FORM C-AR
ANNUAL REPORT

For the fiscal year ended December 31, 2021

Ei.Ventures, Inc.
(Exact name of issuer as specified in its charter)

Delaware	**84-1871358**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1215 South Kihei Road, #424 **Kihei, Hawaii**	**96753**
(Address of principal executive offices)	**(Zip Code)**

(808) 707-5078

Issuer's telephone number, including area code

Common Stock

(Title of each class of securities issued pursuant to Regulation CF)

In this Annual Report on Form C-AR (the "Annual Report"), the terms we", "us", "our", "Company" and "Ei.Ventures" refer to Ei.Ventures, Inc.

THIS REPORT MAY CONTAIN FORWARD-LOOKING STATEMENTS AND INFORMATION RELATING TO, AMONG OTHER THINGS, THE COMPANY, ITS BUSINESS PLAN AND STRATEGY, AND ITS INDUSTRY. THESE FORWARD-LOOKING STATEMENTS ARE BASED ON THE BELIEFS OF, ASSUMPTIONS MADE BY, AND INFORMATION CURRENTLY AVAILABLE TO THE COMPANY'S MANAGEMENT. WHEN USED IN THE ANNUAL REPORT, THE WORDS "ESTIMATE," "PROJECT," "BELIEVE," "ANTICIPATE," "INTEND," "EXPECT" AND SIMILAR EXPRESSIONS ARE INTENDED TO IDENTIFY FORWARD-LOOKING STATEMENTS, WHICH CONSTITUTE FORWARD LOOKING STATEMENTS. THESE STATEMENTS REFLECT MANAGEMENT'S CURRENT VIEWS WITH RESPECT TO FUTURE EVENTS AND ARE SUBJECT TO RISKS AND UNCERTAINTIES THAT COULD CAUSE THE COMPANY'S ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE CONTAINED IN THE FORWARD-LOOKING STATEMENTS. INVESTORS ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH SPEAK ONLY AS OF THE DATE ON WHICH THEY ARE MADE. THE COMPANY DOES NOT UNDERTAKE ANY OBLIGATION TO REVISE OR UPDATE THESE FORWARD-LOOKING STATEMENTS TO REFLECT EVENTS OR CIRCUMSTANCES AFTER SUCH DATE OR TO REFLECT THE OCCURRENCE OF UNANTICIPATED EVENTS.

The market data and certain other statistical information used throughout this Annual Report are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Annual Report, and we believe that these sources are reliable. We have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors. Some data are also based on our good faith estimates.

RISK FACTORS

The SEC requires the Company to identify risks that are specific to its business and its financial condition. The Company is still subject to all the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events, and technological developments (such as cyber-attacks and the ability to prevent such attacks). Additionally, early-stage companies are inherently riskier than more developed companies, and the risk of business failure and complete loss of your investment capital is present. You should consider general risks as well as specific risks when deciding whether to invest.

Risks Relating to Our Business and Strategy for Non-Psychoactive Nutritional Supplement Products

Our product offerings are new in an industry that is still quickly evolving.

Our Nutritional Supplements offering is a new offering developed in 2020. Despite the experience of our management team, the products being offered are new and have no track record from which to project future performance. Additionally, in light of indefinite changes to distribution outlets in light of the COVID-19 pandemic, changes in how goods are obtained, and restrictions on some gyms and recreation centers, there is no guarantee we can build our brand and name recognition as quickly as otherwise hoped.

We will face competition from other nutritional supplement companies and our operating results will suffer if we fail to compete effectively.

The nutritional supplement industry is intensely competitive and subject to rapid and significant technological change. We anticipate having competitors in the United States, Canada, Europe and other jurisdictions, including major multinational supplement companies and established supplement companies. There are numerous other companies operating in the nutritional supplement space, many of which have longer operating histories and far greater financial and personnel resources than we do. Known competitors in our space include Life Extension, LLC, Optimum Nutrition, Inc., Thorne Research, Inc., Garden of Life, LLC, Klaire Laboratories, Inc., Herb Farm, LLC, and Pure Encapsulations, LLC, along with many other companies and sellers on Amazon and other marketplaces. Many of these competitors may have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations.

We believe that our ability to successfully compete will depend on, among other things:

- the success of our research and development efforts to identify and develop strong nutritional supplements;
- our ability to commercialize and market any of our nutritional supplements;
- the price of our products;
- our ability to protect our intellectual property rights related to our products; and
- our ability to manufacture and sell commercial quantities of any nutritional supplements.

We have never been profitable. Currently, we have no products ready to sell, and to date we have not generated any revenue. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never generated revenue and have never been profitable. We have not yet begun manufacturing and selling any supplement products in the United States, Canada, or elsewhere. We have incurred net losses in each year since our inception.

We currently have no agreements with contract manufacturers for the production of nutritional supplements.

We do not currently intend to manufacture the nutritional supplements that we plan to sell. We currently have no agreements with contract manufacturers for the production of the nutritional supplements and the formulation of sufficient quantities of nutritional supplements.

Product safety and quality concerns, including concerns related to perceived quality of ingredients, could negatively affect the Company's business.

The Company's success with regard to nutritional supplements depends in large part on its ability to maintain consumer confidence in the safety and quality of all its products. The Company intends to develop rigorous product safety and quality standards. However, if products taken to market are or become contaminated or adulterated, the Company may be required to conduct costly product recalls and may become subject to product liability claims and negative publicity, which would cause its business to suffer. In addition, regulatory actions, activities by nongovernmental organizations and public debate and concerns about perceived negative safety and quality consequences of certain ingredients in our products may erode consumers' confidence in the safety and quality issues, whether or not justified, and could result in additional governmental regulations concerning the marketing and labeling of the Company's products, negative publicity, or actual or threatened legal actions, all of which could damage the reputation of the Company's products and may reduce demand for the Company's products.

Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving the Company's products and services and maintaining the integrity of the data that supports the safety and efficacy of our products.

Our future success with regard to supplements depends on our ability to maintain and continuously improve our quality management program. An inability to address a quality or safety issue in an effective and timely manner may

also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. In addition, a successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

We must correctly predict, identify, and interpret changes in consumer preferences and demand, offer new products to meet those changes, and respond to competitive innovation. Consumer preferences for our products change continually.

Our success depends on our ability to predict, identify, and interpret the tastes and habits of consumers and to offer products that appeal to consumer preferences. If we do not offer products that appeal to consumers, our sales and market share will decrease. We must distinguish between short-term fads, mid-term trends, and long-term changes in consumer preferences. If we do not accurately predict which shifts in consumer preferences will be long-term, or if we fail to introduce new and improved products to satisfy those preferences, our sales could decline. In addition, because of our anticipated varied customer base, we must offer an array of products that satisfy the broad spectrum of consumer preferences. If we fail to expand our product offerings successfully across product categories, or if we do not rapidly develop products in faster growing and more profitable categories, demand for our products could decrease, which could materially and adversely affect our product sales, financial condition, and results of operations. In addition, achieving growth depends on our successful development, introduction, and marketing of innovative new products and line extensions. Successful innovation depends on our ability to correctly anticipate customer and consumer acceptance, to obtain, protect and maintain necessary intellectual property rights, and to avoid infringing the intellectual property rights of others and failure to do so could compromise our competitive position and adversely impact our business.

One of the potential risks we face in the distribution of our products is liability resulting from counterfeit or tainted products infiltrating the supply chain.

Because we intend to source ingredients from various sources, we will rely on various suppliers and their quality control measures. While we intend to have procedures to maintain the highest quality levels in our products, we may be subject to faulty, spoiled or tainted ingredients or components in our products, which would negatively affect our products and our customers' experience with them and could decrease customer demand for our products. In addition, if there are serious illness or injury due to our products, there can be no assurance that the insurance coverage we plan to maintain is sufficient or will be available in adequate amounts or at a reasonable cost, or that indemnification agreements will provide us with adequate protection.

We are vulnerable to fluctuations in the price and supply of ingredients, packaging materials, and freight.

The prices of the ingredients, packaging materials, and freight are subject to fluctuations in price attributable to, among other things, changes in supply and demand of raw materials or other commodities. The sales prices to our customers will be a delivered price. Therefore, changes in our input costs could impact our gross margins. Our ability to pass along higher costs through price increases to our customers will be dependent upon competitive conditions and pricing methodologies employed in the various markets in which we intend to compete. To the extent competitors do not also increase their prices, customers and consumers may choose to purchase competing products or may shift purchases to lower-priced private label or other value offerings which may adversely affect our results of operations. We will use significant quantities of raw materials and food ingredients as well as packaging materials provided by third-party suppliers. We will also likely buy from a variety of producers and manufacturers, and alternate sources of supply are generally available. However, the supply and price are subject to market conditions and are influenced by other factors beyond our control. The occurrence of any of the foregoing could increase our costs and disrupt our operations.

Substantial disruption to production at our manufacturing and distribution facilities could occur.

A disruption in production at our third-party manufacturing facilities could have an adverse effect on our business. In addition, a disruption could occur at the facilities of our future suppliers or distributors. The disruption could occur for many reasons, including pandemic (such as the novel COVID-19 pandemic), fire, natural disasters, weather, water scarcity, manufacturing problems, disease, strikes, transportation or supply interruption, government

regulation, cybersecurity attacks or terrorism. Alternative facilities with sufficient capacity or capabilities may not be available, may cost substantially more or may take a significant time to start production, each of which could negatively affect our business and results of operations.

Future product recalls or safety concerns could adversely impact our results of operations.

We may be required to recall certain of our products should they be mislabeled, contaminated, spoiled, tampered with or damaged. We also may become involved in lawsuits and legal proceedings if it is alleged that the consumption or use of any of our products causes injury, illness, or death. A product recall or an adverse result in any such litigation could have an adverse effect on our business, depending on the costs of the recall, the destruction of product inventory, competitive reaction and consumer attitudes. Even if a product liability or consumer fraud claim is unsuccessful or without merit, the negative publicity surrounding such assertions regarding our products could adversely affect our reputation and brand image. We also could be adversely affected if consumers in our principal markets lose confidence in the safety and quality of our products.

The consolidation of retail customers could adversely affect us.

Retail customers, such as supermarkets, warehouse clubs, and supplements distributors in our major markets, may consolidate, resulting in fewer customers for our business. Consolidation also produces larger retail customers that may seek to leverage their position to improve their profitability by demanding improved efficiency, lower pricing, increased promotional programs, or specifically tailored products. In addition, larger retailers have the scale to develop supply chains that permit them to operate with reduced inventories or to develop and market their own white-label brands. Retail consolidation and increasing retailer power could adversely affect our product sales and results of operations. Retail consolidation also increases the risk that adverse changes in our customers' business operations or financial performance will have a corresponding material and adverse effect on us. For example, if our customers cannot access sufficient funds or financing, then they may delay, decrease, or cancel purchases of our products, or delay or fail to pay us for previous purchases, which could materially and adversely affect our product sales, financial condition, and operating results.

Evolving tax, environmental, food quality and safety or other regulations or failure to comply with existing licensing, labeling, trade, food quality and safety and other regulations and laws could have a material adverse effect on our consolidated financial condition.

Our activities or products related to nutritional supplements, both in and outside of the United States, are subject to regulation by various federal, state, provincial and local laws, regulations and government agencies, including the U.S. Food and Drug Administration ("FDA"), U.S. Federal Trade Commission, the U.S. Departments of Agriculture, Commerce and Labor, as well as similar and other authorities outside of the United States, International Accords and Treaties and others, including voluntary regulation by other bodies. These laws and regulations and interpretations thereof may change, sometimes dramatically, as a result of a variety of factors, including political, economic or social events. The manufacturing, marketing, and distribution of health supplements are subject to governmental regulation that control such matters as quality and safety, ingredients, advertising, product or production requirements, labeling, import or export of our products or ingredients, relations with distributors and retailers, health and safety, the environment, and restrictions on the use of government programs to purchase certain of our products. We are also regulated with respect to matters such as licensing requirements, trade and pricing practices, tax, anticorruption standards, advertising and claims, and environmental matters. The need to comply with new, evolving or revised tax, environmental, food quality and safety, labeling or other laws or regulations, or new, or changed interpretations or enforcement of existing laws or regulations, may have an adverse effect on our business and results of operations. Further, if we are found to be out of compliance with applicable laws and regulations in these areas, we could be subject to civil remedies, including fines, injunctions, termination of necessary licenses or permits, or recalls, as well as potential criminal sanctions, any of which could have an adverse effect on our business. Even if regulatory review does not result in these types of determinations, it could potentially create negative publicity or perceptions which could harm our business or reputation.

Significant additional labeling or warning requirements may inhibit sales of affected products.

Various jurisdictions may seek to adopt significant additional product labeling or warning requirements relating to the content or perceived adverse health consequences of our products. If these types of requirements become applicable to our products under current or future environmental or health laws or regulations, they may inhibit sales of such products.

Growth rates higher than planned or the introduction of new products requiring special ingredients could create higher demand for ingredients greater than we can source.

Although we believe that there are alternative sources available for our key ingredients, there can be no assurance that we would be able to acquire such ingredients from substitute sources on a timely or cost effective basis in the event that then-current suppliers could not adequately fulfill orders, which would adversely affect our business and results of operations.

We source certain packaging materials and other shipping materials from a number of third-party suppliers.

Although we believe that alternative suppliers are available, the loss of any of our future packaging material suppliers could adversely affect our results of operations and financial condition. Our inability to preserve the current economics of these agreements could expose us to significant cost increases in future years.

We will likely rely, in part, on our third-party co-manufacturers to maintain the quality of our products.

The failure or inability of these co-manufacturers to comply with the specifications and requirements of our products could result in product recall and could adversely affect our reputation. Third-party co-manufacturers will be required to maintain the quality of our products and to comply with our product specifications and requirements for certain certifications. Our third-party co-manufacturers will also be required to comply with all federal, state and local laws with respect to food safety. However, our third-party co-manufacturers may not continue to produce products that are consistent with our standards or that are in compliance with applicable laws, and we cannot guarantee that we will be able to identify instances in which our third-party co-manufacturer fails to comply with our standards or applicable laws. Any such failure, particularly if it is not identified by us, could harm our brand and reputation as well as our customer relationships. We would have these same issues with any new co-manufacturer, and they may be exacerbated due to the newness of the relationship. The failure of any manufacturer to produce products that conform to our standards could materially and adversely affect our reputation in the marketplace and result in product recalls, product liability claims and severe economic loss.

As a health supplement company, all of our products must be compliant with regulations issued by the FDA.

We must comply with various FDA rules and regulations, including those regarding product manufacturing, food safety, required testing and appropriate labeling of our products. It is possible that regulations by the FDA and its interpretation thereof may change over time. As such, there is a risk that our products could become non-compliant with the FDA's regulations and any such non-compliance could harm our business.

Certain of our raw material contracts will likely have minimum purchase commitments that could require us to continue to purchase raw materials even if our sales have declined.

We will likely be contractually obligated to purchase a certain amount of raw materials from our suppliers even if we do not have the customer demand to sustain such purchases. The purchase of raw materials, which we are not able to convert into finished products and sell to our customers would have a negative effect on our business and results of operations.

Our profitability may be negatively affected by inventory shrinkage.

We are subject to the risk of inventory loss and theft. We may experience significant inventory shrinkage and cannot be sure that incidences of inventory loss and theft will decrease in the future or that the measures we are taking will effectively reduce the problem of inventory shrinkage. Although some level of inventory shrinkage is an

unavoidable cost of doing business, if we were to experience higher rates of inventory shrinkage or incur increased security costs to combat inventory theft, our business and results of operations could be affected adversely.

Failure to execute our inventory management process could adversely affect our business.

We must also properly execute our inventory management strategies by appropriately allocating merchandise among our distributors, timely and efficiently distributing inventory to distributors, maintaining an appropriate mix and level of inventory at the distributors and effectively managing pricing and markdowns, and there is no assurance we will be able to do so. Failure to effectively execute our inventory management strategies could adversely affect our performance and our relationship with our customers.

We may not timely identify or effectively respond to consumer trends or preferences, whether involving physical retail, e-commerce retail or a combination of both retail offerings, which could negatively affect our relationship with our customers and the demand for our products and services.

It will be difficult to predict consistently and successfully the products our customers will demand. The success of our business depends in part on how accurately we predict consumer demand, availability of merchandise, the related impact on the demand for existing products and the competitive environment, whether for customers purchasing products at stores, through e-commerce businesses or through the combination of both potential retail offerings. A critical piece of identifying consumer preferences involves price transparency, assortment of products, customer experience and convenience. These factors are of primary importance to customers and they continue to increase in importance, particularly as a result of digital tools and social media available to consumers and the choices available to consumers for purchasing products online, at physical locations, or through a combination of both retail offerings. Failure to timely identify or effectively respond to changing consumer tastes, preferences (including the key factors described above) and spending patterns, whether for physical retail offerings, ecommerce offerings or through a combination of these retail offerings, could negatively affect our relationship with our customers and the demand for our products and services.

Our business and results of operations may be adversely affected if we are unable to maintain our customer experience or provide high quality customer service.

The success of our business largely depends on our ability to provide superior customer experience and high quality customer service, which in turn depends on a variety of factors, such as our ability to continue to provide a reliable and user-friendly website interface for our customers to browse and purchase our products, reliable and timely delivery of our products, and superior after sales services. Our sales may decrease if our website services are severely interrupted or otherwise fail to meet our customer requests. Should we or our third-party delivery companies fail to provide our product delivery and return services in a convenient or reliable manner, or if our customers are not satisfied with our product quality, our reputation and customer loyalty could be negatively affected. As a result, if we are unable to continue to maintain our customer experience and provide high quality customer service, we may not be able to retain existing customers or attract new customers, which could have an adverse effect on our business and results of operations.

Our advertising and marketing efforts may be costly and may not achieve desired results.

We will very likely incur substantial expense in connection with our advertising and marketing efforts. Although we intend to target our advertising and marketing efforts potential customers who we believe are likely to be in the market for the products we sell, we cannot assure you that our advertising and marketing efforts will achieve our desired results. In addition, we will periodically adjust our advertising expenditures in an effort to optimize the return on such expenditures. Any decrease in the level of our advertising expenditures, which may be made to optimize such return could adversely affect our sales.

We may be required to collect sales tax on our direct marketing operations.

With respect to the direct sales, sales or other similar taxes are collected primarily in states where we have a physical presence or personal property. However, various states or foreign countries may seek to impose sales tax collection obligations on out-of-state direct mail companies. A successful assertion by one or more states that we or one or

more of our subsidiaries should have collected or should be collecting sales taxes on the direct sale of our merchandise could have an adverse effect on our business.

Government regulation is evolving and unfavorable changes could harm our business.

We are subject to general business regulations and laws, as well as regulations and laws specifically governing the Internet, e-commerce, electronic devices, and other services. Existing and future laws and regulations may impede our growth. These regulations and laws may cover taxation, privacy, data protection, pricing, content, copyrights, distribution, mobile communications, electronic device certification, electronic waste, energy consumption, environmental regulation, electronic contracts and other communications, competition, consumer protection, web services, the provision of online payment services, information reporting requirements, unencumbered Internet access to our services, the design and operation of websites, the characteristics and quality of products and services, and the commercial operation of unmanned aircraft systems. It is not clear how existing laws governing issues such as property ownership, libel, and personal privacy apply to the Internet, e-commerce, digital content, and web services. Jurisdictions may regulate consumer-to-consumer online businesses, including certain aspects of our seller programs. Unfavorable regulations and laws could diminish the demand for our products and services and increase our cost of doing business.

Changes in federal, state or local laws and regulations could increase our expenses and adversely affect our results of operations.

Our business is subject to a wide array of laws and regulations. The current political environment, financial reform legislation, the current high level of government intervention and activism and regulatory reform may result in substantial new regulations and disclosure obligations and/or changes in the interpretation of existing laws and regulations, which may lead to additional compliance costs as well as the diversion of our management's time and attention from strategic initiatives. If we fail to comply with applicable laws and regulations, we could be subject to legal risk, including government enforcement action and class action civil litigation that could disrupt our operations and increase our costs of doing business. Changes in the regulatory environment regarding topics such as privacy and information security, product safety or environmental protection, including regulations in response to concerns regarding climate change, collective bargaining activities, minimum wage laws and health care mandates, among others, could also cause our compliance costs to increase and adversely affect our business and results of operations.

Failure to obtain new clients or renew client contracts on favorable terms could adversely affect results of operations.

We may face pricing pressure in obtaining and retaining our clients. Our clients may be able to seek price reductions from us when they renew a contract, when a contract is extended, or when the client's business has significant volume changes. On some occasions, this pricing pressure may result in lower revenue from a client than we had anticipated based on our previous agreement with that client. This reduction in revenue could result in an adverse effect on our business and results of operations. Further, failure to renew client contracts on favorable terms could have an adverse effect on our business.

Our business could be negatively impacted by cyber security threats, attacks and other disruptions.

Like others in our industry, we will face advanced and persistent attacks on our information infrastructure where we manage and store various proprietary information and sensitive/confidential data relating to our operations. These attacks may include sophisticated malware (viruses, worms, and other malicious software programs) and phishing emails that attack our products or otherwise exploit any security vulnerabilities. These intrusions sometimes may be zero-day malware that are difficult to identify because they are not included in the signature set of commercially available antivirus scanning programs. Experienced computer programmers and hackers may be able to penetrate our network security and misappropriate or compromise our confidential information or that of our customers or other third-parties, create system disruptions, or cause shutdowns. Additionally, sophisticated software and applications that we procure from third-parties may contain defects in design or manufacture, including "bugs" and other problems that could unexpectedly interfere with the operation of the information infrastructure. A disruption, infiltration or failure of our information infrastructure systems or any of our data centers as a result of software or hardware malfunctions, computer viruses, cyber attacks, employee theft or misuse, power disruptions, natural

disasters or accidents could cause breaches of data security, loss of critical data and performance delays, which in turn could adversely affect our business.

Risks Relating to Our Business and Strategy for Psychoactive Compounds

We may not succeed in developing viable drug candidates, which could result in the entire loss of your investment.

Although we have obtained the rights to a number of novel compositions containing psilocybin, none of them have been tested to evaluate their potential as a new drug product. Part of the use of proceeds of the Regulation A Offering (defined below) and the Regulation Crowdfunding Offering (together, the "Offerings") is to conduct pre-clinical research on one or more of our compositions in order to develop data necessary to file an Investigational New Drug ("IND") application in the United States and/or a clinical trial application ("CTA") in Canada. There is no assurance that the results of these studies will demonstrate that the compositions are viable new drug candidates. If our current compositions are not viable, our business could fail, resulting in the complete loss of your investment.

We will face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We anticipate having competitors in the United States, Canada, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. There are a number of other companies operating in the psilocybin space, many of which have longer operating histories and far greater financial and personnel resources than we do. Known competitors in our space include Champignon Brands Inc., Mind Medicine, Inc., Revive Therapeutics Ltd., COMPASS Pathways, Ltd, Field Trip Health, Inc., Cybin, Inc, and Eluesis, Ltd. Many of these competitors may have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing drugs. These companies may also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the drug candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or approval from the FDA, Health Canada ("HC"), or other regulatory authorities or discovering, developing and commercializing drugs for diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than the drug candidates that we are currently developing or that we may develop, which could render our products obsolete and/or noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- the success of our research and development efforts to identify and develop novel drug candidates;
- the speed at which we develop drug candidates;
- the results of our pre-clinical and clinical trials;
- our ability to recruit and enroll patients for clinical trials;
- the efficacy, safety and reliability of our drug candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals;
- our ability to commercialize and market any of our drug candidates that receive regulatory approval;
- the price of our products;

- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect our intellectual property rights related to our products;
- our ability to manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of our drug candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer, or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our drug candidates obsolete, less competitive or not economical.

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

We are subject to risks related to public health crises such as the COVID-19 pandemic. The COVID-19 pandemic originated in Wuhan, China, in December 2019 and has since spread to a large number of countries, including the United States and most European countries. The pandemic and policies and regulations implemented by governments in response to the pandemic, often directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical service and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The full extent to which COVID-19 will ultimately impact our business, preclinical trials and financial results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Global health concerns, such as the COVID-19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

In response to the COVID-19 pandemic, we took temporary precautionary measures intended to help minimize the risk of the virus to our employees, including closing our executive offices and temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, all of which could negatively affect our business. The extent of the impact of the COVID-19 pandemic on our preclinical studies or clinical trial operations, our supply chain and manufacturing and our office-based business operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of the COVID-19 pandemic, or the effectiveness of actions to contain and treat coronavirus.

The COVID-19 pandemic may also affect employees of third-party CROs located in affected geographies that we will rely upon to carry out our clinical trials. As COVID-19 continues to be present and spread around the globe, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as our clinical trial sites and staff supporting the conduct of our clinical trials, including our trained therapists, or absenteeism due to the COVID-19 pandemic that reduces site resources;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and

others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials;
- limitations in employee resources that would otherwise be focused on conducting our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from regulatory authorities to initiate our planned pre-clinical and clinical work;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA, the EMA, the MHRA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States or the EU or other relevant local geography.

Any negative impact the COVID-19 pandemic has on patient enrollment or treatment or the development of our investigational therapeutic candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our investigational psilocybin therapy and any future therapeutic candidates, if approved, increase our operating expenses, and have a material adverse effect on our financial results. The COVID-19 pandemic has also caused significant volatility in public equity markets and disruptions to the United States and global economies. This increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. Although we have begun to experience the impact of the COVID-19 pandemic on our business and operations, we cannot currently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial conditions. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this ‘‘Risk Factors’’ section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

We may utilize third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves.

Although we intend to acquire through third-party relationships with the drug testing laboratory capacity to conduct our own pre-clinical studies, we may outsource substantial portions of our research and development pre-clinical and clinical study operations and contemplated future small- and large-scale manufacturing to third-party service providers. Any agreements with third-party service providers and clinical research organizations (“CROs”) are expected to be on a study-by-study and project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier’s previously incurred costs. In addition, any CRO that we retain will be subject to the FDA’s, HC’s, and/or another country’s regulatory requirements, and we would not have control over compliance with these regulations by these providers. Consequently, if these providers were not to adhere to applicable governing practices and standards, the development, manufacturing and commercialization of our drug candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we intend to rely on third parties for some functions, our internal capacity to perform these functions will be limited to management oversight. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. It is possible that we could experience difficulties in the future with our third-party service providers. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. We have limited internal resources available to identify and monitor third-party service providers. To the extent we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected, and we may be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

A variety of risks associated with potential international business relationships could materially adversely affect our business.

We may enter into agreements with third parties in Canada or other countries for the development and commercialization of our drug candidates in international markets. International business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- potentially reduced protection for our licensed intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called "parallel importing," which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we increase the number of our ongoing drug development programs and our drug candidates, in the future, commence pre-clinical studies and clinical trials, we will need to increase our drug development, scientific and administrative headcount to manage these programs. In addition, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage pre-clinical and clinical programs effectively, which we anticipate being conducted at numerous sites; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the expertise of our CEO and key employees, and our ability to implement our business strategy successfully could be seriously harmed if we lose the services of our CEO or key employees. Replacing executive officers or key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel or consultants. Our failure to hire or retain key employees or consultants could materially harm our business.

In addition, we will continue to add scientific and medical advisors who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours

There were no arms-length negotiations for our license from Orthogonal Thinker, Inc., and the terms of the License may be more favorable to Orthogonal, and to our detriment, than had the negotiations been arms-length with third parties.

Orthogonal Thinker, Inc. retains significant rights under the License Agreement it has granted to us. The terms of this agreement we established without the benefit of arms-length negotiations. The terms of the agreement may be more favorable to Orthogonal and to our detriment than had the negotiations been arms-length with third parties. All rights to pursue a further application that claims priority to the provisional application, such as a US non-provisional patent application, an international patent application and/or a direct foreign patent application, remain with Orthogonal.

Our plan to acquire one or more drug testing laboratories will subject s to a number of acquisition-related risks.

We may seek to acquire one or more drug testing laboratories. Identification, acquisition and integration of acquisitions is a complex, time-consuming and costly process requiring the employment of additional personnel, including key management and accounting personnel. The acquisition and integration of integration of these businesses with our existing business may require significant financial resources that would otherwise be available for the ongoing development of our drug candidates. Unanticipated problems, delays, costs or liabilities may also be encountered in completion and integration of these acquisitions. Failure to successfully and fully integrate these businesses may have a material adverse effect on our business, financial condition, results of operations and cash flows. Our acquisition strategy will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- we may not be able to find acquisition candidates that meet our business plan;
- we may not be able to afford the acquisition of suitable acquisition candidates;
- there is no assurance that our due diligence review of an acquisition candidate will detect every material defect in its business and/or financial condition;

- we may not be able to negotiate acceptable acquisition terms;
- we have difficulty determining the value of an acquisition target and may pay too much;
- we have limited financial resources to devote to acquisitions;
- we intend to finance acquisitions with a portion of the proceeds from the Offerings;
- we have not entered into any binding agreement for acquisitions, and accordingly no potential acquisition candidates are described in this Annual Report;
- we will be confronted with consolidating technological and administrative functions of acquired businesses;
- we will be confronted with integrating internal controls and other corporate governance matters; and
- we will be confronted with the potential diversion of management's attention from other business concerns.

In addition, we may not realize all of the anticipated benefits from any acquisitions, such as earnings and cost savings, for various reasons, including difficulties integrating operations and personnel, higher and unexpected acquisition and operating costs, unknown liabilities and inaccurate reserve estimates.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data, all of which are vital to our operations and business strategy. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our computer systems and those of our future CROs and other third-party service providers are vulnerable to damage or disruption from hacking, computer viruses, software bugs, unauthorized access or disclosure, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. Unauthorized access, loss or dissemination could disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, and manage various general and administrative aspects of our business. To the extent that any such disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential, proprietary or personal information, we could incur liability, suffer reputational damage or poor financial performance or become the subject of regulatory actions by federal, state or non-US authorities, any of which could adversely affect our business.

Our future employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards, which could significantly harm our business.

We will be exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA, HC, and other regulators, provide accurate information to the FDA, HC, and other regulators, comply with health care fraud and abuse laws and regulations in the United States, Canada, and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Our board of directors plans to adopt a code of ethics and business conduct, but, even with such adoption, it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or

unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we successfully identify and create a candidate drug, we will face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a drug candidate and may have to limit its commercialization.

The use of drug candidates in clinical trials and the sale of any products for which marketing approval is obtained may cause exposure to the risk of product liability claims. Product liability claims may be brought against us or our potential future collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our drug candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our drug candidates.

Insurance policies may be expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not know if we will be able to obtain and maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which may adversely affect our financial position and results of operations.

Risks Relating to Our Financial Position

We have never been profitable. Currently, we have no products ready to submit for regulatory approval or approved for commercial sale, and to date we have not generated any revenue. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never generated revenue and have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet begun any pre-clinical studies or clinical trials or submitted any drug candidates for approval by regulatory authorities in the United States, Canada, or elsewhere. We have incurred net losses in each year since our inception, including net losses of $(666,974) for the year ended December 31, 2020 and $(8,821,619) for the year ended December 31, 2021. We had an accumulated deficit of $(9,488,593) as of December 31, 2021.

To date, we have devoted most of our financial resources to licensing our intellectual property and our corporate overhead. We have not generated any revenues. Since our operations will continue to be focused on research and development efforts for the near term, we expect to continue to incur losses for the foreseeable future, and we expect these losses to increase when we commence pre-clinical studies and clinical trials, seek regulatory approvals for any drug candidates, prepare for and begin the commercialization of any approved products and add infrastructure and personnel to support our drug development efforts and operations as a public company. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In

addition, our expenses could increase if we are required by the FDA, HC or other regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in commencing or completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We anticipate using the proceeds of the Offerings to fund the research and development aimed at identifying and creating prospective drug candidates and facilitating pre-clinical studies of the same. Developing drug products , including conducting research, pre-clinical studies and clinical trials, is expensive. We will require future capital in order to begin and complete the research, development and clinical and regulatory activities necessary to bring our drug candidates to market in the future.

In addition to funding research, development, pre-clinical and subsequent clinical development of any drug candidates, our financial resources will also be used for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our licensed patents to the extent required under our License Agreement. Accordingly, we will continue to require substantial additional capital to continue our research and development activities. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our drug candidates under development.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- whether there is early success in identifying and creating novel prospective drug candidates
- the progress, costs, results of and timing of our drug candidate trials for the treatment of MDD, and the future pre-clinical and clinical development of our drug candidates for other potential indications;
- the number and characteristics of drug candidates that we pursue;
- the ability of our drug candidates to progress through future pre-clinical and future clinical development successfully;
- our need to expand research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our drug candidates;
- the costs of acquiring, licensing or investing in businesses, products, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio rights, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Based on our current financial resources, our expected level of operating expenditures and the expected net proceeds of the Offerings, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. The expected net proceeds from the Offerings, together with our existing cash and cash equivalents, will not be sufficient for us to fund any drug candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of any drug candidates. We expect to

finance our cash needs primarily through equity offerings and potentially through debt financings, collaborations and development agreements.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares, if and when established, to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our drug development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us.

We have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a "development stage" biotechnology company with a limited operating history. Our activities to date have been limited to obtaining an exclusive license for our psilocybin compositions and beginning to develop our transdermal patch. Although we have identified psilocybin as a new drug candidate, we have not started pre-clinical studies or clinical trials or obtained regulatory approvals for any drug candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had an operating history or approved products on the market. Our financial condition and operating results may significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in pre-clinical studies of our drug candidates, including delays in the identification of target indications;
- unsatisfactory results of pre-clinical studies of our drug candidates;
- any delays in regulatory review and approval of any drug candidates, including our ability to receive approval from the FDA and HC for drug candidates, and our planned pre-clinical and clinical studies and other work, as the basis for review and approval of drug candidates;
- delays in the commencement, enrollment and timing of clinical trials;
- difficulties in identifying and treating patients suffering from target indications;
- the success of our future studies through all phases of pre-clinical and clinical development;
- potential side effects of our drug candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop drug candidates;
- our ability to identify and develop additional drug candidates;
- market acceptance of our drug candidates;
- our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to adhere to clinical study requirements directly or with third parties such as contract research organizations;
- our dependency on third-party manufacturers to manufacture our products and key ingredients;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- the costs to us, and our ability and our third-party collaborators' ability to obtain, maintain and protect our licensed intellectual property rights;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- potential product liability claims.

Accordingly, the results of any annual periods should not be relied upon as indications of future operating performance.

Our recurring losses from operations may raise doubt regarding our ability to continue as a going concern.

Because our continuing existence has been dependent upon raising capital to sustain our business, it raises doubt about our ability to continue as a going concern. Such a concern could materially limit our ability to raise additional funds through the issuance of new equity or debt securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Risks Relating to Controlled Substances

Our drug candidates contain controlled substances, the use of which may generate public controversy.

Since our drug candidates contain, or are derived from, 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 drug candidates. These pressures could also limit or restrict the introduction and marketing of one or more of our drug candidates. Adverse publicity from psilocybin misuse or adverse side effects from psilocybin products may adversely affect the commercial success or market penetration achievable by our drug candidates. 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.

The new drug candidates that we are developing are subject to U.S. and Canadian controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during pre-clinical and clinical development and post-approval, and our financial condition.

The drug candidates we plan to develop contain psilocybin, psilocin or other controlled substances as defined in the Controlled Substances Act of 1970 ("CSA") for the United States and in the Controlled Drugs and Substances Act ("CDSA") for Canada. Controlled substances are subject to a high degree of regulation under the CSA and CDSA, which establish, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export or other requirements administered by the Drug Enforcement Administration ("DEA") in the United States and by HC in Canada.

US Controlled Substances Requirements

In the United States, controlled substances are placed into one of five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, 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 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.

Psilocybin is currently classified as a Schedule I controlled substance, which is viewed as having a high potential for abuse and having no currently accepted medical use in treatment in the United States. No prescriptions may be written for Schedule I substances, and such substances are subject to production quotas imposed by the DEA.

The cities of Denver, Colorado, Oakland, California, and Santa Cruz, California have decriminalized psilocybin. However, these limited city/state laws are in conflict with the CSA, which makes psilocybin use and possession illegal at the federal level. Because psilocybin is a Schedule I controlled substance, the development of a legal psilocybin industry under the laws of these states is in conflict with the CSA, which makes psilocybin use and possession illegal on a national level. If psilocybin is treated like cannabis, the federal government has the right to

regulate and criminalize psilocybin, including for medical purposes, and that federal law criminalizing the use of psilocybin preempts state laws that legalize its use.

If and when our drug candidates receive FDA approval, we expect the finished dosage forms of our psilocybin-based drug candidates may be listed by the DEA as a Schedule II, III, IV, or V controlled substance for them to be prescribed for patients in the United States. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take one or more years beyond FDA approval, thereby delaying the launch of our drug products in the United States. However, the DEA is required to issue a temporary order scheduling the drug within 90 days after the FDA approves the drug and the DEA receives a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that any of our drug candidates may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of our drug products.

Facilities conducting research, manufacturing, distributing, importing or exporting or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the manufacturing, development, or distribution of our drug candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are distinct jurisdictions, they may separately schedule our drug candidates. 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 or clinical sites 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 and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

To conduct pre-clinical studies or clinical trials with our drug candidates in the United States prior to approval, each of our research sites may be required to obtain and maintain a DEA researcher registration that will allow those sites to obtain, handle and administer the drug candidate. If the DEA delays or denies the grant of a research registration to one or more research sites, the pre-clinical study or clinical trial could be significantly delayed, and we could lose pre-clinical study or clinical trial sites.

Manufacturing of our drug candidates is, and, if approved, our commercial products may be, subject to the DEA's annual manufacturing and procurement quota requirements, if classified as Schedule II. The annual quota allocated to us or our contract manufacturers for the controlled substances in our drug candidates may not be sufficient to meet commercial demand or complete pre-clinical studies or clinical trials. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our pre-clinical studies or clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations.

If, upon approval of any of our drug candidates, the product is scheduled as Schedule II or III, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the product to pharmacies and other health care providers. We are aware of research that suggests once psilocybin is approver for a medical use, it could be scheduled as Schedule IV. The failure to obtain, or delay in obtaining, or the loss any of those registrations could result in increased costs to us. 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, our products, if approved.

Canadian Controlled Drug Substances Requirements

In Canada, psilocybin is classified by HC as a Schedule III drug under the CDSA, meaning activities such as sale, possession, or production of these substances are prohibited unless they have been authorized for clinical trials or research purposes by HC, consistent with Part J of Canada's Food and Drug Regulations. Under Part J, a party may file a CTA to study psilocybin for a medicinal use. The compliance and monitoring of controlled drugs and substances in Canada is overseen by HC's Office of Controlled Substances, in conjunction with law enforcement agencies. The CDSA provides for the control of substances that can alter mental processes and that may produce harm to health and to society when diverted or misused. Except as authorized under its related regulations, or via an exemption issued under section 56 of the CDSA, most activities involving substances regulated under the CDSA, such as possession, import, export, and production are prohibited. Controlled substances are regulated and grouped into Schedules I to V to the CDSA. Schedule III is considered of less abuse potential than Schedule I.

HC administers the CDSA and its regulations to: (1) allow access for lawful purposes and (2) reduce the risk that controlled substances and precursors will be used for illegal purposes. To meet these two objectives, HC: (1) issues licenses, permits and exemptions, (2) monitors trends of problematic substance use, (3) updates the Schedules to the CDSA based on assessments of new or existing substances, when necessary, (4) works with international organizations and other countries to meet Canada's obligations regarding controlled substances. The CDSA applies to a broad range of parties, including: (1) manufacturers, distributors, importers and exporters who must obtain a license in order to produce, sell, import or export controlled substances and precursors, (2) importers and exporters who must obtain a permit each time they import and export a controlled substance or precursor, (3) health professionals who must comply with requirements when prescribing or administering controlled substances to a patient, and (4) researchers who must obtain permission to have a controlled substance for research purposes.

All regulated parties must comply with requirements for: (1) security, (2) reporting and (3) record-keeping. HC promotes and enforces compliance with the CSDA by: (1) developing and publishing guidance, (2) informing affected parties of any regulatory changes and (3) publishing notices seeking public input on proposed regulatory changes. HC also carries out inspections of regulated parties and monitors regulated activities. HC may take action when a regulated party is not following the rules of the CDSA, including (but are not limited to): (1) issuing warning letters, (2) requiring a corrective action plan and (3) suspending and revoking licenses, permits or exemptions to stop a regulated party from conducting activities. To further enforce the CDSA, HC works with a wide range of partners and stakeholders, including: (1) provincial and territorial governments, (2) other federal departments and agencies, (3) law enforcement agencies, (4) academic, scientific and research communities, (5) non-government organizations, such as national, provincial and territorial health professional associations, (6) federal regulators in other countries and (7) international organizations, such as the United Nations.

In Canada, mushroom spore kits and are legal and are sold openly in stores or on the Internet, as the spores and kits themselves are legal. Online dispensaries exist that openly sell micro doses to Canadian patients with medical prescriptions. The Canadian police tolerates the activity, citing focus on more harmful criminal drug activities. In September 2019, a motion to prevent the sale of psychoactive mushrooms was defeated by Vancouver council.

In addition to HC, the National Association of Pharmacy Regulatory Authorities ("NAPRA") also has a role in scheduling new drugs, which is separate from HC's scheduling process. NAPRA's role in the drug scheduling process occurs after HC has authorized a drug for sale in Canada and determined whether the drug requires a prescription for sale. NAPRA does not have any role or authority in the authorization of new health products for the Canadian market and does not review products that have been classified as requiring a prescription by HC.

While the federal government determines certain conditions of sale, such as the need for a prescription, provincial/territorial governments have the ability to further specify the conditions of sale of drug products. Prior to

1995, each province and territory had its own system for determining the conditions of sale for non-prescription drugs in Canada, leading to wide variability in the way drugs were sold across Canada. In 1995, NAPRA's members, the pharmacy regulatory authorities across Canada, endorsed a proposal for a national drug scheduling model, to align the provincial/territorial drug schedules so that the conditions of sale for drugs would be more consistent across Canada. This harmonized national model is administered by NAPRA and is called the National Drug Schedules (NDS) program.

All of the provinces and territories, except Quebec, have adopted the National Drug Schedules in some manner. The NDS come into force in each province/territory through provincial regulations. In general, the National Drug Schedules capture drugs that have been authorized for sale and classified as non-prescription by HC. Other products approved by HC (e.g. natural health products, medical devices) are outside the scope of the program and are not considered products for scheduling within the NDS.

The NDS program consists of three schedules and four categories of drugs. Schedule I drugs require a prescription for sale. Schedule II drugs require professional intervention from the pharmacist (e.g., patient assessment and patient consultation) prior to sale. Schedule III drugs must be sold in a licensed pharmacy but can be sold from the self-selection area of the pharmacy. Unscheduled drugs can be sold without professional supervision, from any retail outlet.

The drug scheduling process usually begins when NAPRA receives a drug scheduling submission from a pharmaceutical company. The National Drug Scheduling Advisory Committee is an expert advisory committee that reviews the drug scheduling submissions received by NAPRA and formulates drug scheduling recommendations. There is a specific process that must be followed during each drug scheduling review, which is outlined in NAPRA's By-law No. 2 and Rules of Procedures. The model for making drug scheduling recommendations embodies a "cascading principle" in which drugs are assessed against specific scheduling factors. A drug is first assessed using the factors for Schedule I. Should sufficient factors apply, the drug remains in that Schedule. If not, the drug is assessed against the Schedule II factors, and if warranted, subsequently against the Schedule III factors. Should the drug not meet the factors for any schedule, it becomes "Unscheduled" (the fourth category).

According to this cascading principle, it is possible, although rare, for NAPRA to place a product in Schedule I that HC has classified as a non-prescription product. This could occur because of the NAPRA policy for drugs not reviewed, which places drugs into Schedule I until they are reviewed, or because of a range of factors considered by the expert advisory committee when applying the cascading drug scheduling model. As described above, the provinces and territories can add additional conditions of sale for non-prescription drugs but can never be less restrictive than federal legislation.

Once the National Drug Scheduling Advisory Committee has reviewed a particular drug, it will make an interim drug scheduling recommendation. A 30-day consultation period follows, after which the NAPRA Board of Directors will make a final scheduling recommendation. The National Drug Schedules are then amended and the final recommendation is implemented according to the rules in each particular province or territory.

In summary, whereas in the U.S. psilocybin is presumed to have no medical use and is s Schedule I drug, in Canada, psilocybin is classified as a drug with a lower potential for abuse under Schedule III and is being studied in clinically-supervised settings for its potential to treat various conditions such as anxiety, depression, obsessive compulsive disorder and problematic drug use. Currently there are no approved therapeutic products containing psilocybin in Canada or the US. Once a psilocybin- psilocin-containing product were to be approved in Canada, we would expect it to remain Schedule III or a higher level (IV or V) and that NAPRA could schedule as I, requiring a prescription.

Risks Relating to Regulatory Review and Approval of our Drug Candidates

We cannot be certain that any of our new drug candidates will receive regulatory approval, and without regulatory approval we will not be able to market our new drug candidates.

Our business currently depends entirely on the successful development and commercialization of our new drug candidates. Our ability to generate revenue related to product sales, if ever, will depend on the successful

development and regulatory approval of our new drug candidates and our licensing of our new drug candidates, in one or more targeted indications. Drug candidates in development have a high risk of failure. We cannot predict when, or if, a drug candidate will prove effective or safe in humans or will receive regulatory approval.

We have no products currently ready for pre-clinical or clinical research or approved for sale and cannot guarantee that there will ever have marketable products. The development of a new drug candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States, HC in Canada and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our drug candidates in the United States or Canada until we receive approval of a new drug application ("NDA") from the FDA or a Notice of Compliance ("**NOC**") and Drug Identification Number ("DIN") associated with a New Drug Submission ("NDS") from HC, respectively. We have not submitted any applications for any of our new drug candidates.

NDAs and NDSs must include extensive pre-clinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs and NDSs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a NDA or a NDS is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the HC review processes can take years to complete and approval is never guaranteed. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the HC, have their own procedures for approval of drug candidates. Even if a product is approved, the FDA or the HC, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Canada also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a drug candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Canada, or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, pre-clinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our drug candidates or other products. Also, regulatory approval for any of our drug candidates may be withdrawn.

Before we submit an NDA to the FDA or an NDS to HC for any of our drug candidates, we must successfully complete pre-clinical studies and subsequent clinical trials. We cannot predict whether our future studies and trials will be successful or whether regulators will agree with our conclusions regarding our pre-clinical studies or clinical trials.

If we are unable to obtain approval from the FDA, HC or other regulatory agencies for our drug candidates, or if, subsequent to approval, we are unable to successfully commercialize our drug candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

If we receive regulatory approvals, we intend to market our drug candidates in multiple jurisdictions where we have 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 plan to market our drug candidates in jurisdictions where we have no experience in marketing, developing and distributing our products and cannot guarantee that we will ever have marketable 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. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to us obtaining marketing approval for our drug candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our candidates to be marketed or achieving such amendments to the laws and regulations may take a prolonged period of time. We would be unable to market our candidates in countries with such obstacles in the near future or perhaps at all without modification to laws and regulations.

Delays in the commencement and completion of pre-clinical studies and clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our drug candidates.

Delays in the commencement and completion of our future pre-clinical studies and clinical trials could increase our product development costs or limit the regulatory approval of our drug candidates. Based on our current financial resources, our expected level of operating expenditures and expected net proceeds to us from the Offerings, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. We, however, will require additional funding for our business activities. In addition, we do not know whether any future studies or trials of our drug candidates, will begin on time or will be completed on schedule, if at all. The commencement and completion of pre-clinical studies and clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for the commencement of pre-clinical studies and clinical trials;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our drug candidates;
- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients;
- inability to timely manufacture sufficient quantities of the drug candidate required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates; and
- inability to retain enrolled patients after a clinical trial is underway.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In addition, any future clinical trial may be suspended or terminated at any time by us, our future collaborators, the FDA or other regulatory authorities due to a number of factors, including:

- our failure to conduct a clinical trial in accordance with regulatory requirements of our clinical protocols;
- unforeseen safety issues or any determination that any future clinical trial presents unacceptable health risks;
- lack of adequate funding to begin any future clinical trial due to unforeseen costs or other business decisions; and

- a breach of the terms of any agreement with, or for any other reason by, future collaborators that have responsibility for the clinical development of any of our drug candidates.

In addition, if we, or any of our potential future collaborators, are required to conduct additional pre-clinical studies or clinical trials of our drug candidates beyond those contemplated, our ability to obtain regulatory approval of these drug candidates and generate revenue from their sales would be similarly harmed

Our new drug candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen side effects from any of our new drug candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The range and potential severity of possible side effects from systemic therapies is significant. The results of future clinical trials may show that our drug candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings.

If any of our new drug candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our drug candidates, if approved, it is less likely that they will be widely used.

Market acceptance and sales of our drug candidates, if approved, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for our drug candidates, if approved. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our drug candidates. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize our drug candidates.

In March 2010, the Patient Protection and Affordable Care Act, or PPACA, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our current or future drug candidates. In addition, some members of the U.S. Congress have been seeking to overturn at least portions of the legislation and we expect they will continue to review and assess this legislation and alternative health care reform

proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Strong, partisan disagreement in Congress has prevented implementation of various PPACA provisions, and the Trump Administration has made repeal of the PPACA a priority. One of the first executive orders of the Trump administration granted federal agencies broad powers to unwind regulations under the PPACA. On January 11, 2017, the Senate voted to approve a "budget blueprint" allowing Republicans to repeal parts of the law while avoiding Democrat filibuster. The "Obamacare Repeal Resolution" passed 51 – 48 in the Senate. Certain legislators are continuing their efforts to repeal the PPACA, although there is little clarity on how such a repeal would be implemented and what a PPACA replacement might look like. For the immediate future, there is significant uncertainty regarding the health care, health care coverage and health care insurance markets.

The U.S. government has in the past considered, is currently considering and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Future significant changes in the healthcare systems in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether other healthcare policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of drugs, several other types of state and federal healthcare laws, commonly referred to as "fraud and abuse" laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Canada have similar laws. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-

kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

If the FDA and HC and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production, we may not be able to commercialize any of our drug candidates.

We do not currently intend to manufacture the drugs that we plan to sell. We currently have no agreements with contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for our drug candidates' pre-clinical studies and clinical trials and that we believe we will need to conduct prior to seeking regulatory approval. We intend to develop our own active pharmaceutical ingredients.

We do not have agreements for commercial supplies of any of our drug candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize a drug candidate if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture a drug candidate must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the drug candidate manufactured at that facility. We will be completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our drug candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the drug candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our drug candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our drug candidates, cause us to incur higher costs or prevent us from commercializing our drug candidates successfully. Furthermore, if any of our drug candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our drug candidates and to have any such new source approved by the government agencies that regulate our products.

Even if our new drug candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Our drug candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and HC requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMPs. As such, we and

our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and HC and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers 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, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our potential future collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Risks Relating to the Commercialization of Our Products

Even if approved, our drug candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.

The commercial success of our drug candidates, if approved, will depend upon their acceptance among the medical community, including physicians, health care payors and patients. The degree of market acceptance of our drug candidates will depend on a number of factors, including:

- limitations or warnings contained in our drug candidates' approved labeling;
- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our drug candidates;
- limitations in the approved clinical indications for our drug candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- the extent to which our drug candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our drug candidates are designated under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;
- adverse publicity about our drug candidates or favorable publicity about competitive products;
- convenience and ease of administration of our drug candidates; and

- potential product liability claims.

If our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

We have no sales, marketing or distribution capabilities and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution capabilities. To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that our initial drug candidate or any of our other drug candidates will be approved. For drug candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

- we or our third-party sales collaborators may not be able to attract and build an effective marketing or sales force;
- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and
- our direct sales and marketing efforts may not be successful.

We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our drug candidates and our financial condition and operating results.

Because developing drugs, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek collaborations with companies that have more experience. Additionally, if any of our drug candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties. If we are unable to enter into arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our drug candidates.

When we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For example, we may relinquish the rights to a drug candidate in jurisdictions outside of the United States. Our collaboration partner may not devote sufficient resources to the commercialization of our drug candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our drug candidates. In some cases, once we have begun pre-clinical and initial clinical development of a drug candidate, we may be responsible for continuing research, or research programs under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our drug candidates, we would face increased costs, we may be forced to limit the number of our drug candidates we can commercially develop or the territories in which we commercialize them and we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition may be materially and adversely affected.

Risks Relating to Our Licensed Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our licensed patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on our licensor and us obtaining and maintaining patent protection and trade secret protection of our current and future drug candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities and the right under our licensed patent to contest alleged infringement.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our licensed intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future, are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensor will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our licensed or owned patents;
- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of patents we have or are licensed to us;
- we might not have been the first to make the inventions covered by any pending patent applications which have been or may be filed;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain, or are licensed to us, may not provide us with any competitive advantages;
- we, or our licensor, may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Without patent protection on the composition of matter of our drug candidates, our ability to assert our patents to stop others from using or selling our drug candidates in a non-pharmaceutically acceptable formulation may be limited.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our drug candidates or methods involving these candidates in the licensor's patent application. We plan to pursue and request our licensor to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in the parent patent application.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets may be expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Our commercial success will depend, in part, on our ability, and the ability of our licensor, to obtain and maintain patent protection. Our or our licensor's failure to obtain and maintain patent protection for our products may have a material adverse effect on our business.

Pursuant to our License Agreement with Orthogonal, we have obtained rights to a provisional patent application. All rights to pursue a further application that claims priority to the provisional application, such as a US non-provisional patent application, an international patent application and/or a direct foreign application remain with Orthogonal. Our success may depend, in part, on our ability and the ability of Orthogonal to obtain and enforce patent protection for our proposed products and to preserve our trade secrets. Patent positions in the field of biotechnology and pharmaceuticals are generally highly uncertain and involve complex legal and scientific questions. We cannot be certain that Orthogonal's inventor was the first inventor of the inventions covered by the provisional patent application or that they were the first to file. Accordingly, the provisional patent application and any resulting patents licensed to us may not be valid or afford us protection against competitors with similar technology. The failure to maintain and/or obtain patent protection on the technologies underlying our proposed products may have material adverse effects on our competitive position and business prospects.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our drug candidates, or manufacture or use of our drug candidates, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling our drug candidates.

We note that the examination of the pending trademark applications for the PSILLY and PSILLY LIFE marks is currently suspended pending final disposition of the co-pending Application No. 88/784877 for the mark PSILLY, owned by Unorthodocs Printing, LLC, a New York limited liability company. In January 2021, Orthogonal engaged trademark counsel to review whether grounds exist to send Unorthodocs Printing, LLC a cease and desist letter that demands a withdrawal of its pending application.

We cannot be certain that others have not filed patent applications for technology covered by pending applications subject to our License Agreement, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we may obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits may be expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. Currently, we rely upon our licensor to fund the payments under our License Agreement. We are required to reimburse our licensor for these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application,

resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Risks Associated with Our Securities

There is no assurance that purchasers of the Securities will receive a return on their investment.

The Company issued simple agreements for future equity ("SAFE Securities") in the Crowdfunding Offering. On or about March 2022, the SAFEs converted as a result of the Regulation A Offering into shares of the Company's Common Stock (the "Securities"). The Securities are highly speculative and any return on an investment in the Securities is contingent upon numerous circumstances, many of which (including legal and regulatory conditions) are beyond the Company's control. There is no assurance that purchasers will realize any return on their investments or that their entire investments will not be lost.

Our executive officers, directors and Orthogonal, the principal stockholder, have the ability to control all matters submitted to stockholders for approval.

Controlling shares of the stock of Orthogonal are beneficially owned by David Nikzad and Jason Hobson, who are also directors of the Company. Additionally, David currently serves as the President of the Company, and Jason serves as the Treasurer and Secretary. Upon completion of the Offerings, Orthogonal owns a controlling share of our stock and will be able to elect all our directors and control the executive management of the Company. Therefore, David Nikzad and Jason Hobson will be able to control all matters submitted to our stockholders for approval, as well as our management and affairs including the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of the Company on terms that other stockholders may desire.

If the conditions to, and the procedural requirements of, the Plan of Merger are not satisfied, the merger may not take place or may be delayed.

On May 17, 2022, the Company signed an Agreement and Plan of Merger ("Plan of Merger") with Mycotopia Therapies Inc. ("Mycotopia") regarding a potential transaction in which Mycotopia would acquire all of the issued and outstanding shares of the Company. It is anticipated that the Company's stockholders will exchange their equity interests in the Company for newly issued shares of common stock of Mycotopia. Mycotopia's common stock is currently traded over-the-counter under the symbol TPIA. See "Business - Proposed Acquisition by Mycotopia."

The Plan of Merger is conditional on a number of conditions as set out the Plan of Merger. If any of these conditions are not satisfied, then there is a risk that the merger will not take place. The inability to complete the merger may have a negative impact on the Company and the value of the Securities.

No public market for our Common Stock currently exists, and an active trading market may not develop or be sustained.

Our Common Stock is not currently quoted or traded on any trading market, and there can be no assurance that an active public market for our Common Stock will ever develop in the future, even if the proposed merger with Mycotopia takes place. In the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations.
- market visibility for our Common Stock may be limited; and
- a lack of visibility for our Common Stock may have a depressive effect on any market price for our Common Stock that might develop.

Because we have discretion with respect to if, when or where our Common Stock will be publicly traded, there can be no assurance that our Common Stock will ever be quoted or listed or traded on any trading market or, if listed, quoted or traded, that an active public market will develop or be sustained. Moreover, there can be no assurance that security analysts of brokerage firms will provide coverage of our Company, if at all. If there is no active trading market for our Common Stock or coverage of our Company by security analysts of brokerage firms,

you may be unable to dispose of your shares at desirable prices or at all. Moreover, there is a risk that our Common Stock could be delisted from any trading market on which it may be quoted or traded in the future.

The lack of an active trading market may also impair our ability to raise capital to continue to fund operations by selling securities and may impair our ability to acquire additional intellectual property assets by using our securities as consideration.

Even if our Common Stock becomes publicly traded and an active trading market develops, the market price of our Common Stock may be volatile, and purchasers of our Common Stock could incur substantial losses.

Even if our Common Stock becomes publicly traded and even if an active trading market develops for our Common Stock, of which no assurances can be given, the market price of our Common Stock may be volatile and subject to wide fluctuations in response to various factors. The stock market in general, and the market for new drug companies, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our Common Stock may also be influenced by many additional factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, any products we may develop;
- the performance, safety and side effects of any drug candidates we may develop;
- the success of competitive products or technologies;
- results of clinical trials of any drug candidates we may develop or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to any products we may develop;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our drug candidates, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or other products we may develop;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our securities, other comparable companies or our industry generally;
- general economic, industry and market conditions; and
- the other risks described in this "*Risk Factors*" section.

These broad market and industry factors may seriously harm the market price of our Common Stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and prospects.

We do not intend to pay dividends on our Common Stock.

We have not paid any cash dividends on our shares of Common Stock to date. The payment of cash dividends on our Common Stock in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition and will be within the discretion of our board of directors. It is the present intention of our board of directors to retain all earnings, if any, for use in our business operations and,

accordingly, our board of directors does not anticipate declaring any dividends on our Common Stock in the foreseeable future. As a result, any gain you will realize on our Common Stock will result solely from the appreciation of your shares.

You may experience future dilution.

The Company, for business purposes, may from time to time issue additional shares, which may result in dilution of existing shareholders. Dilution is a reduction in the percentage of a stock caused by the issuance of new stock. Dilution can also occur when holders of stock options (such as company employees) or holders of other optionable securities such as warrants exercise their options. When the number of shares outstanding increases, each existing stockholder will own a smaller, or diluted, percentage of the Company, making each share less valuable. Dilution may also reduce the value of existing shares by reducing the stock's earnings per share. There is no guarantee that dilution of the Common Stock will not occur in the future. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the Delaware General Corporation Law, our certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our certificate of incorporation and by-laws provide that we shall indemnify, to the fullest extent authorized by the Delaware General Corporation Law, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of the company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our certificate of incorporation provides that indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we might need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against the Company.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our by-laws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that

investors might be willing to pay in the future for our securities, thereby depressing the market price of our Common Stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following.

- our board of directors has the right to elect directors to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our board of directors;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and
- our board of directors is able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

These provisions may also frustrate or prevent any attempts by our stockholders to replace or remove our current management or members of our board of directors. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our certificate of incorporation and by-laws include a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or agents.

Our certificate of incorporation and by-laws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees, or agents to us or to our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, the certificate of incorporation, or the by-laws; or
- any action asserting a claim governed by the internal affairs doctrine

except that our by-laws provide that as to each of (a) through (d) above, any claim (i) as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten (10) days following such determination), (ii) which is vested in the exclusive jurisdiction of a court or forum other than such court or (iii) for which such court does not have subject matter jurisdiction. In no event, however, shall the Court of Chancery, under our by-laws, constitute an exclusive forum for actions, including derivative actions arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, thereby allowing any such actions to be filed in any court having jurisdiction. Our by-laws further provide that if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for the matters specified above.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees, or agents, which may discourage lawsuits against us or our directors, officers, employees, or agent. If a court were to find either exclusive-forum provision in our certificate of incorporation or By-laws to be inapplicable or unenforceable in an action, we may

incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Purchasers may lack information for monitoring their investment.

The Securities do not have any information rights attached to them and purchasers may not be able to obtain all the information they would want regarding the Company or the Securities. In particular, investors may not be able to receive information regarding the financial performance of the Company with respect to the ability of the Company to continue operations on an ongoing basis.

. The Company is not currently registered with the SEC and currently has no periodic reporting requirements. As a result of these difficulties, as well as other uncertainties, a purchaser may not have accurate or accessible information about the Company or the Securities.

BUSINESS

Overview

Ei.Ventures, Inc., a Delaware corporation (the "Company"), is a start-up company formed in May 2019 with the ambition to develop regulatory approved, plant-derived, psychoactive therapeutic treatment options and non-psychoactive nutritional supplements that address global mental healthcare needs. Our initial research into psychoactive therapeutic compounds is planned to be conducted with respect to psilocybin and/or psilocin.

Mental health conditions such as depression, substance use disorder, or SUD, and anxiety, which are among our anticipated targeted focus indications, are highly prevalent and estimated to affect more than one billion people globally. Additionally, it is expected that more than 50% of the U.S. populations will be diagnosed with a mental health condition at some point in their lifetime. The COVID-19 pandemic has lead to increased incidence of mental health conditions and an increase in persons seeking mental health services. Those suffering from mental health conditions have higher mortality rates than the general population and often experience decreased quality of life as a result of emotional, behavioral, or physical manifestations. Between 2009 and 2019, spending on mental health care in the United States increased by more than 50%, reaching $225 billion, and a Lancet Commission report estimates the global economic cost will reach $16 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors, or SSRIs, and serotonin-norepinephrine reuptake inhibitors, or SNRIs, are well established and effective for certain patients, a significant percentage of patients either respond inadequately or relapse, translating to a significant unmet patient need.

Prior to the Regulation A Offering, the Company was a wholly owned subsidiary of Orthogonal Thinker, Inc., a Delaware corporation ("Orthogonal"), a company engaged in developing intellectual property and operating in the wellness business. On October 8, 2020, the Company agreed to terms with Orthogonal, for a royalty-free license of certain intellectual property (the "License Agreement"), including the compositions addressed in Orthogonal's provisional patent application, the associated intellectual property, and also intellectual property associated with a number of additional psilocybin-based psychoactive compounds and non-psychoactive nutritional supplements not included in the provisional application. The License Agreement grants the Company an exclusive world-wide right to use, manufacture, develop, commercialize, market and sell all of the licensor's intellectual property addressed in the License Agreement with respect to the intellectual property for medicinal, therapeutic, nutraceutical and adult recreational uses, including the matters included in the provisional application. No consideration was paid to Orthogonal for the license. The license is perpetual, subject to limited termination rights, for example, if the Company is found guilty of criminal activity or the Company files for bankruptcy.

Our initial research into psychoactive therapeutic compounds is planned to be conducted with respect to psilocybin and/or psilocin. Psilocybin is a naturally-occurring psychedelic compound produced by more than 200 species of mushrooms, collectively known as psilocybin mushrooms. Psilocybin is quickly converted by the body to psilocin, which is a non-selective serotonin receptor agonist responsible for its pharmacologic effects. Currently in the United Sates, the possession of psilocybin and psilocin is illegal because psilocybin is a Schedule I controlled substance. As a result, the federal government has the right to regulate and criminalize psilocybin, including for medical purposes. In Canada, psilocybin is classified as a schedule III drug, meaning activities such as sale, possession, or production of these substances are prohibited unless they have been authorized for clinical trials or research purposes, consistent with Part J of Canada's Food and Drug Regulations. Current formulations and testing are theoretical—the Company has not taken any steps to test or otherwise verify any of the formulations—and, if approved, actual testing will only proceed in government-approved laboratories.

We intend to continue to build upon our current intellectual property holdings by developing a differentiated portfolio of psychoactive and non-psychoactive products or strategically investing in opportunities with similar goals, on the presumption that they will become regulatorily approved, such approval within the sole determination of the FDA and other comparable regulatory agencies. In the coming years, we believe that we will see significant increases in demand from patients and governments for plant-derived products, including psychoactive therapeutic products. We intend to be well-positioned at that time to expand availability of these products to patients if they become legal and are approved by the FDA and other comparable regulatory agencies, as medical psilocybin becomes recognized worldwide as a viable treatment option for patients suffering from a variety of diseases and conditions.

Our progress with regard to the testing and sale of psychoactive therapeutic options will depend, in large part, on changes to the federal and state regulations in the United States and abroad with regard to biopharmaceutical research involving psychedelics or rescheduling of psilocybin and/or psilocin as a Schedule I controlled substance (or schedule III drug in Canada), along with our ability to obtain and maintain patent protection of current and future compositions. We intend to fund pre-clinical and clinical trials on our current compositions to meet FDA regulations. Current formulations and testing are theorical and, if approved, actual testing will only proceed in government-approved laboratories. Pre-clinical and clinical testing is expensive, is difficult to design and implement and can take years to complete The initial testing that we intend to complete within the next year, for each formulation, which in large part will be theorical includes (1) the development of one or more active pharmaceutical ingredients; (2) product characterization to determine size, shape, strengths and weaknesses, toxicity, bioactivity, and bioavailability; (3) formulation, delivery, and packaging development to devise a formulation that insures the proper drug delivery parameters; (4) pharmacokinetics (PK) and absorption/distribution/metabolism/excretion (ADME) studies; (5) preclinical toxicology testing to determine the bioactivity, safety, and efficacy of the formulations; and (6) Phase 1 clinical trials to evaluate pharmacokinetic parameters and tolerance.

While we navigate through pre-clinical research on our psychoactive compositions and the accompanying strict regulatory environment, we also intend to develop and commercialize non-psychoactive nutritional supplement products that will be synergistic with the psychoactive therapeutic options to address one's whole well-being through a wholly-owned subsidiary, Mana Health Labs, Inc., a Delaware corporation. Through this subsidiary, we intend to make "MANA" a nationally recognized brand in the nutritional supplements industry. We intend to launch the following initial products on or before February 1, 2021: (1) Brain MANA, a non-psychotropic mushroom formulation with enhanced bioavailability, (2) Intelliburst, a natural focus and energy booster, (3) Happy Sexy, a weight loss booster; (4) Sleepy Sexy, a weight loss booster and sleep aid. We plan to manufacture all of our nutritional supplement products from natural ingredients in compliance with U.S. Food and Drug Administration laws and regulations. We intend to package our nutritional supplements in different form, such as tables, gummies, capsules, and powders. We anticipate that all of our products will be GMO-free, which we intend to emphasize in our marketing campaigns to the extent possible.

With the development of our MANA products we aim to successfully operate by understanding and predicting consumer requirements and a changing market. We aspire to develop a broad global presence, size, and scope, and the capacity to invest in the long run, which we believe will be advantageous to the long-term viability of our business. We are developing the MANA product line with the aim to provide consistent value to customers, partners, and investors in the short and long term, with a forward-looking approach, hence, the initiative to develop MANA-branded nutritional supplements.

We also intend, as an intermediate business plan, to pursue the acquisition of one or more drug testing laboratories. There can be no assurance that we will be able to accomplish this intermediate business plan: The Company is organized and directed to operate strictly in accordance with all applicable federal, state and provincial laws. Accordingly, at this time, we do not grow, process, own, handle, transport or sell psilocybin-based products. However, if the legal environment changes in the United States or in Canada, the Company's management may explore business opportunities in the development of laboratories, and growing/cultivation operations, provided that n such business opportunities become legally permissible under applicable federal and state or provincial law.

In August, 2021, the Company announced their engagement with Tioga Research to develop a transdermal patch for sustained delivery of psilocin for mental health applications. Tioga Research will deploy their proprietary technologies and deep expertise to address key psilocin formulation issues, such as delivery and stability. A transdermal delivery route can circumvent issues with oral administration, such as nausea. Tioga Research was founded 2011 to support innovations in skin-applied products, especially topical and transdermal drug products. Tioga Research supports the research and early development of skin-applied products, offering formulation innovation, skin permeation screening, and GLP IVRT/IVPT services. In addition, Tioga Research has pioneered high throughput experimentation ("HTE") technologies for screening skin delivery.

On May 6, 2022, the Company invested in Avicanna Inc., a commercial stage, international biopharmaceutical company focused on the commercialization of evidence-based, cannabinoid-based products. Ei. Ventures invested in this business as Avicanna already has an established scientific platform including R&D and clinical development that has led to the commercialization of more than thirty products across various market

segments. In addition to wellness products, Avicanna leverages its scientific platform, vertical integration, and real-world evidence, to create a pipeline of patent-pending drug candidates that are indication-specific and in various stages of clinical development and commercialization. These cannabinoid-based drug candidates look to address unmet medical needs in the areas of dermatology, chronic pain, and various neurological disorders. This investment creates a relationship with the Company and a laboratory in Canada.

Through our research and with the rapidly growing patient population, we believe that we will need accessible treatment solutions. We believe that future treatment solutions will be in virtual settings in the metaverse. In April, 2022, the Company formed a subsidiary, Pluto11.11, Inc., a Delaware corporation, ("**Pluto11.11**") to focus on emerging technologies such as the Metaverse, blockchain technologies and Web3. Pluto 11.11's mission is to engage and further develop these technologies, specifically investing in physical assets in the Metaverse. The Company expects to utilize the development of these technologies to create a safe, efficient and secure way to provide telehealth services in general and specifically for psychoactive therapeutics. We believe that the Company and Pluto11.11 may have unique opportunities to invest in or acquire companies that are compatible with this mission because of longstanding relationships and the potential for collaboration between such other companies and the Company and Pluto11.11.

As part of the formation of Pluto11.11 and the Company's ambition to address global mental healthcare needs, for which the Company needs a global presence, Ei.Ventures acquired virtual real estate in The Sandbox metaverse. The Company acquired a 12x12 estate comprised of 144 digital parcels of prime commercial space, consisting of 144 LAND parcels located at -36, 0 for 450 ETH. Orthogonal facilitated the Sandbox metaverse purchase transaction and will be the beneficial owner of 12 of the 144 parcels of land as compensation for its services.

Market Opportunity and the Potential for Psilocybin Therapy for Treating MDD

The World Health Organization estimates that over 264 million people worldwide suffer from major depressive disorder, or MDD. The second leading of cause of death in 15-29-year-olds is suicide related to MDD. In the United States, the economic burden of MDD accounts for approximately $200 billion per year. Patients suffering with MDD are treated through a number of approaches. Most treatments for MDD rely on a treatment plan focused on the brain's neurotransmitter monoamine levels. This methodology has exhibit limited efficacy in a significant portion of patients and often results in high relapse rates. We believe that it is time for a new approach to the treatment of MDD that can deliver reliable results and long-term efficacy.

Psilocybin is currently classified as a Schedule I drug in the United States and is similarly prohibited in many jurisdictions. While the legal status of psilocybin currently restricts the research that can be performed on its ability to treat MDD and other conditions, there is a rapidly growing body of evidence that psilocybin may have beneficial effects on depression and other mental health conditions. The FDA and the U.S. Drug Enforcement Administration, or DEA, have permitted the use of psilocybin in clinical studies for the treatment of a range of psychiatric conditions. In particular, recent studies demonstrate that psilocybin may beneficially alter the extracellular release of serotonin and dopamine, resulting in brain network connectivity and increased level of neuroplasticity. These studies are encouraging and demonstrate that psilocybin therapy may have the potential to ensure rapid and enduring mood effects.

With regard to the nutritional supplements, our aim is to operate within the large and growing nutritional supplements industry. According to Nutrition Business Journal's Supplement Business Report 2020, the nutritional supplement industry generated $123.28 billion in sales in 2019 and is projected to grow 8% per annum through 2027. We anticipate several key demographic, healthcare, and lifestyle trends to drive the continued growth of this industry. These trends include increasing awareness of nutritional supplements across major age and lifestyle segments of the U.S. population, and increased focus on fitness and healthy living.

Proposed Acquisition by Mycotopia

On May 17, 2022, the Company signed an Agreement and Plan of Merger ("Plan of Merger") with Mycotopia Therapies Inc. ("Mycotopia") regarding a potential transaction in which Mycotopia would acquire all of the issued and outstanding shares of the Company. It is anticipated that the Company's stockholders will exchange

their equity interests in the Company for newly issued shares of common stock of Mycotopia. Mycotopia's common stock is currently traded over-the-counter under the symbol TPIA.

Under the Plan of Merger, David Nikzad and Jason Hobson would become officers and directors of Mycotopia, which would change its name to PSLY.COM and use PSLY as its trading symbol. If the Plan of Merger is closed, the combined companies intend to pool their resources to develop regulatory approved, plant-derived, psychoactive therapeutic treatment options and non-psychoactive nutritional supplements and related products that address global mental healthcare needs. The goal of the combined companies would be to complete pre-clinical and phase 1 trials and launch therapeutic Psilly into jurisdictions where psilocybin is legal.

The Company and Mycotopia share similar strategic goals, as Mycotopia is focused on the research, development, and commercialization of novel therapeutics based on naturally-derived psilocybin. Performing most of its research in Jamaica, where psilocybin is legal, Mycotopia is focused on mushroom and psychedelic opportunities. Mycotopia is currently working with one of the largest cannabis labs in the Netherlands to develop psychedelics to jointly license certain molecules to be used in psychedelic medicine. Mycotopia also plans to open psylocibin and ketamine clinics in Jamaica under the direction of a licensed clinical psychiatrist. Mycotopia's psylocibin and ketamine clinic will be designed to make the most peaceful and serene setting possible to give patients an ideal situation for psychedelic therapies. The primary focus of each clinic will be to help patients heal and reclaim their life under the direction of a licensed clinical psychiatrist.

The transaction is subject to several closing conditions that the Company and Mycotopia must meet prior to the closing of the merger, including the approval of the stockholders of the Company and Mycotopia. As a result, there can be no assurance that the Company and Mycotopia will close on the merger. Please see the Company's Current Report on Form 1-U filed on May 20, 2022 with additional information regarding the transaction.

Nutritional Supplements Background

While we navigate through pre-clinical research on our psychoactive compositions and the accompanying strict regulatory environment, we also intend to develop and commercialize our non-psychoactive nutritional supplement products that will be synergistic with the psychoactive therapeutic options to address one's whole well-being through a wholly-owned subsidiary. Through this subsidiary, we intend to design our products such that they contain ingredients that are formulated and used to support a healthy lifestyle consistent with the Psilly brand. We are designing the MANA nutritional supplements with the intent to provide a wide variety of brand-leading supplements with the goal of setting the benchmark in areas of quality, product distribution, customer support, and satisfaction. In October 2020, we engaged legal counsel to assist us with the preparation of trademark applications for the products described below. To date, applications have been filed and are pending with the United States Patent and Trademark Office for the BRAIN MANA, MANA, MANA, and BRAIN MANA marks. These applications are owned by Orthogonal and are licensed to us.

Our initial products include:

- Brain MANA
- Intelliburst
- Happy Sexy
- Sleepy Sexy

Brain MANA (Immunity, Mood, Cognition Enhancer)

Our Brain MANA supplement is intended to support a healthy immune system and enhance focus, boost concentration, and improve memory. We intend to formulate Brain MANA using a proprietary six-mushroom blend, along with other natural ingredients to help provide mental capacity support in all significant areas of measure in key brain functions, including memory, concentration, learning, recall, mood and focus.

Intelliburst (Nootropic)

Our Intelliburst supplement is intended to support brain function and performance. Intelliburst is intended to be used as a daily nootropic formulation to support improved cognitive function, particularly executive functions, memory, creativity, and motivation. Nootropics like Intelliburst are also called smart drugs and contain proven nootropic ingredients such as noopept and adrafinil.

Happy Sexy (Fat Burn and Mood Enhancer)

We intend our Happy Sexy to help shed unwanted fat by designing it to increase core temperature to facilitate rapid caloric burn. The conceived design would use fat burn substitutes, several forms of caffeine, and natural mood enhancement ingredients. Studies have shown that happiness burns more calories than unhappy emotional states, such as depression, sadness, or anger. When combined with cardio or other forms of activity and a balanced lifestyle, Happy Sexy would be designed to help accelerate the fat burning process.

Sleepy Sexy (Fat Burn and Sleep Support)

We intend our Sleepy Sexy to help shed unwanted fat by supporting a restful night sleep. The conceived design would combine ingredients that promote thermogenesis during sleep and support appetite maintenance. In addition, the Sleepy Sexy formulation includes natural sleep aids like melatonin, valerian root, and magnesium to help promote a good night's sleep. Studies have shown that good sleep is a key to improved weight loss and maintenance of a healthy weight.

Supplement Market

Global Dietary Supplements Market

In 2016, the dietary supplements market, in which our products are classified, was valued at $133.1 billion and forecasted to experience substantial growth in the coming years. The American National Standards Institute project the market to reach $220 billion by 2021 and $242 billion by 2025 ("*Dietary Supplements Market: Executive Summary,"* April 11, 2018).

This growth is mainly due to the increase in lifestyle diseases and changing mindset toward preventative healthcare worldwide. Globally, the market is also growing rapidly as a result of the rising prevalence of chronic diseases such as arthritis, cardiovascular problems, diabetes, etc. and the favorable outlook towards medical nutrition. Other factors fueling the growth of the market include increasing preference for sports activity as an academic curriculum in education systems and the positive outlook towards sports nutrition. The report observed that individuals taking on hectic jobs and leading busy lifestyles will always need dietary supplements to balance the burden of busy lifestyles.

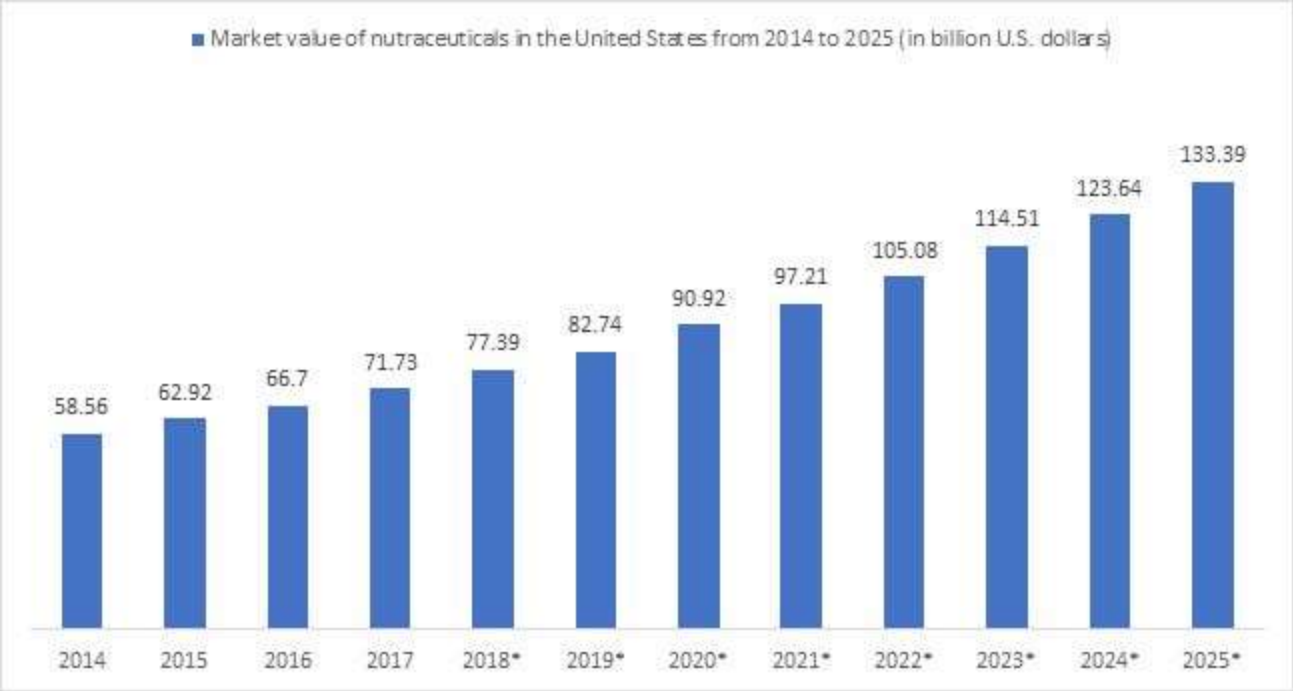
Rising awareness regarding personalized nutritional products should help to fuel the demand for the dietary supplement market. In addition, technological advancements and an increasing investment in research and development of functional foods and supplement products could likely help grow the dietary supplement market.

Functional Food and Nutraceuticals Market in the United States

By definition, functional food has similar appearance with conventional food since it is consumed as part of a usual diet. It is demonstrated to have physiological benefits and/or help to reduce the risk of chronic disease beyond basic nutritional functions. They can be regarded as ingredients that offer health benefits that extend beyond their nutritional value. Some types contain supplements or other additional ingredients designed to improve health.

On the other hand, a nutraceutical is a product that is purified from foods that is generally sold in medicinal forms not usually associated with foods. A nutraceutical is believed to have a physiological benefit or provide protection against chronic disease.

Based upon a report in 2019, the graph below estimates that the United States nutraceutical market was worth approximately $71.73 billion in 2017 and is anticipated to rise to $133.4 billion by 2025 which is more than double of the value in 2014. (Graph available at https://www.statista.com/statistics/910097/us-market-size-nutraceuticals/)



The millennials focus on health, fitness, nutrition, and convenience have been the attributed to growth of the market. Additionally, increasing number of health and fitness clubs, the need to battle various diet-related health issues among the young and the old, as well as the motivation among younger generations to stay fit will continue to support the growth of the market.

We also believe that our supplement line will appeal to those who are interested in the development of our psychoactive products. There is an ongoing shift from treating diseases and illnesses to the adoption of several other measures that can help to prevent or alleviate diseases from the onset. Consequently, this has led to the substantial rise in the nutraceutical market.

Dietary supplements play an important role in the overall health and wellness of Americans. Without doubt, they have become mainstream. Already, 77 percent of U.S. adults take dietary supplements and below are some facts about the dietary supplement consumption in the US:[1]

United States Supplements Market

The dietary supplements market is a sub-category of the Functional Food and Nutraceuticals. Our products are part of this dietary supplements market. In the United States, in 2016, dietary supplement sales reached $31.7 billion. It is estimated that the dietary supplement market will exceed $50 billion by 2023.

[1] https://www.crnusa.org/newsroom/dietary-supplement-use-reaches-all-time-high.

Within the dietary supplements market, Sports supplements will record the fastest growth rate (8.3%), followed closely by the practitioner market (8%), herbal supplements (6.8%) and vitamins (4.6%).[2]

The growth in the US dietary supplements market is attributed to the surge in the geriatric population, the adoption of dietary supplements, and an increasing preventative healthcare measure.[3]

Brand Development

We are working to develop products that are potent and able to perform based on the consumers expectations. To ensure are products meet these standards, we plan to develop various processes to test the purity, potency, and quality of the products we develop. This will allow us to obtain constructive feedback from consumers to help our products obtain the brand recognition we seek.

Part of developing our brand will be the placement of our products. To this end, we intend to market to, and work with, influencers, trainers, and other fitness professionals to best build our brand within our target community. This may include us participating in product demonstrations, fitness conferences, and other fitness and sporting events. We plan to take the feedback and other information we obtain from these sources and product testing to develop confidence in our brand.

Target Market

We will begin our marketing by targeting American males and females who fall in the age group of 18 – 45 years. PEW's research from 2019 identified the American millennials to be those aged 23 – 38; however, our target audience encompasses those between 18 and 45 years and by extension some of them are a little below or above this. The American millennial population is growing at a fast pace and has surpassed the "baby boomers" generation. Based on population estimates from July 2019 by the United States Census Bureau, millennials outnumbered baby boomers by 72.1 million to 71.6 million. By 2033, Millennials are expected to reach 74.9 million.[4]

We believe this is the optimal target group for our products because millennials tend to be well-informed and better educated than other age groups, a factor which is associated with being employed and financially stable. Additionally, there is a gap in earning power between those with a college degree and those with only high school education. To this end, about one-third of millennial men and about 43% of millennial women have at least a bachelor's degree. As a result, 72% of millennials are employed, the highest among all generations (3% of millennials are unemployed and 25% of millennials are not in the labor force). Millennials with a high school diploma or its equivalent have roughly $31,300 median earnings. Those who did not finish college or with an associate degree have their median earnings at $36,000, whereas those with bachelor's degree or higher earn $56,000 as their annual median income.[5]

Millennials also enjoy leisure, exercise, and are, generally, more health conscious. Therefore, we will be targeting primarily this group that tends to favor foods with less artificial ingredients as well as maintain good health through supplements. This focus, in addition to their earning power, provides current and future disposable income to spend on products, like wellness and dietary supplements and confirm our view that this age group makes the best target market for our products.

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2 https://share.ansi.org/Shared%20Documents/Dietary%20Supplements/Dietary%20Supplements%20Executive%20Summary_final.pdf.

3 https://www.marketwatch.com/press-release/covid-19-impact-affects-dietary-supplements-market-globally-in-2020-2020-06-04.

4 https://www.weforum.org/agenda/2020/04/millennials-overtake-baby-boomers-largest-generation-america/.

5 https://www.pewsocialtrends.org/essay/millennial-life-how-young-adulthood-today-compares-with-prior-generations

Competition

We believe our supplements will compete with various products that boost the immune system, support weight loss, and enhance overall health. The following table provides a sample of the products currently on the market with which our products may compete.

Product	Manufacturer	Product Description	Price	Customer Review (5.0)	Best Sellers Rank
CollagenC immune booster shot	Alfa Vitamins Laboratory Inc.	It contains 1,000mg of Vitamin C and 1,000 of Collagen for your skin, hair, nails, and joints. (Shots)	$40	N/A	#535,243 in Health and Household #27,671 in Vitamin Supplements
High potency vitamins C antioxidant support	Sports Research	240 count of 1000mg capsules	$18	4.8	#11,654 in Health & Household
Build PM	Jacked Factory	60 capsules	$24.99	4.3	#17,912 in Health & Household
Night Time Fat Burner	Envy Nutrition	60 capsules	$18.87	3.9	#1,651 in Health & Household
Night Shred	Inno Supps	60 capsules	$44.99	4.4	#4,679 in Health and Household
C4 Original Pre workout	Cellucor	30 servings (Powder)	N/A	4.4	#3 in Sports Nutrition Pre-Workout Powders #782 in Health & Household
Platinum Caffeine	MuscleTech	125 tablets of 220mg	~$6	4.4	#3,408 in Health & Household #7 in Sports Nutrition Endurance & Energy Supplements
Elderberry Capsules with Zinc & Vitamin C	Sports Research, USA	180mg vitamin C	$20	4.8	#12,052 in health and household
Nitro Surge Pre workout	Jacked Factory	30 servings (Powder)	~$25	4.6	#6 in Sports Nutrition Pre-Workout Powders #1,280 in Health & Household

**N/A = Not Available.

Regulation

The supplement industry is subject to several regulatory regimes and entities. The actions of these entities may limit or prohibit our plans to develop our products and market. The FDA or other agencies could take actions against products or product ingredients that, in their determination, present an unreasonable health risk to consumers that would make it illegal for us to sell such products. Such actions or warnings could be based on information received through FDC Act-mandated reporting of serious adverse events. The failure of such products to comply with applicable regulatory and legislative requirements could prevent us from marketing the products or require us

to recall or remove such products from the market, which in certain cases could materially and adversely affect our business strategy, our marketing, financial condition and results of operations. A removal or recall could also result in negative publicity and damage to our reputation that could reduce future demand for our products. See the "RISK FACTORS" section for additional risks related to regulation.

Psychoactive Products Background

Psilocybin and psilocin are naturally-occurring psychedelic compounds found in more than 200 species of mushrooms. They are similar chemically, with psilocin being the psychoactive compound that stimulates the human brain. Psilocin oxidizes and loses its potency very quickly. Psilocybin has an additional element in its composition which prevents oxidization. Because of this psilocybin-containing mushrooms can be dried and kept for a long time without a drop in potency. Psilocybin becomes psilocin in the human body and binds with serotonin receptors in the brain, which regulate the release of neurotransmitter chemicals related to appetite, cognition, anxiety, imagination, learning, memory, mood and perception. Psilocin produces psychedelic experiences and an altered state of consciousness.

Unlike cannabis, for which a large number of people report usage, psilocybin currently is consumed relatively rarely, with only about 0.1 percent of persons surveyed reporting psychedelic use within the past year. Psilocybin is neither physically addictive nor shown to cause psychological dependence. Psilocybin and psilocin produce short-term tolerance in users, which diminishes its effects with repeated dosing. It can take several weeks to a month for tolerance to return to normal levels. As with cannabis, LSD and other hallucinogens, psilocybin has also been linked to a poorly-understood phenomena known as Hallucinogen Persisting Perception Disorder (HPPD), in which sufferers report ongoing distortions to their perception, even years later. Symptoms can range from minor visual issues to disturbing hallucinations.

Psilocybin has the potential to aid in the treatment of depression, eating disorders and addiction, but the study of psychedelics and their applications in medicine and psychology is still in its infancy, hampered by its Schedule I Narcotics status and the United States' "War on Drugs". However, psilocybin has shown promise in combination with psychotherapy. Recent studies have shown that psilocybin and psilocin may act as primary medicines in the treatment of a number of mental disorders.

Various potential competitors to the Company are in differing stages of clinical trials for similar or competing product compounds as follows:

Companies	Stage
Atai Life Sciences AG	Phase 1 and Phase 2
Champignon Brands Inc.	Pre-Clinical/Phase 1
Compass Pathways Ltd	Phase 2(b) TRD
Cybin Inc.	Pre-clinical
Eluesis Ltd.	Phase 1 completed
Field Trip Health, Inc.	Pre-clinical
Mind Medicine Inc.	Phase 1(b) and Phase 2
Tactogen, Inc.	Pre-clinical

We believe that in the coming years and with greater legalization, medical psilocybin will become accepted, resulting in a growth in demand for the availability of psilocybin-based products and services. We see an opportunity, as legal psilocybin industries emerge in North America and around the world, to create a broad-based portfolio of differentiated psilocybin-based products that we intend to develop and bring to market in a legal and professional manner. We believe that many patients will come to rely on medical psilocybin as a substitute to opioids and other narcotics.

Our Vision

Our vision is to build a trusted, valuable, and innovative mental health care company. Accordingly, we intend to pioneer medical, wellness and adult-use psilocybin research, development and processing. Our founders started the Company with the belief that patients and consumers should have safe access to legal, quality-tested pure,

precise and predictable psilocybin products. We believe that in the coming years medical psilocybin will become a mainstream pharmaceutical consumed by mainstream patients. Currently, we believe we are beginning to see a paradigm shift regarding psilocybin. We believe that this shift will result in a move away from prohibition to generate a potentially multibillion dollar industry. As this new market emerges, we believe that trusted brands will lead the industry and gain the confidence of governments, physicians and consumers. Our business is to develop a trusted psilocybin company through the following key strategies.

We are committed to advancing scientific knowledge about the therapeutic potential of psilocybin. We are seeking to recruit a Medical and Scientific Advisory Board comprised of highly accomplished researchers and physicians specializing in psychopharmacological research, ethnopharmacology, brain-imaging techniques such as PET and MRI, organic chemistry, biotechnology and drug development. We intend to develop data and provide that data to researchers and physicians regarding the safety and efficacy of medical psilocybin to encourage mainstream acceptance of medical psilocybin and enhance our reputation as a trusted company. We intend to work collaboratively with regulators to develop research on and studies of medical psilocybin.

We intend to form business partnership with major pharmaceutical companies and established research and development companies. We believe our partnerships with these companies will differentiate us and position us to become a leader in psilocybin innovation. We will seek to establish partnerships with leading research institutions and to conduct pre-clinical studies and clinical trials to generate safety and efficacy data that can position us to develop drugs for NDA and/or NDS and lead to the development of new products.

Our strategy centers on developing a portfolio of psychoactive products intended to be applicable to a diverse set of patients. We hope to one day to offer a wide range of high-quality, pharmaceutical-grade psilocybin and other psychoactive products.

We intend to operate only in areas where our products and activities are permitted under applicable federal, state or provincial laws. Our goal is to increase our total addressable market as countries legalize psilocybin for medical uses and also adult-use access. We intend to be an early leader in the development of medical psilocybin products by developing new and innovative products.

Intellectual Property

The proprietary nature of, and protection for, our compositions, our processes and our know-how are important to our business. We need to rely upon Orthogonal to seek patent protection in the United States and internationally for our compositions and processes and any other inventions to which we have rights under our License Agreement, where available and when appropriate. To the extent we will be able to do so, our policy will be to work with Orthogonal to pursue patents, to maintain our licensed patents and to protect the technology, inventions and improvements that are important to the development of our business. We will also rely on trade secrets that may be important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection by collaborating with Orthogonal and trade secret protection of our current and future compositions and the methods used to develop and manufacture them, as well as successfully defending any patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our compositions depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any patent applications Orthogonal may file in the future, nor can we be sure that any patents that may be granted in the future upon which we rely will be commercially useful in protecting our compositions and processes. For this and more comprehensive risks related to our licensed intellectual property, please see "*Risk Factors — Risks Relating to Our Licensed Intellectual Property*" in the Company's Offering Circular dated April 23, 2021, as supplemented (the "Offering Circular").

Orthogonal in October 2020 received from the inventor the assignment of certain specific proprietary compounds, methods, discoveries and formulations in the field of natural, non-synthetic psychoactive compounds containing psilocybin/psilocin. As part of this assignment, Orthogonal obtained the complete rights to develop, commercialize, license and seek patent protection for the acquired intellectual property.

In March 2020 Orthogonal filed a provisional patent application with the US Patent and Trademark Office seeking patent protection for aspects of the acquired intellectual property. A provisional application is not examined by a patent examiner and remains confidential.

The provisional patent application describes several compositions, such as oral dosage forms, containing psilocybin and/or psilocin in combination with various specified amino acids, vitamins, plant herbs and/or other compounds. The application also describes methods for making these compositions and using these compositions, including for the treatment of anxiety disorders, depressive disorders or compulsive disorders.

On October 8, 2020, the Company agreed to terms with Orthogonal Thinker, Inc. for the License Agreement, a royalty-free license of certain intellectual property, including the compositions addressed in the Company's provisional patent application, the associated intellectual property, and also intellectual property associated with a number of additional psilocybin-based psychoactive compounds and non-psychoactive nutritional supplements not included in the provisional application. The License Agreement grants Ei.Ventures an exclusive world-wide right to use, manufacture, develop, commercialize, market, and sell all of the intellectual property addressed in the License Agreement with respect to the intellectual property for medicinal, therapeutic, nutraceutical and adult recreational uses, including the matters included in the provisional application. No consideration was paid to Orthogonal Thinker, Inc. for the license. The license is perpetual, subject to limited termination rights, for example, if Ei.Ventures is found guilty of criminal activity or files for bankruptcy.

On March 19, 2021, Ei.Ventures filed a Patent Cooperation Treaty (PCT) application, claiming priority to a March 20, 2020 U.S. Provisional patent application. The PCT application is for a composition that contains: (A) a psychoactive compound selected from the group consisting of psilocybin, psilocin, and combinations thereof; and (B) a supplement selected from the group consisting of an amino acid, a vitamin B6, piracetam, gamma aminobutyric acid (GABA), theobromine, caffeine, resveratrol, and combinations thereof. A method of producing the composition and an oral dosage containing the composition are also described in the application. A PCT application is not examined unless it is filed as a national stage application with individual countries. Before September 19, 2022, Ei.Ventures will need to decide whether file further national stage applications that claim priority to the PCT application. We cannot be sure that patents will be granted with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted in the future upon which we rely will be commercially useful in protecting our compositions and processes.

The following trademark applications are pending with the United States Patent and Trademark Office. Each of these applications is owned by Orthogonal and licensed to Ei.Ventures:

- US Trademark Application No. 90/314,558 for the EI.VENTURES mark, filed on November 12, 2020, with Notice of Allowance issued on January 4, 2022;
- US Trademark Application No. 90/314,547 for the  mark, filed on November 12, 2020, with Notice of Allowance issued January 18, 2022;
- US Trademark Application No. 90/323,536 for the  mark, filed on November 17, 2020, with a Notice of Allowance issued January 18, 2022;
- US Trademark Application No. 90/323,539 for the  mark, filed on November 17, 2020, with a Non-final Office Action issued January 10, 2022;
- US Trademark Application No. 88/814,693 for the PSILLY mark, filed on February 28, 2020, which was suspended on December 20, 2020;
- US Trademark Application No. 88/814,694 for the PSILLY LIFE mark, filed on February 28, 2020, which was suspended on December 20, 2020;
- US Trademark Application No. 90/317,444 for the TRUST THE PSILLY mark, filed on November 13, 2020, with a Notice of Allowance received February 1, 2022;

- US Trademark Application No. 90/314,553 for the BRAIN MANA mark, filed on November 12, 2020, and published on November 9, 2021, with Mana Up Labs, LLC filing a 90-day extension of time to oppose on December 8, 2021;
- US Trademark Application No. 90/323,507 for the MANA mark; filed on November 17, 2020, and published on November 9, 2021, with Mana Up Labs, LLC filing a 90-day extension of time to oppose on December 8, 2021, and an Opposition filed on March 9, 2022 to which the Company will need to Answer by May 18, 2022;
- US Trademark Application No. 90/323,525 for the MANA mark, filed on November 17, 2020, which was suspended on November 1, 2021; and
- US Trademark Application No. 90/323,513 for the BRAIN MANA mark, filed on November 17, 2020, and published on November 9, 2021, with Mana Up Labs, LLC filing a 90-day extension of time to oppose on December 8, 2021;
- US Trademark Application No. 90/323,536 for the mark, filed on November 17, 2020, with a Notice of Allowance issued September 7, 2021;
- US Trademark Application No. 97/142,392 for the PSLY mark, filed on November 24, 2021;
- US Trademark Application No. 97/142,446 for the PSLY mark, filed on November 24, 2021;
- US Trademark Application No. 97/146,383 for the mark, filed on November 29, 2021;
- US Trademark Application No. 97/146,433 for the mark, filed on November 29, 2021;

We cannot be sure that applied-for trademark applications will be granted, nor that any trademarks that may be granted in the future upon which we rely will be commercially useful in protecting our proposed branding.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for final manufacture. We intend to rely on third parties for the manufacture of our compositions for future pre-clinical studies and clinical testing, as well as for commercial manufacture of any products that we may be able to commercialize.

For our future drug candidates, we aim to identify and qualify manufacturers and researchers to provide the application program interface, or API, and fill-and-finish services prior to submission of an NDA to the FDA. We expect to fund the development of drug candidates that can be produced cost-effectively at contract manufacturing facilities.

Business Plan

As we move ahead to implement our business plan, we will begin: (1) product characterization on our licensed intellectual property; (2) product formulation, delivery, and packaging development; (3) pharmacokinetics (PK) and absorption/distribution/metabolism/excretion (ADME) studies; (4) conducting pre-clinical and clinical development for our current and future drug candidates; (5) evaluating the acquisition of one or more drug testing laboratories; (6) prosecuting patent applications and protecting our intellectual property rights and (7) expanding current business operations through the acquisition of office space and hiring of additional personnel.

We have used proceeds of the Regulation A Offering to fund development and registration of intellectual property, research, development and testing of a transdermal patch through Tioga Research, as well as making a strategic investment in Avicanna. The Company intends to use further net proceeds of the Regulation A Offering to fund pre-clinical laboratory tests of the licensed compositions, as well as fund further strategic opportunities for the Company in the psychoactive and nutraceutical industries.

The testing of our licensed compositions will include laboratory tests of product chemistry, toxicity and formulation, as well as potential animal studies. In order to conduct tests on drug candidates containing psilocybin in the United States, the drug testing laboratory must be registered with the DEA. Alternatively, in view of the current more favorable drug scheduling status in Canada, making it easier to conduct pre-clinical and clinical research on psilocybin, we may seek to have the necessary testing completed in a Canadian laboratory. We have identified some third-party drug testing laboratories in the United States and Canada who are qualified to conduct the necessary testing but have not yet sought to determine if they are willing to enter into a contract to perform the anticipated research with respect to our compositions or their schedules allow for the testing or sought to negotiate an acceptable contract for these research services.

We also intend to evaluate the acquisition of one or more currently operating drug testing laboratories or the acquisition of improved or unimproved real property with which we could develop our own drug testing laboratory. Through such an acquisition, we would have the infrastructure in place to perform our own pre-clinical research on our psychoactive compositions and facilitate research into nutraceutical compositions. We believe that the acquisition of one or more currently operating drug testing laboratories could provide a risk-attractive return and operational efficiency.

The completion of satisfactory pre-clinical tests is necessary to prepare a submission to the FDA of an IND to begin Phase 1 clinical trials in the United States on our licensed composition or to prepare a submission to HC of a CTA to begin Phase 1 clinical trials in Canada. We would begin Phase 1 clinical trials once the IND is reviewed and approved by the FDA or the CTA is reviewed and approved by HC. In the Phase 1 clinical trials we would test for safety, dosage, tolerance, absorption, metabolism, distribution and elimination. In view of the current more favorable drug scheduling status in Canada, making it easier to conduct pre-clinical and clinical research, we may seek approval of our licensed compositions in Canada prior to the United States.

We intend to work with Orthogonal to file additional patents in the fields of psilocybin-processing technology, formulation, composition, delivery systems and treatment methods. To establish and protect our licensed intellectual property, we expect to rely on a combination of patent and trade-secret laws, as well as confidentiality provisions in our contracts. We also plan to invest in a trademark portfolio.

Our current officers and directors will continue to evaluate the personnel needs of the Company and bring on consultants and employees as needed to execute our business plan. Our officers are expected to devote at least 40 hours per week to our operations. At this time, all of our officers are working remotely, and we do not currently require additional office space. As the Company grows, we will at some point need our own administrative office facility, including all support components such as additional employees and equipment. We anticipate that within the next year we will hire additional personnel such as administrative assistants and clerical staff to help execute our business plan.

The execution of our business plan requires us to raise significant additional capital. There is no assurance that we will successfully obtain the required capital on acceptable terms, or, if obtained, that the amounts will be sufficient to fund our ongoing operations. The inability to secure additional capital would have a material adverse effect on us, including the possibility that we would have to sell or forego a portion or all of our assets or cease operations. If we discontinue our operations, we will not have sufficient funds to pay any amounts to our stockholders.

If we are successful in raising capital through the sale of shares in the Regulation A Offering, we believe that the Company will have sufficient cash resources to fund its plan of operations for the next twelve months. Because our capital requirements depend upon numerous factors, there can be no assurance that our cash resources will be sufficient to fund the timely completion of any aspect of our business plan. Even if we raise additional capital, if our business plan is not successfully executed, our ability to fund our research and development would likely be seriously impaired. Our ability to conduct research and development and continue operations is conditioned upon moving the development of products toward commercialization. If we are not able to demonstrate adequate progress in the development and commercialization of our product, we will not be able to raise the capital we need to continue our business operations, and we will likely not have sufficient liquidity or cash resources to continue operating.

We plan to continually evaluate our business plan to determine the manner in which we can most effectively utilize our limited cash resources.

Depending upon the results of the Regulation A Offering, the Company currently plans to engage in the following activities during the next 12 months:

- Hire additional members of management and executive staff, increase our scientific personnel, administrative and clerical staff to implement our business plan.
- Find and evaluate strategic opportunities and invest in strategically optimal companies.
- Support our involvement in current investments such as Avicanna.
- Continue to work with Tioga Research regarding the research, development and testing of the transdermal patch.
- Evaluate possible CRO, CMO, and drug testing laboratory acquisitions.
- Begin pre-clinical research on our licensed compositions and develop protocols for studies and apply for applicable licensing (country dependent).
- Meet with federal regulators at FDA CDER to communicate intentions.
- Apply for appropriate DEA licenses (to ship material from manufacturing to labs).
- Continue pre-clinical research.
- Make progress on all safety studies, chemistry/identity, CMC's and submit IND to FDA for regulatory and prepare for Phase 1 clinical trials. Alternatively, submit CTA to Health Canada for approval and prepare for phase 1 clinical trials.
- Commence Phase 1 clinical trials.

We believe that the development of data on the use of psilocybin products will increase mainstream acceptance within the medical community. As such, we intend to develop techniques that achieve pharmaceutical-grade Active Pharmaceutical Ingredients ("APIs") extracted from psilocybin mushrooms to allow the Company to partner with academic research partners on studies that meet regulatory agency standards. These studies are planned to include research and development of an investigational study drug to generate the Chemistry and Manufacturing Controls ("CMC") documentation required by regulatory agencies and to assist in designing protocols and determining the formulation of a study drug.

We may provide funding for such studies and/or pharmacokinetic data on the specific study drug. Studies are planned to be conducted to generate data that can be used to support patent filings and determine signals of efficacy to narrow our focus for future studies. Our Medical and Scientific Advisory Board is expected to participate in the study selection process and provide us with additional credibility as a study participant.

Strategic Opportunities

The Company believes there may be opportunities to align strategically with similar companies in various jurisdictions and different components of the psilocybin industry. Mycotopia is a company focused on the research, development, and commercialization of novel therapeutics based on naturally-derived psilocybin. Performing most of its research in Jamaica, where psilocybin is legal, Mycotopia is focused on mushroom and psychedelic opportunities. Should the Company execute a definitive agreement and complete a merger, the Company intends to align itself with Mycotopia to further their research and development by utilizing different jurisdictions.

Further, the Company has begun, through it's subsidiary Pluto11.11, to engage and further develop emerging technologies to create a safe, efficient, and secure way to provide telehealth services in general and specifically to the psychoactive therapeutics. The Company envisions the safest and most efficient way to collect data and provide psychoactive therapeutics will by utilizing the Metaverse, blockchain technologies and Web3. The Company believes Pluto11.11 may have unique opportunities to invest in or acquire companies that are compatible with this mission because of longstanding relationships and the potential for collaboration between such other companies and the Company and Pluto11.11.

Possible Laboratory Acquisitions

On May 6, 2022, the Company invested in Avicanna Inc., a commercial stage, international biopharmaceutical company, focused on the commercialization of evidence-based, cannabinoid-based products. Ei. Ventures invested in this business as Avicanna already has an established scientific platform and laboratory including R&D and clinical development that has led to the commercialization of more than thirty products across various market segments.

The Company may analyze the possibility of, and may work with Avicanna as a laboratory to conduct the research associated with the Company's pre-clinical studies. It is anticipated that these services would include laboratory tests of product chemistry, toxicity and formulation, as well as potential animal studies. If the Company and Avicanna cannot come to agreement on using Avicanna's facility, we would need to identify a third-party drug testing laboratory qualified, willing to enter into a contract to perform the anticipated research with respect to our compositions and having time in its schedule to allow for the testing and seek to negotiate an acceptable contract for these research services. A contract entered with a third-party may not be as favorable as the terms of conducting research in our own laboratory.

Manufacturing

We do not own or operate, and currently have no plans to own or operate any manufacturing facilities or testing facilities. We currently intend to rely solely on third parties for the manufacturing and testing of our compositions for future pre-clinical studies and clinical testing. All current formulations and testing thereof are theoretical and testing shall only occur at third party facilities pursuant to all to legal requirements and/or regulatory approvals.

For our future drug candidates and nutraceutical products we will continue to explore and qualify manufacturers and researchers to provide the application program interface, or API, and fill-and-finish services prior to submission of an NDA to the FDA. We expect to fund the development of drug candidates that can be produced cost-effectively at third party contract manufacturing facilities.

For our nutraceutical products, we intend to outsource manufacturing to a contract supplement manufacturer in a NSF GMP Registered and FDA approved facility in the United States, which such contract supplement manufacturer will also source the ingredients.

Marketing

This year we contracted a third-party to develop our PSLY brand. As we continue, we may perform marketing functions ourselves or through third parties or may take other steps to establish the necessary marketing infrastructure if any of our compositions are approved as drugs.

For our nutraceutical products, we intend to sell directly to consumers through online channels and ecommerce. The nutraceutical products will likely be packaged in bottles using a monthly supply format and shipped via USPS through an outsourced fulfillment center.

Employees

As of the date of this Report, we have 2 full-time employees and approximately 7 consultants. None of our employees is subject to a collective bargaining agreement, and we believe that our relations with our employees generally are good. We anticipate that within the next year we will hire additional personnel including members of executive staff, administrative assistants, and clerical staff to help execute our business plan.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, such as pharmaceutical companies, biotechnology companies, drug delivery companies and academic and research institutions. Many of our

potential competitors have substantially greater financial, scientific, technical, intellectual property, regulatory and human resources than we do, and greater experience than we do developing drug candidates, including obtaining FDA and other regulatory approvals for drug candidates. These competitors include Champignon Brands Inc., Mind Medicine, Inc., Revive Therapeutics. Ltd., COMPASS Pathways, Ltd., Field Trip Health, Inc., Cybin, Inc., and Eluesis, Ltd. Consequently, our competitors may develop products for indications we pursue that are more effective, better tolerated, more widely-prescribed or accepted, more useful and less costly, and they may also be more successful in manufacturing and marketing their products. We also face competition from third parties in recruiting and retaining qualified personnel and in identifying and acquiring or in-licensing new products and drug candidates.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, Canada and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States, by HC through the NDS process before they may be legally marketed in Canada and by the European Medical Associate through the Marketing Authorization Application, or MAA, process before they may be legally marketed in Europe. Our drug candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Regulation of Psilocybin

United Stated Drug Enforcement Agency

Psilocybin and psilocybin extracts are regulated as "controlled substances" as defined in the CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Psilocybin is currently regulated as a Schedule I substance, which by definition has no established medicinal use, and may not be marketed or sold in the United States. A drug may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Psilocybin and psilocybin extracts are listed by the DEA as Schedule I controlled substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. The registered entity must maintain records for the handling of all controlled substances and must make periodic reports to the DEA. These include, for example, distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. The registered entity must also report thefts or losses of any controlled substance and obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA may adjust aggregate production quotas and

individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. In the event of non-compliance, the DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

States

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition.

Currently in the U.S. the possession of psilocybin-containing mushrooms is illegal, because they contain the Schedule I drugs psilocybin and psilocin. However, some cities in various states including Washington, California, Michigan, and Massachusetts have decriminalized or deprioritized the use and possession of psilocybin. Oregon is the first state to decriminalize psilocybin and also legalize it for therapeutic use. The limited city and state laws are in conflict with the federal Controlled Substances Act ("CSA"), which classifies psilocybin and psilocin as schedule 1 drugs. use and possession illegal at the federal level. Because psilocybin is a Schedule I controlled substance, however, the development of a legal psilocybin industry under the laws of these states is in conflict with the CSA, which makes psilocybin use and possession illegal on a national level. The federal government has the right to regulate and criminalize psilocybin, including for medical purposes, and the CSA preempts state laws that legalize its use.

Health Canada

In Canada, psilocybin is classified by HC as a schedule III drug under the CDSA, meaning activities such as sale, possession, or production of these substances are prohibited unless they have been authorized for clinical trials or research purposes by HC, consistent with Part J of Canada's Food and Drug Regulations. Under Part J, a party may file a CTA to study psilocybin for a medicinal use. The compliance and monitoring of controlled drugs and substances in Canada is overseen by HC's Office of Controlled Substances, in conjunction with law enforcement agencies. The CDSA provides for the control of substances that can alter mental processes and that may produce harm to health and to society when diverted or misused. Except as authorized under its related regulations, or via an exemption issued under section 56 of the CDSA, most activities involving substances regulated under the CDSA, such as possession, import, export, trafficking, and production are prohibited. Controlled substances are regulated and grouped into Schedules I to V to the CDSA. Schedule III is considered of less abuse potential than Schedule I.

HC administers the CDSA and its regulations to: (1) allow access for lawful purposes and (2) reduce the risk that controlled substances and precursors will be used for illegal purposes. To meet these two objectives, HC: (1) issues licenses, permits and exemptions, (2) monitors trends of problematic substance use, (3) updates the Schedules to the CDSA based on assessments of new or existing substances, when necessary, (4) works with international organizations and other countries to meet Canada's obligations regarding controlled substances. The CDSA applies to a broad range of parties, including: (1) manufacturers, distributors, importers and exporters who must get a license to produce, sell, import or export controlled substances and precursors, (2) importers and exporters who must get a permit each time they import and export a controlled substance or precursor, (3) health professionals who must comply with requirements when prescribing and giving controlled substances to a patient, and (4) researchers who must get permission to have a controlled substance for research purposes.

All regulated parties must comply with requirements for: (1) security, (2) reporting, and (3) record-keeping. HC promotes and enforces compliance with the CSDA by: (1) developing and publishing guidance, (2) informing affected parties of any regulatory changes, and (3) publishing notices seeking public input on proposed regulatory changes. HC also carries out inspections of regulated parties and monitors regulated activities. HC may take action when a regulated party is not following the rules of the CDSA, including (but are not limited to): (1) issuing warning letters, (2) requiring a corrective action plan, (3) suspending and revoking licenses, permits or exemptions to stop a

regulated party from conducting activities. To further enforce the CDSA, HC works with a wide range of partners and stakeholders, including: (1) provincial and territorial governments, (2) other federal departments and agencies, (3) law enforcement agencies, (4) academic, scientific and research communities, (5) non-government organizations, such as national, provincial and territorial health professional associations, (6) federal regulators in other countries, (7) international organizations, such as the United Nations.

In Canada, mushroom spore kits and are legal and are sold openly in stores or on the Internet, as the spores and kits themselves are legal. Online dispensaries exist that openly sell microdoses to Canadian patients with medical prescriptions. The Canadian police tolerates the activity, citing focus on more harmful criminal drug activities. In September 2019, a motion to prevent the sale of magic mushrooms was defeated by Vancouver council.

In addition to HC, the National Association of Pharmacy Regulatory Authorities (NAPRA) also has a role in scheduling new drugs, which is separate from HC's scheduling process. NAPRA's role in the drug scheduling process occurs after HC has authorized a drug for sale in Canada and determined whether the drug requires a prescription for sale. NAPRA does not have any role or authority in the authorization of new health products for the Canadian market and does not review products that have been classified as requiring a prescription by HC.

While the federal government determines certain conditions of sale, such as the need for a prescription, provincial/territorial governments have the ability to further specify the conditions of sale of drug products. Prior to 1995, each province and territory had its own system for determining the conditions of sale for non-prescription drugs in Canada, leading to wide variability in the way drugs were sold across Canada. In 1995, NAPRA's members, the pharmacy regulatory authorities across Canada, endorsed a proposal for a national drug scheduling model, to align the provincial/territorial drug schedules so that the conditions of sale for drugs would be more consistent across Canada. This harmonized national model is administered by NAPRA and is called the National Drug Schedules (NDS) program.

All of the provinces and territories, except Quebec, have adopted the National Drug Schedules in some manner. The NDS come into force in each province/territory through provincial regulations. In general, the National Drug Schedules capture drugs that have been authorized for sale and classified as non-prescription by HC. Other products approved by HC (e.g. natural health products, medical devices) are outside the scope of the program and are not considered products for scheduling within the NDS.

The NDS program consists of three schedules and four categories of drugs. Schedule I drugs require a prescription for sale. Schedule II drugs require professional intervention from the pharmacist (e.g., patient assessment and patient consultation) prior to sale. Schedule III drugs must be sold in a licensed pharmacy but can be sold from the self-selection area of the pharmacy. Unscheduled drugs can be sold without professional supervision, from any retail outlet.

The drug scheduling process usually begins when NAPRA receives a drug scheduling submission from a pharmaceutical company. The National Drug Scheduling Advisory Committee is an expert advisory committee that reviews the drug scheduling submissions received by NAPRA and formulates drug scheduling recommendations. There is a specific process that must be followed during each drug scheduling review, which is outlined in NAPRA's By-law No. 2 and Rules of Procedures. The model for making drug scheduling recommendations embodies a "cascading principle" in which drugs are assessed against specific scheduling factors. A drug is first assessed using the factors for Schedule I. Should sufficient factors apply, the drug remains in that Schedule. If not, the drug is assessed against the Schedule II factors, and if warranted, subsequently against the Schedule III factors. Should the drug not meet the factors for any schedule, it becomes "Unscheduled" (the fourth category).

According to this cascading principle, it is possible, although rare, for NAPRA to place a product in Schedule I that HC has classified as a non-prescription product. This could occur because of the NAPRA policy for drugs not reviewed, which places drugs into Schedule I until they are reviewed, or because of a range of factors considered by the expert advisory committee when applying the cascading drug scheduling model. As described above, the provinces and territories can add additional conditions of sale for non-prescription drugs but can never be less restrictive than federal legislation.

Once the National Drug Scheduling Advisory Committee has reviewed a particular drug, it will make an interim drug scheduling recommendation. A 30-day consultation period follows, after which the NAPRA Board of Directors will make a final scheduling recommendation. The National Drug Schedules are then amended and the final recommendation is implemented according to the rules in each particular province or territory.

In summary, whereas in the U.S. psilocybin is presumed to have no medical use and is s Schedule I drug, in Canada, psilocybin is classified as a drug with a lower potential for abuse under Schedule III and is being studied in clinically-supervised settings for its potential to treat various conditions such as anxiety, depression, obsessive compulsive disorder and problematic drug use. Currently there are no approved therapeutic products containing psilocybin in Canada or the US. Once a psilocybin- psilocin-containing product were approved in Canada, we would expect it to remain Schedule III or a higher level (IV or V) and that NAPRA could schedule as I, requiring a prescription.

General New Drug Regulation

United States New Drug Application

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters;
- product seizures;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices, or GLPs, or other applicable regulations;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Once a drug candidate is identified for development, it will enter the pre-clinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding

concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the new drug. If a Phase 2 clinical trial is the subject of discussion at the end of Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to published guidance on the SPA process, a sponsor which meets the prerequisites may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the

sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug candidate receiving accelerated approval perform post-marketing clinical trials.

In the recently enacted Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law requires the FDA to issue related draft guidance within a year after the law’s enactment and also promulgate confirming regulatory changes.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical studies or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are considered to be therapeutically equivalent to the listed drug, are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug in accordance with state law.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA or 505(b)(2) application seeking approval of a drug that references a version of the NCE drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA or 505(b)(2) application that includes the change.

An ANDA or 505(b)(2) application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and thus no ANDA or 505(b)(2) application may be filed before the expiration of the exclusivity period.

For a botanical drug, the FDA may determine that the active moiety is one or more of the principal components or the complex mixture as a whole. This determination would affect the utility of any five-year exclusivity as well as the ability of any potential generic competitor to demonstrate that it is the same drug as the original botanical drug.

Five-year and three-year exclusivities do not preclude FDA approval of a 505(b)(1) application for a duplicate version of the drug during the period of exclusivity, provided that the 505(b)(1) applicant conducts or

obtains a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase — the time between IND submission and NDA submission — and all of the review phase — the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or BPCA, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act, or PREA, requires all applications (or supplements to an application) submitted under section 505 of the FDCA (21 U.S.C. Section 355) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain a pediatric assessment unless the applicant has obtained a waiver or deferral. It also authorizes the FDA to require holders of approved NDAs for marketed drugs to conduct pediatric studies under certain circumstances. In general, PREA applies only to those drugs developed for diseases and/or conditions that occur in both the adult and pediatric populations. Products intended for pediatric-specific indications will be subject to the requirements of PREA only if they are initially developed for a subset of the relevant pediatric population.

As part of the FDASIA, Congress reauthorized both BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Canadian New Drug Submission

Given the current more favorable drug scheduling status in Canada, making it easier to conduct pre-clinical and clinical research, we may seek approval to market in Canada prior to the United States. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence pre-clinical studies or clinical trials in such countries and approval of the regulators of such countries or economic areas, such as Canada, before we may market products in those countries or areas. The approval process and requirements governing the conduct of pre-clinical studies, clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In Canada, our future products may also be subject to extensive regulatory requirements. Similar to the United States, the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the United States, the various phases of pre-clinical studies and clinical research in Canada are subject to significant regulatory controls. Medicinal products require a marketing authorization before they may be placed on the market in Canada. There are various application procedures available, depending on the type of product involved. An applicant files a New Drug Submission ("NDS") with HC where it is reviewed by a relevant scientific committee. Both psilocybin and psilocin are controlled under Schedule III of the Controlled Drugs and Substances Act (CDSA) in Canada, meaning activities such as sale, possession, production, and use of these substances are prohibited unless authorized for clinical trial or research purposes under Part J of the Food and Drug Regulations.

Businesses that make, import, package, label, distribute, and/or test drugs must submit an NDS. The Company, therefore, must apply for and receive a Drug Identification Number (DIN) in order to sell or import a drug in Canada. A DIN is required for both prescription and non-prescription drugs. Post-authorization obligations of DIN holders include: notification of when they start selling or when they discontinue the sale of the drug, annual notification to confirm information, adverse drug reaction reporting, annual summary reports, maintenance of records, and recalls. A clinical trial sponsor (a person responsible for the conduct of a trial) must seek permission from HC to conduct a clinical trial. Sponsors must meet certain requirements, including: following good clinical practices, obtaining informed consent from participants, keeping records, ensuring that the drug is manufactured according to GMP, reporting serious unexpected adverse reactions and notifying HC of the discontinuance of a trial. A manufacturer must receive authorization from the Commissioner of Patents in order to sell a drug under Canada's Access to Medicines Regime. The manufacturer must notify the Minister before making the first lot of an authorized drug and before exporting each subsequent lot. The manufacturer must also fulfill the same post-authorization record keeping and reporting obligations as for a new drug sold in Canada.

In particular, businesses must submit sufficient information for the assessment of the new drug's safety, efficacy and quality. Post-authorization obligations include: collecting safety information about the drug and its effects, record keeping and reporting information to HC.

As a controlled drug, prior to possessing or engaging in an activity such as production, sale, provision, sending, delivery, transportation, importation or exportation of a controlled drug regulated under Part G, persons, including businesses, may require authorization from HC. Such authorizations can include a dealer's license. Licensed dealers must meet certain terms and conditions such as security and record-keeping requirements. In addition, licensed dealers must obtain a permit from HC for each import or export of a controlled drug. Compliance with the regulations is monitored by HC. Authorized places such as licensed businesses and pharmacies are subject to on-site inspections to verify compliance.

Further, as a Part J restricted drug, prior to possessing or engaging in an activity such as production, sale, provision, sending, delivery, transportation, importation or exportation of a restricted drug regulated under Part J, persons, including businesses, may require authorization from HC. Such authorizations can include a dealer's license. Licensed dealers must meet certain terms and conditions such as security and record-keeping requirements. In addition, licensed dealers must obtain a permit from HC for each import or export of a restricted drug. To purchase a restricted drug from a licensed dealer for clinical trial or research purposes, research institutions must obtain an authorization from HC. The licensed dealer must also receive authorization from HC in order to make that sale. Compliance with the regulations is monitored by HC. Authorized places such as licensed businesses, and institutions are subject to on-site inspections to verify compliance.

Canadian Drug Approval

Drugs to be marketed or sold in Canada are reviewed and authorized by the Health Products and Food Branch (HPFB) of HC, under the Therapeutic Product Directorate (TPD) or the Biologic and Genetic Therapies Directorate (BGTD), for drugs and biologic, respectively. Each of these Directorates have specific offices and bureaus.

Drugs are authorized to reach that market only once they have successfully gone through the relevant Bureau review process, responsible for assessing their safety, efficacy and quality, and received a favorable decision. Even after a health product receives a favorable decision and can proceed with its sale in Canada, monitoring of its effectiveness and safety continues.

HC's HPFB is the national authority that is responsible for regulating, evaluating, and monitoring the safety, efficacy, and quality of drugs, biologics, genetic therapies and other health products available for the Canadian marketplace. The HPFB's mandate is to manage the health-related risks and benefits of health products and foods for Canadians.

CTA

The drug discovery and pre-clinical phases in Canada are similar to the United States, and the clinical phase begins with the submission of a CTA. The CTA dossier is simple and consists of the following documents (exceptions are possible): administrative form, protocol, protocol summary (HC's template), Informed Consent Form, Investigator's Brochure and quality dossier summary (HC's template per study phase). HC reviews the CTA and notifies the sponsor within 30 calendar days from the date that the application is considered complete. Questions may be issued during the review, and the sponsor will have two calendar days to provide the response (exceptions can apply). CTAs are required for phases I to III clinical trials. The authorization (No Objection Letter) is mandatory prior to initiating the trial and importing the investigational product(s) in Canada.

If the HPFB provides authorization, the study can be underway with human subjects that are informed and have given their consent to be administered the drug for their participation. A Canadian Ethic Committee must also approve the study material (protocol, Investigator's Brochure and Informed Consent Form).

Tests are conducted in a controlled environment where drug administration procedures and results are closely tracked, monitored and analyzed.

Clinical Trial Phases

There are, in summary, four (4) phases in the clinical trials process. Each clinical trial phase for drugs has a different purpose.

Phase 1 – The Safety phase

This phase usually tests an investigational drug on a small group of healthy individuals for the first time (except when not ethically acceptable to do so). The purpose is to determine the pharmacokinetics/pharmacological action of the drugs, find a safe dosage range and identify adverse drug reactions.

Phase 2 – The Effectiveness phase

In this phase, the drug is given to a larger group of individuals with the pathology to be treated (usually several hundred). The purpose is to obtain data on the effectiveness of the drug, to further assess the drug's safety and to determine the best dose.

Phase 3 – The Confirmation Phase

If the results from Phase 2 look promising, the drug manufacturer would proceed into Phase 3 trials. In this phase, the drug is given to even larger groups of patients (usually in the thousands). The purpose of this phase is to confirm the drug's effectiveness, monitor side effects, compare the drug to other commonly used treatments and to collect further information that will allow the drug to be used and marketed safely.

Phase 4 – The Monitoring phase

Phase 4 trials are done after the drug is already approved and sold on the market. The purpose of this phase is to gather more information on the best ways to use a drug, and the long-term benefits and risks to the population.

Unless agreed to with HC, these studies do not need to be submitted under a CTA, when used according to the terms of the market approval.

Application Phase

NDS

If results of all the preclinical studies and the clinical trials show that a drug's potential therapeutic benefit outweighs its risks (e.g., side effects or toxicity), and the chemistry and manufacturing dossier is complete, then the sponsor may decide to file an NDS with the appropriate HPFB Directorate in order to be granted authorization to sell the drug in Canada. A sponsor can submit an NDS whether the clinical trials were done in Canada or in other countries. The NDS must include the results of the quality (Chemistry and manufacturing), preclinical and clinical studies, whether done in Canada or in other countries. The drug's efficacy and safety data are evaluated and the Risk/Benefit analysis is performed, before reaching a decision.

The information requested as part of an NDS application must be detailed enough that HC can make an assessment on the safety and effectiveness of the new drug. All submissions must be provided to HC in an electronic Common Technical Document (eCTD) format. The CTD format is divided into five modules: Module 1 contains region-specific information and Modules 2–5 contain common clinical, nonclinical and quality information with some regional variations.

Abbreviated New Drug Submission (ANDS)

The ANDS regulation was created to make the approval process for generic drugs simpler and more cost effective. Under an ANDS, the manufacturer of a drug has to prove that its product is pharmaceutically equivalent and/and bioequivalent with the innovator's drug.

For the purpose of an ANDS the sponsor may need to perform a bioequivalence study or a physico-chemical comparison (parenteral drugs or drugs for which it is not ethical to conduct the study on healthy volunteer).

Review Process

The HPFB reviews the NDS and all the information about the drug captured during the development process (quality, preclinical and clinical) and evaluates the risks of the drug versus its bene fits to the Canadian population. More specifically, HPFB reviews information regarding the drug's manufacturing, packaging and labelling, as well as information about the drug's therapeutic claims and side effects. What doctors and patients will be told about the drug will also be reviewed, through the drug's monographs and information sheets.

All drugs allowed to be sold in Canada are reviewed to ensure that they meet the requirements of the Food and Drugs Act and its Regulations. Once these requirements are met, the sponsor (usually the Marketing Authorization Holder) would receive a Notice of Compliance, confirming the dossier's compliance with the Food and Drugs Act and its Regulations.

The target review timeline ranging from seven (7) months (accelerated review and ANDS) to one (1) year (standard NDS). The exact time for HC to review drug safety and efficacy information from an NDS depends on the type of drug, the quality of the dossier, the number of questions that HC raises during the review process, the answers provided by the sponsor and if the targeted timelines for the responses are respected.

Once the review is complete, the Regulatory Agency decides to approve (or reject) the use of a new medication.

In some instances, it can take longer than the targeted review timelines. HPFB review timelines are based on internationally competitive performance targets that are usually respected. Typically, the review can take anywhere from six (6) months to two (2) years, rarely more. The average time of the full drug development and approval process from initial research, preclinical studies, through the three (3) phases of clinical trials to drug approval is twelve (12) years (between eight (8) & fifteen (15) years).

The Notice of Compliance: Once the review is complete, if the conclusion is that the benefits of the drug outweigh the risks, that the risks can be managed and confirming the dossier's compliance with the Food and Drugs Act and its Regulations, then the sponsor in Canada receives a Notice of Compliance (NOC), as well as a Drug Identification Number (DIN), which is specific to a drug product to be sold on the Canadian market.

Upon the completion of the review process, if the HPFB finds that there is insufficient evidence to support the safety, efficacy or quality claims of the drug, HPFB will not grant a marketing authorization for that drug. In this case, HPFB will grant a Notice of Non-Compliance. At this point, the sponsor typically has three options: (1) to supply additional information to the HPFB, (2) to re-submit a submission at a later date with additional supporting data (without prejudice), or (3) to ask that HPFB to reconsider its decision.

Accelerated Review Process

For health conditions that are serious, life-threatening or for a severely debilitating disease (e.g., Alzheimer's disease, cancer, AIDS, or Parkinson's Disease), the HPFB can provide faster authorization of a drug as follows:

1. Priority Review (PR): Applies to drugs that shows substantial evidence of clinical effectiveness at the end of the clinical trial phases.

2. Notice of Compliance with conditions (NOC/c): Applies to drugs with promising evidence of clinical effectiveness throughout the clinical trial phases. Approval would be granted to a manufacturer to market and sell that drug in Canada with the condition that the manufacturer execute additional studies to confirm the drug's benefit and safety.

To be considered for PR or NOC/c, the drug must meet the following standards as described by HC; the drug must provide:

- effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or
- a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada

Related to the NOC/c, some of the conditions of the Notice of Compliance include a requirement to closely monitor the drug for safety and to provide HPFB with regular updates. Once the conditions are met, the designation of "with condition" is removed from the NOC.

Post Approval

Once a health product is approved and, on the market, the HPFB requires a sponsor to ensure that the use of its drug is done under the terms of its market authorization.

In addition, Life Cycle Management activities (e.g., post approval submissions to HC, for new indications, new dosage forms, new strengths, manufacturing changes) are required to ensure the maintenance of the product License with its related improvements. In summary, sponsors need to ensure its continued compliance with the Food and Drug Regulations, while their products are on the market.

On the other hand, HC monitors drug information & adverse drug reactions reporting, conducts market surveillance, investigates complaints and manages recalls if necessary, amongst other things.

There are also more processes and regulations to follow and consider, either before, during or after the review process, and before that drug is officially marketed, distributed and sold in Canada. Topics such as licensing, warehousing, wholesale distribution rules and the Drug Establishment License (DEL), regulations around distribution to consumers, regulations around the marketing and advertising activities, provincial requirements, health insurance funding rules, among others.

Patent Linkage and Term Restoration in Canada

Since Canada amended its Patented Medicines (Notice of Compliance) Regulations on September 21, 2017, the Canadian system relating to challenges to patents became more similar to the US Hatch-Waxman system but with some important differences that may impact our ability to market without substantial or any generic drug competition based on the patents that we obtain for our products.

Similar to the US, Canada maintains a list of patents that are applicable to innovative drug products, included in a Patent Register. Innovator companies with an approved NDS may timely list in the Patent Register patents that include at least one claim to approved medicinal ingredients, formulations, dosage forms, or use but not pure process patents.

For NDS products where data protection applies (new chemical products), a generic drug may not be submitted until six years after the innovator's first approval and such generic application may not be approved until eight years after first approval or eight and a half years with a pediatric extension. Unlike the US, however, there is no new clinical data (new use or new formulation with clinical data) exclusivity or orphan drug exclusivity to consider, nor is there any exclusivity for a first generic applicant to challenge a listed patent for an innovator's product.

Patent litigation prior to market entry for a generic drug begins with a Notice of Allegation (NOA), which is similar to the US mechanism for a Paragraph IV Notice Letter in that the generic applicant must only address patents listed in the Patent Register as of its regulatory filing date and patent litigation must be brought within 45 days of notice. However, in Canada, there is no 20-day or other deadline to serve this NOA to the innovator or patent holder. In Canada, a first person cannot bring a patent litigation action for a listed patent outside the regulations unless it did not have a reasonable basis for bringing the action within the 45-day statutory deadline. Unlike the US where patents listed after generic regulatory filings or unlisted patents are not automatically included in pending litigation, in Canada once the NOA is served those newly listed or unlisted patents may also be asserted, provided infringement could result from the making, constructing, using, or selling of the drug in accordance with the submission.

Similar to the US, in Canada there is a statutory stay of generic marketing approval, but the time period is 24 months versus 30 months, and like the US this period may be shortened or extended by a court. Such 24-month stay does not apply "in respect of a patent" if a finding of patent ineligibility is made or a patent has been deleted from the Patent Register. In Canada, unlike the US, there is an additional statutory provision that permits such stay to be renounced by the innovator/patent holder that precludes the ability to bring damages for delayed generic market entry. And similar to the US, while litigation is pending, there is a patent hold, which correlates to a "tentative approval" in the US, where HC indicated that an abbreviated NDS is approved but may not be marketed. If a declaration of infringement is made prior to issuance of an NOC, the NOC issuance will be barred until patent expiry. If the NOC issues prior to declaration of infringement, however, a court may order any other remedy under the Patent Act such as injunctive relief.

Patent litigation in Canada will likely conclude by the 21-month mark from its inception with damages possible for losses flowing from delayed generic entry, if the generic applicant is successful, but such damages do not apply if the statutory stay is renounced. In Canada, damages for delaying generic entry may include damages to the generic applicant's profits, if a court grants a right to elect profits, and a portion of attorney costs is more likely than in the US.

In Canada, post-grant reviews by the Patent Office are possible but uncommon in the form of a re-examination, in contrast to the US, where inter partes review is more common, thereby reducing such risk in Canada.

Finally, Canada provides for a method of Certificates of Supplementary Protection (CSPs) for up to two years in contrast to patent term extension in the US, which has a maximum of five years. A CSP may only be flied if there is more than two years remaining in the patent term, and the DSP must be filed within 120 days of grant of the NOC (for an earlier granted patent) or the patent (for an earlier granted NOC). The patent owner can consent to the NOC holder to file the CSP application.

For a CSP to be available, there application for the authorization for sale must be filed within a deadline to be prescribed relative to the first corresponding foreign application for marketing approval. The prescribed countries include the European Union, the US, Australia, Switzerland, and Japan. The prescribed period for filing the application for sale is 18 months, if the application for the CSP was filed no later than the first anniversary of the day on which the CSP provisions come into force, and 12 months, in any other case.

The term of a CSP is calculated by subtracting five years from the period beginning on the filing date of the patent application and ending on the day on which the authorization for sale is issued. The CSP will take effect at the end of the patent term, and the term may be reduced if the holder of the actions of the CSP result in a period of unjustified delay in obtaining the authorization for sale. Only one patent, however, may be named in each application for CSP correlating to a given medicinal ingredient or combination. CSPs may also be listed in the Patent Register, similar to how extended patents may be so listed in the Orange Book.

Reimbursement

U.S. Reimbursement

Sales of any product we successfully develop will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our drug candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, is expected to have a significant impact on the health care industry. ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to drugs, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, some members of the U.S. Congress have been seeking to overturn at least portions of the legislation and we expect they will continue to review and assess this legislation and alternative health care reform proposals. Any legal challenges to ACA, as well as Congressional efforts to repeal ACA, add to the uncertainty of the legislative changes enacted as part of ACA.

Canadian Reimbursement

Canada has Medicare, a universal (publicly funded) healthcare since the 1960s; however, medication, except drugs administered in hospitals and for certain special populations, are not covered through the universal, publicly-funded, Medicare program. Thus, the majority of the population (about 66%) obtains drug coverage through private insurers, either through their employers or purchased individually. For public funding, each Canadian province and territory operates its own drug plan, which primarily covers seniors, welfare recipients, and other groups for whom drug costs represent a significant financial burden. Some provinces (such as Alberta, British Columbia, Saskatchewan and Quebec) make their drug plans available to all residents who choose to join the plan (Alberta, British Columbia, Saskatchewan) or lack private drug coverage (Quebec). Moreover, the federal government has established drug plans for First Nations (Non-Insured Health Benefits), veterans, penitentiary inmates, armed services personnel, and the federal police. Altogether, approximately 10 million Canadians are covered by publicly funded drug plans, nine million through the provincial plans and another million through the federal one while 10 percent of Canadians lack basic drug coverage.

Provincial bodies control healthcare funding. However, national bodies are important in advising formulary decision making. Quebec, predominately French speaking, does not, for the most part, participate in such pan-Canadian processes that serve the rest of the country (English speaking). Formulary decisions are rendered province by province, hospital by hospital and in some cases, separately for diseases such as cancer and HIV/AIDS.

Decision Makers and Influencers

HC is the federal health department is responsible for approving new drugs based on their safety and efficacy, among other factors. HC releases a formal marketing and distribution authorization (NOCs) if the new

drug's profile conforms to the Food and Drugs Act and Regulations. HC is also responsible for promoting healthy living to Canadians by communicating information on disease prevention, drug safety, and other health-related issues.

The Patented Medicine Prices Review Board (PMPRB) is an independent body within the federal health portfolio, responsible for regulating drug prices for all prescription and non-prescription patented drugs sold in Canada. PMPRB submits to the federal parliament, through the Minister of Health, an annual report including analyses of patented drug prices, price trends, and research and development expenditures of patent-holding drug manufacturers.

The Canadian Agency for Drugs and Technologies in Health (CADTH) is an independent, not-for-profit agency funded by federal, provincial, and territorial governments, that provides evidence-based information about the effectiveness of drugs and other health technologies to Canadian healthcare decision makers. CADTH fulfils its mandate through the Health Technology Assessment (HTA) program, the Common Drug Review (CDR; see below) process, and the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) which identifies and promotes optimal drug therapy.

The Common Drug Review (CDR) is mandated through the CADTH's mandate to accept drug submissions from manufacturers, conducts systematic drug reviews, and provides participating public drug plans (federal, territorial, and all Canadian provinces except Québec) with evidence-based clinical and economic information, and expert advice, to support their formulary listing decisions.

The Canadian Expert Drug Advisory Committee (CEDAC) is part of the CDR process. The CEDAC is composed of drug therapy and evaluation experts, who make formulary listing recommendations to participating drug plans based on scientific evidence and current clinical practice.

The pan-Canadian Oncology Drug Review Process (pCODR) is a cross-jurisdictional review process for all oncology drugs, based on Ontario's existing cancer drug review. Participating provinces (Manitoba, Saskatchewan, British Columbia, Alberta, Nova Scotia, Newfoundland, Prince Edward Island, and New Brunswick) each make their own final funding decision based on input from the Committee to Evaluate Drugs (CED) and the CED-Cancer Care Ontario (CCO) Subcommittee.

Conseil du médicament — Québec is a provincial body accepts drug submissions from manufacturers and makes recommendations concerning listing a drug on the provincial drug formulary (Liste de medicaments). Final listing decision is made by Québec's Minister of Health.

Decision-Making Process

The Common Drug Review (CDR) process currently applies to all provinces except Quebec. Prior to 2002, separate submissions for formulary listing were made to each regional health plan. Submission requirements varied between drug plans. However, all economic evaluations had to comply with either the Ontario economic guidelines or those developed under the auspices of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA, now CADTH) in 1994.

In 2002, Canada initiated the Common Drug Review (CDR) to harmonize the drug review process across the country, in an attempt to optimize the use of healthcare resources and reduce duplication of effort. A CDR submission represents a submission to all participating institutions, including all federal (this covers Non-Insured Health Benefits, the Department of National Defense, Veterans Affairs Canada, the Royal Canadian Mounted Police and Correctional Service Canada), provincial (all provinces, except Quebec) and territorial (Northwest Territories, Yukon, Nunavut) drug plans. The CDR accepts submissions for drugs and combination products (i.e., drugs consisting of two or more active moieties) not previously marketed in Canada, and, under specific circumstances, submissions for new indications. Alberta and British Columbia continue to want submissions for oral HIV/AIDS products made directly to their reimbursement agencies (i.e., Alberta Health and Wellness and British Columbia Centre of Excellence in HIV/AIDS).

The goal of the CDR is to provide participating drug plans with formulary listing recommendations based on a consistent, scientifically rigorous, evidence-based review. Manufacturers submit a dossier to CDR. A review of each product submission is performed by internal reviewers (CDR staff) and external clinical and health economic experts and sent to the manufacturer for comment. The review, manufacturer comments and reviewer replies to the comments are then submitted to CEDAC who meet monthly for deliberation and recommendation.(5) CEDAC may recommend a drug (a) be listed, (b) be listed with restrictions, or (c) not be listed at all. The listing recommendation is posted on CADTH's website. The final listing decision rests with each public drug plan and depends on individual mandates, priorities, and local resources.

The CDR does not review products used for the active treatment of cancer; these are submitted to the pan-Canadian Oncology Drug Review (pCODR). Line extensions for established products are also not submitted to the CDR but directly to individual drug plans. Quebec's public drug plan requires separate formulary submissions, independent of CDR or pCODR. In addition, the province of Ontario has established a Rapid Review Process that is independent of the CDR Process.

The pan-Canadian Oncology Drug Review (pCODR) process applies to all provinces except Quebec. Submissions for drug products for active treatment of cancer that may potentially be funded by the participating provincial and territorial drug plans (i.e., federal, provincial and territorial drug plans, except Quebec) are directed to pCODR who will make a listing recommendation. pCODR is a newly established evidence based cancer drug review process with the role of assessing clinical evidence and cost-effectiveness of new cancer drugs. Manufacturers submit a dossier to the pCODR expert review committee, which also takes into account input by patients and clinician-based tumor groups.

Ontario is participating in the CDR and pCODR processes. However, a product may qualify for the Rapid Review Process, which is independent of the CDR, if evidence is submitted showing that the new chemical entity will either fill a significant unmet medical need or that listing will result in significant savings for the drug plan or the Province. Rapid Review submissions can be made before receipt of the HC Notice of Compliance (NOC, but not earlier than 90 days before expected NOC issuance). Rapid Review submissions filed at least 60 days pre-NOC are eligible to receive a listing decision within 30 days of NOC issuance. Listing decisions are made by the Assistant Deputy Minister and Executive Officer, Ontario Public Drug Programs. (Note that the CDR has also recently piloted a pre-NOC rapid review process.)

Quebec

Quebec's Régime Public D'Assurance Médicaments (Public Drug Insurance Program) provides drug coverage to seniors, welfare recipients, and residents without private drug insurance. The last are required to join the public plan (universal coverage). About 43 percent of Quebeckers are covered by the public plan. To obtain listing on the Quebec formulary (i.e., Liste de Médicaments Assurés) for any potentially covered drug, manufacturers submit a dossier to the Conseil du Médicament, which makes a listing recommendation. The listing decision is made by the Minister of Health and Social Services. The formulary is published three times a year and is available online in a downloadable format.

Hospitals

Hospitals maintain their own formularies through Pharmaceuticals and Therapeutics Committees. Dossiers must be submitted to individual hospitals or hospital consortia.

Private Payers in Canada may cover all HC approved drugs, establish their own formularies, or follow the public drug plan in their province. In Quebec, private insurers are required to cover at least all drugs listed in the provincial formulary. Many private drug plans ask for submission dossiers and specific requirements vary by plan.

Reimbursement and Pricing Approval Process

Pricing approval for brand pharmaceuticals in Canada is regulated by the federal government, through the PMPRB. It acts in a regulatory capacity, to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The price of non-patented drugs, such as generics, is not regulated by the PMPRB. For each strength of each dosage form of each patented medicine sold in Canada, patentees are required to file price and sales information twice a year for price regulation purposes.(6)

The reimbursement process in Canada is governed by a combination of federal, provincial and private plans. Through the publicly-funded Medicare system, all Canadians and residents have free access to coverage for drugs, procedures, and physician services provided in hospitals. Hospital drug formularies are under provincial purview. Outside the hospital setting, drugs are reimbursed to the majority of Canadians by private health insurance plans, either to employees and their families through employer group insurance, or to other persons and their families on an individual basis. Some vulnerable groups, such as seniors, welfare recipients, and native persons, are covered by specific provincial, territorial, or federal plans. Most plans involve copayments and deductibles so that patients contribute to the costs of reimbursed medicines.

Data Requirements

Data requirements are specific to each jurisdiction for which listing status is sought. However there are requirements that are common to all or most jurisdictions; these include: a) the price to be charged for all dosage forms, b) product characteristics (from the Product Monograph), c) clinical efficacy and safety data, e) economic evaluation, and f) budget impact assessment.

Below specific data requirements are outlined for a CDR submission and for a submission to Quebec's Conseil du medicament.

One key requirement for a CDR submission is evidence for the efficacy, effectiveness and safety of a product. Copies of published and unpublished key clinical trials are required, as well as, for ongoing studies, new data generated after marketing authorization was obtained. In addition, a list of all completed and ongoing published and unpublished clinical trials needs to be provided.

Submission of an appropriate economic evaluation, following the most recent CADTH guidelines, is another key requirement of the CDR process. The type of evaluation to be performed depends on the product.

Cost-effectiveness or cost-utility analyses are required if the drug: a) is the first available (no other products listed) to treat a disease or disorder or has established a new therapeutic class; b) has demonstrated differences in safety or efficacy versus comparators in head-to-head randomized controlled trials; or c) in the absence of head-to-

head trials, the manufacturer assumes that such differences exist. (Evidence to support this claim must be provided.) Cost-effectiveness or cost-utility analyses must be based on final outcomes, such as life-years, QALYs or important events (e.g., fracture, stroke, or myocardial infarction), or validated surrogate outcomes.

Products demonstrating benefits in other outcomes (e.g. patient-reported, non-clinical, or surrogate) only require cost-consequence analyses. For all other products, only detailed price comparison and cost tables are to be submitted.

Budget impact analyses (BIAs) are also required for CDR submissions for most of the participating drug plans. Unless a priority review is requested, BIAs do not need to be included with the initial submission package but must follow it within 20 business days. Each BIA must meet the specifications of its respective drug plan and be supported by current market data and regional information. Product information approved by HC, local epidemiological data (prevalence or incidence) where available, and detailed pricing information are also required.

Quebec Submission

With regard to evidence of clinical efficacy and safety, Quebec stipulates that a maximum of five clinical studies can be submitted, including at least one randomized controlled trial published or accepted for publication in a peer-reviewed biomedical journal. In addition to an economic evaluation according to CADTH guidelines, Quebec's Conseil du médicament requires a detailed price justification. Information about the disease of interest—including duration, progression and stages — and the projected impact of the product on the healthcare system also needs to be included in the dossier.

The Company's Property

Our United States corporate headquarters address is 1215 South Kihei Road, #424, Kihei, Hawaii 96753. The Company holds a lease in Sunny Isles, Florida for office space. Consultants and officers are generally working remotely, and we do not currently require additional office space. As the Company grows, we will at some point need our own administrative office facility, including support components such as additional employees and equipment.

As part of the Company's ambition to address global mental healthcare needs, for which the Company needs a global presence, the Company has acquired a presence in The Sandbox metaverse, consisting of a 12x12 estate comprised of 144 parcels of prime commercial space located at -36, 0 for 450 ETH. Orthogonal Thinker, Inc., a Delaware corporation, facilitated the Sandbox metaverse purchase transaction and will be the beneficial owner of 12 of the 144 parcels as compensation for its services.

Legal Proceedings

We are not a party to any legal proceedings.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations for the fiscal years ended December 31, 2021 and December 31, 2020 should be read in conjunction with our financial statements and the related notes included in this Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements.

Overview

The Company is in the very early stages of development. We do not expect to generate significant revenue for at least the next few years due to research and development and general and administrative expenses. The following discussion and analysis should be read in conjunction with our financial statements and notes thereto contained elsewhere in this filing. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that all our expenses will increase substantially as we:

- continue our research and development efforts;
- contract with third-party research organizations to manage our pre-clinical and clinical trials for our drug candidates;
- seek out strategic investments and opportunities;
- outsource the manufacturing of our drug candidates for pre-clinical studies and clinical trials;
- seek to obtain regulatory approvals for our drug candidates;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial and management information systems and personnel to support our research and development and regulatory efforts; and
- operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our drug candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization any of our current or future drug candidates. Until such time, if ever, as we can generate revenue from product sales, we expect to finance our operating activities through a combination of the proceeds of the Regulation A Offering, additional equity offerings or debt financings, collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our drug candidates.

Components of Results of Operations

General and Administrative Expenses

General and administrative expenses consist primarily of:

- personnel expenses, including, advisor fees, travel, and other expenses incurred by personnel in executive and administrative functions;
- share-based compensation expenses resulting from the equity awards granted to employees engaged in executive and administrative functions; and
- legal and professional fees, including consulting, accounting and audit services.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern

of costs incurred, and are reflected on our financial statements as prepaid expense or accrued research and development expenses.

Product or therapeutic candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and related product manufacturing expenses. As a result, we expect that our research and development expenses will continue to increase over the next several years as we: (i) expedite the clinical development for our investigational psilocybin therapy; (ii) fund research for our investigational psilocybin therapy in other neuropsychiatric indications; (iii) seek to develop digital technologies to complement and augment our therapies, and seek to access other novel drug candidates for development in neuropsychiatric and related indications; (iv) improve the efficiency and scalability of our third-party manufacturing processes and supply chain; and (v) build our third-party or in-house process development, analytical and related capabilities, increase personnel costs and prepare for regulatory filings related to our potential or future therapeutic candidates.

Sales and Marketing Expenses

Our marketing expenses consist primarily of costs incurred to promote the Regulation A Offering and build our brand awareness through various online paid advertising channels, including digital and social media, podcasts, and email.

Sales and marketing expenses consist primarily of personnel costs for employees and contractors directly associated with our sales and marketing activities including advertising expenses, public relations, trade shows, travel expenses, and marketing and promotional activities. We expect our sales and marketing expenses to continue to increase in absolute dollars for the foreseeable future as we expand our sales and marketing efforts and continue to promote our Regulation A Offering and our brand, although these expenses may fluctuate depending on the timing of these expenses.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared assuming that the Company will continue as a going concern and in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 6 to our financial statements appearing elsewhere in this report. We believe that the accounting policies are critical for fully understanding and evaluating our financial condition and results of operations.

Net Loss Per Share

Basic net loss per common share attributable to common shareholders is calculated by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as dilutive net loss per share as the inclusion of all potential dilutive common shares which consist of stock options and SAFE securities, would be anti-dilutive.

Results of Operations

Year ended December 31, 2021 Compared to Year ended December 31, 2020

Revenue

We did not generate any revenue in the year ended December 31, 2020 nor in the year ended December 31, 2021. Our ability to generate product revenues in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more drug candidates in the United States.

Operating Expenses

General and Administrative Expenses

General and administrative expenses increased from $404,729 during the year ended December 31, 2020 to $4,771,561 for the year ended December 31, 2021, an increase of 1079%. This increase was primarily due to costs related to increased personnel expenses, including, advisor fees, travel, and other expenses incurred by personnel in executive and administrative functions, and legal and professional fees, including consulting and accounting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued growth, increase in strategic investments, and to build our internal team to support a public company.

Sales and Marketing Expenses

Sales and marketing expenses increased from $159,579 during the year ended December 31, 2020 to $679,236 during the year ended December 31, 2021, an increase of 326%. This increase is due to brand development of the PSILLY brand, marketing campaign and development of the PSILLY drink. In addition, the increase was due to developing a public relations strategy and increase in press coverage. The Company also increased it's spending on advertising and investor-related expenses for the Regulation A Offering.

Research and Development Expenses

Research and development expenses increased from $102,666 during the year ended December 31, 2020 to $215,627 during the year ended December 31, 2021, or 110%. This increase was primarily due to funding the transdermal patch project with Tioga Research.

Other Income (Expense)

For the year ended December 31, 2021, the Company made a fair value adjustment on its SAFE liabilities, which resulted in a loss on derivative liability of $3,152,938, which represents the fair value adjustment based on the difference between the price per share invested for SAFEs and the fair value of shares at the triggering event.

Net Loss

As a result of the above, the Company's net loss increased from $666,974 during the year ended December 31, 2020 to $8,821,619 during the year ended December 31, 2021.

Liquidity and Capital Resources

As of December 31, 2021 the Company had $5,642,766 in cash and cash equivalents.

We have not generated any revenue. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our psilocybin-based products. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue to research, develop, and seek regulatory approval for, our psilocybin-based products. In addition, subject to obtaining regulatory approval of any of our psilocybin-based products, we expect to incur significant commercialization expenses for

product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we anticipate raising capital through private placements, additional Regulation A offerings, and/or public offerings in compliance with applicable securities laws to fund our operating expenses. Based on our current financial resources, our expected level of operating expenditures and, the net proceeds of the Regulation A Offering, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. Thereafter, we will need to obtain additional financing to fund additional research and development, and fund pre-clinical studies and clinical trials for our psilocybin-based products. Because of the numerous risks and uncertainties associated with the Regulation A Offering, and the research, development commercialization and legalization of our psilocybin-based products, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our initial drug candidates.

Our future capital requirements will depend on many factors, including:

- the progress, costs, results and timing of our psilocybin-based products' research and development, pre-clinical studies and future clinical trials, and the clinical development of our psilocybin-based products for other potential indications beyond their initial target indications;
- the willingness of state and federal regulators to accept psilocybin-based products, including the FDA and the HC to accept our future psilocybin-based products;
- the outcome, costs and timing of seeking and obtaining federal and state regulatory approvals, including with the FDA and HC;
- the number and characteristics of psilocybin-based products that we pursue;
- the ability of our psilocybin-based products to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, products, and technologies;
- our ability to maintain, expand and defend the scope of our licensed intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- need and ability to hire additional management and employees and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of the proceeds of the Regulation A Offering, equity offerings or debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt and equity securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us.

Regulation A Offering

The Company commenced an offering on March 22, 2021, qualifying the offer and sale of up to 10,121,457 shares of its Common Stock pursuant to Regulation A of the Securities Act. (the "Regulation A Offering") for up to $50 million in gross proceeds. The Regulation A Offering terminated on March 22, 2022. During 2021, the Company entered into subscription agreements for the sale of 3,041,131 shares of Common Stock in the Regulation

A Offering. As of December 31, 2021, the Company had received gross proceeds of $6,286,041 pursuant to the Regulation A Offering and had issued 1,272,478 shares of Common Stock. As of that date, the Company recorded $8,737,145 in advances for the sale of common stock on its balance sheet, which represents the remaining proceeds to be issued to the Company. Of that advance, $5,854,882 has been received by the Company and $2,882,263 had been paid by the investors to our escrow agent but was receivable from our escrow agent as of December 31, 2021 and is reflected as another receivable on the balance sheet. As of the date of this Report, the Company has received additional subscriptions and is issuing approximately 4,368,898 shares of Common Stock in the Regulation A Offering for total proceeds of an estimated $21,582,356 before issuance costs. Offering expenses incurred to date are estimated to be $700,000.

Issuances of SAFE securities

Between October 2020 and February 2021, the Company entered into simple agreements for future equity ("SAFE Securities"), in reliance on Regulation CF, Regulation S, Regulation D and Section 4(a)(2) of the Securities Act, with investors for total proceeds of $1,583,598.18 authorized to raise capital for general business purposes. The Regulation A Offering triggered the conversion of the SAFE Securities. The proceeds of these issuances were used for legal and marketing expenses related to the Regulation A Offering. On or about April 1, 2022, the SAFEs converted as a result of the Regulation A Offering into shares of the Company at a valuation cap of $111,000,000. The total number of shares issued to the holders of SAFE Securities was 955,471.

RECENT OFFERINGS OF SECURITIES

We have made the following issuances of securities within the last three years.

Date of Commencement of Offering (MM/YYYY)	Offering Exemption Relied Upon	Securities Offered	Final Amount Sold	Final Proceeds	Use of Proceeds
03/2021	Regulation A	Common Stock	4,368,898	$21,582,356	Conducting pre-clinical and clinical development, and related research programs, intellectual property development or acquisition and working capital and general corporate purposes
11/2020	Regulation Crowdfunding, Regulation D Rule 506(c), and Regulation S	SAFEs	N/A	$1,583,589.18 (Net Proceeds)	Employee compensation, legal, accounting, and marketing, and other general corporate expenses.

DIRECTORS AND OFFICERS

As of the date of this Annual Report, the Company's officers and directors are as follows:

Name	Age	Position
David Nikzad	45	Director, President
Jason A. Hobson	50	Director, Treasurer, Secretary

David Nikzad joined the Company in 2019, upon its formation. Mr. Nikzad is an experienced operator, entrepreneur, and angel investor. He is an "investor savant" and backer of the most disruptive entrepreneurs. With a keen eye for winning ideas, he has an impressive track record of investing success. David's ability to find companies that become leaders in their respective industries is a gift. As an advisor to early-stage companies in Silicon Valley, he has successfully led the development of new and existing companies, built teams and guided operations. He was one of the first investors in Betterment, which now manages billions in assets. He is also an investor in several other Y Combinator companies, and co-founder of Reinmkr Satsang, a Venture capital firm. All told, David has invested in 100+ start-up and emerging companies over the last twenty years. He has served in a number of roles in the Company, including Chairman and Chief Executive Officer of Ei.Ventures since 2019.

Jason A. Hobson joined the Company in 2016, upon its formation. He is an attorney, entrepreneur and angel investor, with investments in 75+start-up and emerging companies. He is a founding partner of the law firm of Hobson Bernardino + Davis LLP. He was previously in-house counsel for a national tax credit equity syndication firm which syndicated limited partnership interests and was also previously a senior attorney with the Century City and San Francisco offices of Pillsbury Winthrop Shaw Pittman LLP (formerly Pillsbury Madison & Sutro LLP), where he was a member of Corporate and Securities Practice Group. In 2012, Jason was appointed to a state commission with an oversight function to the California Public Utilities Commission with respect to energy programs across the State of California. He is a graduate of the University of California Hastings College of Law, UCLA Anderson School of Management (Management Development for Entrepreneurs certificate), Waseda University (Tokyo Japan) and California State University.

On May 8, 2022, Cecilio Robles resigned as Chief Strategic Officer of the Company and will no longer provide consulting or advisory services to the Company.

Composition of our Board of Directors

Our board of directors currently consists of two members, David Nikzad and Jason Hobson. Our directors are elected annually, hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. Our certificate of incorporation provides that the authorized number of directors comprising our board of directors shall be fixed by a majority of the total number of directors. There are no family relationships among any of our directors or executive officers.

Our board of directors does not currently have an audit committee, a compensation committee or a nominating and governance committee. Our board of directors intends to establish an audit committee and a compensation committee, when required by any applicable trading market on which we list or have quoted our Common Stock or at such earlier time as our board of directors may decide in its discretion. Each committee established will operate under a charter to be approved by our board of directors.

Scientific Advisory Board

Linda Strause, Ph.D. joined the Company in 2020 as a member of our Scientific Advisory Board. Dr. Strause has worked in the pharmaceutical development industry for over 30 year and has held senior positions in a variety of functional areas. Linda brings a 360 degree perspective to the drug development industry. She has served as a principal investigator, senior level manager with a global contract research organization (CRO), vice president with a site management company, executive level positions within the biotechnology industry, and as chair of an independent hospice and palliative care IRB. Her broad experience includes operational planning as well as global accountability for developing and managing clinical sites in North and South America, EU, Central Eastern Europe and Israel. In those roles she has developed and implemented a process to ensure efficient and timely approvals, contract and budget negotiations, and compliance with both ethical and data privacy regulations. Linda's unique senior-level experience in the biotech, CRO and site segments of the pharmaceutical development industry has enabled me to develop winning enterprise strategies for providers to conduct high quality and cost-effective clinical research. She currently applies this knowledge as co-founder of G. Randall and Sons, Inc., a corporation which developed a hemp product optimized to deliver a balance highly purified hemp oil and natural terpenes along with, amino acids, proteins, glycoproteins, enzymes, fatty acids, terpenes, flavonoids, vitamin A, and other elements to specific functional cell systems to optimize nutrient enrichment.

Code of Ethics and Business Conduct

We have not yet adopted a code of ethics and business conduct, which would apply to our employees, directors, and officers, including our principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our board of directors plans to adopt a code of ethics when required by any applicable trading market on which we list or have our Common Stock quoted or at such earlier time as our board of directors may decide in its discretion.

Executive Compensation

As of December 31, 2021, the Company paid $125,000 in executive compensation to each of Jason Hobson and David Nikzad. The Company has not paid or agreed to pay Mr. Hobson or Mr. Nikzad in their capacities as directors. In the future the Company may need to hire additional officers, directors, scientific advisory board members and other employees, which will impact the Company's financial condition and results of operations, as discussed herein.

There are no compensatory plans or arrangements, including payments to be received from the Company with respect to any executive officer, that would result in payments to such person because of his or her resignation, retirement or other termination of employment with the Company, any change in control or a change in the person's responsibilities following a change in control of the Company.

2020 Equity Incentive Plan

On May 21, 2020, the board of directors and our stockholders approved the Ei.Ventures, Inc. 2020 Equity Incentive Plan, (the "**Plan**"). The Plan was amended on July 20, 2021. The Plan is a stock-based compensation plan that provides for discretionary grants of stock options, stock appreciation rights, restricted stock awards and restricted stock unit awards to employees, non-employee directors and consultants. The purpose of the Plan is to attract, motivate and retain directors, employees and others in a position to affect the financial and operational performance of our Company and to recognize contributions made to our Company by these persons and to provide them with additional incentive to achieve the objectives of our Company. As of the date of this Report, the Company has granted or committed to grant 6,538,006 options under the amended Plan.

The following is a summary of our Plan.

Administration

The Plan is administered by our board of directors, unless we establish a committee of the board of directors for this purpose. We refer to the body administering our Plan as the "**Administrator**." The Administrator will have full authority to select the individuals who will receive awards under the Plan, determine the form and amount of each of the awards to be granted, and establish the terms and conditions of awards.

Number of Shares of Common Stock

The number of shares of the Common Stock that may be issued under the Plan is 11,500,000, of which the Company has issued 6,538,006 to directors, employees, and advisors. Shares issuable under the Plan may be authorized but unissued shares or treasury shares. If there is a lapse, forfeiture, expiration, termination or cancellation of any award made under the Plan for any reason, the shares subject to the award will again be available for issuance. Any shares subject to an award that are delivered to us by a participant, or withheld by us on behalf of a participant, as payment for an award or payment of withholding taxes due in connection with an award will not again be available for issuance, and all such shares will count toward the number of shares issued under the Plan. The number of shares of Common Stock issuable under the Plan is subject to adjustment, in the event of any reorganization, recapitalization, stock split, stock distribution, merger, consolidation, split-up, spin-off, combination, subdivision, consolidation or exchange of shares, any change in the capital structure of our Company or any similar corporate transaction. In each case, the Administrator has the discretion to make adjustments it deems necessary to preserve the intended benefits under the Plan. No award granted under our Plan may be transferred, except by will or the laws of descent and distribution.

Eligibility

All employees, including consultants, for purposes of our Plan and all non-employee directors are eligible to receive awards under the Plan.

Awards to Participants

The Plan provides for discretionary awards of stock options, stock awards and stock unit awards to participants. Each award made under the Plan will be evidenced by a written award agreement specifying the terms and conditions of the award as determined by the administrator in its sole discretion, consistent with the terms of the Plan.

Stock Options

The Administrator has the discretion to grant non-qualified stock options or incentive stock options to participants and to set the terms and conditions applicable to the options, including the type of option, the number of shares subject to the option and the vesting schedule; provided that the exercise price of each stock option will be the fair market value (as defined in the Plan) of the Common Stock on the date on which the option is granted, except that the exercise price per share under a non-qualified stock option may be less than 100% of the fair market value of such shares on the date such option is granted provided that, and only if, the board of directors approves a

lower price after consideration of the application of Section 409A of the Internal Revenue Code, each option will expire no later than ten years from the date of grant and no dividend equivalents may be paid with respect to stock options.

In addition, an incentive stock option granted to an employee is subject to the following rules: (i) the aggregate fair market value (determined at the time the option is granted) of the shares of common stock with respect to which incentive stock options are exercisable for the first time by a key employee during any calendar year (under all incentive stock option plans of our Company and its subsidiaries) cannot exceed $100,000, and if this limitation is exceeded, that portion of the incentive stock option that does not exceed the applicable dollar limit will be an incentive stock option and the remainder will be a non-qualified stock option; (ii) if an incentive stock option is granted to an employee who owns stock possessing more than 10% of the total combined voting power of all class of stock of our Company, the exercise price of the incentive stock option will be 110% of the fair market value of the common stock on the date of grant and the incentive stock option will expire no later than five years from the date of grant; and (iii) no incentive stock option can be granted after ten years from the date the Plan was adopted.

Stock Awards

The Administrator has the discretion to grant stock awards to participants. Stock awards will consist of shares of Common Stock granted without any consideration from the participant or shares sold to the participant for appropriate consideration as determined by the board of directors. The number of shares awarded to each participant, and the restrictions, terms and conditions of the award, will be at the discretion of the Administrator. Subject to the restrictions, a participant will be a shareholder with respect to the shares awarded to him or her and will have the rights of a shareholder with respect to the shares, including the right to vote the shares and receive dividends on the shares; provided that dividends otherwise payable on any performance-based stock award will be held by us and will be paid to the holder of the stock award only to the extent the restrictions on such stock award lapse, and the Administrator in its discretion can accumulate and hold such amounts payable on any other stock awards until the restrictions on the stock award lapse.

Stock Units

The Administrator has the discretion to grant stock unit awards to participants. Each stock unit entitles the participant to receive, on a specified date or event set forth in the award agreement, one share of Common Stock or cash equal to the fair market value of one share on such date or event, as provided in the award agreement. The number of stock units awarded to each participant, and the terms and conditions of the award, will be at the discretion of the Administrator. Unless otherwise specified in the award agreement, a participant will not be a shareholder with respect to the stock units awarded to him prior to the date they are settled in shares of Common Stock. The award agreement may provide that until the restrictions on the stock units lapse, the participant will be paid an amount equal to the dividends that would have been paid had the stock units been actual shares; provided that dividend equivalents otherwise payable on any performance-based stock units will be held by us and paid only to the extent the restrictions lapse, and the Administrator in its discretion can accumulate and hold such amounts payable on any other stock units until the restrictions on the stock units lapse.

Payment for Stock Options and Withholding Taxes

The Administrator may make one or more of the following methods available for payment of any award, including the exercise price of a stock option, and for payment of the minimum required tax obligation associated with an award: (i) cash; (ii) cash received from a broker-dealer to whom the holder has submitted an exercise notice together with irrevocable instructions to deliver promptly to us the amount of sales proceeds from the sale of the shares subject to the award to pay the exercise price or withholding tax; (iii) by directing us to withhold shares of Common Stock otherwise issuable in connection with the award having a fair market value equal to the amount required to be withheld; and (iv) by delivery of previously acquired shares of Common Stock that are acceptable to the administrator and that have an aggregate fair market value on the date of exercise equal to the exercise price or withholding tax, or certification of ownership by attestation of such previously acquired shares.

Provisions Relating to a "Change in Control" of our Company

Notwithstanding any other provision of the Plan or any award agreement, in the event of a "Change in Control" of our Company, the Administrator has the discretion to provide that all outstanding awards will become fully exercisable, all restrictions applicable to all awards will terminate or lapse, and performance goals applicable to any stock awards will be deemed satisfied at the highest target level. In addition, upon such Change in Control, the Administrator has sole discretion to provide for the purchase of any outstanding stock option for cash equal to the difference between the exercise price and the then fair market value of the Common Stock subject to the option had the option been currently exercisable, make such adjustment to any award then outstanding as the Administrator deems appropriate to reflect such Change in Control and cause any such award then outstanding to be assumed by the acquiring or surviving corporation after such Change in Control.

Effect of Termination of Continuous Service; Company Repurchase Right

The right to exercise an option (to the extent that it is vested) following termination of a participant's employment or service with our Company will expire three (3) months following the termination of employment or service, except (i) to the extent any longer period is permitted under the rules of section 422 of the Internal Revenue Code with respect to a participant's death or disability, and (ii) if a participant's employment or service with our Company is terminated for cause, as that term is defined in the Plan, then, immediately upon the termination of the participant's employment or service with us, all vested and unvested awards granted to participant shall be immediately forfeited and automatically terminate. With respect to an award of our restricted Common Stock, upon a death or disability, all of the shares of restricted Common Stock subject to an award shall become immediately vested. Upon the termination of a participant's employment or service with the Company for any reason, we will have the right, but not the obligation, until the first anniversary of the termination of the participant's employment or service to repurchase some or all of the vested shares and/or the vested options from the participant, the participant's estate (in the case of the participant's death), or any permitted transferee of such vested shares and/or vested options. When exercising this right, we shall pay the participant an amount per share equal to the lesser of (i) the price per share paid by the participant for such shares and (ii) the lesser of the fair market value of the shares as of the date of termination of the participant's employment with us and the date we exercise the repurchase right.

Amendment of Award Agreements; Amendment and Termination the Plan; Term of the Plan

The Administrator may amend any award agreement at any time, provided that no amendment may adversely affect the right of any participant under any agreement in any material way without the written consent of the participant, unless such amendment is required by applicable law, regulation or stock exchange rule. The board of directors may terminate, suspend or amend the Plan, in whole or in part, from time to time, without the approval of the shareholders, unless such approval is required by applicable law, regulation or stock exchange rule, and provided that no amendment may adversely affect the right of any participant under any outstanding award in any material way without the written consent of the participant, unless such amendment is required by applicable law, regulation or rule of any stock exchange on which the shares are listed. Notwithstanding the foregoing, neither the Plan nor any outstanding award agreement can be amended in a way that results in the repricing of a stock option under generally accepted accounting principles. No awards may be granted under the Company's Plan on or after the tenth anniversary of the effective date of the Plan.

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS

The following table sets out, as of December 31, 2021, the voting securities of the Company that are owned by executive officers and directors, and other persons holding more than 10% of any class of the Company's voting securities or having the right to acquire those securities. The table assumes that all options and warrants have vested. The Company's voting securities include all shares of Common Stock.

Name and Address of Beneficial Owner	Title of Class	Amount and Nature of Beneficial Ownership	Amount and Nature of Beneficial Ownership Acquirable	Percent
Orthogonal Thinker, Inc., 20533 Biscayne Blvd., Suite 4-616, Aventura, FL 33180*(1)	Common Stock	60,000,000		87.25 %
David Nikzad	Options	1,666,650		2.42%
Jason Hobson	Options	1,666,650		2.42%

* David Nikzad is the controlling stockholder of Orthogonal Thinker, Inc.
(1) This percentage is on a fully diluted basis, including all outstanding options as of the date of this filing. It does not include approximately 3.7 million shares for which the Company has received subscriptions in the Regulation A Offering, but has not yet completed the clearance and settlement to issue such shares.

INTEREST OF MANAGEMENT AND OTHERS IN CERTAIN TRANSACTIONS

In addition to compensation arrangements, we describe below agreements and transactions and series of similar transactions, since our inception, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and

- any of our directors, executive officers, or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Orthogonal and the Company are parties to the License Agreement described above. The Company also entered into a Posting Agreement with Orthogonal Portal, LLC, a Utah limited liability company and wholly-owned subsidiary of Orthogonal ("**Orthogonal Portal**") on December 29, 2020 (the "**Posting Agreement**") whereby the Company engaged Orthogonal Portal to provide certain services as the Company's funding platform and technology provider in connection with the Regulation A Offering. Under the Posting Agreement, the Company shall pay Orthogonal Portal a total of $500,000. The Company has made payments, but has yet to pay off the full amount, which it plans to pay off by December 31, 2022. There were no arms-length negotiations for the Posting Agreement and the terms of the Posting Agreement may be more favorable to Orthogonal Portal, and, by extension, Orthogonal, and to our detriment, than had the negotiations been arms-length with third parties.

The Company paid a 8.33% broker fee to Orthogonal Thinker, Inc. in connection with the acquisition of the 144 digital parcels in the Sandbox. The broker fee was paid by a transfer of 12 digital parcels of the Sandbox to Orthogonal Thinker, Inc. EI Ventures, Inc. is a subsidiary of Orthogonal Thinker, Inc.

DESCRIPTION OF SECURITIES

SAFEs Offered in 2020 Offering

In February 2021, the Company completed a Regulation Crowdfunding offering in which it entered into SAFE agreements (Simple Agreement for Future Equity) with investors in exchange for cash investments totaling

$1,567,089.18. On or about April 1, 2022, the SAFEs converted as a result of the Regulation A Offering into shares of the Company at a valuation cap of $111,000,000. We request that you please review our organizational documents in conjunction with the following summary information. As of December 31, 2021, these SAFE agreements had not yet converted.

General

Our authorized capital stock consists of 100,000,000 shares of Common Stock, $0.0001 par value. As of the date of this Report, there were 65,324,369 shares of Common Stock outstanding and no shares of preferred stock outstanding. As of the date of this Report, the Company has granted or committed to grant 6,538,006 options under its 2020 Equity Incentive Plan. The rights of the option holders under the 2020 Equity Incentive Plan are described in *"Directors and Officers*" above. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you.

Common Stock

Common stockholders of record are entitled to one vote for each share held on all matters to be voted on by stockholders. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Holders of our Common Stock are entitled to receive ratable dividends when, as and if declared by the board of directors out of funds legally available therefor.

Upon our dissolution, liquidation or winding up, holders of our Common Stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our Common Stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Repurchases

We may seek to repurchase our outstanding securities from time to time in market or private transactions.

Dividends

We have not paid any cash dividends on our shares of Common Stock to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition and will be within the discretion of our board of directors. It is the current intention of our board of directors to retain all earnings, if any, for use in our business operations and, accordingly, our board of directors does not anticipate declaring any dividends in the foreseeable future.

Our Transfer Agent

The transfer agent for our securities is Odyssey Trust Company ("Odyssey Trust").

Quotation of our Securities

There has been no public market for our securities. Currently, we do intend to seek a trading market for the Common Stock on any exchange or the OTC Markets.

Certain Anti-Takeover Provisions of our Certificate of Incorporation and By-laws

Special meeting of stockholders

Our by-laws provide that special meetings of our stockholders may be called only by a majority vote of our board of directors.

Exclusive Forum

Our certificate of incorporation and by-laws provide that the Court of Chancery of the State of Delaware or, if such court does not have jurisdiction, the federal district court for the District of Delaware, shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law, the certificate of incorporation or the by-laws or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Under our by-laws, these provisions do not apply to any claim brought to enforce any duty or liability arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, thereby allowing any such claims to be filed in any court having jurisdiction. Although we believe these provisions benefit the company by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, they may have the effect of discouraging lawsuits against our officers and directors.

REGULATORY INFORMATION

Disqualification. No disqualifying events have been recorded with respect to the Company or its officers or directors.

Ongoing Reporting

The Company's annual report may be found at: ei.ventures/cfinvestors .

SIGNATURES

Pursuant to the requirements of Regulation Crowdfunding, the issuer has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

EI.VENTURES, INC.

/s/ David Niksad
David Niksad, Chief Executive Officer
Date: May 25, 2022

The following persons in the capacities and on the dates indicated have signed this report.

/s/ David Niksad
David Niksad, Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer and Director

Date: May 25, 2022

/s/ Jason Hobson
Jason Hobson, Director
Date: May 25, 2022

EXHIBIT A TO FORM C

AUDITED FINANCIAL STATEMENTS OF Ei.VENTURES, INC. FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020.

To the Board of Directors and Management
Ei.Ventures, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ei.Ventures, Inc. (the "Company") as of December 31, 2021 and 2020, and the related statements of operations, stockholder's deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years ended December 31, 2021 and 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit, 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 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.

/s/ Tanner LLC

We have served as the Company's auditor since 2019.
Salt Lake City, Utah
May 24, 2022

Ei.Ventures, Inc.
Balance Sheets
At December 31,

	2021	2020
Assets		
Current assets:		
Cash	$ 5,642,766	$ 63,289
Other receivable	2,904,485	-
Prepaid expenses and other current assets	191,495	16,000
Total current assets	8,738,746	79,289
Property and equipment, net	41,005	-
Intangible assets	1,657,586	-
Total assets	$ 10,437,337	$ 79,289
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 840,050	$ -
Accrued expenses	21,173	2,500
Simple Agreements for Future Equity (SAFEs)	4,720,027	743,763
Advances for sale of common stock	8,737,145	-
Total current liabilities	14,318,395	746,263
Commitments and contigencies		
Stockholders' deficit:		
Common stock, $.0001 par value: 100,000,000 shares authorized, 61,272,478 shares outstanding	6,127	6,000
Additional paid in capital	5,601,408	(6,000)
Accumulated deficit	(9,488,593)	(666,974)
Total stockholders' deficit	(3,881,058)	(666,974)
Total liabilities and stockholders' deficit	$ 10,437,337	$ 79,289

Ei.Ventures, Inc.
Statements of Operations
For the Years Ended December 31,

	2021	2020
Revenue	$ -	$ -
Operating expenses:		
General and administrative	4,771,561	404,729
Sales and marketing	679,236	159,579
Research and development	215,627	102,666
Total operating expenses	5,666,424	666,974
Operating loss	(5,666,424)	(666,974)
Other income (expense):		
Loss on derivative liability	(3,152,938)	-
Interest and Depreciation	(2,258)	-
Net loss	$ (8,821,619)	(666,974)
Basic/diluted loss per share	$ (0.15)	$ (0.01)
Number of weighted average shares outstanding	60,257,452	60,000,000

Ei.Ventures, Inc.
Statements of Stockholders' Deficit
For the Years Ended December 31, 2021 and 2020

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, January 1, 2020	60,000,000	$ 6,000	$ (6,000)	$ -	$ -
Net loss	-	-	-	(666,974)	(666,974)
Balance at December 31, 2020	60,000,000	6,000	(6,000)	(666,974)	(666,974)
Proceeds from sale of common stock, net of offering costs of $3,208,384	1,272,478	127	3,079,965	-	3,080,092
Stock-based compensation	-	-	2,527,443	-	2,527,443
Net loss	-	-	-	(8,821,619)	(8,821,619)
Balance at December 31, 2021	61,272,478	$ 6,127	$ 5,601,408	$ (9,488,593)	$ (3,881,058)

Ei.Ventures, Inc.
Statements of Cash Flows
For the Years Ended December 31,

	2021	2020
Cash flow from operating activities:		
Net loss	$ (8,821,619)	$ (666,974)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,248	-
Loss on derivative liability	3,152,938	-
Stock-based compensation	2,527,443	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(175,495)	(16,000)
Accounts payable and accrued expenses	458,723	2,500
Net cash used in operating activities	(2,855,762)	(680,474)
Cash flow from investing activities:		
Purchases of intangible assets	(1,257,586)	-
Purchases of property and equipment	(43,253)	-
Net cash used in investing activities	(1,300,839)	-
Cash flows from financing activities:		
Advances for sale of common stock	5,832,660	-
Net proceeds from issuance of common stock	3,080,092	-
Proceeds from issuance of SAFEs	823,326	743,763
Net cash provided by financing activities	9,736,078	743,763
Net change in cash	5,579,477	63,289
Cash at the beginning of the period	63,289	-
Cash at the end of the period	$ 5,642,766	$ 63,289

Supplemental disclosure of noncash investing and financing activities:

Advances for sale of common stock held by transfer agent	$ 2,904,485	$ -
Payable for purchase of intangible assets	$ 400,000	$ -

Notes to the Financial Statements
As of December 31, 2021 and 2020
And for the Years Then Ended

1. NATURE OF THE BUSINESS

a. Ei. Ventures, Inc., a Delaware corporation (the "Company"), is a start-up company that was incorporated on May 3, 2019, with the ambition to engage in the discovery, development and commercialization of regulatory approved, plant-derived, psychoactive, and non-psychoactive therapeutic compounds that address global mental healthcare needs.

2. BASIS OF PREPARATION

a. The accompanying financial statements (the "Financial Statements") have been prepared by the Company assuming that the company will continue as a going concern and in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC").

3. USE OF ESTIMATES

a. Preparation of the financial statements in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect reported amounts and disclosures. These estimates are based on information available as of the date of the financial statements. On an ongoing basis, management evaluates these estimates and assumptions using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could vary from those estimates.

4. CONCENTRATION OF CREDIT RISK

a. The Company maintains its cash in bank deposit accounts which, at times, exceed federally insured limits. As of December 31, 2021, and 2020, the Company had approximately $5,200,000 and $0 of cash that exceeded federal insurance limits. To date, the Company has not experienced a material loss or lack of access to its invested cash; however, no assurance can be provided that access to the Company's invested cash will not be affected by adverse conditions in the financial markets.

5. FINANCIAL RISK MANAGEMENT

a. Liquidity: The Company has incurred significant net losses since inception that have accumulated to approximately $9,488,593 as of December 31, 2021, and the Company used net cash in operating activities totaling approximately $2,855,762 during the year ended December 31, 2021. The net losses and use of cash in operating activities resulted primarily from administrative, research and development, and marketing efforts. The Company has relied in the past upon cash flows from debt and equity issuances to fund operations. Management believes that current resources will be adequate to fund operations beyond one year from the date the financial statements were available to be issued.

6. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. Property and equipment: Property and equipment are stated at cost, less accumulated depreciation. Management reviews the major assets periodically to determine if impairment or changes in circumstance affect the overall value of the assets. With the most recent asset purchases, no impairment was considered due to the recent nature of the purchases. The Company's property and equipment had a cost of $43,253 and accumulated depreciation totaling $2,248 as of December 31, 2021. The Company uses the straight-line depreciation method for all fixed assets as follows:

   i. Computer - 3-5 years

   ii. Furniture and fixtures - 5-7 years

b. Intangible Assets: The Company's intangible assets consist of virtual real estate in the metaverse acquired during 2021 and is considered to have an indefinite life. The Company's virtual assets are presented at cost, less impairment.

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

   The Company recognizes the financial statement amount of an uncertain tax position only after considering the probability that a tax authority would sustain the position in an examination. For tax positions meeting a "more-likely-than-not" threshold, the amount recognized in the financial statements is the amount expected to be realized upon settlement with the tax authority. For tax positions not meeting the threshold, no financial statement benefit is recognized.

   As of December 31, 2021 and 2020, management believes that the Company had no material uncertain tax positions. The Company currently has no federal or state examinations in progress.

   Estimated interest and penalties related to the underpayment or late payment of income taxes are classified as a component of income tax provision in the accompanying statements of operations.

d. Research and development: Research and development expenses primarily include the formulation of product and medical advisory board costs. The Company expenses research and development costs as incurred.

e. Recent accounting pronouncements: In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The amendments in this update require the recognition of lease assets and lease liabilities by lessees for those leases classified as operating or finance leases. ASU 2016-02 requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term (other than leases that meet the definition of a short-term lease).

The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied in current lease accounting. This amendment is required for the Company's December 31, 2022 financial statements, and early adoption is permitted. ASU 2016-02 must be adopted using a modified retrospective transition and provides for certain practical expedients. The Company is evaluating the impact the adoption this update will have on the company's financial statements.

f. Management has evaluated events and transactions for potential recognition or disclosure through the date the financial statements were available to be issued.

g. Lease: The Company entered a lease on September 1, 2021, with a required payment of about $33,000 which includes the first and last month's rent as well as the security deposit. The lease is for the period of 6 months. There is no further liability after the 6-month contract has expired.

7. INTANGIBLE ASSETS

a. The Company's intangible assets consist of 132 digital parcels estate in The Sandbox, acquired on December 21, 2021 with a total cost basis of $1,657,586 and a cost basis per parcel of $12,557. Each of the 132 digital parcels is the virtual equivalent of 96 by 96 meters. The Company plans to develop the virtual real estate for future therapeutic applications.

8. TAXES

a. The Company's income tax provision differs from the amount computed at the statutory rates for the years ended December 31, 2021, or 2020 due to the change in the valuation allowance.

b. Deferred income taxes reflect the impact of temporary differences between assets and liabilities for financial reporting purposes and the amounts recognized for income tax reporting purposes, net operating loss carryforwards and other tax credits. The differences are measured by applying currently enacted tax laws. The significant components of the Company's deferred tax assets and liabilities were as follows:

	December 31,	
	2021	2020
Deferred Tax assets:		
Stock-based compensation	$ 618,617	$ -
Fixed asset depreciation and amortization	(10,403)	-
Net operating losses	913,818	159,815
Gross deferred tax assets	1,522,032	159,815
Valuation allowance	(1,522,032)	(159,815)
Net deferred tax assets	$ -	$ -

c. As of December 31, 2021, the Company maintained a full valuation allowance on its domestic net deferred tax assets. The domestic deferred tax assets predominantly relate to stock compensation and net operating losses. The domestic valuation allowance was estimated based on an assessment of both positive and negative evidence to determine whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required on a jurisdiction-by-jurisdiction basis. The Company's history of cumulative losses, along with expected future U.S. losses, required that a full valuation allowance be recorded against all domestic 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 a reversal of the valuation allowance. The valuation allowance increased by $1,362,217 for the year ended December 31, 2021. As of December 31, 2021, the Company had federal NOL carryforwards of $3,733,528. The utilization of the net operating loss carryforward is dependent upon the tax laws in effect at the time the net operating loss carryforwards can be utilized and may be significantly limited based on ownership changes as set forth in Section 382 of the Internal Revenue Code.

9. SAFE SECURITIES

The Company issued SAFE securities in 2021 and 2020 in exchange for cash. These funds were classified as liabilities and adjusted to fair value as of each reporting period.

Under the SAFEs, the funds contributed by the investors will convert to shares of common stock upon closing of a qualifying common stock offering. The criteria for conversion of the SAFEs occurred in 2021. The SAFE securities outstanding as of December 31, 2021 were converted to common stock in April 2022.

During the year ended December 31, 2021, a fair value adjustment was made to the SAFE liability resulting in a loss on derivative liability totaling $3,152,938.

10. CAPITAL STOCK

a. The Company was originally authorized to issue 10,000 shares with a par value of $0.001, and 2,000 shares were issued to the sole stockholder at no cost. In May 2020, the Company's Certificate of Incorporation was amended, increasing the total number of authorized shares to be issued of 10,000,000, having a par value of $0.001 per share. Connected to this, the Company effected a thousand-for-one stock split, and the outstanding shares increased from 2,000 to 2,000,000.

b. On March 24, 2021, the Company's Certificate of Incorporation was amended, increasing the total number of authorized shares to be issued of 100,000,000, having a par value of $0.0001 per share. Connected to this, the Company effected a thirty-for-one stock split, and the outstanding shares increased from 2,000,000 to 60,000,000. The effect of the stock split has been reflected retroactively in these financial statements.

11. STOCK OPTIONS

a. The Company’s stock option plan, originally approved on May 16, 2020 , and amended on July 20, 2021 (“the Plan”), provides for the grant of stock awards, incentive stock options, nonqualified options, stock appreciation rights, shares of restricted stock, restricted stock unit awards, and other stock awards. Under the terms of the Plan, there were 11,500,000 common shares authorized for grant to employees, officers, directors, and consultants as of December 31, 2021. The Board of Directors determines the terms of each grant. Generally, the options have a vesting period of 3 years with 33% vesting after the first year of service and remainder vesting monthly thereafter. The options generally have a 10-year contractual life. Certain stock options have provisions to accelerate vesting upon the occurrence of certain events. As of December 31, 2021 and 2020, there were 10,214,800 and 6,466,500 stock options outstanding, respectively. We used the Black-Scholes option pricing model as the method for determining the estimated fair value for all stock options granted to directors and consultants. The risk-free interest rate is based on rates published by the government for bonds with a maturity, representative of the expected remaining life of the options at the valuation date. Volatility was determined by analyzing the volatility of comparable companies over a period comparable to the expected life of the options. Stock-based compensation expense for the years ended December 31, 2021 and 2020 totaled $2,527,443 and $0, respectively and was booked to general and administrative expense on the statement of operations. As of December 31, 2021 and 2020, the Company had $14,346,502 and $0 of unrecognized stock-based compensation costs related to nonvested awards that will be recognized over a weighted-average period of 6 years.

The following sets forth the outstanding stock options and related activity under the Plan:

Options	Options Granted	Weighted Avg Exercise Price	Weighted Avg Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	-	-	-	-
Options issued in 2020	5,733,180	0.01	8.5	$ -
Outstanding at December 31, 2020	5,733,180	0.01	8.5	$ 57,332
Options issued in 2021	3,733,300	4.94	9.5	-
Outstanding at December 31, 2021	9,466,480	1.95	8.9	$18,459,636
Exercisable at December 31, 2021	2,303,640	1.95	8.9	$ 4,492,098

The following summarizes the information about stock options outstanding as of December 31, 2021:

Options Outstanding				Options Exercisable	
Exercise Price	Number Outstanding	Weighted Avg Remaining Contractual Life (Years)	Weighted Avg Exercise Price	Number Exercisable	Weighted Avg Exercise Price
1.95	9,466,480	8.9	1.95	2,303,640	1.95

The fair value of each stock-based award granted was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for the year ended December 31, 2021: risk free interest rate 0.98%, expected stock price volatility 132%, expected dividend yield 0%, expected life of options 6.5 years. It was determined during the 2020 audit that the option expense was immaterial and therefor no expense was recorded.

12. COMMON STOCK

a. On March 22, 2021, the Company qualified to commence an offering of up to 10,121,457 shares of its Common Stock at a price of $4.94 per share under Regulation A of the Securities Act of 1933, as amended (the "Regulation A Offering"). During 2021, the Company entered into subscription agreements for the sale of 3,041,131 shares of common stock in the Regulation A Offering. As of December 31, 2021, the Company had issued 1,272,478 of such shares for gross proceeds of $6,286,041. The remaining $8,737,145 has been accrued as advances for sale of common stock on the December 31, 2021, balance sheet. Of that advance, $5,854,882 has been received by the Company and $2,882,263 had been paid by the investors to our escrow agent but was receivable from our escrow agent as of December 31, 2021 and is reflected as another receivable on the balance sheet. The other receivable was collected from the escrow agent and the shares of common stock are to be issued in March 2022.

13. RECLASSIFICATION

a. Certain amounts in the 2020 financial statements have been reclassified to conform with current year presentation.

14. RELATED PARTY DISCLOSURES

a. EI Ventures, Inc. paid a 8.33% broker fee to Orthogonal Thinker, Inc. in connection with the acquisition of the 144 digital parcels in the Sandbox. The broker fee was paid by a transfer of 12 digital parcels of the Sandbox to Orthogonal Thinker, Inc. EI Ventures, Inc. is a subsidiary of Orthogonal Thinker, Inc.

15. SUBSEQUENT EVENTS

a. From January 1, 2022 through May 24, 2022, the Company has received about $21.6 Million but has yet to issue the approximately 4,368,898 shares for funds accepted in its Regulation A Offering.

b. Subsequent to year-end, both the other advances and the SAFEs that existed as of December 31, 2021, were converted into 955,471 common shares.