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

FORM 10-K

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

For the fiscal year ended March 31, 2021 or

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

For the transition period from _____ to _____

Commission File No. 000-53832

VITALITY BIOPHARMA, INC.

(Exact name of registrant as specified in charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

75-3268988

(IRS Employer
Identification No.)

1901 Avenue of the Stars, 2nd Floor
Los Angeles, California 90067

(Address of principal executive office, including zip code)

(530) 231-7800

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.001 par value

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company (as defined in Rule 12b-2 of the Act). See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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 is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of September 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$5,796,387, based on the closing price of \$0.17 for the registrant's common stock as quoted on the OTC Markets on that date. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the registrant's outstanding common stock are held by affiliates. The treatment of these persons as affiliates for purposes of this calculation is not conclusive as to whether such persons are, in fact, affiliates of the registrant.

As of May 18, 2021, there were 50,840,147 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

TABLE OF CONTENTS

| | Page |
|--|-------------|
| PART I | |
| Item 1. Business | 1 |
| Item 1A. Risk Factors | 5 |
| Item 1B. Unresolved Staff Comments | 18 |
| Item 2. Properties | 18 |
| Item 3. Legal Proceedings | 18 |
| Item 4. Mine Safety Disclosures | 18 |
| PART II | |
| Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 19 |
| Item 6. Selected Financial Data | 20 |
| Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations | 20 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk | 24 |
| Item 8. Financial Statements and Supplementary Data | 24 |
| Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure | 24 |
| Item 9A. Controls and Procedures | 24 |
| Item 9B. Other Information | 24 |
| PART III | |
| Item 10. Directors, Executive Officers and Corporate Governance..... | 25 |
| Item 11. Executive Compensation | 28 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters ... | 30 |
| Item 13. Certain Relationships and Related Transactions, and Director Independence..... | 32 |
| Item 14. Principal Accounting Fees and Services..... | 32 |
| PART IV | |
| Item 15. Exhibits, Financial Statement Schedules | 33 |
| Item 16. Form 10-K Summary..... | 33 |

This Annual Report on Form 10-K includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to expectations concerning matters that are not historical facts, and are generally identified by words such as “believe”, “expect”, “anticipate”, “estimate”, “intend”, “strategy”, “may”, “will likely” and similar words or phrases. A forward-looking statement is neither a prediction nor a guarantee of future events or circumstances, and our actual results could differ materially and adversely from those expressed in any forward-looking statement. The forward-looking statements contained in this Annual Report are all based on currently available market, operating, financial and competitive information and assumptions and are subject to various risks and uncertainties that are difficult to predict, any of which could cause actual results to differ materially from those expressed in such forward-looking statements. These risks and uncertainties may include, without limitation, risks related to general economic and business conditions; our ability to continue as a going concern; our ability to obtain financing necessary to operate our business; our limited operating history; our ability to recruit and retain qualified personnel; our ability to manage any future growth; our ability to research and successfully develop our planned products; our ability to successfully complete potential acquisitions and collaborative arrangements; and other factors including those set forth below under the caption “Risk Factors” in Part I, Item 1A and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, Item 7, and elsewhere in this Annual Report, as well as in the other reports we file with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they were made, and, except as required by law, we undertake no obligation to revise or update any forward-looking statement for any reason.

Unless the context otherwise requires, all references to “we,” “our,” “us,” “Vitality Biopharma,” and the “Company” in this Annual Report refer to Vitality Biopharma, Inc., a Nevada corporation and our consolidated subsidiaries. We do not currently hold any trademarks, and all trademarks used in this Annual Report are the property of their respective owners.

PART I

Item 1. Business

Company Overview

Unless otherwise provided in this Annual Report, references to the “Company,” “we,” “us,” and “our” refer to Vitality Biopharma, Inc., a Nevada corporation formed on June 29, 2007 as Legend Mining Inc., and its consolidated subsidiaries. On October 10, 2011, we completed a merger with our wholly-owned subsidiary, Stevia First Corp., whereby we changed our name from “Legend Mining Inc.” to “Stevia First Corp.” On July 15, 2016, our Board of Directors and shareholders approved a name change to “Vitality Biopharma, Inc.”

Vitality Biopharma is a company focused on the advancement of pharmaceuticals and innovative technologies that improve the lives of patients. We seek to achieve this objective through the development of novel cannabinoid pharmaceutical prodrugs known as cannabosides. We conduct our operations using our own personnel and facilities with the support of third-party resources to advance our drug development programs.

Our cannabosides are cannabinoid-glycoside prodrugs, which were discovered through application of the Company’s proprietary enzymatic bioprocessing technologies, that are converted within the body after administration from an inactive molecule into a pharmacologically active drug. Currently, the Company has produced more than 25 novel cannabosides, including glycosylated tetrahydrocannabinol (THC), cannabidiol (CBD), cannabidivarin (CBDV) and cannabinol (CBN), that are covered by worldwide patent applications for composition of matter, method of production and method of use.

Additionally, the Company is evaluating the expansion of its corporate strategy to create long-term sustainable value for its shareholders by building a more diversified portfolio of assets through organic growth and strategic acquisitions. Specifically, the Company is considering special situation opportunities in a variety of industries, including without limitation, businesses that utilize innovative technologies to address the unfavorable environmental impacts of climate change.

Our corporate headquarters is located in Los Angeles, California. As of May 18, 2021, we employed three full-time employees, including one research professional working in our office and laboratory space in Rocklin, California. We also have, in the past, engaged the services of scientific and regulatory consultants to assist in our research and development activities, which is an approach that provides us with flexible and highly-experienced resources to advance our clinical efforts while maintaining a relatively lower overhead cost structure.

Cannaboside Prodrugs

A prodrug is a compound that, after administration, is metabolized into a pharmacologically active drug. Prodrugs are often designed to improve drug properties and reduce known or expected toxicities and adverse side effects. By using our proprietary enzymatic bioprocessing technologies, our clinical research team has developed a novel family of prodrugs by combining cannabinoid and glucose molecules. The resulting compounds, known as cannabosides, have unique commercial applications and patentable compositions of matter, which are separate and distinct from ordinary cannabinoids. The advantages of cannabosides may include: (i) administration in a convenient oral formulation, (ii) targeted delivery with release in the colon or large intestine, (iii) improved stability with limited degradation or drug metabolism, and (iv) delayed release enabling longer-lasting effects and fewer administrations by patients.

Our proprietary glycosylation process, which results in adding one or more glucose molecules to compounds, may enable our new cannabosides to act as prodrugs that achieve targeted delivery of the bioactive compounds of cannabinoids to the gastrointestinal tract. Glycosylated compounds are generally more stable and water soluble, so upon ingestion, we believe they will remain intact and transit through the esophagus, stomach and upper intestine with limited absorption or degradation from stomach acids. However, once the glycosylated compounds reach the large intestine, we expect them to encounter glycoside hydrolase enzymes secreted by the human intestinal microbiota that will cleave the polar glucose residues and release the active cannabinoid compound primarily in the large intestine or colon.

We have focused our research and development activities on the glycosylation of cannabinoids given their well-known positive effects on the human endocannabinoid system. Our research and development activities originally focused on the glycosylation of CBD and then later expanded into the glycosylation of THC. The use of the cannabinoid THC has been shown to provide substantial anti-inflammatory benefits on the human body, among other benefits, but is limited as a pharmaceutical option given its psychoactive and intoxicating properties. However, by glycosylating THC, we have learned through initial animal studies that the binding of glucose and THC molecules restricts the release of THC into the body’s digestive system until the prodrug reaches the large intestine, at which point the glycoside hydrolase enzymes cleave the glucose from the prodrug and the THC is released in a targeted and restricted manner. Further, we have learned through our initial animal studies that this targeted release of THC, which could be provided in very low doses to achieve physiologically beneficial results, serves as an anti-inflammatory agent in the lower gastrointestinal tract and minimizes the amount of THC absorbed into the blood stream, therefore avoiding the psychoactive and intoxicating properties that hinder the broader pharmaceutical use of THC.

We are developing our THC-glycoside prodrugs for the treatment of gastrointestinal diseases, including inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS) because of the targeted release described previously. IBD is a frequently chronic inflammatory condition where parts of the digestive system become inflamed from an overactive immune response. The disease can lead to irreversible damage to the gastrointestinal tract and may require surgery to remove affected areas of the intestine. Two major forms of the disease are Crohn's disease, which can affect any part of the digestive system, and ulcerative colitis, which often affects the colon or large intestine. The disease is often unpredictable with periods of painful and debilitating symptoms followed by periods of remission with limited symptoms. IBS has similar symptoms to IBD, including abdominal pain, but the underlying disease process is quite different. IBS is a functional gastrointestinal disorder that commonly affects the large intestine and is characterized by abdominal cramping, diarrhea, constipation, and pain. Currently, patients suffering from IBD are frequently prescribed anti-inflammatory drugs such as steroids, biologics and immunosuppressants, and patients suffering from IBS are prescribed antibiotics, antidepressants and gastrointestinal motility compounds, all of which often result in unwanted side effects.

Our most promising THC-glycoside (VBX-100) is being developed as an oral prodrug for the treatment of IBD and IBS. VBX-100 was selected from our THC-glycoside portfolio for compatibility with commercial production techniques and the optimal prodrug delivery profile that maximizes intestinal anti-inflammatory properties while minimizing psychoactive or intoxicating effects. Initial pre-clinical studies on the efficacy of VBX-100 in animal models have shown favorable outcomes, including reduced inflammation of the gastrointestinal tract and no measurable systemic THC found in tissue examined using highly-sensitive testing equipment. Our pre-clinical development plan, which includes dose range finding studies, GLP toxicology studies, pharmacokinetic studies and other pre-clinical research, is anticipated to be completed during the 2nd half of calendar year 2022, subject to the Company securing sufficient additional funding or entering into a strategic partnership. After our satisfactory completion of all of the prerequisite pre-clinical *in vitro* and *in vivo* studies, an Investigational New Drug (IND) application would be filed with the U.S. Food and Drug Administration (FDA) and, upon receiving FDA approval, we would initiate our Phase 1 clinical trial, subject to the Company securing sufficient additional funding or entering into a strategic partnership.

In addition to our research and development activities related to our THC-glycoside compounds, we are expanding and diversifying our research and development activities to include the potential safety, efficacy and commercialization of our patented CBD-glycoside compounds. CBD has well-known anti-anxiety, anti-inflammatory and anti-microbial properties, but unlike THC, CBD is non-psychoactive and non-intoxicating. By glycosylating CBD, we can create CBD-glucose compounds that may enable a targeted and concentrated delivery of CBD in the gastrointestinal tract. Currently we are evaluating the optimal CBD-glycoside delivery mechanism, which may include an aqueous drink formulation since our glycosylation process significantly improves the water solubility of the CBD molecule.

Enzymatic Processing Methods

The Company originally developed its proprietary enzymatic bioprocessing technologies to attach glucose molecules to the molecules of stevia as part of our activities in the stevia processing industry. We then expanded the application of this proprietary technology to attach glucose molecules to cannabinoids, including THC and CBD. We may pursue additional opportunities to develop new products utilizing this proprietary technology.

Government Regulation

Due to our development of pharmaceutical products, we are subject to extensive regulation by the FDA and other federal, state, and local agencies. Also, since we are researching and developing cannabinoid-based products, we are subject to regulation by the U.S. Drug Enforcement Administration (DEA). If we expand our clinical research, product development or commercialization activities outside of the United States in the future, we anticipate that we would then be subject to additional regulation by the applicable foreign jurisdictions and governing bodies, which may have different requirements.

The FDA is the main regulatory body that controls pharmaceutical and biologic drugs in the United States, with additional layers of regulation from other federal, state and local agencies. The Federal Food, Drug, and Cosmetic Act governs most of the requirements for the development and marketing of our pharmaceutical products. The FDA's drug approval process is extensive, generally including: pre-clinical animal studies of drug safety, efficacy and dosing, submission and approval of an IND application, clinical studies in humans to determine safety, efficacy and dosing (Phase 1 – 3 studies), submission and approval of a New Drug Application (NDA), and additional post-approval requirements. Failure to comply with any FDA-requirements may result in the FDA refusing to approve our application.

The DEA establishes procedures and monitors research and development activities of “controlled substances” subject to the Controlled Substances Act. Our research and development activities focus on cannabinoids, particularly THC and CBD derived from the cannabis plant, which the DEA has classified as Schedule I substances. Schedule I substances are defined as drugs with no currently accepted medical use and a high potential for abuse. In May 2019, the DEA informed us that it had determined that they consider our VBX-100 prodrug a Schedule I substance. As a result, any developing, testing, manufacturing, or clinical studies involving our VBX-100 prodrug, and by inference potentially all of our THC-glycoside molecules, are required to be properly licensed by the DEA and adhere to strict diversion control standards. Our current research and development efforts involving our THC-glycoside molecules are conducted at our Rocklin laboratory, which holds a DEA-issued Controlled Substance Registration Certificate for “Research” that expires on May 31, 2022 and is renewable on an annual basis. Our research and development activities are also approved by and operated in compliance with the State of California’s Research Advisory Panel, which is a division of the California Department of Justice that oversees research performed within the state using DEA Schedule I and II substances.

Orphan Drug Designation

In January 2018, we filed a request with the FDA’s Office of Orphan Products Development (OOPD) for an Orphan Drug Designation of our VBX-100 prodrug for the treatment of pediatric ulcerative colitis. In March 2018, the OOPD denied our request based, in part, on the FDA’s decision to no longer grant Orphan Drug Designation status to drugs for pediatric subpopulations of common diseases (i.e., diseases or conditions with an overall prevalence of over 200,000), unless the use of the drug in the pediatric subpopulation meets the regulatory criteria for an orphan subset, or the disease in the pediatric subpopulation is considered a different disease from the disease in the adult population.

However, in December 2019, we received a letter from the OOPD informing us that the FDA determined that the Company may be eligible for pediatric-subpopulation designation because we submitted our original request for an Orphan Drug Designation before the guidance *Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases* was finalized in July 2018.

As a result, in May 2020, we filed a response letter with the OOPD addressing the other deficiencies noted in the Company’s original submission in January 2018, which included, among other things (1) support for the prevalence of pediatric ulcerative colitis; (2) our scientific rationale for the specific animal models used in our pre-clinical animal studies; and (3) more comprehensive supporting documentation for the use of VBX-100 in pediatric patients with ulcerative colitis. In August 2020, we received a letter from the OOPD informing us that it was unable to grant our request for an Orphan Drug Designation status because our VBX-100 prodrug was administered before and after colitis was induced in our *in vivo* mouse studies, which resulted in the need for more scientific data to support the efficacy of our VBX-100 prodrug in a treatment-only setting. As a result, we were advised to perform a second *in vivo* mouse study in which our VBX-100 prodrug would be administered only after colitis was induced in order to provide a clear indication that the active drug was released only after ulcerative colitis was present. In May 2021, we completed the treatment-only *in vivo* mouse study and filed a supplemental response letter with the OOPD providing the requested *in vivo* treatment-only mouse study results in support of our position that VBX-100 may be effective as a treatment for pediatric ulcerative colitis.

Intellectual Property

In September 2015, we filed our first provisional U.S. patent application entitled “Cannabinoid Glycoside Prodrugs and Methods of Synthesis”, which described novel CBD-glycosides and THC-glycosides along with methods of production through enzymatic biosynthesis. In October 2015, we filed our second provisional U.S. patent application that added CBDV-glycosides as additional cannabosides, plus added numerous methods of use claims for our cannabinoid-glycosides. In July 2016, we filed our third provisional U.S. patent application that greatly expanded on the cannabinoid substrates for glycosylation by adding (i) the phytocannabinoid cannabitol (CBN), (ii) the endocannabinoids anandamide, 2-AG, 1-AG, and synaptamide, and (iii) the vanilloids capsaicin, vanillin, and curcumin. In September 2016, one year after the filing of our first provisional patent, our non-provisional cannabinoid glycoside patent was filed, which included all prior material plus additional data derived from our ongoing research and laboratory studies. Also, in September 2016, we filed an expanded international patent application under the Patent Cooperation Treaty system, which included 79 patent claims covering nearly 200 individual compounds, including our THC and CBD prodrugs. In March and April 2018, this application was filed for national and regional prosecution in major pharmaceutical markets worldwide, including the United States, Canada, Mexico, Europe, China, Japan, Australia, New Zealand and Brazil.

In May 2017, we filed a U.S. patent application entitled “Antimicrobial Compositions Comprising Cannabinoids and Methods of Using the Same”, which described compositions and methods of use involving cannabinoid-glycosides that provide antimicrobial activity to treat microbial infections in the intestines, including *Clostridioides difficile* (*C. diff*) infections. In May 2018, one year after the filing of the provisional U.S. patent, we filed a non-provisional U.S. patent for the use of cannabinoid-glycosides to deliver cannabinoids to the gastrointestinal tract to treat *C. diff* infections.

In January 2020, the USPTO granted our first patent entitled “Kaurenoic Acid Glycoside Precursors and Methods of Synthesis”, which demonstrates the validity of our glycosylation platform to produce novel and patentable glycoside molecules and serves as a foundational building block for the Company’s subsequent research of glycosylated cannabinoids.

In March 2020, we filed an international patent application under the Patent Cooperation Treaty system entitled “Novel Cannabinoid Glycosides and Uses Thereof” that expands upon our 2016 patent filings covering glycosylated cannabinoids. Our new 2020 patent filings cover additional novel CBD and THC-glycosides and include research data supporting the improved characteristics and commercial production strategies for these new molecules.

In December 2020, we filed a provisional U.S. patent application entitled “Continuous Enzymatic Perfusion Reactor System”, which described our improved reactor system for the efficient enzymatic glycosylation of hydrophobic small molecules, including cannabinoids.

We believe our intellectual property portfolio of cannabinoid-glycosides possess significant value and, as a result, we have allocated substantial resources to ensure that our U.S. and international patents are properly filed and successfully prosecuted. As our research efforts involving cannabinoid-glycosides continue to progress, we plan to develop and file additional patents to cover compositions of matter, methods of production and methods of use to further expand our growing family of intellectual property assets and create long-term value for our shareholders.

Competition

The Company operates in a highly competitive and dynamic market environment, frequently against much larger and better capitalized competitors. Currently, the Company’s cannabinoid prodrug development program competes against many well-capitalized, multinational pharmaceutical drug manufacturers that are developing, producing and marketing pharmaceutical drugs for the treatment of IBD and IBS. Additionally, an increasing number of cannabinoid drug manufacturers are entering the market with cannabinoid-based drug development programs to treat a wide range of diseases, which could include IBD and IBS. Our expectation is that competition from traditional pharmaceutical drug developers and non-traditional cannabinoid-based drug developers will continue to increase over the next 12 months.

Stock Relisting and Going Concern

On November 7, 2018, the SEC temporarily suspended the trading of the Company’s common stock on the OTC marketplace. The Company’s common stock resumed trading with limited liquidity on the grey market on November 21, 2018. Grey market stocks are not traded or quoted on an exchange or inter-dealer quotation system, but are reported by broker-dealers to their self-regulatory organization who, in turn, distribute the trade data to market data vendors and financial websites. On March 9, 2021, the Financial Industry Regulatory Authority (“FINRA”) processed a Form 211 application relating to the initiation of priced quotations of the Company’s common stock, and commencing on March 10, 2021, the Company’s common stock was quoted on the OTC Link ATS. The Company is currently seeking approval to obtain Depository Trust Company eligibility for the Company’s common stock.

Since inception, the Company has funded its operations primarily through equity and debt financings. During the year ended March 31, 2021, the Company incurred a net loss of \$880,851 and used \$1,605,076 of cash in our operating activities. These factors raise substantial doubt about the Company’s ability to continue as a going concern for the next twelve months from the date that the financial statements are issued which are a part of this Annual Report on Form 10-K. In addition, the Company’s independent registered public accounting firm, in their report on the Company’s March 31, 2021 audited financial statements, raised substantial doubt about the Company’s ability to continue as a going concern. No assurance can be given that any future financing or capital, if needed, will be available or, if available, that it will be on terms that are satisfactory to the Company. If we cannot raise the capital or financing we need to continue our operations, our business could fail.

Employees

As of May 18, 2021, we employed three full-time employees, including one research professional working in our office and laboratory space in Rocklin, California. We also have engaged the services of scientific and regulatory consultants to assist with our research and development activities, which is an approach that provides us with flexible and highly-experienced resources to advance our clinical efforts while maintaining a relatively lower and variable overhead cost structure.

Properties

Our corporate headquarters is a leased office located at 1901 Avenue of the Stars, 2nd Floor, Los Angeles, California 90067. Our office and laboratory space at 2224A Sierra Meadows Drive, Rocklin, California 95677 requires a lease payment of approximately \$2,700 per month under a lease agreement that expires on March 31, 2022. We believe our current facilities are adequate to support our corporate strategy over the next 12 months.

General Information

We maintain a corporate website at: www.vitality.bio. Information contained on our website is not incorporated by reference in this Annual Report. We file reports with the Securities and Exchange Commission (SEC) and make available free-of-charge through our website our annual reports, quarterly reports, current reports, proxy and information statements and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act).

Item 1A. Risk Factors

The following risk factors should be considered carefully in addition to the other information contained in this Annual Report. This Annual Report contains forward-looking statements. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks.

Risks Related to Our Business

We have a history of operating losses and expect to continue to incur losses and we may never become profitable. The Company's independent registered public accounting firm has issued a report questioning our ability to continue as a going concern.

For the fiscal year ended March 31, 2021, the Company incurred a net loss of \$880,851 and used \$1,605,076 of cash in our operating activities. We have incurred losses since inception, resulting in an accumulated deficit of \$47,427,709 as of March 31, 2021. These factors raise substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date that the financial statements are issued which are a part of this Annual Report on Form 10-K. In addition, the Company's independent registered public accounting firm, in their report on the Company's March 31, 2021 audited financial statements, raised substantial doubt about the Company's ability to continue as a going concern. We expect to incur further losses as we continue to develop our business. We have not yet received significant revenues from sales of products or services and have recurring losses from operations.

We expect to incur substantial losses for the near future, and we may never achieve or maintain profitability. Even if we succeed in obtaining regulatory approval to market our products, we may still incur losses for the foreseeable future. We also expect to experience negative cash flow for the near future, as we plan to use all available resources to fund our operations and if we proceed with an expansion of our corporate strategy as discussed elsewhere in this Annual Report, to make significant capital expenditures. As a result, we would need to generate significant revenues if we are to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability. Our failure to achieve or maintain profitability could negatively impact the value of our common stock and you could lose some or all of your investment.

We will need to raise substantial additional capital to operate our business. If we cannot obtain the capital we need to continue our operations, our business could fail.

We will need to raise additional funds in order to continue operating our business beyond the near term. Since inception, we have primarily funded our operations through equity and debt financings. If we do issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it would increase our leverage relative to our earnings, if any, or to our equity capitalization, requiring us to pay additional interest expense. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments. If we pursue capital through alternative sources, such as collaborations or other similar arrangements, we may be forced to relinquish rights to our proprietary compounds, technology or other intellectual property or marketing rights, which could result in our receipt of only a portion of any revenue that may be generated from a partnered product or business. We also may raise funds by selling some or all of our assets. Regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

Over the 12 months following March 31, 2021, we expect our total operating expenditures to be approximately \$1,400,000. However, our estimate of total expenditures could increase if we encounter unanticipated difficulties. In addition, our estimates of the amount of cash necessary to fund our business may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Further, our operational expenses may increase substantially during our current fiscal year if we pursue an expansion of our current operational goals and research and development activities. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations and/or forego other attractive business opportunities that may arise. If any of these were to occur, there is a substantial risk that our business would fail. Sources of additional funds may not be available on acceptable terms or at all. In addition, weak economic and capital market conditions could result in increased difficulties in raising capital for our operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable, or at all. If we cannot raise the funds that we need, we will be unable to continue our operations, and our stockholders could lose their entire investment in the Company.

We currently face, and will continue to face, significant competition.

Our major competitors for the development of pharmaceutical products related to cannabinoids and inflammatory disorders include major pharmaceutical companies, smaller companies, and academic research groups that are devoted to biological or pharmaceutical research either independently or by providing contract research services. A number of multinational pharmaceutical companies are developing products in similar therapeutic areas, including, but not limited to, Biogen, Teva Neuroscience, Pfizer, Endo Pharmaceuticals, Genzyme, Novartis, Bayer Healthcare, and additional companies such as GW Pharmaceuticals, Arena Pharmaceuticals, Corbus Pharmaceuticals, Trait Biosciences, and Zynerva Pharmaceuticals are developing cannabinoid pharmaceuticals for treatment of various clinical indications and commercial applications.

Our limited operating experience could make our operations inefficient or ineffective.

We are an early-stage company with only a limited operating history upon which to base an evaluation of our current business and future prospects and how we will respond to competitive, financial or technological challenges. In order to conserve our cash resources, we have significantly scaled back our product research and development efforts such that we are almost exclusively focused on pursuing the orphan drug designation approval and exploring strategic alternatives. We only recently commenced operations in the development of pharmaceutical products and have limited experience with these activities and the revenue and income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business, and limited experience responding to such trends. We may make errors in predicting and reacting to relevant business trends and we will be subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our business, results of operations and financial condition to suffer or fail.

The coronavirus pandemic is adversely affecting and will continue to adversely affect our business.

Since inception, the Company has funded its operations primarily through equity and debt financings. In the event that the coronavirus pandemic has an adverse financial effect on our potential sources of financing, our operations would be negatively affected. The coronavirus pandemic may also make it more difficult for us to pursue capital through alternative sources, such as collaborations or other similar arrangements, since we expect that many potential strategic partners are either suffering financially or operationally as a result of the coronavirus pandemic or are focused on the development of treatment therapies or vaccines for the coronavirus. The duration and breadth of the coronavirus pandemic is uncertain and the ultimate impact cannot be reasonably estimated at this time.

We may not be able to manage our expansion of operations effectively.

Assuming we are able to attract additional capital, we may seek to expand our operations. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train qualified personnel. Our management will also be required to develop relationships with customers, suppliers and other third parties. Our current and planned operations, personnel, systems, and internal procedures and controls may not be adequate to support our future growth. If we are unable to manage our growth effectively, we may not be able to take advantage of market opportunities, execute our business strategies or respond to competitive pressures.

If we are unable to hire and retain qualified personnel, we may not be able to implement our business plan.

As of May 18, 2021, we employed three full-time employees, including one professional dedicated to research and development. Attracting and retaining qualified scientific, management and other personnel will be critical to our success. There is intense competition for qualified personnel in our area of activities and we may not be able to attract and retain the qualified personnel necessary for the development of our business. In addition, we may have difficulty recruiting necessary personnel as a result of our limited operating history. The loss of key personnel or the failure to recruit necessary additional personnel could impede the achievement of our business objectives.

We may choose to hire part-time employees or use consultants. As a result, certain of our employees, officers, directors and consultants may from time to time serve as officers, directors and consultants of other companies. These other companies may have interests in conflict with ours. In addition, we expect to rely on independent organizations, advisors and consultants to provide certain services, including product testing and development plan construction. The services of these independent organizations, advisors and consultants may not be available to us on a timely basis when needed or on acceptable terms, and if they are not available, we may not be able to find qualified replacements. If we are unable to retain the services of qualified personnel, independent organizations, advisors and consultants, we may not be able to implement our business plan.

If we are unable to market and distribute our products effectively, we may be unable to generate significant revenue.

We currently have no sales, marketing or distribution capabilities. We intend to build these capabilities internally, as needed, and also to pursue collaborative arrangements regarding the sales and marketing of our products, including steps necessary to commercialize our pharmaceutical products. However, we may be unable to establish or maintain any such collaborative arrangements, or if able to do so, they may not provide us with the sales and marketing benefits we expect. To the extent that we decide not to, or are unable to, enter into successful collaborative arrangements with respect to the sales and marketing of our cannabinoid products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with appropriate expertise. We may be unable to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition and results of operations could be materially adversely affected.

We may seek orphan drug status for our products for the treatment of certain diseases or conditions, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Regulatory authorities in some jurisdictions, including the United States and European Union, may designate drugs for relatively small patient populations as orphan drugs. The FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals annually in the United States, or, if the disease or condition affects more than 200,000 individuals annually in the United States, if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. In the European Union, Orphan Drug Designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug approval. This period may be reduced to six years if the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable so that market exclusivity is no longer justified.

As a result, even if our products receive orphan exclusivity, the FDA or European Medicines Agency (EMA) can still approve other drugs that have a different active ingredient for use in treating the same indication. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our products or the EMA could reduce the term of exclusivity if our products are sufficiently profitable.

In January 2018, we filed a request with the FDA's Office of Orphan Products Development (OOPD) for an Orphan Drug Designation of our VBX-100 prodrug for the treatment of pediatric ulcerative colitis, which was denied in March 2018. However, in December 2019, we received a letter from the OOPD informing us that the FDA has determined that the Company may be eligible for pediatric-subpopulation designation because we submitted our original request for an Orphan Drug Designation before the guidance *Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases* was finalized in July 2018. In May 2020, we filed a response letter with the OOPD addressing the other deficiencies noted in the Company's original submission in January 2018. In August 2020, we received a letter from the OOPD informing us that it was unable to grant our request for an Orphan Drug Designation status because our VBX-100 prodrug was administered before and after colitis was induced in our *in vivo* mouse studies, which resulted in the need for more scientific data to support the efficacy of our VBX-100 prodrug in a treatment-only setting. As a result, we were advised to perform a second *in vivo* mouse study in which our VBX-100 prodrug would be administered only after colitis was induced in order to provide a clear indication that the active drug was released only after ulcerative colitis was present. In May 2021, we completed the treatment-only *in vivo* mouse study and filed a supplemental response letter with the OOPD providing the requested *in vivo* treatment-only mouse study results in support of our position that VBX-100 may be effective as a treatment for pediatric ulcerative colitis.

While we have sought orphan drug designation for our VBX-100 prodrug, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA or EMA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, we may never receive such designation, or there may be a delay in receiving such designation that would impact our expected timeframe for clinical development.

We are dependent on the success of our products, which are still in pre-clinical development and will require significant capital resources and years of clinical development effort.

We currently have no pharmaceutical products on the market, and our product candidates are still in pre-clinical development. Our business depends on the successful clinical development, regulatory approval and commercialization of our product candidates, and additional pre-clinical testing and substantial clinical development and regulatory approval efforts will be required before we are permitted to commence commercialization, if ever. The clinical trials and manufacturing and marketing of product candidates will be subject to extensive and rigorous review and regulation by numerous government authorities in the United States and other jurisdictions where we intend to test and, if approved, market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for use in each target indication, and potentially in specific patient populations. This process can take many years and may include post-marketing studies and surveillance, which would require the expenditures of substantial resources beyond our current resources. Of the large number of drugs in development for approval in the United States and the European Union, only a small percentage successfully complete the FDA or EMA regulatory approval processes, as applicable, and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research, development and clinical programs, we are not certain that any of our product candidates will be successfully developed or commercialized.

Because the results of pre-clinical testing are not necessarily predictive of future results, our products may not have favorable results in our planned clinical trials.

Any positive results from our pre-clinical testing of our products may not necessarily be predictive of the results from our planned clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical development, and we cannot be certain that we will not face similar setbacks. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. If we fail to produce positive results in our clinical trials, the development timeline and regulatory approval and commercialization prospects for our products and, correspondingly, our business and financial prospects, would be materially adversely affected.

Failures or delays in the completion of our pre-clinical studies or the commencement and completion of our clinical trials could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

To date, we have not completed our pre-clinical animal studies or commenced any clinical trials. Successful completion of such pre-clinical animal studies and clinical trials is a prerequisite to submitting an NDA to the FDA or a marketing authorization application (MAA) to the EMA. Clinical trials are expensive, difficult to design and implement, can take many years to complete and their outcomes are uncertain. A product candidate can unexpectedly fail at any stage of clinical development. The historic failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;

- delays or inability in manufacturing or obtaining sufficient quantity or quality of a product candidate or other materials necessary to conduct clinical trials due to regulatory and manufacturing constraints, including delays or an inability to hire appropriate staff or consultants with requisite expertise in chemistry and manufacturing controls for pharmaceutical products;
- difficulties obtaining Institutional Review Board (IRB), DEA or comparable foreign regulatory authority, or ethics committee approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant indication and competition from other clinical trial programs for similar indications;
- severe or unexpected toxicities or drug-related side effects experienced by patients in our clinical trials or by individuals using drugs similar to our product candidates;
- DEA or comparable foreign regulatory authority-related recordkeeping, reporting or security violations at a clinical trial site, leading the DEA, state authorities or comparable foreign regulatory authorities to suspend or revoke the site's controlled substance license and causing a delay or termination of planned or ongoing clinical trials;
- regulatory concerns with cannabinoid products generally and the potential for abuse of those products;
- difficulties retaining patients who have enrolled in a clinical trial who may withdraw due to lack of efficacy, side effects, personal issues or loss of interest;
- ambiguous or negative interim results; or
- lack of adequate funding to continue the clinical trial.

In addition, a clinical trial may be suspended or terminated by us, the FDA, IRBs, ethics committees, data safety monitoring boards or other foreign regulatory authorities overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- inspection of the clinical trial operations, clinical trial sites, or drug manufacturing facilities by the FDA, the DEA, the EMA or other foreign regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any safety issues that could be identified in our ongoing toxicology studies;
- adverse side effects or lack of effectiveness; and
- changes in government regulations or administrative actions.

We intend to focus on prodrugs for certain indications, and may fail to capitalize on other product candidates or other indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are focusing on research programs relating to our proprietary products for certain indications, which concentrates the risk of product failure in the event the products prove to be unsafe, ineffective or inadequate for clinical development or commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that could later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on proprietary research and development programs relating to our products may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for our products, we may relinquish valuable rights to our products through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to our products.

The regulatory approval processes of the FDA, the EMA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to market our product candidates in the United States or the European Union until we receive approval of an NDA from the FDA or an MAA from the EMA, respectively, or in any foreign countries until we receive the requisite approval from such countries. Prior to submitting an NDA to the FDA or an MAA to the EMA for approval of our product candidates we will need to complete our ongoing pre-clinical studies, as well as Phase 1, Phase 2 and Phase 3 clinical trials. We are still conducting pre-clinical studies and have not yet commenced our clinical program or tested any product in humans. Successfully initiating and completing our clinical program and obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of our product candidates for many reasons, including, among others, because:

- we may not be able to demonstrate that our product candidates are safe and effective in treating patients to the satisfaction of the FDA or EMA;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval;
- the FDA or EMA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or EMA may require that we conduct additional clinical trials;
- the FDA or EMA or other applicable foreign regulatory authorities may not approve the formulation, labeling or specifications of our product candidates;
- the contract research organizations, or CROs, and other contractors that we may retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or EMA may find the data from pre-clinical studies and clinical trials insufficient to demonstrate that our products' clinical and other benefits outweigh their safety risks;
- the FDA or EMA may disagree with our interpretation of data from our pre-clinical studies and clinical trials;
- the FDA or EMA may not accept data generated at our clinical trial sites or may disagree with us over whether to accept efficacy results from clinical trial sites outside the United States where the standard of care is potentially different from that in the United States;
- if and when our NDAs or MAAs are submitted to the FDA or EMA, as applicable, the regulatory agency may have difficulties scheduling the necessary review meetings in a timely manner, may recommend against approval of our application or may recommend or require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy (REMS), which would use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks, as a condition of approval or post-approval, and the EMA may grant only conditional approval or impose specific obligations as a condition for marketing authorization, or may require us to conduct post-authorization safety studies;
- the FDA, EMA, DEA or other applicable foreign regulatory agencies may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract;
- the DEA or other applicable foreign regulatory agency may establish quotas that limit the quantities of controlled substances available to our manufacturers; or
- the FDA or EMA may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our products.

Even if our products receive regulatory approval, they may still face future development and regulatory difficulties.

If we seek and obtain regulatory approval for any of our products, such approval would be subject to extensive ongoing requirements by the DEA, FDA, EMA and other foreign regulatory authorities related to the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA, EMA and other comparable foreign regulatory authorities. If the FDA, EMA or any other comparable foreign regulatory authority becomes aware of new safety information after approval of any of our product candidates, these regulatory authorities may require labeling changes or establishment of a REMS, impose significant restrictions on a product's indicated uses or marketing, impose ongoing requirements for potentially costly post-approval studies or post-market surveillance, or impose a recall.

In addition, manufacturers of therapeutic products and their facilities are subject to continual review and periodic inspections by the FDA, the EMA and other comparable foreign regulatory authorities for compliance with current good manufacturing practices (cGMP) regulations. Our current facilities and staff have never undergone such an inspection, and we currently rely upon outside consultants and advisors to provide guidance on chemistry and manufacturing controls for pharmaceutical products. Further, manufacturers of controlled substances must obtain and maintain necessary DEA and state registrations and registrations with applicable foreign regulatory authorities, and must establish and maintain processes to ensure compliance with DEA and state requirements and requirements of applicable foreign regulatory authorities governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue untitled letters or warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us; or
- require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and may otherwise have a material adverse effect on our business, financial condition and results of operations.

Our products will be subject to controlled substance laws and regulations; failure to receive necessary approvals may delay the launch of our products and failure to comply with these laws and regulations may adversely affect the results of our business operations.

Our products will contain controlled substances as defined in the federal Controlled Substances Act of 1970 (CSA). Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently “accepted medical use” in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While cannabis is a Schedule I controlled substance, products approved for medical use in the United States that contain cannabis or cannabis extracts must be placed in Schedules II - V, since approval by the FDA satisfies the “accepted medical use” requirement. If and when our products receive FDA approval, the DEA will make a scheduling determination and place them in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. If approved by the FDA, we expect the finished dosage forms of our products to be listed by the DEA as a Schedule II, III, IV or V controlled substance. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. The scheduling process may take additional time after FDA approval, thereby significantly delaying the launch of our products. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that our products may have potential for abuse, it may require us to generate more clinical data than that which is currently anticipated, which could increase the cost and/or delay the launch of our products.

Because our products will contain compounds considered to be Schedule I substances, to conduct pre-clinical studies and clinical trials with our products in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to procure necessary materials from suppliers, and to handle and dispense our products. If the DEA delays or denies the grant of a research registration to one or more research sites, the pre-clinical studies or clinical trials could be significantly delayed, and we could lose and be required to replace clinical trial sites, resulting in additional costs.

We will also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute our products to pharmacies and other healthcare providers, and these distributors would need to obtain Schedule II through V distribution registrations. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If our products are Schedule II drugs, pharmacies would have to maintain enhanced security with alarms and monitoring systems and they must adhere to recordkeeping and inventory requirements. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

We may manufacture the commercial supply of our products, or necessary raw materials, outside of the United States. If our products are each approved by the FDA and classified as a Schedule II or III substance, an importer can import that product for commercial purposes if it obtains from the DEA an importer registration and files an application with the DEA for an import permit for each importation. The DEA provides annual assessments/estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our products and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted.

Individual states have also established controlled substance laws and regulations. Although state-controlled substance laws often mirror federal law, states may schedule our product candidates in a different manner. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement actions and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of our products and raw materials may require import and export licenses. In the United States, the FDA and U.S. Customs and Border Protection, and in other countries, similar regulatory authorities, regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process requires the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of our products and materials may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in delays in clinical trials or, upon commercialization, a partial or total loss of revenue from one or more shipments of our products. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from one or more shipments of our products could have a material adverse effect on our business, results of operations and financial condition.

Failure to obtain regulatory approval in jurisdictions outside the United States and the European Union would prevent our product candidates from being marketed in those jurisdictions.

In order to market and sell our products in jurisdictions other than the United States and the European Union, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The regulatory approval process outside the United States and the European Union generally includes all of the risks associated with obtaining FDA and EMA approval, but can involve additional testing. We may need to partner with third parties in order to obtain approvals outside the United States and the European Union. In addition, in many countries worldwide, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States and the European Union on a timely basis, if at all. Even if we were to receive approval in the United States or the European Union, approval by the FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions. Similarly, approval by one regulatory authority outside the United States and the European Union would not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or the EMA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in other foreign jurisdictions, the commercial prospects of those product candidates may be significantly diminished and our business prospects could decline.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

In the United States there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell any product candidates for which we obtain marketing approval.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could negatively impact our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products.

Even if we are able to commercialize our products, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our products, if approved, will depend substantially on the extent to which the costs of these products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we receive for any of our approved products. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree.

The intended use of a drug product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Outside the United States, particularly in member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations or the successful completion of health technology assessment procedures with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines, but monitor and control company profits. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be adversely affected.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the U.S. federal healthcare Anti-Kickback Statute impacts our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent (including through impermissible promotion of our products for off-label uses) or making a false statement or record to avoid, decrease or conceal an obligation to pay money to the federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, and the rules and regulations promulgated thereunder, establish federal standards for maintaining the privacy and security of certain patient health information known as Protected Health Information (PHI). As amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), HIPAA establishes federal standards for administrative, technical and physical safeguards relevant to the electronic transmission of PHI and imposes notification obligations in the event of a breach of the privacy or security of PHI. In addition to adhering to the requirements of HIPAA, entities considered “covered entities” under HIPAA (such as health plans, healthcare clearinghouses, and certain healthcare providers) are required to obtain assurances in the form of a written contract from certain business associates to which they transmit PHI (or who create, receive, transmit or maintain PHI on the covered entity’s behalf) to ensure that the privacy and security of such information is maintained in accordance with HIPAA requirements. HITECH made changes to HIPAA including extending the reach of HIPAA beyond HIPAA covered entities to business associates, increased the maximum civil monetary penalties for violations of HIPAA, and granted enforcement authority to state attorneys general. Failure to comply with HIPAA/HITECH can result in civil and criminal liability, including civil monetary penalties, fines and imprisonment;
- the U.S. federal physician payment transparency requirements under the Affordable Care Act require applicable manufacturers of covered drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and certain other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and certain other healthcare providers or marketing expenditures. Additionally, state and foreign laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA/HITECH, thus complicating compliance efforts.

Comparable laws and regulations exist in the countries within the European Economic Area (EEA). Although such laws are partially based upon European Union law, they may vary from country to country. Healthcare specific, as well as general European Union and national laws, regulations and industry codes constrain, for example, our interactions with government officials and healthcare practitioners, and the handling of healthcare data. Non-compliance with any of these laws or regulations could lead to criminal or civil liability.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Our products, if approved, may be unable to achieve broad market acceptance and, consequently, limit our ability to generate revenue from new products.

Even when product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our products by physicians and patients. The market acceptance of any product depends on a number of factors, including the indication statement and warnings approved by regulatory authorities in the product label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payors such as government healthcare systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any factor preventing or limiting the market acceptance of our product candidates could have a material adverse effect on our business, results of operations and financial condition.

If we receive regulatory approvals, we may market our products in multiple jurisdictions where we have limited or no operating experience and may be subject to increased business and economic risks that could affect our financial results.

If we receive regulatory approvals, we may market our products in jurisdictions where we have limited or no experience in marketing, developing and distributing our products. Certain markets have substantial legal and regulatory complexities that we may not have experience navigating. We are subject to a variety of risks inherent in doing business internationally, including risks related to the legal and regulatory environment in non-U.S. jurisdictions, including with respect to privacy and data security, trade control laws and unexpected changes in laws, regulatory requirements and enforcement, as well as risks related to fluctuations in currency exchange rates and political, social and economic instability in foreign countries. If we are unable to manage our international operations successfully, our financial results could be adversely affected.

In addition, controlled substance legislation may differ in other jurisdictions and could restrict our ability to market our products internationally. Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to us obtaining marketing approval for our products in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our products to be marketed, or the approval of such amendments to the laws and regulations may take a prolonged period of time. We would be unable to market our products in countries with such obstacles in the near future or perhaps at all without modification to laws and regulations.

Our products will contain controlled substances, the use of which may generate public controversy.

Since our products will contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our products. These pressures could also limit or restrict the introduction and marketing of our products. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable by our products. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

If we fail to protect or enforce our intellectual property rights or secure rights to the intellectual property of others, the value of our intellectual property rights would diminish.

We expect to continue to develop our intellectual property portfolio as we increase our research and development efforts. We may be unable to obtain patents or other protection for any technologies we develop, because such technologies are not coverable by patents or other forms of registered intellectual property, because third parties file patents covering the same claims earlier than we do, or for other reasons. If we are able to obtain issued patents, we cannot predict the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents. Others may obtain patents claiming aspects similar to those covered by our patents and patent applications, which may limit the efficacy of the protections afforded by any patents we may obtain.

Our success will also depend upon the skills, knowledge and experience of our personnel, our consultants and advisors as well as our licensors and contractors. To help protect any proprietary know-how we develop and any inventions for which patents may be unobtainable or difficult to obtain, we expect to rely on trade secret protection and confidentiality agreements. To this end, we expect to require our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

If we infringe the rights of third parties we could be prevented from selling products and forced to pay damages or defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs. In that case, we could be required to:

- obtain licenses from such third parties, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement, which may not be feasible;
- stop using the subject matter claimed in the patents held by others;
- pay damages; and/or
- defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

Any of these outcomes could divert management attention and other resources and could significantly harm our operations and financial condition.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development efforts and our manufacturing processes may involve the controlled storage, use and disposal of certain hazardous materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be eliminated. We may not be able to obtain and maintain insurance on acceptable terms, or at all, to cover costs associated with any such accidental contamination. In the event of such an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and exceed our financial resources. We may incur significant costs to comply with current or future environmental laws and regulations.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

If we are able to develop and commercialize our proposed products, we could become subject to product liability claims. If we are not able to successfully defend against such claims, we may incur substantial liabilities or be required to limit commercialization of our proposed products. If we are unable to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability, claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Government regulation of our products could increase our costs, prevent us from offering certain products or cause us to recall products.

The processing, formulation, manufacturing, packaging, labeling, advertising and distribution of our products is subject to regulation by one or more federal agencies, and various agencies of the states and localities in which our products are manufactured and sold. These government regulatory agencies may attempt to regulate any of our products that fall within their jurisdiction. Such regulatory agencies may not accept the evidence of safety for any new ingredients that we may want to market, may determine that a particular product or product ingredient presents an unacceptable health risk, may determine that a particular statement of nutritional support that we want to use is an unacceptable drug claim or an unauthorized version of a food “health claim,” may determine that a particular product is an unapproved new drug, or may determine that particular claims are not adequately supported by available scientific evidence. Such a determination would prevent us from marketing particular products or using certain statements of nutritional support on our products. We also may be unable to disseminate third-party literature that supports our products if the third-party literature fails to satisfy certain requirements.

In addition, a government regulatory agency could require us to remove a particular product from the market. Any product recall or removal would result in additional costs to us, including lost revenues from any products that we are required to remove from the market, any of which could be material. Any such product recalls or removals could lead to liability, substantial costs and reduced growth prospects.

If any of our products contain plants, herbs or other substances not recognized as safe by a government regulatory agency, we may not be able to market or sell such products in that jurisdiction. Any such prohibition could materially adversely affect our results of operations and financial condition. Further, if more stringent statutes are enacted, or if more stringent regulations are promulgated, we may not be able to comply with such statutes or regulations without incurring substantial expense, or at all.

We are not able to predict the nature of future laws, regulations, repeals or interpretations or to predict the effect additional governmental regulation, if and when it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, or other new requirements. Any such developments could involve substantial additional costs to us, which we may not be able to fund, and could have a material adverse effect on our business operations and financial condition.

Risks Related to our Common Stock

Our common stock is illiquid and the price of our common stock may be negatively impacted by any negative operational results and factors unrelated to our operations.

Our common stock is quoted on the OTC and trading on the OTC is frequently highly volatile, with low trading volume. We have experienced significant fluctuations in the price and trading volume of our common stock, which may be caused by factors relating to our business and operational results and/or factors unrelated to the Company, including general market conditions. An active market for our common stock may never develop, in which case it could be difficult for stockholders to sell their common stock. The market price of our common stock could continue to fluctuate substantially.

Trading of our stock is restricted by the SEC's "penny stock" regulations and certain FINRA rules, which may limit a stockholder's ability to buy and sell our common stock.

Our securities are covered by certain "penny stock" rules, which impose additional sales practice requirements on broker-dealers who sell low-priced securities to persons other than established customers and accredited investors. For transactions covered by these rules, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to sale, among other things. These rules may affect the ability of broker-dealers and holders to sell our common stock and may negatively impact the level of trading activity for our common stock. To the extent our common stock remains subject to the penny stock regulations, such regulations may discourage investor interest in and adversely affect the market liquidity of our common stock.

The Financial Industry Regulatory Authority (FINRA) has adopted rules that require a broker-dealer, when recommending an investment to a customer, to have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit an investor's ability to buy and sell our common stock and could have an adverse effect on the market for our shares.

If we issue and sell additional shares of our common stock in the future, our existing stockholders will be diluted and our stock price could fall.

Our articles of incorporation authorize the issuance of up to 1,000,000,000 shares of common stock, of which, as of May 18, 2021, 50,840,147 shares were outstanding and 13,204,504 shares were reserved for issuance under our stock incentive plan or other outstanding options or warrants. As a result, we have a large number of shares of common stock that are authorized for issuance and are not outstanding or otherwise reserved, and could be issued at the discretion of our Board of Directors. We expect to seek additional financing in the future in order to fund our operations, and if we issue additional shares of common stock or securities convertible into common stock, our existing stockholders will be diluted. Our Board of Directors may also choose to issue shares of our common stock or securities convertible into or exercisable for our common stock to acquire assets or companies, for compensation to employees, officers, directors, consultants and advisors, to fund capital expenditures and to enter into strategic partnerships. Additionally, shares of common stock could be issued for anti-takeover purposes or to delay or prevent changes in control or management of the Company. Our Board of Directors may determine to issue shares of our common stock on terms that our stockholders do not believe enhance stockholder value, or that may ultimately have an adverse effect on our business or the trading price of our common stock. Further, the issuance of any such shares may cause further dilution to the ownership interest of our current stockholders, reduce the book value per share of our common stock and may contribute to a reduction in the market price for our common stock.

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.

Certain of our executive officers, directors and stockholders own a significant percentage of our outstanding capital stock. As of May 18, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 40.4% of our outstanding shares of common stock. Accordingly, our directors, executive officers and certain stockholders have significant influence over our affairs due to their substantial stock ownership coupled with their positions on our management team. For example, these stockholders may be able to control or influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that some of our stockholders may believe is in their best interest.

We are subject to the reporting requirements of federal securities laws, compliance with which involves significant time, expense and expertise.

We are a public reporting company and are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act of 2002. The ongoing costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, are significant and may cause unexpected increases in operational expenses. Our present management team is relatively small and may be unable to manage the ongoing costs and compliance effectively. It may be time consuming, difficult and costly for us to hire additional financial reporting, accounting and other finance staff in order to build and retain a management team with adequate expertise and experience in operating a public company.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. We have paid no cash dividends on any of our capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters is a leased office located at 1901 Avenue of the Stars, 2nd Floor, Los Angeles, California 90067. Our office and laboratory space at 2224A Sierra Meadows Drive, Rocklin, California 95677 requires a lease payment of approximately \$2,700 per month under a lease agreement that expires on March 31, 2022. We believe our current facilities are adequate to support our corporate strategy over the next 12 months.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation that arises in the ordinary course of our business. Neither we nor any of our property is currently subject to any proceedings the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on our financial position or results of operations.

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 has been quoted through various over-the-counter quotation systems at various times since 2009. Our common stock currently trades on the OTC Markets under the symbol "VBIO."

The following table sets forth the range of reported high and low closing bid quotations for our common stock for the fiscal quarters indicated as reported by OTC Markets Group. Common stock price reflects inter-dealer quotations, does not include retail markups, markdowns or commissions and does not necessarily represent actual transactions.

| | <u>High</u> | <u>Low</u> |
|---|-------------|------------|
| Fiscal 2020 | | |
| First Quarter ended June 30, 2019..... | 0.53 | 0.18 |
| Second Quarter ended September 30, 2019 | 1.61 | 0.10 |
| Third Quarter ended December 31, 2019 | 0.15 | 0.05 |
| Fourth Quarter ended March 31, 2020 | 0.09 | 0.01 |
| Fiscal 2021 | | |
| First Quarter ended June 30, 2020..... | 0.10 | 0.03 |
| Second Quarter ended September 30, 2020 | 2.00 | 0.06 |
| Third Quarter ended December 31, 2020 | 0.20 | 0.06 |
| Fourth Quarter ended March 31, 2021 | 1.61 | 0.06 |

Transfer Agent

The transfer agent and registrar for our common stock is Securities Transfer Corporation, 2901 North Dallas Parkway, Suite 380, Plano, Texas 75093.

Holders of Common Stock

As of May 18, 2021, there were 74 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Equity Compensation Plan Information

During the year ended March 31, 2021, we did not issue any options, warrants or other securities under our equity compensation plan (as amended, the "Equity Incentive Plan"). Except as listed in the table below, as of March 31, 2021, we do not have any equity-based plans, including individual compensation arrangements, which have not been approved by our stockholders.

The following table provides information as of March 31, 2021 with respect to our equity compensation plans:

Equity Compensation Plan Information

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|--|--|--|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders ⁽¹⁾ | 4,791,600 | \$ 1.10 | - |
| Equity compensation plans not approved by security holders | 1,205,944 | \$ 0.32 | 6,478,397 |
| Total..... | 5,997,544 | \$ 0.91 | 6,478,397 |

(1) As of March 31, 2021, 6,478,397 shares of our common stock remained available for future issuance pursuant to the Equity Incentive Plan.

Item 6. Selected Financial Data

Not applicable.

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

Certain statements contained in this Annual Report are “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, and are subject to the “safe harbor” created by these sections. Future filings with the SEC, future press releases and future oral or written statements made by us or with our approval, which are not statements of historical fact, may also contain forward-looking statements. Because such statements include risks and uncertainties, many of which are beyond our control, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements can be found under the caption “Risk Factors” in Part I, Item 1A, and elsewhere in this Annual Report. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

The following discussion should be read in conjunction with the financial statements and the accompanying notes for the years ended March 31, 2021 and 2020 appearing elsewhere in this Annual Report. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption “Risk Factors” in Part I, Item 1A.

Plan of Operations

We are a company focused on the advancement of pharmaceuticals and innovative technologies that improve the lives of patients. We seek to achieve this objective through the development of novel cannabinoid pharmaceutical prodrugs known as cannabosides.

We believe our internally-developed cannabosides or cannabinoid-glycoside prodrugs will be converted within the body after administration from an inactive molecule into a pharmacologically active drug. Currently, the Company has produced more than 25 novel cannabosides, including glycosylated tetrahydrocannabinol (THC), cannabidiol (CBD), cannabidivarin (CBDV) and cannabinol (CBN), that are covered by worldwide patent applications for composition of matter, method of production and method of use. We are currently developing our most promising THC-glycoside (VBX-100) as an oral prodrug for the treatment of IBD and IBS. VBX-100 was selected from our THC-glycoside portfolio for compatibility with commercial production techniques and the optimal prodrug delivery profile that maximizes intestinal anti-inflammatory properties while minimizing psychoactive or intoxicating effects.

In addition to our research and development activities related to our THC-glycoside compounds, we are expanding and diversifying our research and development activities to include the potential safety, efficacy and commercialization of our patented CBD-glycoside compounds. CBD has well-known anti-anxiety, anti-inflammatory and anti-microbial properties, but unlike THC, CBD is non-psychoactive and non-intoxicating. By glycosylating CBD, we can create CBD-glucose compounds that may enable a targeted and concentrated delivery of CBD in the gastrointestinal tract. Currently we are evaluating the optimal CBD-glycoside delivery mechanism, which may include an aqueous drink formulation since our glycosylation process greatly improves the water solubility of the CBD molecule.

Additionally, the Company is evaluating the expansion of its corporate strategy to create long-term sustainable value for its shareholders by building a more diversified portfolio of assets through organic growth and strategic acquisitions. Specifically, the Company is considering special situation opportunities in a variety of industries, including without limitation, businesses that utilize innovative technologies to address the unfavorable environmental impacts of climate change.

Critical Accounting Policies

We believe the following critical accounting policies require us to make significant judgments and estimates in the preparation of our financial statements.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires 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 the reported amounts of revenues and expenses during the period. The more significant estimates and assumption by management include, among others, assumptions used in valuing assets acquired in business acquisitions, reserves for accounts receivable, assumptions used in valuing equity instruments issued for services, the valuation allowance for deferred tax assets, accruals for potential liabilities, and assumptions used in the determination of the Company's liquidity. Actual results could differ from those estimates.

Stock-Based Compensation

The Company periodically issues stock options and restricted stock awards to employees and non-employees in non-capital raising transactions for services and for financing costs. The Company accounts for such grants issued and vesting based on ASC 718, Compensation-Stock Compensation whereby the value of the award is measured on the date of grant and recognized for employees as compensation expense on the straight-line basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

Revenue

The Company's revenue recognition policies will follow the guidance of Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*. ASC 606 creates a five-step model that requires entities to exercise judgment when considering the terms of contracts, which includes (1) identifying the contracts or agreements with a customer, (2) identifying our performance obligations in the contract or agreement, (3) determining the transaction price, (4) allocating the transaction price to the separate performance obligations, and (5) recognizing revenue as each performance obligation is satisfied.

Recent Accounting Pronouncements

Please refer to Footnote 1 of the accompanying financial statements for management's discussion of recent accounting pronouncements.

Results of Operations

Fiscal Years Ended March 31, 2021 and March 31, 2020

The following table sets forth our results of operations for the years ended March 31, 2021 and 2020.

| | Years Ended March 31, | |
|---|------------------------------|-----------------------|
| | 2021 | 2020 |
| Operating Expenses: | | |
| General and administrative..... | \$ 1,929,308 | \$ 2,680,217 |
| Research and development..... | 408,905 | 1,009,894 |
| Rent - related party..... | - | 2,600 |
| Loss from operations..... | (2,338,213) | (3,692,711) |
| Other Income: | | |
| Gain on extinguishment of liabilities | 1,456,574 | - |
| Change in fair value of derivative liability..... | - | 35,710 |
| Other income..... | 788 | 24,772 |
| Loss from continuing operations..... | (880,851) | (3,632,229) |
| Loss from discontinued operations..... | - | (733,126) |
| Net loss..... | <u>\$ (880,851)</u> | <u>\$ (4,365,355)</u> |

Our net loss during the fiscal year ended March 31, 2021 was \$880,851 compared to a net loss of \$4,365,355 for the fiscal year ended March 31, 2020 (a decrease of \$3,484,504). The lower net loss of \$3,484,504 was due to: (i) a \$750,909 decrease in general and administrative expenses during fiscal year 2021 compared to fiscal year 2020, (ii) a \$600,989 decrease in research and development expenses during fiscal year 2021 compared to fiscal year 2020, (iii) a \$1,456,574 recognition of gains on extinguishment of liabilities during fiscal year 2021 compared to no gains recognized during fiscal year 2020, and (iv) no loss from discontinued operations during fiscal year 2021 compared to a loss from discontinued operations of \$733,126 during fiscal year 2020.

During the fiscal year ended March 31, 2021, we incurred general and administrative expenses in the aggregate amount of \$1,929,308 compared to \$2,680,217 incurred during the fiscal year ended March 31, 2020 (a decrease of \$750,909). General and administrative expenses generally include corporate overhead, salaries and other compensation costs, financial and administrative contracted services, marketing, consulting costs and travel expenses. The largest decrease in general and administrative expenses was in our legal fees, which totaled \$228,244 during the fiscal year 2021, compared to \$727,017 during the fiscal year 2020 (a decrease of \$498,773). We also recorded wages of \$644,708 during fiscal year 2021, compared to \$805,633 during fiscal year 2020 (a decrease of \$160,925).

During the fiscal year ended March 31, 2021, we incurred research and development costs of \$408,905 compared to \$1,009,894 incurred during the fiscal year ended March 31, 2020 (a decrease of \$600,989). The Company's non-personnel research and development expenses, including study expenses, raw materials and laboratory costs, were \$87,347 during fiscal year 2021, compared to \$310,069 during fiscal year 2020 (a decrease of \$222,722). The Company's research and development personnel costs were \$241,003 during fiscal year 2021, compared to \$487,859 during fiscal year 2020 (a decrease of \$246,856). We also recorded \$80,555 related to stock-based compensation in our research and development costs during fiscal year 2021, compared to \$214,567 during fiscal year 2020 (a decrease of \$134,012).

During the fiscal year ended March 31, 2020, we incurred related party rent of \$2,600. No such costs were incurred during the fiscal year ended March 31, 2021.

Loss from continuing operations was \$880,851 during the fiscal year ended March 31, 2021 compared to a loss from continuing operations of \$3,632,229 during the fiscal year ended March 31, 2020 (a decrease of \$2,751,378). The lower net loss of \$2,751,378 was due to: (i) a \$750,909 decrease in general and administrative expenses during fiscal year 2021 compared to fiscal year 2020, (ii) a \$600,989 decrease in research and development expenses during fiscal year 2021 compared to fiscal year 2020, and (iii) a \$1,456,574 recognition of gains during fiscal year 2021 compared to no gains recognized during fiscal year 2020.

During the fiscal year ended March 31, 2020, the loss from discontinued operations was \$733,126. No losses from discontinued operations were reported for the fiscal year ended March 31, 2021. For the year ended March 31, 2020, discontinued operations included \$44,698 of revenue and \$777,824 of expenses, including \$630,231 of general and administrative expenses and \$143,232 of cost of sales.

During the fiscal year ended March 31, 2021, we recorded net other income in the amount of \$1,457,362, consisting of a gain on the extinguishment of a note payable of \$97,516, gain on settlement with vendor of \$1,062,405, gain on the extinguishment of an advance of \$296,653, and other income of \$788. During the fiscal year ended March 31, 2020, we recorded other income of \$60,482, consisting of other income of \$24,772 and a gain related to the change in fair value of derivative liability of \$35,710 during the fiscal year ended March 31, 2020.

The decrease in net loss from continuing operations attributable to common stockholders during the fiscal year ended March 31, 2021 compared to the fiscal year ended March 31, 2020 in an amount equal to \$2,751,378 is primarily due to: (i) a \$750,909 decrease in general and administrative expenses during fiscal year 2021 compared to fiscal year 2020, (ii) a \$600,989 decrease in research and development expenses during fiscal year 2021 compared to fiscal year 2020, and (iii) a \$1,456,574 recognition of gains during fiscal year 2021 compared to no gains recognized during fiscal year 2020.

Liquidity and Capital Resources

We have incurred losses since inception resulting in an accumulated deficit of \$47,427,709, and further losses are anticipated in the development of our business.

The continuation of our business is dependent upon us raising additional capital and eventually attaining and maintaining profitable operations. We do not have any firm commitments for future capital. We do not presently have any revenue to fund our business from our operations, and we will need to obtain all of our necessary funding from external sources in the near term. We may not be able to obtain additional financing on commercially reasonable or acceptable terms, when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we may be required to sell, delay, scale back or eliminate some or all of our proposed operations.

As of March 31, 2021, we had total current assets of \$887,332. Our total current assets as of March 31, 2021 were comprised of cash in the amount of \$884,137 and prepaid expenses in the amount of \$3,195. Our total current liabilities as of March 31, 2021 were \$33,440, represented entirely by a lease payment attributable to our wholly-owned subsidiary, The Control Center, Inc., for which Vitality Biopharma, Inc. is not responsible. At March 31, 2021, we had working capital of \$853,892. We had no long-term liabilities as of March 31, 2021.

Sources of Capital

We do not expect to generate any revenue in the near term. We currently have no commitments for any future funding. As of March 31, 2021, we had cash in the amount of \$884,137. Based on our corporate strategy described above under the heading “Plan of Operations”, our total expenditures for the fiscal year ending March 31, 2022, are expected to be approximately \$1,400,000, which is comprised of research and development and general operating expenses. Based on our cash balance of \$884,137 on March 31, 2021, and our estimated total expenditures of approximately \$1,400,000 for the 12-month period ending March 31, 2022, we do not expect to have sufficient funds to operate our business over the next 12 months. Furthermore, our estimate of total expenditures could increase if we encounter unanticipated difficulties. In addition, our estimates of the amount of cash necessary to fund our business may prove to be too low, and we could spend our available financial resources much faster than we currently expect. If we cannot raise the capital necessary to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail.

Since inception, we have primarily funded our operations through equity and debt financings. We expect to continue to fund our operations primarily through equity and debt financings in the foreseeable future. However, sources of additional funds may not be available when needed, on acceptable terms, or at all. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments. If we pursue capital through alternative sources, such as collaborations or other similar arrangements, we may be forced to relinquish rights to our proprietary technology or other intellectual property and could result in our receipt of only a portion of any revenue that may be generated from a partnered product or business. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

Net Cash Used in Operating Activities

We have not generated positive cash flows from operating activities. For the fiscal year ended March 31, 2021, net cash used in operating activities was \$1,605,076 compared to net cash used in operating activities of \$3,590,516 for the fiscal year ended March 31, 2020. Net cash used in operating activities during the fiscal year ended March 31, 2021 consisted primarily of a net loss of \$880,851, a decrease in accounts payable of \$216,683, and the gain on extinguishment of liabilities of \$1,006,574, net of the cash received of \$450,000, offset by \$461,856 related to stock-based compensation. Net cash used in operating activities during the fiscal year ended March 31, 2020 consisted primarily of a net loss of \$4,365,355, offset by \$626,668 related to stock-based compensation, and an increase in accounts payable and accrued liabilities of \$221,563, and cash used in operating activities-discontinued operations of \$742,225.

Net Cash Provided By Investing Activities

No cash was provided by investing activities during the fiscal years ended March 31, 2021 or 2020.

Net Cash Provided By Financing Activities

During the fiscal year ended March 31, 2021, net cash provided from financing activities was \$96,988 from a note payable issued in connection with the Company's PPP loan. No cash was provided by financing activities during the fiscal year ended March 31, 2020.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to stockholders.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this item are set forth at the end of this Annual Report beginning on page F-1 and are incorporated herein by reference.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that information relating to the Company is accumulated and communicated to management, including our principal officers, as appropriate to allow timely decisions regarding required disclosure. Our Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021, and have concluded that our disclosure controls and procedures were effective as of March 31, 2021.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Internal control over financial reporting is defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act as a process designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's internal control over financial reporting as of March 31, 2021 based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013) (COSO). Based on the assessment, management concluded that, as of March 31, 2021, the Company's internal controls over financial reporting were effective.

Changes in Internal Control over Financial Reporting

There are no changes in our internal control over financial reporting during the quarter ended March 31, 2021, that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Set forth below is certain information regarding our current directors and executive officers:

| Name | Position | Age | Director/Executive Officer Since |
|--------------------------------------|--------------------------------------|------------|---|
| Edward Feighan ⁽²⁾⁽³⁾ | Chairman of the Board of Directors | 73 | November 2018 |
| Richard Celeste ⁽¹⁾⁽²⁾⁽³⁾ | Director | 83 | January 2019 |
| Michael Cavanaugh | Director and Chief Executive Officer | 47 | November 2018 / May 2019 |
| Richard McKilligan | Chief Financial Officer and Counsel | 57 | May 2019 |
| Dr. Brandon Zipp | Chief Science Officer | 40 | September 2020 |

- (1) Member of Audit Committee
- (2) Member of Compensation Committee
- (3) Member of Nomination and Corporate Governance Committee

Business Experience

The following is a brief account of the education and business experience of our current directors and executive officers:

Edward Feighan, Chairman, is currently the Chairman and CEO of Covius LLC, a privately-held firm providing a range of services to the mortgage securitization industry. Mr. Feighan has been an owner and Director of Continental Heritage Insurance Company, an early leader in the cannabis insurance market which provides surety bonds and other insurance solutions to the emerging cannabis markets, for more than twenty years. Previously, Mr. Feighan served as Chairman and CEO of ProCentury Insurance Corporation (NASDAQ: PROS) from its IPO in 2004 until the sale of the company to another public insurance group in 2008. In 1996, Mr. Feighan was the founding CEO of Century Business Services (NYSE: CBZ). Mr. Feighan held elective office in Cleveland, Ohio for twenty consecutive years from 1973 to 1993. After being elected to three terms in the Ohio House of Representatives from 1973 to 1979, Mr. Feighan served a four-year term as a Cuyahoga County Commissioner in the State of Ohio. Subsequently, Mr. Feighan served five terms as a Member of the United States House of Representatives from 1983 to 1993. During those ten years, Mr. Feighan served on the U.S. House Judiciary Committee and Foreign Affairs Committee. Mr. Feighan earned his law degree from Cleveland State University in 1978. The Board believes Mr. Feighan's extensive operational and executive experience with growth companies pursuing business combination transactions, as well as his fundraising and regulatory insight and public service experience, provides the Company a critical voice and perspective as the Company continues to develop its business and grow its operations.

Richard Celeste, Director, is a consultant and Chair of the Board of Health Effects Institute (Boston, MA), Founding Chair and Member of the Board of the US Olympic Museum (Colorado Springs, CO) and Chair of the Board of Global Communities (Silver Spring, MD). In addition, Mr. Celeste serves on the Boards of Battelle for Kids (Columbus, OH) and The Gates Family Foundation (Denver, CO). Mr. Celeste served as the Director of the Peace Corps from 1979-1981, as Governor of Ohio from 1983 to 1991, and as the United States Ambassador to India from 1997 to 2001. Mr. Celeste also served as the President of Colorado College from 2002-2011. The Board believes Mr. Celeste's fundraising and regulatory insight and public service experience provides the Company a critical voice and perspective as the Company continues to develop its business and grow its operations.

Michael Cavanaugh, Chief Executive Officer and Director, is currently the Chief Investment Officer of Tower 1 Partnership, LLC, an investment firm focused on private and public investments in a variety of industries and manager of several affiliated investment partnerships. In 2018, Mr. Cavanaugh was Managing Director and Chief Financial Officer of Kaulig Companies, a single-member family office with interests in private equity, real estate and wealth management. From 2016 to 2018, Mr. Cavanaugh was Managing Director of Conway MacKenzie, a national turnaround consulting firm, where he established and managed the firm's Cleveland, Ohio office and provided interim management and restructuring services to distressed and underperforming businesses. From 2006 to 2009 and 2011 to 2015, Mr. Cavanaugh was an executive with Resilience Capital Partners, a private equity firm focused on special situation control equity investments, where he served in several capacities, including as a Partner and member of the firm's Investment Committee and as an officer and director of numerous portfolio companies. Mr. Cavanaugh received a B.A. from Columbia University in 1996, an M.B.A. from the University of Michigan Business School in 2003, and a J.D. from the University of Michigan Law School in 2003. The Board believes Mr. Cavanaugh's extensive executive management experience and financial, legal and capital raising expertise will be valuable to the Company as it continues to develop its business and grow its operations.

Richard McKilligan, Chief Financial Officer and Counsel, joined the Company in April 2012 as Controller, Counsel and Secretary. Mr. McKilligan is also a director of Bristol Investment Fund, Ltd, a private investment fund. He served as Chief Financial Officer, General Counsel and Secretary of Research Solutions, Inc. (NASDAQ: RSSS) from 2007 to 2011 and Chief Compliance Officer and Counsel to Bristol Capital Advisors, LLC, an SEC-registered investment adviser, from 2006 to 2008. Mr. McKilligan earned his law degree from Cornell Law School, his MBA from the University of Chicago Booth School of Business, and his undergraduate degree in Accountancy from the University of Illinois at Urbana-Champaign. He is a member of the State Bar of California, the New York State Bar Association and the Florida Bar.

Dr. Brandon Zipp, Chief Science Officer, joined the Company in December 2012 as Staff Scientist. Dr. Zipp became Director of Research and Development in 2014, and was appointed as Chief Science Officer in 2020. Dr. Zipp received a Ph.D. in Biochemistry and Molecular Biology and a B.S. in Molecular and Cellular Biology from the University of California at Davis.

Term of Office

In accordance with our Bylaws, our directors are elected at each annual meeting of stockholders and serve until the next annual meeting of stockholders or until their successor has been duly elected and qualified, or until their earlier death, resignation or removal.

Director Independence

The Nomination and Corporate Governance Committee reviews the independence of each director annually and makes recommendations to the Board based on its findings. During these reviews, the Nomination and Corporate Governance Committee will consider transactions and relationships between each director (and his or her immediate family and affiliates) and the Company and our management to determine whether any such transactions or relationships are inconsistent with a determination that the director was independent under the independence standards established by the Board from time to time and under the applicable rules of any applicable stock exchange, except to the extent permitted by such rules. The Nomination and Corporate Governance Committee has conducted its annual review of director independence, and in accordance with the recommendation of the Nomination and Corporate Governance Committee, the Board has determined that all of our directors are independent other than Mr. Cavanaugh, our Chief Executive Officer. Accordingly, our Board of Directors is comprised of a majority of independent directors.

Board and Committee Meetings

The Board of Directors held six meetings during fiscal 2021. The directors also, on occasion, communicate informally to discuss the affairs of the Company and, when appropriate, take formal action by written consent of all of the directors, in accordance with our Certificate of Incorporation, Bylaws and Nevada law. Our Board has three standing committees: the Audit Committee, the Compensation Committee and the Nomination and Corporate Governance Committee. Members of such committees met formally and informally from time to time throughout the fiscal year ended March 31, 2021 on committee matters, with the Audit Committee holding six meetings, the Compensation Committee holding no meetings, and the Nomination and Corporate Governance Committee holding no meetings. Each director attended, in person or by telephone, at least 75% of the meetings of the Board and any committee of which he or she was a member.

Attendance at Annual Meeting

Although the Company does not have a policy with respect to attendance by members of the Board of Directors at its annual meeting of stockholders, all directors are encouraged to attend. The Company did not hold a stockholders meeting last year.

Committees

General. The Board of Directors has three standing committees: an Audit Committee, a Compensation Committee, and a Nomination and Corporate Governance Committee.

Audit Committee. Mr. Celeste is currently the sole member of our Audit Committee. Our Board has determined that Mr. Celeste is independent within the meaning of applicable SEC rules and qualifies as an audit committee financial expert, as such term is defined in Item 407(d)(5)(ii) of SEC Regulation S-K. The Audit Committee has oversight responsibilities for, among other things: the preparation of our financial statements; oversight of our financial reporting and disclosure processes; the administration, maintenance and review of our system of internal controls regarding accounting compliance; the appointment of our independent registered public accounting firm and review of its qualifications and independence; the review of reports, written statements and letters from our independent registered public accounting firm; and our compliance with legal and regulatory requirements in connection with the foregoing.

Compensation Committee. The Compensation Committee currently consists of Messrs. Feighan and Celeste, with Mr. Feighan serving as Chairman. Our Board has determined that Messrs. Feighan and Celeste meet the definition of a “non-employee director” under Rule 16b-3 under the Securities Exchange Act of 1934, as amended, the requirements of Section 162(m) of the Internal Revenue Code for “outside directors.” The duties of our Compensation Committee include, without limitation: reviewing, approving and administering our compensation programs and arrangements to ensure that they are effective in attracting and retaining key employees and reinforcing business strategies and objectives; determining the objectives of our executive officer compensation programs and the specific objectives relating to CEO compensation, including evaluating the performance of the CEO in light of those objectives; approving the compensation of our other executive officers and our directors; review and recommend for approval by the Board the frequency with which the Company should submit to the stockholders an advisory vote on the compensation of the Company’s named executive officers, taking into account any prior stockholder advisory vote on the frequency with which the Company shall hold a stockholder advisory vote on compensation of the Company’s named executive officers; and administering our as-in-effect incentive-compensation and equity-based plans. In making its compensation decisions and recommendations (other than with respect to the compensation of our Chief Executive Officer), the Compensation Committee takes into account the recommendation of our Chief Executive Officer. Other than giving his recommendation, our Chief Executive Officer does not participate in the Compensation Committee’s decisions regarding his own compensation.

Nomination and Corporate Governance Committee. The Nomination and Corporate Governance Committee of our Board of Directors currently consists of Messrs. Feighan and Celeste, with Mr. Feighan serving as Chairman. The responsibilities of the Nomination and Corporate Governance Committee include, without limitation: assisting in the identification of nominees for election to our Board of Directors, consistent with approved qualifications and criteria; determining the composition of the Board of Directors and its committees; recommending to the Board of Directors the director nominees for the annual meeting of stockholders; establishing and monitoring a process of assessing the effectiveness of the Board of Directors; developing and overseeing a set of corporate governance guidelines and procedures; and overseeing the evaluation of our directors and executive officers. In considering potential new directors, the Committee may review individuals from various disciplines and backgrounds. Among the qualifications to be considered in the selection of candidates are broad experience in business, finance or administration; familiarity with the Company’s industry; and prominence and reputation. Our Board of Directors does not assign specific weights to particular criteria and no particular criterion is a prerequisite for each prospective nominee. Our Board of Directors does not have a policy with regard to the consideration of diversity in identifying director candidates, but our Board of Directors believes that the backgrounds and qualifications of its directors, considered as a whole, should provide a composite mix of experience, knowledge, and abilities that will allow our Board of Directors to fulfill its responsibilities. The Board does not currently use an independent search firm in identifying candidates for service on the Board.

Board Leadership Structure

Mr. Feighan serves as Chairman of the Board, a position he has held since November 2019. The Company has determined its current structure to be most effective as the Chairman serves as a liaison between its directors and management and helps to maintain communication and discussion among the Board and management, while allowing the CEO to focus on the execution of business strategy, growth and development. The Chairman serves in a presiding capacity at Board meetings and has such other duties as are determined by the Board from time to time.

The Board’s Role in Risk Oversight

Our Board oversees the Company’s risk management efforts by reviewing information provided by management in order to oversee risk identification, risk management, and risk mitigation strategies. Our Board committees assist the Board in overseeing our material risks by focusing on risks related to the particular area of concentration of that committee. For example, our Compensation Committee oversees risks related to our executive compensation plans and arrangements, our Audit Committee oversees the financial reporting, internal control and related-party transaction risks, and our Nomination and Corporate Governance Committee oversees risks associated with the business conduct of the Company. Each committee reports its discussions of the applicable relevant risks at such Board meetings as appropriate. The full Board of Directors incorporates the insight provided by these reports into its overall risk management analysis.

Communications with Directors

Stockholders may communicate their concerns directly to the entire Board of Directors or specifically to non-management directors. Such communication can be confidential or anonymous, if so designated, and may be submitted in writing to the following address:

Board of Directors
Vitality Biopharma, Inc.
c/o Richard McKilligan, Corporate Secretary
1901 Avenue of the Stars, 2nd Floor
Los Angeles, CA 90067

All communications received as described above will be opened by our Secretary for the sole purpose of determining whether the contents constitute a communication to our directors. Any contents that are not in the nature of advertising, promotions of a product or service, or patently offensive material will be forwarded promptly to the director or directors to whom it is addressed. In the case of communications to our Board of Directors or to any group of directors, our Secretary will make sufficient copies of the contents to send to each addressee.

Compensation Committee Interlocks and Insider Participation

In fiscal 2021, none of our executive officers or directors was a member of the board of directors of any other company where the relationship would be construed to constitute an interlocking relationship (as described in Item 407(e)(iii) of SEC Regulation S-K).

Code of Business Conduct and Ethics

The Company's Code of Business Conduct and Ethics applies to all of its employees, including its Chief Executive Officer and its Chief Financial Officer. The Code of Business Conduct and Ethics and all Committee charters are posted on the Company's website at <https://vitality.bio/investors/profile-copy/>.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who own more than 10% of a registered class of our equity securities (the "Reporting Persons") to file with the SEC reports on Forms 3, 4 and 5 concerning their ownership of and transactions in our common stock and other equity securities.

Based solely on a review of SEC filings and other procedures performed as deemed necessary, we believe that all Reporting Persons complied with these requirements during our fiscal year 2021.

Item 11. Executive Compensation

The following table summarizes all compensation recorded by us in each of the fiscal years ended March 31, 2021 and March 31, 2020 for (i) our current principal executive officer and principal financial officer, and (ii) our next most highly compensated executive officer other than our principal executive officer and principal financial officer serving as an executive officer at the end of our 2021 fiscal year and whose total compensation exceeded \$100,000 in our 2021 fiscal year.

Summary Compensation Table

| Name | Fiscal Year | Salary (\$) | Option Awards (non-cash) ⁽¹⁾ | Total (\$) |
|--|-------------|-------------|---|------------|
| Michael Cavanaugh, Chief Executive Officer ⁽²⁾ (principal executive officer) | 2021 | 256,000 | 113,489 | 369,489 |
| | 2020 | 211,000 | 106,344 | 317,344 |
| Richard McKilligan, Chief Financial Officer ⁽³⁾ (principal financial officer) | 2021 | 185,000 | 34,198 | 219,198 |
| | 2020 | 185,000 | 69,497 | 254,497 |
| Dr. Brandon Zipp, Chief Science Officer ⁽⁴⁾ .. | 2021 | 195,000 | 79,292 | 274,292 |

(1) The method used and the assumptions made to calculate the amortization included in this table are described in Footnote 5 of the financial statements and the accompanying notes for the years ended March 31, 2021 and 2020 appearing elsewhere in this Annual Report.

(2) Includes amortization of an option to purchase 500,000 shares of common stock with an exercise price of \$0.35 per share, granted in May 2019 and an option to purchase 250,000 shares of common stock with an exercise price of \$0.30 per share, granted in June 2019. Mr. Cavanaugh was appointed Chief Executive Officer in May 2019.

(3) Includes amortization of an option to purchase 370,234 shares of common stock with an exercise price of \$0.50 per share, granted in July 2016, an option to purchase 75,000 shares of common stock with an exercise price of \$1.81 per share, granted in December 2017, and an option to purchase 250,000 shares of common stock with an exercise price of \$0.30 per share, granted in June 2019.

- (4) Dr. Zipp first became an executive officer in the fiscal year ended March 31, 2021. Includes amortization of an option to purchase 370,234 shares of common stock with an exercise price of \$0.50 per share, granted in July 2016, an option to purchase 75,000 shares of common stock with an exercise price of \$1.81 per share, granted in December 2017, and an option to purchase 500,000 shares of common stock with an exercise price of \$0.35 per share, granted in May 2019.

Employment Agreements

Dr. Zipp and Mr. McKilligan entered into employment agreements with the Company, each dated September 24, 2020 (the “Zipp Employment Agreement” and the “McKilligan Employment Agreement”, respectively, and together, the “Employment Agreements”). The Employment Agreements have initial terms ending September 24, 2021.

Under the Zipp Employment Agreement, Dr. Zipp will receive an annualized base salary of \$180,000 and in the event of a change of control, which includes a sale of a majority of the equity of the Company or a sale of a majority of the Company’s assets (a “Change of Control”), the Company shall pay to Dr. Zipp a bonus equal to 2.5% of the net proceeds of such Change of Control on the ending date of the first payroll period following the Change of Control. Dr. Zipp is also entitled to severance payments equal to one year’s of his then-current base salary in the event of termination by the Company without cause or for good reason after a Change of Control. Such severance benefits will be reduced by any remuneration received by Dr. Zipp for other employment and payment is subject to the receipt of a release of claims in favor of the Company and its affiliates from Dr. Zipp.

Under the McKilligan Employment Agreement, Mr. McKilligan will receive an annualized base salary of \$180,000 and in the event of a Change of Control, the Company shall pay to Mr. McKilligan a bonus equal to 0.5% of the net proceeds of such Change of Control on the ending date of the first payroll period following the Change of Control. Mr. McKilligan is also entitled to severance payments equal to six months’ of his then-current salary in the event of termination by the Company without cause or for good reason after a Change of Control. Such severance benefits will be reduced by any remuneration received by Mr. McKilligan for other employment and payment is subject to the receipt of a release of claims in favor of the Company and its affiliates from Mr. McKilligan.

Outstanding Equity Awards at Fiscal Year-End

| | Option Awards | | | | |
|---|--|-------------|---------------|----------------------------|------------------------|
| | Number of securities underlying unexercised option | | | Option Exercise Price (\$) | Option Expiration Date |
| | Grant Date | Exercisable | Unexercisable | | |
| Michael Cavanaugh ⁽¹⁾ | 5/8/2019 | 500,000 | - | 0.35 | 5/8/2029 |
| | 6/27/2019 | 125,000 | 125,000 | 0.30 | 6/27/2029 |
| Richard McKilligan ⁽²⁾ | 8/6/2012 | 10,000 | - | 2.70 | 8/6/2022 |
| | 1/1/2015 | 20,000 | - | 3.40 | 1/1/2025 |
| | 5/21/2015 | 20,000 | - | 2.10 | 5/21/2025 |
| | 7/18/2016 | 370,234 | - | 0.50 | 7/18/2026 |
| | 12/27/2017 | 75,000 | - | 1.81 | 12/27/2027 |
| | 6/27/2019 | 125,000 | 125,000 | 0.30 | 6/27/2029 |
| Brandon Zipp ⁽³⁾ .. | 3/11/2013 | 2,500 | - | 4.20 | 3/11/2023 |
| | 3/12/2013 | 7,500 | - | 4.40 | 3/12/2023 |
| | 4/3/2014 | 15,000 | - | 4.20 | 4/3/2024 |
| | 1/1/2015 | 20,000 | - | 3.40 | 1/1/2025 |
| | 5/21/2015 | 20,000 | - | 2.10 | 5/21/2025 |
| | 7/18/2016 | 370,234 | - | 0.50 | 7/18/2026 |
| | 12/27/2017 | 75,000 | - | 1.81 | 12/27/2027 |
| | 5/8/2019 | 500,000 | - | 0.35 | 5/8/2029 |

- (1) Granted under the Company’s Equity Incentive Plan, the awards include an option to purchase 500,000 shares of common stock, 250,000 of which vested in May 2020 and 250,000 of which became fully exercisable on May 8, 2021, and an option to purchase 250,000 shares of common stock, 125,000 of which vested in June 2020 and 125,000 of which become fully exercisable on June 27, 2021.

- (2) Granted under the Company's Equity Incentive Plan, the awards include an option to purchase 10,000 shares of common stock, all of which were vested and fully exercisable as of January 1, 2015, an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of January 1, 2017, an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of May 21, 2017, an option to purchase 370,234 shares of common stock, all of which were vested and fully exercisable as of July 1, 2018, an option to purchase 75,000 shares of common stock, all of which were vested and fully exercisable as of December 27, 2019, and an option to purchase 250,000 shares of common stock, 125,000 of which vested in June 2020 and 125,000 of which become fully exercisable on June 27, 2021.
- (3) Granted under the Company's Equity Incentive Plan, the awards include an option to purchase 2,500 shares of common stock, all of which were vested and fully exercisable as of March 11, 2016, an option to purchase 7,500 shares of common stock, all of which were vested and fully exercisable as of March 21, 2016, an option to purchase 15,000 shares of common stock, all of which were vested and fully exercisable as of April 3, 2016, an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of January 1, 2017, an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of May 21, 2017, an option to purchase 370,234 shares of common stock, all of which were vested and fully exercisable as of July 1, 2018, an option to purchase 75,000 shares of common stock, all of which were vested and fully exercisable as of December 27, 2019, and an option to purchase 500,000 shares of common stock, 250,000 of which vested in May 2020, and 250,000 of which became fully exercisable on May 8, 2021.

Compensation of Directors

Directors receive a combination of cash and equity awards as compensation for their service. There are no additional fees paid for meetings attended although our directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our Board of Directors and committees.

Director Compensation Table

The following table shows compensation paid to our non-employee directors during the fiscal year ended March 31, 2021:

| <u>Name</u> | <u>Fees earned or paid in cash</u> | <u>Option awards (non-cash)⁽¹⁾</u> | <u>All other compensation</u> | <u>Total</u> |
|--------------------------------------|--|---|-----------------------------------|--------------|
| Richard Celeste ⁽¹⁾ | \$ 36,000 | \$ 79,292 | \$ - | \$ 115,292 |
| Edward Feighan ⁽¹⁾ | \$ 136,000 | \$ 113,489 | - | \$ 249,489 |

- (1) As of March 31, 2021, the aggregate number of stock and option awards held by each of our non-employee directors was as follows: (i) Mr. Celeste held an option award to purchase 500,000 shares of our common stock with an exercise price of \$0.35 per share, all of which are fully vested, and (ii) Mr. Feighan held an option award to purchase 500,000 shares of our common stock with an exercise price of \$0.35 per share, all of which are fully vested, and an option to purchase 250,000 shares of our common stock with an exercise price of \$0.30 per share, 125,000 of which vested in June 2020 and 125,000 of which become fully exercisable on June 27, 2021. The method used and the assumptions made to calculate the amortization are described in Footnote 5 of the financial statements and the accompanying notes for the years ended March 31, 2021 and 2020 appearing elsewhere in this Annual Report.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock by (i) each person who, to our knowledge, beneficially owns more than 5% of our common stock, (ii) each of our directors and named executive officers, and (iii) all of our current executive officers and directors as a group. Unless otherwise indicated in the footnotes to the following table, the address of each person named in the table is: c/o Vitality Biopharma, Inc., 1907 Avenue of the Stars, 2nd Floor, Los Angeles, California 90067. Shares of our common stock subject to options, warrants or other rights currently exercisable or exercisable within 60 days after May 18, 2021, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants, convertible notes or other rights, but are not deemed outstanding for computing the beneficial ownership percentage of any other person.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage Beneficially Owned ⁽¹⁾ |
|---|--|---|
| Directors and Named Executive Officers: | | |
| Edward Feighan ⁽²⁾ | 3,440,917 | 6.8 |
| Richard Celeste ⁽³⁾ | 500,000 | 1.0 |
| Michael Cavanaugh ⁽⁴⁾ | 1,629,791 | 3.2 |
| Richard McKilligan ⁽⁵⁾ | 745,234 | 1.4 |
| Dr. Brandon Zipp ⁽⁶⁾ | 1,074,234 | 2.1 |
| Current Directors and Executive Officers as a Group (5 persons) | 7,390,176 | 14.5 |
| Joseph LoConti ⁽⁷⁾ | 13,153,063 | 25.9 |

- (1) Based on 50,840,147 shares of our common stock issued and outstanding as of May 18, 2021. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.
- (2) Includes (i) 502,500 shares of the Company's common stock acquired in connection with a Securities Purchase Agreement dated October 19, 2018, (ii) 100,376 shares of the Company's common stock acquired in connection with a Share Exchange Agreement dated October 19, 2018, (iii) 1,402,813 shares of the Company's common stock acquired in connection with an amendment dated January 18, 2019 to the Securities Purchase Agreement dated October 19, 2018, and (iv) options to purchase 750,000 shares of common stock, 375,000 of which vested in May and June 2020, 250,000 of which vested on May 8, 2021, and 125,000 of which shall vest on June 27, 2021. Also includes (x) 167,500 shares of the Company's common stock acquired by The Feighan Family Fund, LLC (the "Feighan Fund"), an entity beneficially owned by Mr. Feighan in connection with a Securities Purchase Agreement dated October 19, 2018, (y) 50,124 shares of the Company's common stock acquired by the Feighan Fund in connection with a Share Exchange Agreement dated October 19, 2018, and (z) 467,604 shares of the Company's common stock acquired by the Feighan Fund in connection with an amendment dated January 18, 2019 to the Securities Purchase Agreement dated October 19, 2018.
- (3) Includes an option to purchase 500,000 shares of common stock, 250,000 of which vested in May 2020 and 250,000 of which vested on May 8, 2021.
- (4) Includes (i) 50,000 shares of the Company's common stock acquired in connection with a Securities Purchase Agreement dated October 19, 2018, (ii) 257,500 shares of the Company's common stock acquired in connection with a Share Exchange Agreement dated October 19, 2018, (iii) 572,291 shares of the Company's common stock acquired in connection with an amendment dated January 18, 2019 to the Securities Purchase Agreement dated October 19, 2018, and (iv) options to purchase 750,000 shares of common stock, 375,000 of which vested in May and June 2020, 250,000 of which vested on May 8, 2021, and 125,000 of which shall vest on June 27, 2021.
- (5) Includes (i) a grant of 10,000 shares of restricted common stock, which vested as of January 1, 2015, (ii) an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of January 1, 2017, (iii) an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of May 21, 2017, (iv) an option to purchase 370,234 shares of common stock, all of which were vested and fully exercisable as of July 1, 2018, (v) an option to purchase 75,000 shares of common stock, all of which were vested and fully exercisable as of December 27, 2019, and (vi) an option to purchase 250,000 shares of common stock, 125,000 of which vested in June 2020, and 125,000 of which shall vest on June 27, 2021.
- (6) Includes (i) 64,000 shares of common stock, of which 50,000 shares were purchased on the open market and 14,000 of which represent restricted stock awards and were vested and fully exercisable as of January 1, 2016, (ii) an option to purchase 2,500 shares of common stock, all of which were vested and fully exercisable as of March 11, 2016, (iii) an option to purchase 7,500 shares of common stock, all of which were vested and fully exercisable as of March 21, 2016, (iv) an option to purchase 15,000 shares of common stock, all of which were vested and fully exercisable as of April 3, 2016, (v) an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of January 1, 2017, (vi) an option to purchase 20,000 shares of common stock, all of which were vested and fully exercisable as of May 21, 2017, (vii) an option to purchase 370,234 shares of common stock, all of which were vested and fully exercisable as of July 1, 2018, (viii) an option to purchase 75,000 shares of common stock, all of which were vested and fully exercisable as of December 27, 2019, and (xi) an option to purchase 500,000 shares of common stock, 250,000 of which vested in May 2020, and 250,000 of which vested on May 8, 2021.
- (7) This information is based solely on Amendment No. 2 to Schedule 13D filed on April 2, 2019. Joseph LoConti has reported the sole power to vote and dispose of 7,022,584 shares of the Company's common stock and the shared power to vote and dispose of 6,130,479 shares of the Company's common stock. Mr. LoConti's address is 200 Park Avenue, Suite 400, Orange Village, Ohio 44122.

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

Transactions with Related Persons

On April 23, 2012, we entered into a lease agreement with One World Ranches LLC pursuant to which we leased from One World Ranches LLC, an entity jointly owned by Dr. Avtar Dhillon, the former Chairman of our Board of Directors and his wife, Diljit Banins, certain office and laboratory space located in Yuba City, California. Our rent payments thereunder were \$2,300 per month until May 1, 2017 and increased to \$2,600 per month on May 1, 2017. That lease agreement terminated on May 1, 2020.

On May 8, 2019, the Company and Mr. Robert Brooke, the former Chief Executive Officer of the Company, entered into a separation agreement and release on May 8, 2019 (the “Separation Agreement”). Pursuant to the Separation Agreement, Mr. Brooke received a severance payment equal to six-months’ salary, payable in six equal monthly installments of \$18,750, reimbursement of COBRA payments for up to 12 months, and agreed to release any and all claims against the Company and its affiliates.

Except as described above, during the fiscal years ended March 31, 2021 and 2020, and through the filing of this Annual Report, there have been no transactions, and there are no currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of \$120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years and in which any related person had or will have a direct or indirect material interest.

Director Independence

Our Board of Directors has determined that Messrs. Feighan and Celeste would qualify as “independent” as that term is defined by Nasdaq Listing Rule 5605(a)(2). Mr. Cavanaugh would not qualify as “independent” because he currently serves as our Chief Executive Officer.

Item 14. Principal Accounting Fees and Services

Independent Registered Public Accounting Firm’s Fee Summary

The following table provides information regarding the fees billed to us by Weinberg & Company, P.A., our independent registered public accounting firm, for services rendered in the fiscal years ended March 31, 2021 and 2020. All fees described below were approved by our Board of Directors:

| | For the years ended March 31, | |
|--------------------------|-------------------------------|------------|
| | 2021 | 2020 |
| Audit Fees | \$ 83,227 | \$ 86,716 |
| Audit-Related Fees | - | - |
| Tax Fees | 34,849 | 23,831 |
| All Other Fees | - | - |
| Total Fees | \$ 118,076 | \$ 110,547 |

Audit Fees. The fees identified under this caption were for professional services rendered by Weinberg & Company, P.A. for the audit of our annual financial statements. The fees identified under this caption also include fees for professional services rendered by Weinberg & Company, P.A. for the review of the financial statements included in our quarterly reports on Forms 10-Q. In addition, the amounts include fees for services that are normally provided by the auditor in connection with regulatory filings and engagements for the years identified.

Audit-Related Fees. The fees identified under this caption consist of assurance and related services reasonably related to the performance of the audit or review of financial statements and not reported under the caption “*Audit Fees*”.

Tax Fees. Tax fees consist principally of assistance related to tax compliance and reporting.

All Other Fees. These fees consist primarily of accounting consultation fees related to potential collaborative agreements. We incurred no such fees in during the fiscal years ended March 31, 2021 or 2020.

Pre-Approval Policies and Procedures

Our Audit Committee’s charter requires our Audit Committee to pre-approve all audit and permissible non-audit services to be performed for the Company by our independent registered public accounting firm, giving effect to the “de minimis” exception for ratification of certain non-audit services allowed by the applicable rules of the SEC, in order to assure that the provision of such services does not impair the auditor’s independence. Since the establishment of our Audit Committee on August 24, 2012, the Audit Committee approved in advance all services provided by our independent registered public accounting firm. All engagements of our independent registered public accounting firm for 2012 entered into prior to the establishment of the Audit Committee were pre-approved by the Board of Directors.

PART IV

Item 15. Exhibits, Financial Statement Schedules

- (a) (1) The financial statements filed as a part of this Annual Report are as follows:

| | |
|---|-----|
| Report of Independent Registered Public Accounting Firm..... | F-2 |
| Consolidated Balance Sheets as of March 31, 2021 and 2020 | F-4 |
| Consolidated Statements of Operations for the years ended March 31, 2021 and 2020 | F-5 |
| Consolidated Statements of Stockholders' Equity for the years ended March 31, 2021 and 2020 | F-6 |
| Consolidated Statements of Cash Flows for the years ended March 31, 2021 and 2020 | F-7 |
| Notes to Consolidated Financial Statements | F-8 |

- (2) Schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.
- (3) The exhibits filed with this Annual Report are set forth in the Exhibit Index included at the end of this Annual Report, which is incorporated herein by reference.

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.

VITALITY BIOPHARMA, INC.

Date: May 19, 2021

By: /s/ Michael Cavanaugh

Michael Cavanaugh
Chief Executive Officer
(Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael Cavanaugh as his or her true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

| SIGNATURE | TITLE | DATE |
|---|---|--------------|
| <u>/s/ Michael Cavanaugh</u> Michael Cavanaugh | Chief Executive Officer and Director (Principal Executive Officer) | May 19, 2021 |
| <u>/s/ Edward Feighan</u> Edward Feighan | Director | May 19, 2021 |
| <u>/s/ Richard Celeste</u> Richard Celeste | Director | May 19, 2021 |

EXHIBIT INDEX

| | |
|----------|---|
| 2.1 | Agreement and Plan of Merger, dated September 14, 2011, by and between Stevia First Corp. and Legend Mining Inc. (Incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the SEC on October 14, 2011.) |
| 3.1.1 | Articles of Incorporation of Stevia First Corp. (Incorporated by reference to Exhibit 3.1 to the registrant's Registration Statement on Form S-1 filed with the SEC on August 6, 2008 (File No. 333-152830).) |
| 3.1.2 | Certificate of Amendment of Articles of Incorporation of Vitality Biopharma, Inc. (Incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the SEC on July 19, 2016.) |
| 3.2.1 | Bylaws of Stevia First Corp. (Incorporated by reference to Exhibit 3.2 to the registrant's Registration Statement on Form S-1 filed with the SEC on August 6, 2008 (File No. 333-152830).) |
| 3.2.2 | Certificate of Amendment of Bylaws of Stevia First Corp. (Incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the SEC on February 7, 2012.) |
| 10.1# | Stevia First Corp. 2012 Stock Incentive Plan (Incorporated by reference to Annex A of to the registrant's Proxy Statement on Schedule 14A filed with the SEC on June 24, 2016.) |
| 10.2 | Securities Purchase Agreement, dated October 19, 2018 by and among Vitality Biopharma, Inc., and the Purchasers listed on the signature pages thereto (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on October 23, 2018.) |
| 10.3 | Securities Exchange Agreement, dated October 19, 2018 by and among Vitality Biopharma, Inc., and the Shareholders listed on the signature pages thereto (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the SEC on October 23, 2018.) |
| 10.4 | Amendment to Securities Purchase Agreement, dated as of January 18, 2019 by and among Vitality Biopharma, Inc. and the Investors listed on the signature pages thereto (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on January 22, 2019.) |
| 10.5 | Separation Agreement and Release, dated May 8, 2019, by and between the registrant and Robert Brooke. (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on May 14, 2019.) |
| 10.6# | Third Amendment to Vitality Biopharma, Inc. 2012 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the SEC on May 14, 2019.) |
| 10.7# | Employment Agreement between the Company and Dr. Brandon Zipp, dated September 24, 2020 (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on September 25, 2020.) |
| 10.8# | Employment Agreement between the Company and Richard McKilligan, dated September 24, 2020 (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the SEC on September 25, 2020.) |
| 23.1* | Consent of Weinberg & Company, P.A. |
| 23.3* | Power of Attorney (included on the signature page to this Annual Report.) |
| 31.1* | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934 |
| 31.2* | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934 |
| 32.1* | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2* | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |
| * | Filed herewith |
| # | Management contract or compensatory plan or arrangement. |

Financial Statements

| | <u>Page</u> |
|--|-------------|
| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Balance Sheets as of March 31, 2021 and 2020..... | F-4 |
| Consolidated Statements of Operations for the years ended March 31, 2021 and 2020 | F-5 |
| Consolidated Statements of Stockholders' Equity for the years ended March 31, 2021 and 2020..... | F-6 |
| Consolidated Statements of Cash Flows for the years ended March 31, 2021 and 2020..... | F-7 |
| Notes to Consolidated Financial Statements..... | F-8 |

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Vitality Biopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vitality Biopharma, Inc. (the “Company”) as of March 31, 2021 and 2020, the related consolidated statements of operations, stockholders’ equity, and cash flows for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations 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 1. 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 financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the 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 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 financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Gain on extinguishment of liabilities

As described in Note 2 to the consolidated financial statements, the Company recorded a gain on the extinguishment of liabilities of \$1,456,574 during the year ended March 31, 2021, including a gain on settlement with a vendor of \$1,062,405, and a gain on extinguishment of an advance of \$296,653 that was time barred by the statute of limitations.

We identified management’s evaluation of the Company’s settlement with vendor and extinguishment of the advance as a critical audit matter as these were unusual and significant transactions that required a high degree of auditor judgement and audit effort.

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

- We read the terms of the settlement agreement.
- We evaluated the reasonableness of management's assessment that the outstanding advance was time barred by the statute of limitations.
- We evaluated the Company's accounting analysis in determining applicable accounting treatment.
- We performed inquiries of management and of outside legal counsel.

We have served as the Company's auditor since 2012.

/s/ Weinberg & Company, P.A.
Los Angeles, California
May 19, 2021

VITALITY BIOPHARMA, INC.
CONSOLIDATED BALANCE SHEETS

| | <u>March 31, 2021</u> | <u>March 31, 2020</u> |
|---|------------------------------|------------------------------|
| <u>Assets</u> | | |
| <u>Current Assets</u> | | |
| Cash and cash equivalents | \$ 884,137 | \$ 2,392,225 |
| Prepaid expenses..... | 3,195 | 15,666 |
| Total current assets | <u>887,332</u> | <u>2,407,891</u> |
| Deposits | 9,502 | 35,752 |
| Operating lease right-of-use asset..... | <u>-</u> | <u>123,606</u> |
| Total Assets | <u>\$ 896,834</u> | <u>\$ 2,567,249</u> |
| <u>Liabilities and Stockholders' Equity</u> | | |
| <u>Current Liabilities</u> | | |
| Accounts payable and accrued liabilities | \$ 33,440 | \$ 862,528 |
| Advance | - | 296,653 |
| Operating lease liability, short-term | <u>-</u> | <u>125,679</u> |
| Total liabilities | <u>33,440</u> | <u>1,284,860</u> |
| Commitments and contingencies | | |
| <u>Stockholders' Equity</u> | | |
| Common stock, par value \$0.001 per share; 1,000,000,000 shares authorized; 50,840,147 shares issued and outstanding, respectively | 50,640 | 50,640 |
| Additional paid-in-capital | 48,240,463 | 47,778,607 |
| Accumulated deficit | <u>(47,427,709)</u> | <u>(46,546,858)</u> |
| Total stockholders' equity | <u>863,394</u> | <u>1,282,389</u> |
| Total Liabilities and Stockholders' Equity | <u>\$ 896,834</u> | <u>\$ 2,567,249</u> |

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

VITALITY BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

| | Years Ended March 31, | |
|--|------------------------------|-----------------------|
| | 2021 | 2020 |
| Revenues..... | \$ - | \$ - |
| Operating Expenses: | | |
| General and administrative | 1,929,308 | 2,680,217 |
| Research and development | 408,905 | 1,009,894 |
| Rent - related party | - | 2,600 |
| Total operating expenses | <u>2,338,213</u> | <u>3,692,711</u> |
| Loss from operations | <u>(2,338,213)</u> | <u>(3,692,711)</u> |
| Other income | | |
| Gain on extinguishment of liabilities | 1,456,574 | - |
| Change in fair value of derivative liability | - | 35,710 |
| Other income | 788 | 24,772 |
| Total other income | <u>1,457,362</u> | <u>60,482</u> |
| Loss from continuing operations | (880,851) | (3,632,229) |
| Loss from discontinued operations | <u>-</u> | <u>(733,126)</u> |
| Net loss | <u>\$ (880,851)</u> | <u>\$ (4,365,355)</u> |
| Net loss per share from continuing operations - basic and diluted | \$ (0.02) | \$ (0.07) |
| Net loss per share from discontinued operations - basic and diluted | <u>-</u> | <u>(0.01)</u> |
| Net loss per share - basic and diluted..... | <u>\$ (0.02)</u> | <u>\$ (0.08)</u> |
| Weighted average number of common shares outstanding - basic and diluted . | <u>50,840,147</u> | <u>51,541,377</u> |

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

VITALITY BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED MARCH 31, 2021 and 2020

| | Common Stock | | Additional Paid-in- | Accumulated | |
|--|---------------------|------------------|--------------------------------|------------------------|-------------------|
| | Shares | Amount | Capital | Deficit | Total |
| Balance, March 31, 2019 | 52,290,147 | \$ 52,090 | \$47,150,489 | \$ (42,181,503) | \$ 5,021,076 |
| Cancellation of shares | (1,450,000) | (1,450) | 1,450 | - | - |
| Fair value of vested stock options | - | - | 626,668 | - | 626,668 |
| Net Loss | - | - | - | (4,365,355) | (4,365,355) |
| Balance, March 31, 2020 | 50,840,147 | 50,640 | 47,778,607 | (46,546,858) | 1,282,389 |
| Fair value of vested stock options | - | - | 461,856 | - | 461,856 |
| Net Loss | - | - | - | (880,851) | (880,851) |
| Balance, March 31, 2021 | <u>50,840,147</u> | <u>\$ 50,640</u> | <u>\$48,240,463</u> | <u>\$ (47,427,709)</u> | <u>\$ 863,394</u> |

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

VITALITY BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Years Ended March 31, | |
|---|------------------------------|----------------|
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Net loss | \$ (880,851) | \$ (4,365,355) |
| Less: Loss from discontinued operations | - | 733,126 |
| Loss from continuing operations | (880,851) | (3,632,229) |
| Adjustments to reconcile loss from continuing operations to net cash used in operating activities: | | |
| Fair value of vested stock options | 461,856 | 626,668 |
| Operating lease expense | 123,606 | 129,781 |
| Change in fair value of derivative liability | - | (35,710) |
| Gain on extinguishment of liabilities, net of cash received of \$450,000 | (1,006,574) | - |
| Accrual of interest added to note payable | 528 | - |
| Changes in operating assets and liabilities: | | |
| Prepaid expense and other current assets | 12,471 | (12,366) |
| Deposits | 26,250 | (13,090) |
| Accounts payable and accrued liabilities | (216,683) | 221,563 |
| Accounts payable – related party | - | (5,200) |
| Operating lease liability | (125,679) | (127,708) |
| Net cash used in operating activities – continuing operations | (1,605,076) | (2,848,291) |
| Net cash used in operating activities – discontinued operations | - | (742,225) |
| Net cash used in operating activities | (1,605,076) | (3,590,516) |
| Cash provided by financing activities: | | |
| Proceeds from PPP loan | 96,988 | - |
| Net cash provided by financing activities – continuing operations | 96,988 | - |
| Net increase (decrease) in cash and cash equivalents | (1,508,088) | (3,590,516) |
| Cash and cash equivalents - beginning of period | 2,392,225 | 5,982,741 |
| Cash and cash equivalents - end of period | \$ 884,137 | \$ 2,392,225 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid during the period for: | | |
| Income taxes | \$ 800 | \$ 800 |
| Supplemental non-cash investing and financing activities: | | |
| Initial recognition of operating lease right-of-use assets and operating lease obligations upon adoption of new lease accounting standard | \$ - | \$ 253,387 |
| Cancellation of shares | - | 1,450 |

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

VITALITY BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE
FISCAL YEARS ENDED MARCH 31, 2021 AND 2020

1. BUSINESS OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Vitality Biopharma, Inc. (the “Company”, “we”, “us” or “our”), was incorporated in the State of Nevada on June 29, 2007.

In 2015, the Company developed a new class of cannabinoids known as cannabosides, which were discovered through application of the Company’s proprietary enzymatic bioprocessing technologies. In 2016, the Company received approvals from the U.S. Drug Enforcement Administration (the “DEA”) and the State of California to initiate studies and manufacturing scale-up at its research and development facilities in order to develop cannabosides. Currently, we do not have any commercial products and have not yet generated any revenues from our cannabinoid prodrug pharmaceuticals.

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying financial statements, during the year ended March 31, 2021, the Company incurred a net loss of \$880,851 and used \$1,605,076 of cash in our operating activities. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued. The financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The ability to continue as a going concern is dependent on the Company attaining and maintaining profitable operations in the future and/or raising additional capital to meet its obligations and repay its liabilities arising from normal business operations when they come due. We estimate as of March 31, 2021, we will have sufficient funds to operate the business for the next eight months. Since our existing cash balances are estimated to be insufficient to fund our currently planned level of operations, we likely will need additional financing or other sources of capital to fund our planned future operations. Further, these estimates could differ if we encounter unanticipated difficulties, or if our estimates of the amount of cash necessary to operate our business prove to be wrong, and we use our available financial resources faster than we currently expect. No assurance can be given that any future financing or capital, if needed, will be available or, if available, that it will be on terms that are satisfactory to the Company.

We do not presently have, nor do we expect in the near future to have, significant revenue to fund our business from our operations, and will need to obtain most of our necessary funding from external sources in the near term. Since inception, the Company has experienced recurring operating losses and negative operating cash flows, and we have funded our operations primarily through equity and debt financings, and we expect to continue to rely on these sources of capital in the future. However, if we raise additional funds by issuing equity or convertible debt securities, our existing stockholders’ ownership will be diluted, and obtaining commercial loans would increase our liabilities and future cash commitments. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations.

COVID-19

The Company is subject to risks and uncertainties of the COVID-19 pandemic that could adversely impact our business, our liquidity and access to capital markets and our business development activities. The Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines.

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

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Vitality Healthtech, Inc., and have been prepared in accordance with accounting principles generally accepted in the United States of America. Intercompany balances and transactions have been eliminated in consolidation. The Company’s fiscal year end is March 31.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires 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 the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. The more significant estimates and assumptions by management include, among others, assumptions used in valuing assets acquired in business acquisitions, reserves for accounts receivable, assumptions used in valuing equity instruments issued for services, the valuation allowance for deferred tax assets, and accruals for potential liabilities. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of acquisition to be cash equivalents. From time to time, the Company's cash account balances exceed the balances covered by the Federal Deposit Insurance System. The Company has never suffered a loss due to such excess balances.

Financial Assets and Liabilities Measured at Fair Value

The Company follows the authoritative guidance issued by the Financial Accounting Standards Board ("FASB") for fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy was established, which prioritizes the inputs used in measuring fair value into three broad levels as follows:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.
- Level 3 Unobservable inputs based on the Company's assumptions.

The Company is required to use observable market data if such data is available without undue cost and effort.

The Company believes that because of their short maturity, the carrying amounts of cash, accounts payable and accrued liabilities approximate fair value.

As of March 31, 2021 and March 31, 2020, the Company's balance sheet includes no Level 2 liabilities. The following table sets forth a summary of the changes in the estimated fair value of our embedded derivative liabilities during the years ended March 31, 2021 and 2020:

| | Year ended March 31, 2021 | Year ended March 31, 2020 |
|--|--|--|
| Fair value at beginning of period | \$ - | \$ 35,710 |
| Net change in the fair value of derivative liabilities | - | (35,710) |
| Fair value at end of period | <u>\$ -</u> | <u>\$ -</u> |

Derivative Financial Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company uses a probability weighted average Black-Scholes-Merton Option Pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes. Under this method, deferred income tax assets and liabilities are recognized for the estimated tax consequences attributable to differences between the financial statement carrying values and their respective income tax basis (temporary differences). The effect on deferred income tax assets and liabilities of a change in tax rates is recognized as income (loss) in the period that includes the enactment date.

Leases

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

Stock-Based Compensation

The Company periodically issues stock options and restricted stock awards to employees and non-employees in non-capital raising transactions for services. The Company accounts for such grants issued and vesting based on ASC 718, Compensation-Stock Compensation whereby the value of the award is measured on the date of grant and recognized for employees as compensation expense on the straight-line basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services. The Company recognizes the fair value of stock-based compensation within its Statements of Operations with classification depending on the nature of the services rendered.

The fair value of the Company's stock options is estimated using the Black-Scholes-Merton Option Pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life of the stock options or restricted stock, and future dividends. Compensation expense is recorded based upon the value derived from the Black-Scholes-Merton Option Pricing model and based on actual experience. The assumptions used in the Black-Scholes-Merton Option Pricing model could materially affect compensation expense recorded in future periods.

Basic and Diluted Loss Per Share

Basic loss per share is computed by dividing the net loss applicable to common stockholders by the weighted average number of outstanding common shares during the period. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Diluted loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued. Shares of restricted stock are included in the diluted weighted average number of common shares outstanding from the date they are granted unless they are antidilutive. Diluted loss per share excludes all potential common shares if their effect is anti-dilutive. The following potentially dilutive shares were excluded from the shares used to calculate diluted earnings per share as their inclusion would be anti-dilutive:

| | March 31, | |
|----------------|------------------|------------------|
| | 2021 | 2020 |
| Options | 5,997,544 | 6,546,710 |
| Warrants | 146,668 | 1,135,003 |
| Total | <u>6,144,212</u> | <u>7,681,713</u> |

Patents and Patent Application Costs

Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Accordingly, patent costs are expensed as incurred.

Research and Development

Research and development costs consist primarily of fees paid to consultants and outside service providers, patent fees and costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates. Research and development costs are expensed as incurred.

Segments

The Company operates in one segment for the development of pharmaceuticals products. In accordance with the "Segment Reporting" Topic of the ASC, the Company's chief operating decision maker has been identified as the Chief Executive Officer, who reviews operating results to make decisions about allocating resources and assessing performance for the entire Company. Existing guidance, which is based on a management approach to segment reporting, establishes requirements to report selected segment information quarterly and to report annually entity-wide disclosures about products and services, major customers, and the countries in which the entity holds material assets and reports revenue. All material operating units qualify for aggregation under "Segment Reporting" due to their similar customer base and similarities in: economic characteristics; nature of products and services; and procurement, manufacturing, and distribution processes. Since the Company operates in one segment, all financial information required by "Segment Reporting" can be found in the accompanying financial statements.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires entities to use a forward-looking approach based on current expected credit losses to estimate credit losses on certain types of financial instruments, including trade receivables. This may result in the earlier recognition of allowances for losses. ASU 2016-13 is effective for the Company beginning April 1, 2023, and early adoption is permitted. The Company does not believe the potential impact of the new guidance and related codification improvements will be material to its financial position, results of operations and cash flows.

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

2. GAIN ON EXTINGUISHMENT OF LIABILITIES

| | Years Ended March 31, | |
|--|------------------------------|-------------|
| | 2021 | 2020 |
| Gain on settlement with vendor (a) | \$ 1,062,405 | \$ - |
| Gain on extinguishment of advance (b)..... | 296,653 | - |
| Gain on forgiveness of PPP Loan (c) | 97,516 | - |
| Gain on extinguishment of debt | <u>\$ 1,456,574</u> | <u>\$ -</u> |

(a) Gain on settlement with vendor

From 2016 to 2019, the Company recorded approximately \$1.1 million due to a vendor for services, of which \$612,405 had not been paid and was included in accounts payable at March 31, 2020 and through November 30, 2020. In December 2020, the Company reached a settlement with the vendor to forgive the \$612,405 of outstanding invoices, and in addition, the Company received a payment from the vendor of \$450,000. This resulted in a gain on settlement of \$1,062,405 during the year ended March 31, 2021.

(b) Gain on extinguishment of advance

In July 2018, the Company received a payment from a third party in the amount of \$296,653. Since the Company has not been able to confirm the nature of this payment, it had previously recorded this payment as an advance that was included in current liabilities. At March 31, 2021, the Company, after consultation with outside legal counsel, determined that any claim to recover that advance was time barred by the statute of limitations and the Company recorded relief of this liability and a gain from debt extinguishment of \$296,653 during the year ended March 31, 2021.

(c) Gain on forgiveness of PPP Loan

On May 6, 2020, the Company was granted a loan (the "PPP loan") from U.S. Bank for \$96,988 pursuant to the Paycheck Protection Program under the CARES Act. The PPP loan bore interest at 1% per annum with the first six months of interest deferred, and was unsecured and guaranteed by the Small Business Administration (the "SBA"). The Company used the entire PPP loan amount for qualifying expenses as described in the CARES Act, including qualifying payroll costs, qualifying group health care benefits, qualifying rent, and qualifying utilities. On November 21, 2020, we received notice that the SBA had reviewed the forgiveness application of our PPP loan and provided forgiveness of the entire principal of our PPP loan plus accrued interest of \$528, and we recognized a gain on extinguishment of the PPP loan of \$97,516 during the year ended March 31, 2021.

3. DISCONTINUED OPERATIONS

In October 2018, the Company acquired Summit Healthtech, Inc., now known as Vitality Healthtech, Inc. and its subsidiary The Control Center, Inc. (collectively, "Summit Healthtech"). In May 2019, the Company decided to close Summit Healthtech due to poor financial and operating performance. Summit Healthtech ceased all operations and closed on June 14, 2019. In addition to the clinical operations of Summit Healthtech, the Company was engaged in the business of selling research diagnostic testing kits (collectively referred to as the "Company's clinical and test kit operations").

In May 2019, the Company decided to close the Company's clinical and test kit operations. The Company's clinical and test kit operations meet the discontinued operations criteria and are reported as such in all periods presented on the accompanying consolidated financial statements. During the year ended March 31, 2020, costs to close the Company's clinical and test kit operations, primarily made up of severance and related benefits, totaled approximately \$165,000, and are included in loss from discontinued operations.

As part of the acquisition of Summit Healthtech, the Company issued 1,450,000 shares of common stock to Dr. Arif Karim, the former owner of The Control Center, Inc. Dr. Karim had entered into an employment agreement with Summit Healthtech, Inc. prior to the acquisition by the Company. On October 30, 2019, the Company reached a settlement with Dr. Karim, whereby the Company and Dr. Karim released all claims against each other, including any claims under the Executive Employment Agreement between Vitality Healthtech, Inc. and Dr. Karim dated October 12, 2018, and the Share Purchase Agreement by and among The Control Center, Inc., Dr. Karim and Vitality Healthtech, Inc. also dated October 12, 2018. In exchange for the releases, the Company paid Dr. Karim \$120,000, which is included in the costs to close the Company's clinical and test kit operations, and the 1,450,000 shares of the Company's common stock issued to Dr. Karim were cancelled with no adjustment to the purchase price recorded.

The following table presents the summarized components of loss from discontinued operations for the Company's clinical and test kit operations:

| | Years Ended March 31, | |
|---|------------------------------|---------------------|
| | 2021 | 2020 |
| Revenue..... | \$ - | \$ 44,698 |
| Cost of sales | - | 143,232 |
| Research and development..... | - | 4,361 |
| General and administrative..... | - | 630,231 |
| Impairment of goodwill and intangible assets..... | - | - |
| Loss from discontinued operations..... | <u>\$ -</u> | <u>\$ (733,126)</u> |

4. OPERATING LEASE

At March 31, 2020, the Company's wholly-owned subsidiary, The Control Center, Inc. ("TCC") had an operating lease agreement for its office space. The lease expired on February 28, 2021. Lease expense for the lease was recognized on a straight-line basis over the lease term. The lease did not contain any residual value guarantees or material restrictive covenants. The lease commenced in 2016 and upon the adoption of ASC 842 on April 1, 2019, an operating lease right-of-use asset and operating lease liability were recognized based on the present value of remaining lease payments over the remaining lease term. In addition, at March 31, 2020, TCC had a sublease agreement in place for the office space that also expired February 28, 2021. Sublease income was not significant during the years ended March 31, 2021 and 2020.

The components of lease expense and supplemental cash flow information related to leases for the period are as follows:

| | Year Ended March 31, 2021 | Year Ended March 31, 2020 |
|--|--|--|
| <u>Lease Cost</u> | | |
| Operating lease cost (included in general and administrative expenses in the accompanying statement of operations)..... | \$ 123,606 | \$ 137,600 |
| <u>Other Information</u> | | |
| Cash paid for amounts included in the measurement of lease liabilities for the years ended March 31, 2021 and 2020 | \$ 93,241 | \$ 136,095 |
| Weighted average remaining lease term – operating leases (in years)..... | - | 0.9 |
| Average discount rate – operating leases | 4.0% | 4.0% |

The supplemental balance sheet information related to leases for the period is as follows:

| | At March 31, 2020 |
|--|------------------------------|
| <u>Operating Leases</u> | |
| Long-term right-of-use asset | <u>\$ 123,606</u> |
| Short-term operating lease liability | \$ 125,679 |
| Long-term operating lease liability..... | - |
| Total operating lease liabilities..... | <u>\$ 125,679</u> |

Lease expenses were \$123,606 and \$153,999 during the years ended March 31, 2021 and March 31, 2020, respectively.

As of March 31, 2021, TCC owed unpaid lease payments under the lease totaling \$33,440, which are included in accounts payable and accrued liabilities on the accompanying consolidated balance sheet. TCC has had no assets, employees or operations since its closure in May 2019. The Company is a party to a guaranty that specifies that the Company has no further liability under the lease as of March 31, 2021, and therefore the Company does not intend to make these payments.

5. STOCK BASED COMPENSATION

Stock options issued during fiscal 2021

The Company granted no option awards during the year ended March 31, 2021.

Stock options issued during fiscal 2020

During the year ended March 31, 2020, the Company granted to directors and employees options to purchase an aggregate of 3,250,000 shares of the Company's common stock with exercise prices of between \$0.30 to \$0.35 per share, that expire ten years from the date of grant, and all have vesting periods of up to 24 months. The fair value of each option award was estimated on the date of grant using the Black-Scholes-Merton Option Pricing model based on the following assumptions: (i) volatility rate of 176.50%, (ii) discount rate of 1.73%, (iii) zero expected dividend yield, and (iv) expected life of 6 years, which is the average of the term of the options and their vesting periods. The total fair value of the option grants to employees at their grant dates was approximately \$1,026,000.

During the years ended March 31, 2021 and 2020, total stock-based compensation expense related to vested stock options was \$461,856 and \$626,668, respectively. At March 31, 2021, the remaining unamortized cost of the outstanding stock-based awards was approximately \$74,000 and will be amortized on a straight-line basis over a weighted average remaining vesting period of 2 years.

A summary of the Company's stock option activity during the fiscal years ended March 31, 2020 and 2021 is as follows:

| | Shares | Weighted Average Exercise Price |
|---|---------------|--|
| Balance outstanding at March 31, 2019 | 3,456,710 | \$ 1.40 |
| Granted..... | 3,250,000 | 0.34 |
| Exercised | - | - |
| Expired | - | - |
| Forfeited | (160,000) | 1.92 |
| Balance outstanding at March 31, 2020 | 6,546,710 | \$ 0.89 |
| Granted..... | - | - |
| Exercised | - | - |
| Expired | (32,500) | 2.17 |
| Forfeited | (516,666) | 1.42 |
| Balance outstanding at March 31, 2021 | 5,997,544 | \$ 0.91 |
| Balance exercisable at March 31, 2021 | 4,622,544 | \$ 1.42 |

At March 31, 2021, the 5,997,544 outstanding stock options had no intrinsic value.

A summary of the Company's stock options outstanding and exercisable as of March 31, 2021 is as follows:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Grant- date Stock Price |
|---|------------------------------|--|---|
| Options Outstanding, March 31, 2021 | 750,000 | \$ 0.30 | \$ 0.30 |
| | 2,000,000 | \$ 0.35 | \$ 0.35 |
| | 1,664,542 | \$ 0.50 | \$ 0.50 |
| | 128,000 | \$ 0.96 | \$ 0.96 |
| | 130,000 | \$ 1.00 | \$ 10.00 |
| | 500,834 | \$ 1.50 - 1.95 | \$ 1.50 - 1.95 |
| | 657,500 | \$ 2.00 - 2.79 | \$ 2.00 - 2.79 |
| | 123,334 | \$ 3.10 - 3.80 | \$ 3.10 - 3.80 |
| | 43,334 | \$ 4.00 - 4.70 | \$ 4.00 - 4.70 |
| | <u>5,997,544</u> | | |
| Options Exercisable, March 31, 2021 | 375,000 | \$ 0.30 | \$ 0.30 |
| | 1,000,000 | \$ 0.35 | \$ 0.35 |
| | 1,664,542 | \$ 0.50 | \$ 0.50 |
| | 128,000 | \$ 0.96 | \$ 0.96 |
| | 130,000 | \$ 1.00 | \$ 10.00 |
| | 500,834 | \$ 1.50 - 1.95 | \$ 1.50 - 1.95 |
| | 657,500 | \$ 2.00 - 2.79 | \$ 2.00 - 2.79 |
| | 123,334 | \$ 3.10 - 3.80 | \$ 3.10 - 3.80 |
| | 43,334 | \$ 4.00 - 4.70 | \$ 4.00 - 4.70 |
| | <u>4,622,544</u> | | |

6. WARRANTS

A summary of warrants to purchase common stock issued during the fiscal years ended March 31, 2020 and 2021 is as follows:

| | Shares | Weighted Average Exercise Price |
|---|----------------|--|
| Balance outstanding at March 31, 2019..... | 1,135,003 | \$ 2.19 |
| Granted | - | - |
| Exercised | - | - |
| Expired | - | - |
| Balance outstanding at March 31, 2020..... | 1,135,003 | \$ 2.19 |
| Granted | - | - |
| Exercised | - | - |
| Expired | (988,335) | 2.10 |
| Balance outstanding and exercisable at March 31, 2021 | <u>146,668</u> | <u>\$ 3.00</u> |

At March 31, 2021, the 146,668 outstanding stock warrants had no intrinsic value.

7. INCOME TAXES

The Company had no income tax expense for the years ended March 31, 2021 or 2020 due to its history of operating losses. The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

| | Years Ended March 31, | |
|---|------------------------------|-------------|
| | 2021 | 2020 |
| Federal statutory tax rate | (21)% | (21)% |
| State tax rate, net of federal benefit..... | (7)% | (7)% |
| Total federal and state tax rate..... | (28)% | (28)% |
| Valuation allowance | 28% | 28% |
| Effective tax rate..... | <u>-%</u> | <u>-%</u> |

Deferred tax assets and liabilities consist of the following:

| | March 31, | |
|--|--------------|--------------|
| | 2021 | 2020 |
| Net deferred tax assets: | | |
| Net operating loss carryforwards | \$ 5,531,000 | \$ 5,364,000 |
| Stock-based compensation | 3,200,000 | 3,071,000 |
| Research credits | 64,000 | 64,000 |
| Operating lease liability | - | 35,000 |
| Gross deferred tax assets | 8,795,000 | 8,534,000 |
| Less: valuation allowance | (7,687,000) | (7,658,000) |
| Total deferred tax assets | 1,108,000 | 876,000 |
| Deferred tax liabilities: | | |
| Derivative income | 1,108,000 | 841,000 |
| Operating lease right-of-use asset | - | 35,000 |
| Total deferred tax liabilities | 1,108,000 | 876,000 |
| Net deferred income tax assets (liabilities) | \$ - | \$ - |

The provisions of ASC Topic 740, *Accounting for Income Taxes*, require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. For the years ended March 31, 2021 and 2020, based on all available objective evidence, including the existence of cumulative losses, the Company determined that it was more likely than not that the net deferred tax assets were not fully realizable. Accordingly, the Company established a full valuation allowance against its net deferred tax assets. The Company intends to maintain a full valuation allowance on net deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. During the years ended March 31, 2021 and 2020, the valuation allowance increased by \$29,000 and \$1.0 million, respectively.

At March 31, 2021 and 2020, the Company had available Federal and state net operating loss carryforwards (“NOLs”) to reduce future taxable income. For Federal purposes, the amounts available were approximately \$20.8 million and \$19.7 million, respectively. For state purposes, approximately \$16.8 million and \$16.7 million was available at March 31, 2021 and 2020, respectively. The Federal carryforwards expire on various dates through 2041 and the state carryforwards expire through 2038. Due to restrictions imposed by Internal Revenue Code Section 382 regarding substantial changes in ownership of companies with loss carryforwards, the utilization of the Company’s NOLs may be limited as a result of changes in stock ownership. NOLs incurred subsequent to the latest change in control are not subject to the limitation.

The Company’s operations are based in California and it is subject to Federal and California state income tax. Tax years after 2016 are open to examination by United States and state tax authorities.

The Company adopted the provisions of ASC 740, which requires companies to determine whether it is “more likely than not” that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. ASC 740 also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions. As of March 31, 2021 and 2020, no liability for unrecognized tax benefits was required to be recorded or disclosed.

8. RELATED PARTY TRANSACTIONS

During the year ended March 31, 2020, the Company paid rent of \$2,600 to One World Ranches LLC, which is jointly-owned by Dr. Avtar Dhillon, the former Chairman of the Board of Directors of the Company, and his wife.

9. COMMITMENTS AND CONTINGENCIES

The Company received a letter in February 2021 from counsel for the Company’s previous director’s and officer’s insurance carrier (the “insurer”) demanding that the Company reimburse the insurer for sums advanced by the insurer to a former director of the Company as defense costs in connection with a claim purportedly arising under a previous directors and officers insurance policy. The Company believes it has no liability for this claim on the basis of, among other things, Nevada law, the Company’s governing documents and the language of the policy. Accordingly, as of March 31, 2021, no contingent liability has been recorded in the Company’s consolidated statements of financial condition for this matter.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333 -181048 and No. 333-192398) pertaining to the Stevia First Corp. 2012 Stock Incentive Plan, as amended, of our report dated May 19, 2021, with respect to the financial statements of Vitality Biopharma, Inc. as of March 31, 2021 and 2020, and for the years then ended (which report includes an explanatory paragraph relating to substantial doubt about Vitality Biopharma, Inc.'s ability to continue as a going concern) which appear in the Vitality Biopharma, Inc.'s Annual Report on Form 10-K for the year ended March 31, 2021 filed with the Securities and Exchange Commission on May 19, 2021. We also consent to the reference to our firm under the heading "Experts" in the Registration Statements.

/s/ Weinberg & Company P.A.

Los Angeles, California
May 19, 2021

CERTIFICATION

I, **Michael Cavanaugh**, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vitality Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 19, 2021

/s/ Michael Cavanaugh

By: **Michael Cavanaugh**

Title: Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, **Richard McKilligan**, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vitality Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 19, 2021

/s/ Richard McKilligan

By: **Richard McKilligan**

Title: Chief Financial Officer

(Principal Financial Officer)

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

The undersigned, Michael Cavanaugh, the Chief Executive Officer of Vitality Biopharma, Inc. (the “Company”), hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge, the Annual Report on Form 10-K for the period ended March 31, 2021, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of the Company.

/s/ Michael Cavanaugh

Chief Executive Officer

(Principal Executive Officer)

Date: May 19, 2021

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

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

The undersigned, Richard McKilligan, the Chief Financial Officer of Vitality Biopharma, Inc. (the “Company”), hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge, the Annual Report on Form 10-K for the period ended March 31, 2021, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of the Company.

/s/ Richard McKilligan

Chief Financial Officer

(Principal Financial Officer)

Date: May 19, 2021