

Risk Factors Comparison 2024-04-01 to 2023-03-31 Form: 10-K

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As a smaller reporting company, we are not required to provide a statement of risk factors. However, we believe this information may be valuable to our shareholders for this filing. We reserve the right to not provide risk factors in our future filings. Our primary risk factors and other considerations include: We have a limited operating history and historical financial information upon which you may evaluate our performance. You should consider, among other factors, our prospects for success in light of the risks and uncertainties encountered by companies that, like us, are in their early stages of development. We may not successfully address these risks and uncertainties or successfully implement our existing and new products. If we fail to do so, it could materially harm our business and impair the value of our common stock. Even if we accomplish these objectives, we may not generate positive cash flows or profits. We were incorporated in Delaware on August 10, 2007. Our business to date has focused on developing and improving our technologies, potential products, filing patents, and hiring management and staff personnel. Unanticipated problems, expenses and delays are frequently encountered in establishing a new business and developing new products. These include, but are not limited to, inadequate funding, lack of consumer acceptance, competition, product development, and inadequate sales and marketing. The failure by us to meet any of these conditions would have a materially adverse effect upon us and may force us to reduce or curtail operations. No assurance can be given that we can or will ever operate profitably. We may not be able to meet our future capital needs. To date, we have generated limited revenue. Our future capital requirements will depend on many factors, including our ability to develop our products, generate cash flow from operations, and competing market developments. Our ability to achieve future profitability is dependent on a variety of factors, many of which are outside of our control. Failure to achieve profitability or sustain profitability, if achieved, may require us to raise additional financing, which could have a material negative impact on the market value of our Common Stock. Any equity financings will result in dilution to our then-existing stockholders. Sources of debt financing may result in high interest expense. Any financing, if available, may be on unfavorable terms. If we cannot obtain achieve or sustain profitability or additional funding, our technology and product development and commercialization efforts may be reduced or discontinued and we may not be able to continue operations. We have experienced recurring net losses since inception, and as of December 31, ~~2022~~ 2023, had an accumulated deficit of \$ ~~78-87, 327-765, 845-981~~. We believe that we will continue to incur substantial operating expenses in the foreseeable future as we continue to invest to develop and expand ~~and~~ technology and product offerings and attract new customers. These efforts may prove more expensive than we anticipate, and we may not succeed in obtaining the net revenue and operating margins necessary to offset these expenses. Accordingly, we may not be able to achieve profitability, and we may incur significant losses for the foreseeable future. Development of our technology and our product development efforts are highly dependent on the amount of cash and cash equivalents on hand combined with our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, issuing additional equity or debt. In addition, we may also raise additional capital through additional equity offerings and licensing our future products in development. While we will continue to explore these potential opportunities, there can be no assurances that we will be successful in raising sufficient capital on terms acceptable to us, or at all, or that we will be successful in licensing our future products. ~~8~~ 9 Our ~~9~~ Our business plan, which is focused on the development and commercialization of alcohol detection devices, is dependent upon our SOBRSafe™ technology. If that technology proves to be ineffective at detecting alcohol in person's system through secretions from their skin it would significantly impact our business. Our business is dependent upon our SOBRSafe™ technology. Our business plan calls for us to develop and commercialize alcohol detection devices based on our SOBRSafe™ technology. In the event that our technology proves to be ineffective at detecting alcohol in person's system through secretions from their skin, it would significantly impact our business. Our quarterly and annual operating results may fluctuate significantly and may not fully reflect the underlying performance of our business. This makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate significantly as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Such fluctuations in quarterly and annual operating results may decrease the value of our common stock. Because our quarterly operating results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: · the level of adoption and demand for our products in our key industries like probation management, fleet & facility, alcohol rehabilitation and young drivers; · positive or negative coverage in the media, or changes in commercial perception, of our products or competing products, including our brand reputation; · the degree of competition in our industry and any change in the competitive landscape, including consolidation among competitors or future partners; · any safety, reliability or effectiveness concerns that arise regarding our products; · unanticipated pricing pressures in connection with the sale of our products; · the effectiveness of our sales and marketing efforts, including our ability to deploy a sufficient number of qualified representatives to sell and market our products; · the timing of customer orders for our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold; · unanticipated delays in product development or product launches; · the

cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third- party suppliers; · our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products; · our ability to achieve and maintain compliance with all regulatory requirements applicable to our products and services; · our ability to obtain, maintain and enforce our intellectual property rights; · our ability and our third- party suppliers' ability to supply the components of our products in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements; and · introduction of new products or technologies that compete with our products. **9The 10The** cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could deviate materially from our expectations and our business could suffer. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it will negatively affect our business, financial condition and results of operations. ~~The continued spread of COVID-19 variants and uncertain market conditions may adversely affect our business, financial condition and results of operations. We are closely monitoring the coronavirus and the directives from federal and local authorities regarding not only our workforce, but how it impacts companies we work with for the development of our SOBRsafe™ technology and the devices that deploy that technology. The extent to which the COVID-19 continues to impact our financial conditions and results of operations, or those of our third- party suppliers, will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time, including the duration of new outbreaks, information which may emerge concerning the severity of COVID-19 and the actions being taken to contain COVID-19 or treat its impact, among others. Governmental agencies can fluctuate in their implementation of social distancing and "work from home" regulations. If those regulations increase then the chances increase that more and more companies may be forced to either shut down, slow down or alter their work routines. Since the development and testing of our SOBR technologies and the potential platform devices is a "hands on" process, these alternative work arrangements could significantly slow down our anticipated schedules for the marketing and sale of our SOBR devices, which could have a negative impact our business.~~ Because we face intense competition, we may not be able to operate profitably in our markets. The market for our products is highly competitive and is becoming more so, which could hinder our ability to successfully market our products. We may not have the resources, expertise or other competitive factors to compete successfully in the future. We expect to face additional competition from existing competitors and new market entrants in the future. Many of our competitors have greater name recognition and more established relationships in the industry than we do. As a result, these competitors may be able to: · develop and expand their product offerings more rapidly; · adapt to new or emerging changes in customer requirements more quickly; · take advantage of acquisition and other opportunities more readily; and · devote greater resources to the marketing and sale of their products and adopt more aggressive pricing policies than we can. **10If** our products do not gain ~~expected~~ market acceptance, prospects for our sales revenue may be affected. We intend to use the SOBR Safe™ technology in various platforms in the preventative, probation management, fleet & facility, alcohol rehabilitation and young drivers' markets. Currently, most alcohol sensing devices are breath analyzers and ankle bracelets employed in the judicially-mandated market where the use is usually required by law as a punishment for committing a crime. We will be asking companies and institutions that have an interest in monitoring whether their employees or contractors have alcohol in their systems due to their job responsibilities (such as fleet and school bus drivers, factory machinists, forklift operators, etc.), to adopt a new requirement that their employees or contractors must abide in order to remain employed. While we believe this will be attractive to many companies and industries, we must achieve some level of market acceptance to be successful. If we are unable to achieve market acceptance, our investors could lose their entire investment. If critical components become unavailable or contract manufacturers delay their production, our business will be negatively impacted. We currently stay ahead of supply chain issues by utilizing multiple sources, but if for reasons out of our control parts are not available, it could impact customer contracts and revenue. We currently outsource supply chain and manufacturing of the SOBRcheck™ device to third- party manufacturers. The stability of component supply will be crucial to maintaining our manufacturing process. Due to the fact we currently manufacture the device utilizing in part, "off the shelf" parts and components, some of our critical devices and components being supplied by certain third- party manufacturers, we may be unable to acquire necessary amounts of key components at competitive prices. We have selected these particular manufacturers based on their ability to consistently produce these products according to our requirements in an effort to obtain the best quality product at the most cost- effective price. However, the loss of all or one of these suppliers or delays in obtaining shipments would have an adverse effect on our operations until an alternative supplier could be found, if one may be located at all. If we get to that stage of growth, such loss of manufacturers could cause us to breach any contracts we have in place at that time and would likely cause us to lose sales. **If 11If** our contract manufacturers fail to meet our requirements for quality, quantity and timeliness, our business growth could be harmed. We currently outsource the manufacturing of devices utilizing the **SOBRsafe** SOBR @ Safe™ alcohol detection system to several contract manufacturers. These manufacturers will procure all of the raw materials for us and provide all necessary facilities and labor to manufacture our products. If these companies were to terminate their agreements with us without adequate notice or fail to provide the required capacity and quality on a timely basis, we would be delayed in our ability or unable to process and deliver our products to our customers. Our products could contain defects or they may be installed or operated incorrectly, which could reduce sales of those products or result in claims against us. Although we have quality assurance practices in place to ensure good product quality, defects still may be found in the future in our future products. End-users could lose their confidence in our products and / or our company if they unexpectedly use defective products or use our products improperly. This could result in loss of revenue, loss of profit margin, or loss of market share. We have limited

experience manufacturing our products in large- scale commercial quantities, and we face a number of manufacturing risks that may adversely affect our manufacturing abilities which could delay, prevent or impair our growth. Our growth strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand. We outsource with United States based third party manufacturing companies. If any of our manufacturing facilities suffer damage, or a force majeure event, such damage or event could materially impact our ability to operate, which could materially and adversely affect our business and financial performance. **11** **We** are also subject to numerous other risks relating to our manufacturing capabilities, including: · quality and reliability of components, sub- assemblies and materials that we source from third- party suppliers, who are required to meet our quality specifications, almost all of whom are single source suppliers for the items and materials that they supply; · our inability to secure components, sub- assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms; · our inability to maintain compliance with quality system requirements or pass regulatory quality inspections; · our failure to increase production capacity or volumes to meet demand; · potential risks associated with disruptions in our supply chain, such as on account of the COVID- 19 pandemic or other macroeconomic events; · lead times associated with securing key components; · our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and · difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner. These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to purchase components, sub- assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although some future products may share product features, components, sub- assemblies and materials with our existing products, the manufacture of these products may require modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub- assemblies and materials or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations. **12** **We rely on third party intellectual property licenses and agreements to provide and facilitate the basis for and production of our patent-pending technology including our manufactured SOBRcheck™ and SOBRsure™ devices. We have limited control over our third- party business partners and contract manufacturers who rely on intellectual property and patents of other parties to supply primary components for our devices. This presents potential manufacturing supply and reliability, quality compliance, and intellectual property infringement risks or expiry of exclusive rights to the intellectual property. Further, there is no assurance components or changes to the intellectual property rights will meet our quality requirements to ensure quality and reliability of our devices. Should our third- party business partners and contract manufacturers not maintain exclusive rights to the intellectual property or should the content of the patents change, this could impact the effectiveness of our current device designs and impair our ability to produce quality products.** Because our technology is innovative and disruptive, we may require additional time to enter the market due to the need to further discover the profile companies within our target markets. Our products are new to the marketplace. As a result, we will need time to penetrate our target markets by ~~furthering~~ **further** developing the profile companies that could benefit the most from our products and technology. If we are not successful in discovering these companies it could greatly slow our growth and adversely impact our financial condition. We are currently selling our products through direct sales and distributors, and will need time to develop relationships in order to secure customers and grow revenue. Any failure to maintain and grow our direct sales force and distributor network could harm our business. The members of our direct sales force are adequately trained and possess technical expertise, which we believe is critical in driving the awareness and adoption of our products. The members of our U. S. sales force are at- will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of comparable expertise and qualifications, or if we are unable to successfully employ such expertise in replacement personnel, our product sales, revenues and results of operations could be materially harmed. **12** **In** order to generate future growth, we will continue to identify and recruit qualified sales and marketing professionals. Training them on our products and on our internal policies and procedures requires significant time, expense and attention. It can take several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products, placing us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in product sales and revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time to reduce fixed costs, could have material adverse effect on our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our products will depend, to a significant extent, on our ability to expand our sales and marketing efforts. Our business may be harmed if these efforts and expenditures do not generate a corresponding increase in revenue. If we fail to successfully promote our products in a cost- effective manner, we may fail to attract or retain the market acceptance necessary to realize a sufficient return on our promotional efforts, or to achieve broad adoption of our products. **We** **13** **We** need to ensure strong product performance and reliability to maintain and grow our business. We need to maintain and, if needed, improve the performance and reliability of our products to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. In addition, our SOBRsafe™ technology, and the software and

hardware incorporated into our SOBRcheck™ and SOBRsure™ devices may contain errors or defects, especially when first introduced and while we have made efforts to test this software and hardware extensively, we cannot assure that the software and hardware, or software and hardware developed in the future, will not experience errors or performance problems. Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches, and such failure could negatively affect our business, financial condition and results of operations. We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing, inventory management and other related functions. We do not have redundant information technology in all aspects of our systems at this time. Despite the implementation of security and back-up measures, our internal computer, server, and other information technology systems as well as those of our third-party consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, accidental or intentional exposure of our data by employees or others with authorized access to our networks, computer viruses, malware, ransomware, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and / or proprietary data, including personal information, including health-related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. If we or our third-party consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. The COVID-19 pandemic has generally increased the risk of cybersecurity intrusions. Our reliance on internet technology and the number of our employees who are working remotely may create additional opportunities for cybercriminals to exploit vulnerabilities. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems or data or systems of our commercial partners, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer reputational harm. Failure to maintain or protect our information technology systems effectively could negatively affect our business, financial condition and results of operations. ~~13~~ If we are unable to recruit and retain qualified personnel, our business could be harmed. Our growth and success highly depend on qualified personnel. Competition in the industry could cause us difficulty in recruiting or retaining a sufficient number of qualified technical personnel, which could harm our ability to develop new products. If we are unable to attract and retain necessary key talents, it would harm our ability to develop competitive products and retain good customers and could adversely affect our business and operating results. We may be unable to adequately protect our proprietary rights. ~~We~~ ~~14~~ We currently have one “use” patent covering the SOBRsafe™ alcohol detection system and / or the SOBR devices and two provisional patents pending with the United States Patent and Trademark Office. These patents are not specific to the components, but rather the overall solution provided by the SOBR devices. Our ability to compete partly depends on the superiority, uniqueness and value of our intellectual property. To protect our proprietary rights, we will rely on a combination of patent, copyright and trade secret laws, confidentiality agreements with our employees and third parties, and protective contractual provisions. Despite these efforts, any of the following occurrences may reduce the value of our intellectual property: · Our applications for patents relating to our business may not be granted and, if granted, may be challenged or invalidated; · Issued patents may not provide us with any competitive advantages; · Our efforts to protect our intellectual property rights may not be effective in preventing misappropriation of our technology; · Our efforts may not prevent the development and design by others of products or technologies similar to or competitive with, or superior to those we develop; or · Another party may obtain a blocking patent and we would need to either obtain a license or design around the patent in order to continue to offer the contested feature or service in our products. We may become involved in lawsuits to protect or enforce our patents that would be expensive and time consuming. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties. In addition, we may become subject to interference or opposition proceedings conducted in patent and trademark offices to determine the priority and patentability of inventions. The defense of intellectual property rights, including patent rights through lawsuits, interference or opposition proceedings, and other legal and administrative proceedings, would be costly and divert our technical and management personnel from their normal responsibilities. An adverse determination of any litigation or defense proceedings could put our pending patent applications at risk of not being issued. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure could have a material adverse effect on our business and our financial results. ~~14~~ ~~The~~ ~~15~~ ~~The~~ ~~internal~~ ~~controls~~ ~~we~~ ~~utilize~~ ~~to~~ ~~produce~~ ~~reliable~~ ~~financial~~ ~~reports~~ ~~had~~ ~~material~~ ~~weaknesses~~ ~~provide~~ ~~no~~ ~~assurance~~ ~~that~~ ~~we~~ ~~will~~ ~~,at~~ ~~all~~ ~~times~~ ~~,in~~ ~~the~~ ~~future~~ ~~be~~ ~~able~~ ~~to~~ ~~report~~ ~~that~~ ~~our~~ ~~internal~~ ~~controls~~ ~~over~~ ~~financial~~ ~~reporting~~ ~~are~~ ~~effective~~ . If we ~~develop~~ ~~continued~~ ~~to~~ ~~have~~ material weaknesses in our internal controls, we may not be able to report our financial results accurately or timely or to detect fraud, which could have a material adverse effect on our business. An effective internal control environment

is necessary for us to produce reliable financial reports and is an important part of our effort to prevent financial fraud. There are inherent limitations on the effectiveness of internal controls, including collusion, management override, and failure of human judgment. In addition, control procedures are designed to reduce rather than eliminate business risks. If we ~~continue to~~ fail to maintain an effective system of internal controls we may be unable to produce reliable, timely financial reports or prevent fraud, which could have a material adverse effect on our business, including subjecting us to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such actions could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline or limit our access to **capital**. We are required to periodically evaluate the effectiveness of the design and operation of our internal controls over financial reporting. **In the past we have identified material weaknesses in our internal controls. As of December 31, 2022, the specific weaknesses our management identified include: (i) we do not have sufficient segregation of duties within our accounting functions, and (ii) we have not documented all our internal controls. Enhancements, modifications, and changes to our internal controls during fiscal 2023 were necessary in order to eliminate these weaknesses.** Based on these evaluations, we ~~concluded~~ **conclude** in our Annual Report on Form 10-K for the year ended December 31, ~~2022~~ **2023**, as well as in all of our quarterly and annual reports since evaluations and disclosure regarding our internal controls became required disclosure, that we have material weaknesses in our internal controls. **Enhancements, modifications, and changes to our internal controls produce reliable financial reports are operating effectively** necessary in order to eliminate these weaknesses. As of December 31, 2022, the specific weaknesses our management has identified include: (i) we do not have sufficient segregation of duties within our accounting functions, and (ii) ~~we have not documented all our internal controls~~. See “Internal Control Over Financial Reporting”, herein. **15** ~~We~~ **There are inherent limitations on the effectiveness.....** limit our access to capital. We may be dependent on outside advisors to assist us. In order to supplement the business experience of management, we may employ accountants, technical experts, appraisers, attorneys or other consultants or advisors. The selection of any such advisors will be made by management and without any control from shareholders. Additionally, it is anticipated that such persons may be engaged by us on an independent basis without a continuing fiduciary or other obligation to us. We are subject to the significant influence of one of our current stockholders, and their interests may not always coincide with those of our other stockholders. Gary Graham, ~~and Cord Carpenter~~ **and Cord Carpenter** currently beneficially ~~owns~~ **own** approximately ~~15~~ **12.4 % and 5.0 %, respectively**, of our outstanding common stock. As a result, **These stockholders are** ~~Mr. Graham is~~ able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Because the interests of Mr. Graham may not always coincide with those of our other stockholders, such stockholder may influence or cause us to take actions with which our other stockholders disagree. Our management has discretion as to how to use any proceeds from the sale of securities. We reserve the right to use the funds obtained from the sale of our securities for purposes our management deems to be in the best interests of the company and our stockholders in order to address changed circumstances or opportunities. As a result of the foregoing, our success will be substantially dependent upon the discretion and judgment of management with respect to application and allocation of the net proceeds from the sale of our securities. The issuance of additional common stock and / or the resale of our issued and outstanding common stock could cause substantial dilution to investors. Our ~~Articles~~ **Certificate** of Incorporation authorize the issuance of up to 100,000,000 shares of common stock and 25,000,000 shares of preferred stock. Our Board of Directors has the authority to issue additional shares of common stock and to issue options and warrants to purchase shares of our common stock without shareholder approval. Future issuances of common stock could represent further substantial dilution to investors. In addition, the Board of Directors could issue large blocks of voting stock to fend off unwanted tender offers or hostile takeovers without further stockholder approval. ~~15~~ ~~Our~~ **Our** common stock has been thinly traded and we cannot predict the extent to which a trading market will develop. Our common stock is listed on Nasdaq ~~Capital Market~~. Our common stock is thinly traded compared to larger more widely known companies. Thinly traded common stock can be more volatile than common stock trading in an active public market. We cannot predict the extent to which an active public market for our common stock will develop or be sustained. **We may not be able to maintain our listing on the Nasdaq, which could have a material adverse effect on us and our stockholders. We may not be able to maintain our listing on the Nasdaq, which could have a material adverse effect on us and our stockholders. The standards for continued listing on Nasdaq include, among other things, that the minimum bid price for the listed securities may not fall below \$ 1.00 for a period in excess of 30 consecutive business days and stockholders' equity maintain a minimum value of at least \$ 2,500,000. During the months of October 2023 and November 2023, our common stock traded at levels below \$ 1.00 per share in excess of the 30- business day requirement. On November 15, 2023, we received a deficiency letter from the Listing Qualifications Department (the “ Staff ”) of the Nasdaq notifying us that, for the preceding 30 consecutive business days, the closing bid price of our common stock remained below the minimum \$ 1.00 per share requirement for continued inclusion on Nasdaq. In accordance with the Nasdaq Listing Rules, we have been provided an initial period of 180 calendar days, or until May 13, 2024 (the “ Compliance Date ”), to regain compliance with the Bid Price Requirement. If at any time before the Compliance Date the closing bid price of our common stock is at least \$ 1.00 for a minimum of ten consecutive business days, the Staff will provide us with written confirmation of compliance with the Bid Price Requirement. 16** If we do not regain compliance with the Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would then be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the Bid Price Requirement, and would need to provide written notice of its intention to cure the deficiency during the additional 180 calendar day compliance period, which compliance could be achieved by effecting a reverse stock split, if necessary. At December 31, 2023, our stockholders' equity was below the Nasdaq minimum Stockholders' Equity Requirement of \$ 2,500,000. At the date of

this filing, we have not received a deficiency letter from the Staff of the Nasdaq regarding this listing requirement. Upon notification of deficiency by the Staff, we will have 45 days to submit a plan to regain compliance with this Nasdaq listing standard. Staff may extend this deadline for up to an additional five calendar days upon good cause shown and may request such additional information from us as is necessary to make a determination regarding whether to grant such an extension. If the plan is accepted, Nasdaq can grant an extension of up to 180 calendar days from the date of notification to evidence compliance. We are currently evaluating opportunities to increase our stockholders' equity including but not limited to capital financing and debt conversion inducement options. If the closing bid price of our common stock or the value of our stockholders' equity were to fail to meet Nasdaq's respective minimum requirements within the prescribed periods, or if we otherwise fail to meet any other applicable requirements of Nasdaq and we are unable to regain compliance, Nasdaq may make a determination to delist our common stock. The delisting of our common stock from Nasdaq could negatively impact us by (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) impacting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing or limiting us from accessing the public capital markets; and (iv) impairing our ability to provide equity incentives to our employees. There can be no assurance that we will regain compliance or otherwise maintain compliance with any of the other listing requirements. Nonetheless, we intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options, including a reverse stock split, to regain compliance with the Bid Price Requirement, and evaluating capital financing and debt conversion inducement options to gain compliance with the Stockholders' Equity Requirement. Future sales of our common stock in the public market could lower the price of our common stock and impair our ability to raise funds in future securities offerings. Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of its securities. The market price of our common stock may be volatile and may be affected by market conditions beyond our control. The market price of our common stock is subject to significant fluctuations in response to, among other factors: · variations in our operating results and market conditions specific to Biomedical Industry companies; · changes in financial estimates or recommendations by securities analysts; · announcements of innovations or new products or services by us or our competitors; · the emergence of new competitors; · operating and market price performance of other companies that investors deem comparable; · changes in our board or management; · sales or purchases of our common stock by insiders; · commencement of, or involvement in, litigation; · changes in governmental regulations; and · general economic conditions and slow or negative growth of related markets. In addition, if the market for stocks in our industry, or the stock market in general, experience a loss of investor confidence, the market price of our common stock could decline for reasons unrelated to our business, financial condition or results of operations. If any of the foregoing occurs, it could cause the price of our common stock to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to the board of directors and management. **17**