assets (liabilities)	$ 12,378,869	$ 10,794,091
Valuation allowance	(12,378,869)	(10,794,091)
Total deferred income taxes	$ -	$ -

ASC 740 *Income Taxes* requires that the tax benefit of net operating losses ("NOLs"), temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Management believes that realization of the deferred tax assets arising from the above-mentioned future tax benefits from operating loss carryforwards is currently not more likely than not and, accordingly, has provided a valuation allowance. The valuation allowance increased by $1.6 million for the year ended December 31, 2023 and increased by $1.7 million for the year ended December 31, 2022.

As of December 31, 2023 and 2022 the Company's deferred tax asset contains the tax effect of approximately $41.4 million and $36.2 million of Federal NOLs, respectively. The Federal NOLs generated prior to December 31, 2017 were written off of the deferred tax asset, while NOLs generated subsequent to this date remain. Under the Tax Cuts and Jobs Act, all Federal NOLs incurred after December 31, 2017 are carried forward indefinitely for Federal tax purposes.

	Net Operating Losses recorded as Federal deferred tax asset	**Net Operating Losses recorded as State deferred tax asset**
Total expiring operating losses (incurred prior to December 31, 2017)	-	-
Non-expiring operating losses (incurred after December 31, 2017)	41,443,359	2,371,136
Total Operating Loss	$41,443,359	$ 2,371,136

In the ordinary course of its business the Company incurs costs that, for tax purposes, may be qualified research expenditures within the meaning of IRC Code Sec. 41 and are, therefore, may be eligible for the Increasing Research Activities credit under IRC Code Sec. 41. The Company has not claimed a credit pursuant to IRC Code Sec. 41 on its federal returns, i.e. no deferred tax asset is recorded on the books.

As of December 31, 2023, the Company has no uncertain tax positions. It is the Company's policy to account for interest and penalties related to uncertain tax positions as interest expense and general and administrative expense, respectively in its statements of operations. No interest or penalties have been recorded related to the uncertain tax positions.

It is not expected that there will be a significant change in uncertain tax positions in the next 12 months. The Company is subject to U.S. federal and state income tax as well as to income tax in multiple state jurisdictions. In the normal course of business, the Company is subject to examination by tax authorities. As of the date of the financial statements, there are no tax examinations in progress. The statute of limitations for tax years ended after December 31, 2019, are open for federal and state tax purposes.

The 2017 Tax Act amended Section 174 of the Internal Revenue Code which affects the Federal tax treatment of research and experimental (R&E) expenditures. Preceding this law change, R&E expenditures were expensed as incurred for Federal Income Tax purposes. In taxable years beginning after December 31, 2021, R&E expenditures must be capitalized and amortized over 5 years for expenditures incurred in the United States, or 15 years for expenditures incurred outside the United States. Due to the nature of the Company's operations, R&E expenditures are a significant portion of total expenditures. The Company calculated an estimated amount for income tax provision purposes based on guidance available to determine the capitalized amount.

NOTE 13 - SUBSEQUENT EVENTS

2021 Plan Evergreen Provision

Under the 2021 Plan, the shares reserved automatically increase on January 1st of each year, for a period of not more than ten years from the date the 2020 Plan is approved by the stockholders of the Company, commencing on January 1, 2022, and ending on (and including) January 1, 2029, by an amount equal to 5% of the shares of common stock outstanding as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board of Directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence. On January 1, 2024, 119,117 shares were added to the 2021 Plan as a result of the evergreen provision.

Short Term Loan

On March 5, 2024, the Company entered into a short-term unsecured loan agreement to finance a portion of the Company's directors' and officers', and employment practices liability insurance premiums. The note in the amount of $517,560 carries an 8.5% annual percentage rate and will be paid down in nine equal monthly payments of $59,563 beginning on March 10, 2024.