Risk Factors Comparison 2024-03-28 to 2023-03-09 Form: 10-K

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You should carefully consider the risk factors set forth below and in other reports that we file from time to time with the Securities and Exchange Commission and the other information in this Annual Report on Form 10- K. The matters discussed in the risk factors, and additional risks and uncertainties not currently known to us or that we currently deem immaterial, could have a material adverse effect on our business, financial condition, results of operation and future growth prospects and could cause the trading price of our common stock to decline. Risks Related to Our Business and Operations We have ~~had~~ a history of losses **,** and we **expect** ~~may be unable~~ to ~~achieve~~ **incur significant expenses** and ~~sustain profitability~~ **continuing losses for the foreseeable future** and ~~positive~~ **there is substantial doubt regarding our ability to continue as a going concern. We have incurred significant losses and negative** cash flows from operations ~~. We have experienced net~~ **since inception and expect to incur additional** losses **until such time that we can generate significant revenue and profit in our tobacco business, which casts substantial doubt regarding our ability to continue as a going concern. As of March 25, 2024, we had cash and cash equivalents** of approximately $ ~~59~~ **2** . ~~8~~ **2** million ~~and $ 32 . 6 million during the years ended December 31, 2022~~ **Doubts about our ability to continue as a going concern have** and **could continue to** ~~2021, respectively, and negative~~ **negatively** ~~cash flow from~~ **impact our relationships with our commercial partners and our ability, as part of our cost- cutting measures, to obtain, maintain, restructure and / or terminate agreements with them, or negatively impact our negotiating leverage with such parties, which could have a material adverse effect on our business, financial condition and results of** operations ~~of approximately $ 51. 7 million during the year ended December 31, 2022. While our~~ **or result in litigation. Furthermore** ~~current balance of cash and cash equivalents , short- term investment securities~~ **any loss of key personnel ,** ~~working capital~~ **employee attrition or material erosion of employee morale arising out of doubts about our ability to operate as a going concern could have a material adverse effect on our ability to effectively conduct our business** , and **could impair our ability to execute our business plan, thereby having a material adverse effect on our business, financial condition and results of operations. We need additional funding to execute our business plan and to continue operations even with the** proceeds from ~~senior secured credit facility are adequate~~ **recent warrant inducement and exchange concluded in February 2024. We continue** to ~~sustain~~ **seek and evaluate opportunities to raise additional funds through the issuance of our securities, asset sales, and through arrangements with strategic partners. If capital is not available to us when, and in the amounts needed, we could be required to liquidate our inventory and assets, cease** ~~our~~ **or curtail** ~~current planned~~ operations, ~~generating positive cash flows in the future will depend on our~~ **or** ~~ability to successfully generate revenue from~~ **seek protection under applicable bankruptcy laws** ~~our~~ **or similar state proceedings** ~~contract manufacturing operations and sales of our VLN ® cigarettes and hemp- based cannabinoid products as well as our ability to cost- effectively develop, create, acquire, sell and / or market other proprietary tobacco and hemp products, and / or generate royalty revenue from the licensing of our intellectual property~~ . There ~~is~~ **can be** no ~~guarantee~~ **assurance** that we will be able to ~~achieve~~ **raise the capital we need to continue** ~~or~~ **our** ~~sustain positive cash flows and profitability~~ **operations. Without additional capital, we will be unable to continue our operations** in the future. **We may be unable to comply with the covenants in our senior secured debentures.** Our **senior secured debentures contain customary representations, warranties and covenants including among other things and subject to certain exceptions, covenants that restrict us from incurring additional indebtedness, creating or permitting liens on assets, making or holding any investments, repaying outstanding indebtedness, paying dividends or distributions and entering into transactions with affiliates. We are also required to maintain certain quarterly revenue targets. As a result of these covenants, our** ~~inability~~ **ability** to ~~successfully achieve positive cash flows~~ **respond to changes in business** and ~~profitability~~ **economic conditions and engage in beneficial transactions, including to obtain additional financing as needed, may be restricted. Furthermore, our failure to comply with the covenants could result in a default under such agreements, which could permit the debt holders to accelerate our obligation to repay the debt. Although we recently received a waiver with respect to our compliance with such covenants, there is no assurance that we** will **be able to secure a similar waiver for the failure to comply with any future covenants. If any of our debt is accelerated, we likely would not have sufficient funds available to repay it. Substantially all of our assets, including intellectual property, are collateralized under the debentures. If such debt is accelerated, we could be required to liquidate our inventory,** ~~decrease~~ ~~cease~~ ~~our~~ **or curtail operations, or seek protection under applicable bankruptcy laws or similar state proceedings. Additionally, the senior secured debentures may be converted into shares of the Company' s common stock on the earlier of (i) June 30, 2024 and (ii) the public announcement of a Fundamental Transaction (as defined in the senior secured debentures). If the senior secured debentures are converted into common stock in whole or in part, the existing stockholders could incur significant dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of our common stock. We could continue to incur restructuring and impairment charges as we continue to pursue a cost cutting initiative and pursue strategic alternatives. We continue to evaluate opportunities to optimize the cost structure of our operations in order to implement a cost savings initiative. The actions driven from these opportunities could result in significant charges which could adversely affect our financial condition and results of operations. Future actions could result in restructuring and related charges, including but not limited to impairments and employee termination costs and costs associated with terminating contracts that could be significant. We have incurred significant impairment charges for** long- ~~term viability~~ **lived assets, including goodwill and intangible assets, which are subject to periodic impairment analysis and review, and remain subject to the potential for additional charges.**

Identifying and assessing whether impairment indicators exist, or if events or changes in circumstances have occurred, including market conditions, operating results, competition and general economic conditions, requires significant judgment. Any of the above future actions could result in charges that could have ~~and~~ **an** ~~prospects~~ **adverse effect on our financial condition and results of operations. The cost- cutting initiatives have led, and may continue to lead, to legal claims by service providers and other third- parties. Any resulting litigation could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business** . Our competitors generally have, and any future competitors may have, greater financial resources and name recognition than we do, and they may therefore develop products or other technologies similar or superior to ours, or otherwise compete more successfully than we do. **We** ~~In the tobacco industry, we~~ are competing with large tobacco companies and large pharmaceutical companies that have greater resources that us. The tobacco industry consists of major domestic and international companies, most of which have existing relationships in the markets in which we plan to sell, as well as financial, technical, research and development, marketing, sales, manufacturing, scaling capacity, distribution, lobbying and other resources and name recognition substantially greater than ours. In addition, we expect new competitors will enter the markets for similar tobacco products in the future and the nature and extent of this market entrance cannot be quantified at this time. ~~In the cannabis industry, many large companies are entering into the cannabis space, along with smaller regional companies and competition from the black market.~~ Potential customers may choose to do business with more established competitors because of their perception that our competitors are more stable, can scale operations more quickly, have greater manufacturing capacity, have robust marketing and sale programs and lend greater credibility to governmental regulators and others. In addition, large companies have the ability to provide entry- level pricing for premium products in order make us less competitive. If **we** ~~weare~~ -- **are** unable to compete successfully against larger companies with more financial resources and name recognition, our business and prospects would be materially adversely affected. Our competitors may develop products that are less expensive, safer or otherwise more appealing, which may diminish or eliminate the commercial success of our VLN ® cigarettes or any other potential products that we may commercialize. If our competitors develop very low nicotine tobacco without infringing on our intellectual property or other products that are less expensive, safer or otherwise more appealing than our ~~VLNC~~ **RNC** cigarettes or any of our other potential products, or that reach the market before ours, we may not achieve commercial success. Currently, there are numerous companies developing ~~Modified Risk Tobacco~~ products **for which they may submit MRTPAs** , working to develop low nicotine tobacco and other tobacco alternative products ~~in an effort~~ to provide products that are potentially safer for human consumption or to otherwise assist consumers to cease or begin to switch from smoking. If one of such competitors develops a cigarette that is safe for human consumption, a safer alternative for nicotine that is widely accepted, superior low nicotine tobacco or ~~otherwise~~ **18otherwise** develops a superior quitting method, it could render our ~~VLNC~~ **RNC** tobacco and cigarettes obsolete, which would have a material adverse impact on our business and operations and our ability to achieve profitability ~~. In the cannabis industry, there are numerous companies conducting research and development on the cannabis plant in order to develop new and differentiated products and many companies are selling hemp and cannabis- derived products~~ . Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages that we believe we derive from our research approach and proprietary technologies. Our competitors may: ● develop and market similar or new products that are less expensive, safer, or otherwise more appealing than our products; ● develop similar or new technologies and products that render our products obsolete; ● operate larger research and development programs or have substantially greater financial resources than we do; ● have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent; ● more effectively negotiate third- party licenses and strategic relationships; ● commercialize competing products before we or our partners can launch our products; ● be more effective in marketing and creating brand awareness of their products that we are; ● develop tobacco ~~or hemp plants~~ with superior traits to ours; ● initiate or withstand substantial price competition more successfully than we can; and / or ● take advantage of acquisition or other opportunities more readily than we can. Our research and development process may not develop marketable products cost- effectively or at all, which would result in loss of our investment into such process. We do not know whether our research and development process will result in marketable products. Even if we develop marketable products, we may not be able to obtain the necessary ~~approvals or~~ marketing authorizations for these potential products or our anticipated time of bringing these potential products to the market may be substantially delayed. The development of new products is costly, time- consuming, and has no guarantee of success. Any such delays or the inability to effectively develop new products in a cost- effective manner, or at all, would have a material adverse effect on our business and a loss of our financial resources. **We** ~~22We may be unable to successfully integrate GVB' s operations into ours and, even if successfully integrated, we may be unable achieve the expected benefits of such acquisition. The integration of an acquired company requires, among other things, coordination of administrative functions, research and development operations, accounting and finance functions, and the expansion of information and management systems. Integration, especially a large integration such as the integration of GVB, may prove to be difficult due to the necessity of coordinating geographically separate organizations and integrating key personnel with disparate business backgrounds and accustomed to different corporate cultures. Any difficulties or problems encountered in the integration of GVB' s business or operations could~~ have **in** ~~a material adverse effect on our business. Even if successfully integrated, there~~ -- **the past** ~~can be no assurance that our operating performance after an acquisition such as the acquisition of GVB will be successful or will fulfill management' s objectives. We may continue to acquire or invest~~ **invested** in other companies **and may do so in the future** , which may divert our management' s attention, result in additional dilution to our stockholders, and consume resources that are necessary to sustain our business or result in losses. We may ~~continue to~~ acquire or invest in complementary solutions, services, technologies, or businesses in the future ~~, such as our acquisition of GVB~~ . We may also enter into relationships with other businesses to expand our intellectual property portfolio, which could involve preferred or exclusive licenses or investments in other companies. Negotiating these transactions

can be time- consuming, difficult and expensive, and our ability to complete these transactions may often be subject to conditions or approvals that are beyond our control. Consequently, these transactions, even if undertaken and announced, may not close or may not yield the benefits that we expect **. Many of our acquisitions in the past have not yielded the results or synergies that we anticipated** . In addition, we may only be able to conduct limited due diligence on an acquired company' s operations. Following an acquisition, we may be subject to liabilities arising from an acquired company' s past or present operations and these liabilities may be greater than the warranty and indemnity limitations that we negotiate. Any liability that is greater than these warranty and indemnity limitations could have a negative impact on our financial condition. ~~Acquisitions~~ **19Acquisitions** may also disrupt our business, divert our resources, and require significant management attention that would otherwise be available for the development of our business. Moreover, the anticipated benefits of any acquisition, investment, or business relationship may not be realized or we may be exposed to unknown liabilities, including litigation against the companies that we may acquire. The ~~coronavirus pandemic (COVID- 19) or another pandemic may cause a variety of business disruptions and future business risks. The COVID- 19 pandemic previously disrupted our business operations and there is a risk that state and federal authorities' responses to the COVID- 19 pandemic or another pandemic may disrupt our business in the future. The COVID- 19 pandemic caused delays by third party providers of goods or services to our business, the inability to operate in- person at our offices, interruptions to our sales, research and development, and administrative activities, and disruptions to our manufacturing operations, including the ability to staff our manufacturing operations at full capacity or at all. At times during 2020 and 2021, we were unable to have our full staff (or any staff) in our laboratory in Buffalo (and subsequently in Rockville) and some of our external research and development partners operated (or are still operating) on a modified or limited schedule, which slowed our research activities. The future extent of the impact of the COVID- 19 pandemic or another pandemic, including our ability to execute our business strategies as planned, will depend on future developments, including the duration and severity of the pandemic, which are highly uncertain and cannot be predicted. 23The~~ failure of our information systems to function as intended or their penetration by outside parties with the intent to corrupt them could result in business disruption, litigation and regulatory action, and loss of revenue, assets, or personal or confidential data (cybersecurity). We use information systems to help manage business processes, collect and interpret business data and communicate internally and externally with employees, suppliers, customers and others. Some of these information systems are managed by third- party service providers. We have backup systems and business continuity plans in place, and we take care to protect our systems and data from unauthorized access. However, a failure of our systems to function as intended, or penetration of our systems by outside parties intent on extracting or corrupting information or otherwise disrupting business processes, could **interrupt our business and** place us at a competitive disadvantage, result in a loss of revenue, assets or personal or other sensitive data, litigation and regulatory action, cause damage to our reputation and that of our brands and result in significant remediation and other costs. Any cybersecurity incident could cause substantial harm to our business and result in regulatory action, fines, and / or substantial costs ~~. We have limited experience in managing growth. If we fail to manage our growth effectively, we may be unable to execute our business plan or to address competitive challenges adequately. From 2013 to December 31, 2022, we grew from nine (9) employees to one hundred ninety- eight (198) employees. The continued future growth in our business will place a significant strain on our managerial, administrative, operational, financial, information technology and other resources. We intend to continue to expand our overall business, customer base, employees and operations, which will require substantial management effort and significant additional investment in our infrastructure. We will be required to continue to improve our operational, financial and management controls and our reporting procedures and we may not be able to do so effectively. As such, we may be unable to manage our growth effectively and such failure would have a material adverse impact on our operations~~ . Business interruptions, whether caused by natural disaster, terrorism, economic downturns, global pandemics or other events, could negatively impact our business. A natural disaster (such as an earthquake, hurricane, fire, or flood), pandemics ~~(including the COVID- 19 pandemic)~~ , widespread power outage or internet failure or hack, or an act of terrorism could cause substantial delays in our operations, damage or destroy our equipment or facilities, and cause us to incur additional expenses and lose revenue. The insurance we maintain against natural disasters may not be adequate to cover our losses in any particular case, which would require us to expend significant resources to replace any destroyed assets, thereby materially and adversely affecting our financial condition and prospects. Other global incidents could have a similar effect of disrupting our business to the extent they reach and impact the areas in which we operate, the availability of inventory we need, the customers we serve, the partners on whom we rely for products or services or the employees who operate our businesses. For example, ~~the outbreak of COVID- 19 or~~ another pandemic **or comparable heath concern** could disrupt our supply chain for tobacco, as well as negatively impact employee productivity, including affecting the availability of employees reporting for work. Any business interruption caused by such unforeseen events could have a material adverse impact on our business and operations. ~~from being~~ **Our prior operations** in the hemp / cannabis space could have a material adverse effect on our business,financial condition,and results of operations **.We previously operated in the cannabis space** .The hemp plant and the marijuana plant are both part of the same cannabis genus of plant,except that hemp,by definition,has not more than 0.3 % THC content and is legal under the federal 2018 Farm Bill and certain state laws,but the same plant with a higher THC content is defined as marijuana,which is legal under certain state laws,is not legal under federal law.The similarities between these plants can cause confusion,and our **previous** activities with legal hemp may be incorrectly perceived as us ~~being~~ **having been** involved in federally illegal marijuana.Also,despite growing support for the marijuana industry and legalization of marijuana in certain U.S.states,many individuals and businesses remain opposed to the marijuana industry.Any ~~negative~~ **negativity** ~~press~~ resulting from **our prior cannabis operations** ~~the incorrect perception that we have entered into the marijuana space~~ could result in a loss of current or future business.It could also adversely affect the public' s perception of us and lead to reluctance by new parties to do business with us or to own our common stock.We cannot assure you that additional business partners,including but not limited to financial institutions,banking institutions and customers,will not attempt to end or curtail their relationships with us.Any such

negative press or cessation of business could have a material adverse effect on our business,financial condition,and results of operations. ~~Any business- Risks~~ **20Risks** Related to the Tobacco IndustryWe may be unsuccessful in our efforts to commercialize our ~~VLNC~~ **RNC** tobacco ~~as a Modified~~ **using the reduced** ~~Exposure~~ **exposure** ~~Cigarette~~ **claims authorized by the FDA** . While ~~we have received authorization for our MRTP application by~~ the FDA **issued** ~~and~~ **an exposure modification order in connection with our MRTPA and we** have been **commercializing** ~~rolling out~~ our VLN ® **cigarettes** in select markets across the United States ~~and abroad~~ , there are no guarantees regarding the commercial viability of our ~~VLNC~~ **RNC** tobacco cigarettes. To date, there has never been a comparable product sold in the marketplace and we have only **commercialized** ~~rolled out~~ the cigarettes on a limited basis. **We have obtained an exposure modification order for our VLN ® cigarettes, which enables us to make certain claims regarding the reduction of nicotine within** ~~These~~ **these** products **. Specifically, we are permitted to market the products with the claims " 95 % less nicotine, " " helps reduce your nicotine consumption, " and " greatly reduces your nicotine consumption, " and we are required to use the claim " helps you smoke less " in connection with the other authorized claims; we** may not **market our VLN cigarettes for claims that have not been authorized pursuant to an FDA order. Although we believe these claims have the potential to increase our product sales, these products may never** achieve consumer acceptance at levels that make the product commercially viable for profitable sales. In addition, the process of **commercializing** ~~rolling out~~ such product and creating consumer awareness could take longer and cost more than we expect. ~~Further~~ **In addition** , ~~on July 28~~ **even if we believe that certain legislative or regulatory changes may increase product demand** , ~~2017,~~ **such as** the **proposals that** FDA ~~publicly announced that it intends~~ **has historically made with respect** to **requiring** ~~implement new regulations that will mandate~~ minimally or non- addictive levels of nicotine in all cigarettes sold in the U. S. **,** ~~There~~ **there** can be no assurance that ~~the FDA will implement~~ such ~~new~~ regulations ~~or~~ , if implemented, ~~when such regulations would take effect or whether such regulations~~ would increase or create demand for our ~~VLNC~~ **RNC** cigarettes. ~~24The~~ -- **The** commercial success of our ~~VLNC~~ **RNC** tobacco cigarettes will depend on a number of factors, including, but not limited to our ability to: ● achieve, maintain and grow market **identify of,** acceptance of, and demand for, such products; ● successfully create consumer awareness of such products; ● market the product with the phrase " Helps You Smoke Less " **and any other required warnings or statements** ; ● maintain, manage or scale the necessary sales, marketing, manufacturing and other capabilities and infrastructure that are required to successfully commercialize such products; ● grow or otherwise maintain an adequate supply of ~~VLNC~~ **RNC** tobacco; ● maintain and extend intellectual property protection for such products; ● comply with applicable legal and regulatory requirements, including FDA and MSA regulations ~~on~~ **or requirements with respect to product** advertising **and our obligations in connection with our PMTAs and MRTPs** ; ● competitively price our products; ● compete with other similar products or new technologies (if any); ● obtain cost- effective distribution outlets; and ● effectively sell our products into established markets where there is substantial market dominance by large tobacco enterprises. If we are unsuccessful in commercializing our ~~VLNC~~ **RNC** tobacco cigarettes, or such commercialization takes longer or costs more than we currently expect, our financial results, business and future prospects would be materially adversely effected. ~~We~~ **21We** have limited experience marketing and selling Modified Exposure Cigarettes and our working capital and inventory estimates based on demand expectations may be incorrect, which could harm our operating results and financial condition. While members of management and our board of directors are experienced in the selling of conventional cigarette **and other consumer** products, we have limited experience in **introducing a new low nicotine category for** selling ~~Modified Exposure~~ **our VLN** ~~Cigarettes~~ **cigarettes pursuant to an exposure modification order** . As we work ~~towards~~ **to** ~~commercializing~~ **commercialize** one or more of our ~~potential~~ products for sale, including our VLN cigarettes, we base our working capital and inventory decisions on management' s estimates of future demand. If demand for such potential new products does not increase as quickly as we have estimated, our inventory costs ~~and~~ **, demands on** working capital **,** expenses could ~~rise~~ **increase** , and our business and operating results could suffer. Alternatively, if we experience sales **that exceed** ~~in excess of~~ our estimates, our working capital and inventory needs may be higher than those currently anticipated. Since our ~~VLNC~~ **RNC** tobacco is not widely available and must be grown specifically for our potential products, any shortage in such tobacco could prevent us from increasing sales to meet demand and any surplus could result in inventory obsolescence and become a total loss. Our inability to incorrectly estimate demand for future products could negatively harm our operating results and financial condition. ~~25The~~ -- **The** manufacturing **and sale** of tobacco products subjects us to significant governmental regulation and the failure to comply with such regulations could have a material adverse effect on our business and subject us to substantial fines or other regulatory actions. Companies that manufacture and / or sell tobacco products face significant governmental regulation, especially in the United States pursuant to the Tobacco Control Act, including but not limited to efforts aimed at reducing the incidence of tobacco use, restricting marketing and advertising, imposing regulations on packaging, mandating warnings and disclosure of flavors or other ingredients, prohibiting the sale of tobacco products with certain flavors or other characteristics, requiring compliance with certain environmental standards, limiting or prohibiting the sale of tobacco products by certain retail establishments and the sale of tobacco products in certain packaging sizes, and seeking to hold retailers and distributors responsible for the adverse health effects associated with both smoking and exposure to environmental tobacco smoke. **The Tobacco Control Act requires** ~~Manufacturers~~ **manufacturers** of tobacco products **to** ~~must comply with FDA regulations which require~~ , among other things, ~~compliance~~ **provide the FDA** with **a list of ingredients added to tobacco products in** the ~~FDA' s evolving regulations on Current Good Manufacturing~~ **manufacturing process and register any establishment engaged in** ~~Practices (" cGMP (s) "), which are enforced by~~ the ~~FDA through its facilities inspection program~~ **manufacture, preparation, or processing of a tobacco product** . The manufacture of products is subject to strict quality control, testing and record **-** keeping requirements, and continuing obligations regarding the submission of safety reports and other post- market information. **The Tobacco Control Act also authorizes the FDA to promulgate regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, and storage of a tobacco product conform to current good manufacturing**

practice (“ CGMP ”). On March 8, 2023, the FDA issued a proposed rule to promulgate such CGMP regulations. The proposed rule, if finalized, would establish requirements for manufacturers of finished and bulk tobacco products on the methods used in, and the facilities and controls used for, the manufacture, pre- production design validation, packing, and storage of tobacco product. We cannot guarantee that our current manufacturing facility **or any other manufacturing** will ~~pass~~ **successfully complete** FDA inspections and / or similar inspections in foreign ~~countries to produce our tobacco products~~, or that future ~~changes to cGMP~~ **CGMP regulations** ~~manufacturing standards~~ will not also negatively affect the cost or sustainability of our manufacturing facility. ~~We~~ **Our failure to comply with applicable manufacturing regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of marketing orders, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position. In addition, we** and our customers for whom we manufacture tobacco products also face significant governmental regulation, including efforts aimed at reducing the incidence of tobacco use. **We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.** Actions by the FDA and other **foreign,** federal, state or local governments or agencies may impact the adult tobacco consumer acceptability of or access to tobacco products (for example, through product standards proposed by the FDA for nicotine and flavors including menthol), delay or prevent the launch of new or modified tobacco products or products with **reduced exposure** claims ~~of reduced risk~~, ~~require~~ **22require** the recall or other removal of tobacco products from the marketplace, impose additional manufacturing, labeling or packing requirements, interrupt manufacturing or otherwise significantly increase the cost of doing business. Any one or more of these actions may have a material adverse impact on us or the business of our customers for whom we make tobacco products, which could have a negative impact on our results of operations. ~~We expect~~ **For example, the Tobacco Control Act requires the FDA to issue new cigarette health warnings that would include a color graphic component depicting the negative health consequences of smoking. In March 2020, the FDA published a final rule fulfilling this statutory requirement. The final rule, entitled “ Required Warnings for Cigarette Packages and Advertisements, ” specifies the 11 new textual warning label statements and accompanying color graphics that manufacturers would have to include with cigarette packaging and advertisements. On December 7, 2022, the U. S. District Court for the Eastern District of Texas vacated the final rule, and the case is currently pending before the U. S. Court of Appeals for the Fifth Circuit. It is possible that** significant regulatory developments ~~to~~ **will** take place over the next few years ~~in many~~ **across global** markets, driven principally by the World Health Organization’ s Framework Convention on Tobacco Control (“ FCTC ”). The FCTC is the first international public health treaty on tobacco, and its objective is to establish a global agenda for tobacco regulation with the purpose of reducing initiation of tobacco use and encouraging cessation. In addition, the FCTC has led to increased efforts by tobacco control advocates and public health organizations to reduce the appeal of tobacco products. Our operating results could be significantly affected by any significant increase in the cost of complying with new regulatory requirements. Compliance with current and future regulations regarding tobacco could have a material impact on our business and operations and could result in fines, government actions to restrict or prevent sales of products, as well as result in substantial costs and expenses. We may become subject to litigation related to cigarette smoking and / or exposure to environmental tobacco smoke, or ETS, which could severely impair our results of operations and liquidity. Although we are not currently subject to legal proceedings related to cigarette smoking or ETS, we may become subject to litigation related to the sale of our Modified Exposure Cigarettes or other tobacco products we sell or manufacture in the future. Legal proceedings covering a wide range of matters related to tobacco use are pending or threatened in various U. S. and foreign jurisdictions. Various types of claims are raised in these proceedings, including product liability, consumer protection, antitrust, tax, contraband shipments, patent infringement, employment matters, claims for contribution, and claims of competitors and distributors. ~~26Litigation~~ -- **Litigation** is subject to uncertainty **,** and it is possible that there could be adverse developments in pending cases. An unfavorable outcome or settlement of pending tobacco related litigation could encourage the commencement of additional litigation. The variability in pleadings, together with the actual experience of management in litigating claims, demonstrates that the monetary relief that may be specified in a lawsuit bears little relevance to the ultimate outcome. Damages claimed in some tobacco- related ~~litigation~~ **litigations** are significant and, in certain cases, range into the billions of dollars. We anticipate that new cases will continue to be filed. The FCTC encourages litigation against tobacco product manufacturers. It is possible that our results of operations, cash flows, or financial position could be materially affected by an unfavorable outcome or settlement of litigation. Our ~~NASCO~~ production facility **(NASCO)** is integral to our tobacco business and adverse changes or developments affecting our facility may have an adverse impact on our business. Our ~~NASCO~~ production facility is integral to our tobacco business. Adverse changes or developments affecting this facility, including, but not limited to, disease or infestation of our raw materials, a fire, an explosion, a serious injury or fatality, a power failure, a natural disaster, an epidemic, pandemic or other public health crisis, or a material failure of our security infrastructure, could reduce or require us to entirely suspend operations. A significant failure of our site security measures and other facility requirements, including failure to comply with applicable regulatory requirements, could have an impact on our ability to continue operating under our facility licenses and our prospects of renewing our licenses, and could also result in a suspension or revocation of these licenses. ~~The~~ **23The** loss of a significant customer for whom we manufacture tobacco products could have an adverse impact on our results of operation. Currently, a significant portion of our revenues (and corresponding accounts receivable) from manufacturing tobacco products are derived from a small number of large customers, and we do not have agreements with such customers requiring them to purchase a minimum amount of products from us or guaranteeing any minimum future purchase amounts from us. Such customers may, at any time, delay or decrease their level of purchases from us or cease doing business with us altogether. Since many of our manufacturing costs are fixed, if sales to such customers cease or are reduced, we may not obtain sufficient purchase orders from other customers necessary to offset any such losses or reductions, which could have a negative impact on our results of operations. Product liability claims, product recalls,

or other claims could cause us to incur losses or damage our reputation. The risk of product liability claims ~~or~~ **,** product recalls, and associated adverse publicity, is inherent in the development, manufacturing, marketing, and sale of tobacco products. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business and financial condition. A successful product liability claim against us could require us to pay a substantial monetary award. Though we currently have no pending product liability claims against us, we cannot assure you that such claims will not be made in the future and any such claim could cause us to incur substantial losses or damage our reputation. Cigarettes are subject to substantial taxes. Significant increases in cigarette- related taxes have been proposed or enacted and are likely to continue to be proposed or enacted in numerous jurisdictions. These tax increases may affect the sales of our potential products and our third- parties customers' tobacco products manufactured at our factory, which could result in decreased sales and profitability of our manufacturing business. Tax regimes, including excise taxes, sales taxes, and import duties, can disproportionately affect the retail price of manufactured cigarettes versus other tobacco products, or disproportionately affect the relative retail price of our Modified Exposure Cigarettes versus lower- priced cigarette brands manufactured by our competitors. Increases in cigarette taxes are expected to continue to have an adverse impact on sales of cigarettes resulting in (i) lower consumption levels, (ii) a shift in sales from manufactured cigarettes to other tobacco products or to lower- price cigarette categories, (iii) a shift from local sales to legal cross- border purchases of lower price products, and (iv) illicit products such as contraband and counterfeit. ~~27Government~~ -- **Government** mandated prices or taxes, production control programs, shifts in crops driven by economic conditions, climatic or adverse weather patterns may increase the cost or reduce the quality and / or supply of the tobacco and other agricultural products used to manufacture our products. We depend on a small number of independent tobacco farmers to grow our specialty proprietary tobaccos with specific nicotine contents for our products. As with other agricultural commodities, the price of tobacco leaf can be influenced by imbalances in supply and demand, and crop quality can be influenced by variations in weather patterns, diseases, and pests. This risk is greater for us, as there would be no alternative supply of ~~VLNC~~ **RNC** tobacco in the event that one of our growers ~~experienced~~ **experiences** a material adverse event with respect to a particular ~~VLNC~~ **RNC** tobacco crop or the quantity or quality was not as we anticipated, and we would not be able to supply leaf for our VLN ® cigarettes. We must also compete with other tobacco companies for contract production with independent tobacco farmers. Tobacco production in certain countries is subject to a variety of controls, including government mandated prices and production control programs. Changes in the patterns of demand for agricultural products could cause farmers to plant less tobacco. Any significant change in tobacco leaf prices or taxes, quality and quantity could affect our profitability and our business. ~~We~~ **24We** distribute and sell our products outside of the U. S., which subjects us to other regulatory risks. In addition to the ~~approval~~ **authorization** to market and sell our ~~VLNC~~ **RNC** tobacco cigarettes **using** ~~as a Modified~~ **modified** ~~Exposure Cigarette~~ **risk claims** in the U. S., we continue to seek governmental ~~approvals~~ **authorizations** required to market our ~~VLNC~~ **RNC** tobacco cigarettes and our other products in other countries. Marketing of our products is not permitted in certain countries until we have obtained required ~~approvals~~ **authorizations** or exemptions in these individual countries. The regulatory review process varies from country to country, and ~~approval~~ **authorization** by foreign governmental authorities is unpredictable, uncertain, and generally expensive. Our ability to market our potential products could be substantially limited due to delays in receipt of, or failure to receive, the necessary ~~approvals~~ **authorizations** or ~~clearances~~ **exemptions** . We anticipate commencing the applications required in some or all of these countries in the future. Failure to obtain necessary regulatory ~~approvals~~ **authorizations or exemptions** could impair our ability to generate revenue from international sources. We may become subject to governmental investigations on a range of matters. Tobacco companies are often subject to investigations, including allegations of contraband shipments of cigarettes, allegations of unlawful pricing activities within certain markets, allegations of underpayment of custom duties and / or excise taxes, and allegations of false and misleading usage of descriptors such as " lights " and " ultra- lights. " We cannot predict the outcome of any investigations to which we may become subject, but we may be materially affected by an unfavorable outcome of potential future investigations **. Our business model inherently loses customers. Our VLN ® cigarette is designed to help people smoke less and eventually quit smoking completely. If our product is successful, we will lose customers as a result. A significant loss in VLN ® customers, or our inability to add new VLN ® customers faster than we lose customers, could prevent our VLN ® business from growing and have a material negative impact on the results of our operations** . We may be unsuccessful in anticipating changes in adult consumer preferences, responding to changes in consumer purchase behavior or managing through difficult competitive and economic conditions, which could have an adverse effect on business. In the tobacco industry, we are subject to intense competition and changes in adult consumer preferences. To be successful, we must: ● anticipate and respond to new and evolving adult consumer preferences; ● develop, manufacture, market and distribute new and innovative products that appeal to adult consumers (including, where appropriate, through arrangements with, or investments in, third parties); ● improve productivity; and ● protect or enhance margins through cost savings and price increases. ~~28The~~ -- **The** willingness of adult consumers to purchase premium consumer tobacco products, such as our ~~VLNC~~ **RNC** cigarettes, depends in part on economic conditions. In periods of economic uncertainty, adult consumers may purchase more discount brands and / or, in the case of tobacco products, consider lower- priced tobacco products, which could have a material adverse effect on the business and profitability. ~~We~~ **25We** may be unsuccessful in developing and commercializing adjacent products or processes, including innovative tobacco products that may reduce the health risks associated with certain other tobacco products and that appeal to adult tobacco consumers. Some innovative tobacco products may reduce the health risks associated with certain other tobacco products, while continuing to offer adult tobacco consumers products that meet their taste expectations and evolving preferences. Examples include tobacco- containing and nicotine- containing products that reduce or eliminate exposure to cigarette smoke and / or constituents identified by public health authorities as harmful, such as electronically heated tobacco products, oral nicotine pouches, and e- vapor products. We may not succeed in our efforts to develop and commercialize any adjacent products. Further, we cannot predict whether regulators, including the FDA, will permit the marketing or sale of any

particular innovative products (including products with claims of reduced risk to adult consumers), the speed with which they may make such determinations or whether regulators will impose an unduly burdensome regulatory framework on such products. In addition, the FDA could, for a variety of reasons, determine that innovative products currently on the market, or those that have previously received authorization, including with a claim of reduced exposure, are not appropriate for the public health and the FDA could require such products be taken off the market. We also cannot predict whether any products will appeal to adult tobacco consumers or whether adult tobacco consumers' purchasing decisions would be affected by reduced-risk claims on such products if permitted. Adverse developments on any of these matters could negatively impact the commercial viability of such products. If we do not succeed in ~~their~~ **our** efforts to develop and commercialize innovative tobacco products or to obtain **or maintain** regulatory ~~approval~~ **authorizations** for the marketing or sale of products, including ~~with~~ **for the use of** claims of reduced ~~risk~~ **exposure**, but one or more of our competitors does succeed, we may be at a competitive disadvantage, which could have an adverse effect on our ability to commercialize our products. An extended disruption at a facility or in service by a supplier, distributor or distribution chain service provider could have a material adverse effect on our business. We face risks inherent in reliance on one manufacturing facility and a small number of key suppliers, distributors and distribution chain service providers. A pandemic (including COVID- 19), natural or man- made disaster or other disruption that affects the manufacturing operations, the operations of any key supplier, distributor or distribution chain service provider or any other disruption in the supply or distribution of goods or services (including a key supplier' s inability to comply with government regulations or unwillingness to supply goods or services to a tobacco company) could have a material adverse effect on our business. The FDA could force the removal of our products from the U. S. market. The FDA has broad authority over the regulation of tobacco products. The FDA could, among other things, force us to remove from the U. S. market our ~~VLNC~~ **RNC** tobacco cigarettes even after the FDA authorization on December 17, 2019 of our PMTA **for us to market our RNC tobacco cigarettes,** or the authorization of our MRTP application on December 23, 2021, ~~for~~ **to enable** us to ~~market in the U. S.~~ **use certain modified exposure claims with respect to** our ~~VLNC~~ **VLN** ~~tobacco~~ **®** cigarettes ~~, as well as the FDA could levy fines or change their regulations on advertising~~. In addition, the ~~authorization~~ **exposure modification order that enables us** to market our VLN ® cigarettes as ~~MRTP~~ **MRTPs** ~~products~~ was granted for a period of five years, which is the maximum duration for a marketing granted order for such products under the Family Smoking Prevention & Tobacco Control Act (PUBLIC LAW 111 – 31 — JUNE 22, 2009). Consequently, **we** ~~the Company~~ will need to reapply to FDA ~~to~~ under a new MRTP application to extend ~~its marketing granted authorization~~ **the FDA' s exposure modification order** beyond December 23, 2026. The MRTP authorization process is a complex, substantial and lengthy regulatory undertaking. The FDA may or may not grant continued authorization **of these product claims**, **including** based on FDA' s assessment of whether the product application (s) satisfy the statutory requirements for such an order ~~.~~**, and whether we have adequately complied with the conditions imposed on us in connection with the FDA' s exposure modification order, such as requirements relating to recordkeeping, reporting and post- market studies**. Any ~~adverse~~ action by the FDA to remove our products from the U. S. market ~~or~~**, including** the **termination** ~~29failure to have our~~ **or** ~~authorization to market~~ **non- renewal of the exposure modification orders for** our VLN ® cigarettes ~~renewed~~ would have a material adverse impact on our business. ~~A~~ **26A** ban on menthol or flavored tobacco products could have a material adverse impact on our business. On April 27, 2022, the FDA proposed new rules to prohibit menthol as a characterizing flavor in cigarettes and prohibit all characterizing flavors (other than tobacco) in cigars. There has been increasing activity on the state and local levels with respect to scrutiny of menthol and flavored tobacco products, including a recent law passed by the State of California prohibiting tobacco retailers from selling most flavored and menthol tobacco products, including VLN ® Menthol King. If these proposed rules are finalized and implemented, if new rules are proposed or if additional states or governments pass laws similar to the State of California, we could be negatively impacted through decreased sales, a requirement to remove non- compliant tobacco products from the marketplace, associated interruptions in manufacturing or business disruptions. In addition, although we ~~expect~~ **believe** that our VLN ® Menthol King reduced nicotine cigarettes will be exempted from FDA' s menthol ban on cigarettes, there is no guarantee that they will be exempted by the FDA or any other state or local government. Accordingly, the implementation of these proposed or new laws or rules may have a material adverse impact on our results of operations. Risk Factors Related to the Hemp /..... as the perception of cannabis use. Risks Related to Intellectual PropertyCertain of our proprietary rights have expired or may expire or may not otherwise adequately protect our intellectual property, products and potential products, and if we cannot obtain adequate protection of our intellectual property, products and potential products, we may not be able to successfully market our products and potential products. Our commercial success will depend, in part, on obtaining and maintaining intellectual property protection for our technologies, products, and potential products. We will only be able to protect our technologies, products, and potential products from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or to the extent that other market exclusionary rights apply. ~~35The~~ -- **The** patent positions of life sciences companies, like ours, 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 such companies' patents has emerged to date in the United States. The general patent environment outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. Additionally, life science companies like ours are often dependent on creating a pipeline of products. We may not be able to develop additional potential products or proprietary technologies that produce commercially viable products or that are themselves patentable. Our issued patents may be subject to challenge and potential invalidation by third parties and our competitors may develop processes to achieve similar results without infringing on our patents. Changes in either the patent laws or in the interpretations of patent laws in the United States, or in other countries, may diminish the value of our intellectual property. In addition, others may independently develop similar or alternative products and technologies that

may be outside the scope of our intellectual property. Should third parties develop alternative methods of regulating nicotine in tobacco or obtain patent rights to similar products or technology without infringing on our intellectual property rights, this may have an adverse effect on our business. The expiration of a portion of the QPT patent family in 2018 may provide third parties with the freedom to target the QPT gene in the tobacco plant. This could result in experiments to try to reduce nicotine levels in tobacco plants to levels that may satisfy the planned new nicotine reduction regulations coming from the FDA. There can be no assurance about whether any third- parties will or will not be successful in such efforts, how long or short in time such efforts will entail and / or if such efforts will or will not infringe other genes and other intellectual property on which we have continuing patent protection that would need to be used, in combination with QPT, to result in ~~VLNC~~ **RNC** tobacco. If independent researchers or our competitors are able to successfully reduce nicotine levels in tobacco plants without violating our patent protections, our ability to license our technology would be negatively impacted and we would likely face increased competition. ~~We~~ **27We** also rely on license agreements and trade secrets to protect our technology, products, and potential products, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. While we believe that we use reasonable efforts to protect our trade secrets, our own, our licensees' or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non- disclosure and confidentiality agreements with employees, consultants, advisors, and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements will provide adequate protection for our trade secrets, know- how, or other proprietary information, or prevent their unauthorized use or disclosure. To the extent that consultants or key employees apply technological information independently developed by them or by others to our products and potential products, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favor. Key employees are required to assign all intellectual property rights in their discoveries to us. However, these key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods, or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed. ~~36The~~ -- **The** ability to commercialize our **existing and** potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business. The ability to commercialize our potential products will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third- party intellectual property rights in our field are complicated, and third- party intellectual property rights in these fields are continuously evolving. While we have conducted searches for such third- party intellectual property rights, we have not performed specific searches for third- party intellectual property rights that may raise freedom- to- operate issues, and we have not obtained legal opinions regarding commercialization of our potential products. As such, there may be existing patents that may affect our ability to commercialize our potential products. In addition, because patent applications are published up to 18 months after their filing, and because patent applications can take several years to issue, there may be currently pending third- party patent applications and freedom- to- operate issues that are unknown to us, which may later result in issued patents. If a third- party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including: ● infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay ~~the~~ regulatory ~~approval~~ **authorization** ~~process~~ **processes** , and can divert management' s attention from our core business strategy; ● substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor' s patent or other proprietary rights; ● a court order prohibiting us from commercializing our potential products or technologies unless the holder licenses the patent or other proprietary rights to us, which such holder is not required to do; ● if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and ● redesigning our process so that it does not infringe the third- party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our potential products to market. ~~Such~~ **28Such** actions could harm our competitive position and our ability to generate revenue and could result in increased costs. Our patent applications may not result in issued patents, which may have a material adverse effect on our ability to prevent others from commercially exploiting products similar to ours. We own or exclusively control many issued patents and pending patent applications. We cannot be certain that these patent applications will issue, in whole or in part, as patents. Patent applications in the United States are maintained in secrecy until the patents are published or are issued. Since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we are the first creator of inventions covered by pending patent applications or the first to file patent applications on these inventions. We also cannot be certain that our pending patent applications will result in issued patents or that any of our issued patents will afford protection against a competitor. In addition, patent applications filed in foreign countries are subject to laws, rules and procedures that differ from those of the United States, and thus we cannot be certain that foreign patent applications related to U. S. patents will be issued. Furthermore, if these patent applications issue, some foreign countries provide significantly less effective patent enforcement than in the United States. ~~37The~~ -- **The** status of patents involves complex legal and factual questions and the breadth of claims allowed is uncertain. Accordingly, we cannot be certain that the patent applications that we or our licensors file will result in patents being issued, or that our patents and any patents that may be issued to us in the near future will afford protection against competitors with similar

technology. In addition, patents issued to us may be infringed upon or designed around by others and others may obtain patents that we need to license or design around, either of which would increase costs and may adversely affect our operations. We license certain patent rights from third- party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects could be harmed. We license rights to third- party intellectual property that is necessary or useful for our business, and we may enter into additional licensing agreements in the future. Our success could depend in part on the ability of some of our licensors to obtain, maintain, and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed and may in some instances retain rights to the intellectual property that allows them to compete with us. Even if patents are issued with respect to these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we could. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Our worldwide exclusive licenses relating to tobacco from NCSU involve multiple patent families and trade secrets. The exclusive rights under the NCSU agreements expire on the date on which the last patent or registered plant variety covered by the subject license expires in the country or countries where such patents or registered plant varieties are in effect. The NCSU licenses relate predominately to issued patents, and our exclusive rights in the NCSU licenses are expected to expire in **2042** ~~2036. Our worldwide sublicense from Anandia, a plant biotechnology company based in Vancouver, Canada, grants us exclusive rights in the United States and co- exclusive rights with Anandia everywhere else in the world (except not in Canada where Anandia retains exclusive rights) to certain patents and patent applications relating to certain genes in the hemp / cannabis plant that are required for the production of cannabinoids, the " active ingredients " in the cannabis plant. The Anandia sublicense continues through the life of the last- to- expire patent, which is expected to be in 2035~~ . If any of our license agreements or other intellectual property agreements are not effective at preventing others from competing with us and / or using our intellectual property, our business could be adversely affected. Risks Related to Ownership of Our Common **StockNasdaq may delist** ~~StockAn active trading market for~~ our common stock **from trading on its exchange** ~~may not be sustained and you may not be able to resell your shares at or above the price at~~ which **could limit investors' ability to** ~~you purchased them. An active trading market~~ -- **make transactions in** ~~for our shares may not be sustained. In the absence of an active trading market for~~ our common stock ~~, shares of~~ **and subject us to additional trading restrictions. Our** common stock **is currently** ~~may not be able to be resold at or above the purchase price of such shares. Although there can be no assurances, we expect that our common stock will continue to be~~ listed on the ~~NASDAQ~~ **Nasdaq** Capital Market (" NASDAQ ") **. If Nasdaq delists our common stock from trading on its exchange, we could face significant material adverse consequences, including: ● a limited availability of market quotations for our common stock; 29 ● reduced liquidity with respect to our securities; ● a determination that shares of our common stock are " penny stock " which will require brokers trading in our shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares; ● a limited amount of news and analyst coverage; and ● a decreased ability to issue additional common stock or obtain additional financing in the future. On November 7, 2023, the Company received a deficiency letter from the Nasdaq Listing Qualifications Department notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company' s common stock has been below the minimum $ 1. 00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (a) (2) (" Rule 5550 (a) (2) "). In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), the Company has been given 180 calendar days, or until May 5, 2024, to regain compliance with Rule 5550 (a) (2). If the Company does not regain compliance with Rule 5550 (a) (2) by May 5, 2024, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, except for the minimum bid price requirement. In addition, the Company would be required to provide written notice to Nasdaq of its intent to cure the deficiency during the second compliance period. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement under the Nasdaq Listing Rules such as a reverse stock split. On January 24, 2024, the stockholders approved a proposal to amend the Company' s Articles of Incorporation to effect a reverse stock split of the Company' s outstanding common stock at a ratio between 1- for- 2 and 1- for- 16, to be determined at the discretion of the Board of Directors, for the purpose of complying with the Nasdaq Listing Rules, subject to the Board or Directors' discretion to abandon such amendment. The Company has not implemented the reverse stock split as of March 25, 2024. An active trading market for our common stock may not be sustained and you may not be able to resell your shares at or above the price at which you purchased them. An active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, shares of common stock may not be able to be resold at or above the purchase price of such shares. Although there can be no assurances, we expect that our common stock will continue to be listed on the NASDAQ** . However, even if our common stock continues to be listed on the NASDAQ, there is no assurance that an active market for our common stock will continue in the foreseeable future. There also can be no assurance that we can maintain such listing on the NASDAQ. If we are ever no longer listed on the NASDAQ or other national stock exchange in the future, then it would be more difficult to dispose of shares or to obtain accurate quotations as to the market value of our common stock compared to securities of companies whose shares are traded on national stock exchanges. ~~38Our~~ -- **Our** stock price may be highly volatile and could decline in value. Our common stock is currently traded on the NASDAQ and the market price for our common stock has been volatile. Further, the market prices for securities in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may

have a significant impact on the market price of our common stock: ● general economic conditions, including adverse changes in the global financial markets; ● actual and anticipated fluctuations in our quarterly financial and operating results; ● developments or disputes concerning our intellectual property or other proprietary rights; ● introduction of technological innovations or new commercial products by us or our competitors; **30** ● issues in manufacturing or distributing our products or potential products; ● market acceptance of our products or potential products; ● FDA or other United States or foreign regulatory actions affecting us or our industry; ● litigation or public concern about the safety of our products or potential products; ● negative press or publicity regarding us or our common stock; ● the announcement of litigation against us or the results of on- going litigation; ● additions or departures of key personnel; ● third- party sales of large blocks of our common stock or third party short- selling activity; ● third- party articles regarding us or our securities; ● pending or future shareholder litigation; ● sales of our common stock by our executive officers, directors, or significant stockholders; and ● equity sales by us of our common stock or securities convertible into common stock to fund our operations. These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock, such as the current class action and derivative lawsuits. Such lawsuits and any future related lawsuits could cause us to incur substantial costs defending the lawsuit and can also divert the time and attention of our management, which would have a negative adverse impact on our business. See the risk factor below entitled: " We are named defendant in certain litigation matters, including federal securities class action lawsuits and derivative complaints; if we are unable to resolve these matters favorably, then our business, operating results and financial condition may be adversely affected. " We are named defendant in certain litigation matters, including federal securities class action lawsuits and derivative complaints; if we are unable to resolve these matters favorably, then our business, operating results and financial condition may be adversely affected. We are currently involved in certain litigation matters, including securities class action and derivative litigation. See" Item 3 – Legal Proceedings" included in this Annual Report on Form 10- K. We cannot at this time predict the outcome of these matters or any future litigations matters (whether related or unrelated) or reasonably determine the probability of a material adverse result or reasonably estimate range of potential exposure, if any, that these matters or any future matters might have on us, our business, our financial condition or our results of operations, although such effects, including the cost to defend, any judgements or indemnification obligations, among others, could be materially adverse to us. In addition, in the future, we may need to record litigation reserves with respect to these matters. Further, ~~39regardless~~ -- **regardless** of how these matters proceed, it could divert our management' s attention and other resources away from our business. Future sales of our common stock will result in dilution to our common stockholders. Sales of a substantial number of shares of our common stock in the public market may depress the prevailing market price for our common stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if any of the holders of outstanding options or warrants exercise or convert those shares, as applicable, our common stockholders will incur dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of our common stock. **31** ~~We do not expect to declare any dividends on our common stock in the foreseeable future. We have not paid cash dividends to date on our common stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our business, and we do not anticipate paying any cash dividends on our common stock for the foreseeable future. Additionally, the terms of any future debt facilities may preclude us from paying dividends on the common stock. As a result, capital appreciation, if any, of our common stock could be the sole source of gain for the foreseeable future. Anti- takeover provisions contained in our articles of incorporation and bylaws, as well as provisions of Nevada law, could impair a takeover attempt. Our amended and restated articles of incorporation and bylaws currently contain provisions that, together with Nevada law, could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our board of directors. Our corporate governance documents presently include the following provisions: ● providing for a " staggered " board of directors in which only one- third (1 / 3) of the directors can be elected in any year; ● authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend, and other rights superior to our common stock; and ● limiting the liability of, and providing indemnifications to, our directors and officers. These provisions, alone or together, could delay hostile takeovers and changes in control of our Company or changes in our management. As a Nevada corporation, we also may become subject to the provisions of Nevada Revised Statutes Sections 78. 378 through 78. 3793, which prohibit an acquirer, under certain circumstances, from voting shares of a corporation' s stock after crossing specific threshold ownership percentages, unless the acquirer obtains the approval of the stockholders of the issuer corporation. The first such threshold is the acquisition of at least one- fifth, but less than one- third of the outstanding voting power of the issuer. We may become subject to the above referenced Statutes if we have 200 or more stockholders of record, at least 100 of whom are residents of the State of Nevada and do business in the State of Nevada directly or through an affiliated corporation. As a Nevada corporation, we are subject to the provisions of Nevada Revised Statutes Sections 78. 411 through 78. 444, which prohibit an " interested stockholder " from entering into a combination with the corporation, unless certain conditions are met. An " interested stockholder " is a person who, together with affiliates and associates, beneficially owns (or within the prior two years did own) 10 percent or more of the corporation' s voting stock. Any provision of our amended and restated articles of incorporation, our bylaws or Nevada law that has the effect of delaying or deterring a change in control of our Company could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. 40~~