Risk Factors Comparison 2024-03-20 to 2023-03-16 Form: 10-K

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You should consider carefully the risks, uncertainties and other factors described below, in addition to the other information set forth in this Form 10- K, before making an investment decision. Any of these risks, uncertainties and other factors could materially and adversely affect our business, financial condition, results of operations, cash flows or prospects. In that case, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock. See also " Cautionary Statement Regarding Forward- Looking Statements. " Risks Related to Our Business We have a limited operating history upon which investors can evaluate our future prospects. We have a limited operating history upon which an evaluation of our business plan or performance and prospects can be made. The business and prospects of the Company must be considered in the light of the potential problems, delays, uncertainties and complications encountered in connection with a newly established business and new industry. The risks include, but are not limited to, the possibility that we will not be able to develop functional and scalable products and services, or that although functional and scalable, our products and services will not be economical to market; that our competitors hold proprietary rights that preclude us from marketing such products; that our competitors market a superior or equivalent product; that we are not able to upgrade and enhance our technologies and products to accommodate new features and expanded service offerings; or the failure to receive necessary regulatory clearances for our products. To successfully introduce and market our products at a profit, we must establish brand name recognition and competitive advantages for our products. There are no assurances that we can successfully address these challenges and if unsuccessful, we and our business, financial condition and operating results could be materially and adversely affected. The current and future expense levels of our business are based largely on estimates of planned operations and future revenues rather than experience. It is difficult to accurately forecast future revenues because our business is new and our market has not been developed. If our forecasts prove incorrect, the business, operating results and financial condition of the Company may be materially and adversely affected. Moreover, we may be unable to adjust our spending in a timely manner to compensate for any unanticipated reduction in revenues. As a result, any significant reduction in planned or actual revenues may immediately and adversely affect our business, financial condition and operating results. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. As described in Note 2 of our accompanying audited financial statements, our auditors have issued a going concern opinion on our December 31, ~~2022~~ **2023** financial statements, expressing substantial doubt that we can continue as an ongoing business for the next twelve months after issuance of their report based on our current development plans and our operating requirements and us having suffered recurring losses from operations and having a net capital deficiency. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot raise the necessary capital to continue as a viable entity, we could experience a material adverse effect on our business and our stockholders may lose some or all of their investment in us. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward- looking statements and involve risks and uncertainties. We have no revenues and we cannot predict when we will achieve first revenues and sustained profitability. We have no revenues and cannot definitely predict when we will achieve revenues and profitability. We do not anticipate generating significant revenues until we successfully develop, achieve regulatory clearance, commercialize and sell our proposed products, of which we can give no assurance. We are unable to determine when we will generate significant revenues from the sale of any such products. We cannot predict when we will achieve profitability, if ever. Our inability to become profitable may force us to curtail or temporarily discontinue our research and development programs and our day- to- day operations. Furthermore, there can be no assurance that profitability, if achieved, can be sustained on an ongoing basis. We may never complete the development and commercialization of products that we are currently developing and future development of new generations of any of our other proposed products. We have no assurance of success as to the completion and of the commercial launch of our products or the completion and development of any new generations of products that are currently under development or other proposed or contemplated products, for any of our target markets. We continue to seek to improve our technologies while we are developing them so that they result in commercially viable products. Failure to improve on any of our technologies could delay or prevent their successful development for our target markets. Developing any technology into a marketable product is a risky, time consuming and expensive process. You should anticipate that we will encounter setbacks, discrepancies requiring time consuming and costly redesigns and changes, and that there is the possibility of outright failure. We may not meet our product development and commercialization milestones. We have established milestones, based upon our expectations regarding our technologies, which we use to assess our progress toward developing our products. These milestones relate to technology development and design improvements as well as dates for achieving development goals. If our products exhibit technical defects or are unable to meet cost or performance goals, our commercialization schedule could be delayed and potential purchasers of our initial commercial products may decline to purchase such products or may opt to pursue alternative products. We may also experience shortages of the components used in our devices. The contract manufacturing operations that we will use could be disrupted by fire, earthquake or other natural disaster, a labor- related disruption, failure in supply or other logistical channels, electrical outages or other reasons. If there were a disruption to manufacturing facilities, we would be unable to manufacture devices until these manufacturing capabilities are restored or alternative manufacturing facilities are engaged. Generally, we have met our milestone schedules when making technological advances in our product. We can give no assurance

that our development and commercialization schedule will continue to be met as we further develop products currently under development or any of our other future products. Our business is dependent upon physicians utilizing and prescribing our solution; if we fail to engage physicians to utilize our solution, our revenues may never materialize or may not meet our projections. The success of our cardiac diagnosis and monitoring business is dependent upon physicians prescribing and utilizing our solution. The utilization of our solution by physicians for use in the prescription of cardiac monitoring is directly influenced by a number of factors, including: • the ability of the physicians with whom we work to obtain sufficient reimbursement and be paid in a timely manner for the professional services they provide in connection with the use of our monitoring solutions; • establishing ourselves as a cardiac monitoring technology company by publishing peer reviewed publications showing efficacy of our solutions, • our ability to educate physicians regarding the benefits of our cardiac monitoring solutions over alternative diagnostic monitoring solutions, • our demonstrating that our proposed products are reliable and supported by us in the field; • supplying and servicing sufficient quantities of products directly or through marketing alliances; and • pricing our devices and technology service fees in a medical device industry that is becoming increasingly price sensitive. If we are unable to drive physician utilization, our revenues may never materialize or may not meet our projections. We are subject to extensive governmental regulations relating to the manufacturing, labeling, and marketing of our products. Our medical technology products and operations are subject to regulation by the FDA, and other foreign and local governmental authorities. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and post market surveillance of our medical products. Under the United States Federal Food, Drug, and Cosmetic Act, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. We believe that our products currently under development and planned products will be Class II medical devices. Class II medical devices are subject to additional controls, including full applicability of the Quality System Regulations, and requirements for 510 (k) pre- market notification. The FDA may disagree with the classification of a new Class II medical device and require the manufacturer of that device to apply for approval as a Class III medical device. If the FDA determines that our Class II medical Products should be classified as Class III medical devices, we could be precluded from marketing the devices for clinical use within the United States for a period of time, the length of which depends on the specific change in the classification. Reclassification of our Class II medical Products as Class III medical devices could significantly increase our regulatory costs, including the timing and expense associated with required clinical trials and other costs. In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products in foreign countries. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. The policies of the FDA and foreign regulatory authorities may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our products and could also increase the cost of regulatory compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad. The FDA and non- U. S. regulatory authorities require that our products be manufactured according to rigorous standards. These regulatory requirements may significantly increase our production costs and may even prevent us from making our products in quantities sufficient to meet market demand. If we change our approved manufacturing process, the FDA may need to review the process before it may be used. Failure to comply with applicable regulatory requirements discussed could subject us to enforcement actions, including warning letters, fines, injunctions, and civil penalties, product recall or seizure of our products, operating restrictions, partial suspension or total shutdown of our production, and even criminal prosecution. Federal, state, and non- U. S. regulations regarding the manufacture and sale of medical devices are subject to future changes. The complexity, timeframes and costs associated with obtaining marketing clearances are unknown. Although we cannot predict the impact, if any, these changes might have on our business, the impact could be material. Following the introduction of a product, these agencies will also periodically review our design and manufacturing processes and product performance. The process of complying with the applicable good manufacturing practices, adverse event reporting, clinical trial and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing, or sale of our products. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA and other agencies have resulted in increased enforcement activity, which increases the compliance risk for the Company and other companies in our industry. In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re- register products already on the market or otherwise impact our ability to market our products in those countries. Once clearance or approval has been obtained for a product, there is an obligation to ensure that all applicable FDA, and other regulatory requirements continue to be met. Additionally, injuries caused by the malfunction or misuse of cardiac devices, even where such malfunction or misuse occurs with respect to one of our competitor' s products, could cause regulatory agencies to implement more conservative regulations on the medical cardiac monitoring industry, which could significantly increase our operating costs. If we are not able to both obtain and maintain adequate levels of third- party reimbursement for our products, it would have a material adverse effect on our business. Healthcare providers and related facilities are generally reimbursed for their services through payment systems managed by various governmental agencies worldwide, private insurance companies, and managed care organizations. The manner and level of reimbursement in any given case may depend on the site of care, the procedure (s) performed, the final patient diagnosis, the device (s) utilized, available budget, the efficacy, safety, performance

and cost- effectiveness of our planned products and services, or a combination of these or other factors, and coverage and payment levels are determined at each payer' s discretion. The coverage policies and reimbursement levels of these third- party payers may impact the decisions of healthcare providers and facilities regarding which medical products they purchase and the prices they are willing to pay for those products. Thus, changes in reimbursement levels or methods may impact sales of our products. We have no direct control over payer decision- making with respect to coverage and payment levels for our medical device products and services. Additionally, we expect many payers to continue to explore cost- containment strategies (e. g., comparative, and cost- effectiveness studies, so- called " pay- for- performance " programs implemented by various public and private payers, and expansion of payment bundling schemes such as Accountable Care Organizations, and other such methods that shift medical cost risk to providers) that may potentially impact coverage and / or payment levels for our products and services. The ability of physicians and other providers to successfully utilize our cardiac diagnostic and monitoring solutions and successfully allow payors to reimburse for the physicians' technical and professional fees is critical to our business because physicians and their patients will select solutions other than ours in the event that payors refuse to adequately reimburse our technical fees and physicians' professional fees. Changes in reimbursement practices of third- party payers could affect the demand for our products and services and our revenue levels. The sales of our proposed products and services could depend, in part, on the extent to which healthcare providers and facilities or individual users are reimbursed by government authorities, private insurers and other third- party payers for the costs of our products, or the services performed with our products. The coverage policies and reimbursement levels of third- party payers, which can vary among public and private sources and by country, may affect which products customers purchase and the prices they are willing to pay for those products and services in a particular jurisdiction. Reimbursement rates can also affect the acceptance rate of new technologies. Legislative or administrative reforms to reimbursement systems in the United States or abroad, or changes in reimbursement rates by private payers, could significantly reduce reimbursement for medical actions using the Company' s products or result in denial of reimbursement for those products, which would adversely affect customer demand, or the price customers may be willing to pay for such products and services. We may experience difficulty in obtaining reimbursement for our services from commercial payors that consider our technology to be experimental and investigational, which would adversely affect our revenue and operating results. Many commercial payors refuse to enter into contracts to reimburse the fees associated with medical devices or services that such payors determine to be " experimental and investigational. " Commercial payors typically label medical devices or services as " experimental and investigational " until such devices or services have demonstrated product superiority evidenced by a randomized clinical trial. For example, clinical trials have been performed on some mobile cardiac telemetry devices, proving higher diagnostic yield than monitoring devices and services that are already being reimbursed. Certain remaining commercial payors, however, have stated that they do not believe the data from the clinical trials justifies the removal of the experimental designation for mobile cardiac telemetry solutions. As a result, certain commercial payors may refuse to reimburse the technical and professional fees associated with cardiac monitoring solutions such as the one expected to be offered by the Company. If commercial payors decide not to reimburse physicians or providers for their services during the utilization of our cardiac monitoring solutions, our revenue could fail to materialize or meet our projections. Reimbursement by Medicare is highly regulated and subject to change; our failure to comply with applicable regulations could decrease our expected revenue and may subject us to penalties or have an adverse impact on our business. The Medicare program is administered by CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, and how and where we provide our cardiac solutions. Our failure to comply with applicable Medicare rules could result in the inability of physicians to receive reimbursement as they will likely utilize our cardiac monitoring solution under the Medicare payment program. Consolidation of commercial payors could result in payors eliminating coverage of mobile cardiac monitoring solutions or reducing reimbursement rates. When payors combine their operations, the combined company may elect to reimburse physicians for cardiac monitoring services at the lowest rate paid by any of the participants in the consolidation. If one of the payors participating in the consolidation does not reimburse for these services at all, the combined company may elect not to reimburse at any rate. Reimbursement rates tend to be lower for larger payors. As a result, as payors consolidate, our expected average reimbursement rate may decline. Product defects could adversely affect the results of our operations. The design, manufacture and marketing of our hardware and software products involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA, or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries or deaths relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals. Interruptions or delays in telecommunications systems or in the data services provided to us by cellular communication providers or the loss of our wireless or data services could impair the delivery of our cardiac monitoring services. The success of our cardiac monitoring services will be dependent upon our ability to transmit, store, retrieve, process and manage data and to maintain and upgrade our data processing and communication capabilities. Our monitoring solution relies on a third- party wireless carrier to transmit data over its data network. All data sent by our monitors via this wireless data network is expected to be routed directly to healthcare providers and data centers or third- party ECG monitoring centers. We are therefore dependent upon a third party wireless carrier to provide data transmission services to us. As we expand our commercial activities, an increased burden is expected to be placed upon our data processing systems and the equipment upon which they rely. Interruptions of our data networks, or the data networks of our wireless carrier, for any extended length of time, loss of stored data or other computer problems could have a material adverse effect on our business and operating results.

Frequent or persistent interruptions in our cardiac monitoring services could cause permanent harm to our reputation and could cause current or potential users or prescribing physicians to believe that our systems are unreliable, leading them to switch to our competitors. Such interruptions could result in liability, claims and litigation against us for damages or injuries resulting from the disruption in service. Our systems are also expected to be vulnerable to damage to or interruption of telecommunication services from earthquakes, floods, fires, power loss, telecommunication failures, terrorist attacks, computer viruses, break- ins, sabotage, and acts of vandalism. Despite any precautions that we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions in these services. We do not carry business interruption insurance to protect against losses that may result from interruptions in service as a result of system failures. Moreover, the communications and information technology industries are subject to rapid and significant changes, and our ability to operate and compete is dependent on our ability to update and enhance the communication technologies used in our systems and services. Interruptions in computing and data management cloud systems could impair the delivery of our cardiac monitoring services. The success of our cardiac monitoring services will be dependent upon our ability to perform computing functions associated with our cardiac signal processing algorithms and data management. The diagnostic and monitoring functions rely on the uninterrupted availability of third- party cloud based computational and data management services. Availability of the cloud- based infrastructure is a critical link in our ability to deliver our services and could have a material adverse effect on our business and operating results. Furthermore, loss of data due to catastrophic events at the sites for these cloud based computer systems could cause permanent harm to our customers. These adverse events associated with unavailability of our cloud based computational infrastructure could result in liability, claims and litigation against us for damages or injuries resulting from the disruption in service. Our systems are also expected to be vulnerable to damage or interruption in cloud computational services from earthquakes, floods, fires, power loss, technical failures, terrorist attacks, computer viruses, break- ins, sabotage, and acts of vandalism. Despite any precautions that we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions in these services. We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims. The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Product liability insurance is expensive and, if available, may not be available on acceptable terms at all periods of time. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of our products, cause a significant financial burden on the Company, or both, which in either case could have a material adverse effect on our business and financial condition. We require additional capital to support our present business plan and our anticipated business growth, and such capital may not be available on acceptable terms, or at all, which would adversely affect our ability to operate. We will require additional funds to further develop our business plan. We may choose to raise additional capital in order to expedite and propel growth more rapidly. We can give no assurance that we will be successful in raising any additional funds. We may need to raise additional funds, doing so through debt and equity offerings, in order to meet our expected future liquidity and capital requirements, including capital required for the development completion and introduction of our future products and technologies. Any such financing that we undertake will likely be dilutive to current stockholders. We intend to continue to make investments to support our business growth, including patent or other intellectual property asset creation. In addition, we may also need additional funds to respond to business opportunities and challenges, including our ongoing operating expenses, protecting our intellectual property, satisfying debt payment obligations, developing new lines of business and enhancing our operating infrastructure. While we may need to seek additional funding for such purposes, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our Common Stock. We may also seek to raise additional funds through arrangements with collaborators or other third parties. We may not be able to negotiate any such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all our business plans. We cannot predict our future capital needs and we may not be able to secure additional financing. We will need to raise additional funds in the future to fund our working capital needs and to fund further expansion of our business. We may require additional equity or debt financings, collaborative arrangements with corporate partners or funds from other sources for these purposes. No assurance can be given that necessary funds will be available for us to finance our development on acceptable terms, if at all. Furthermore, such additional financings may involve substantial dilution of our stockholders or may require that we relinquish rights to certain of our technologies or products. In addition, we may experience operational difficulties and delays due to working capital restrictions. If adequate funds are not available from operations or additional sources of financing, we may have to delay or scale back our growth plans. The results of our research and development efforts are uncertain and there can be no assurance of the commercial success of our products. We believe that we will need to incur additional research and development expenditures to continue development of our existing proposed products as well as research and development expenditures to develop new products and services. The products and services we are developing and may develop in the future may not be technologically successful. In addition, the length of our product and service development cycle may be greater than we originally expected, and we may experience delays in product development. If our resulting products and services are not technologically successful, they may not achieve market acceptance or compete effectively with our competitors' products and services. If we fail to retain certain of our key personnel and attract and retain additional qualified personnel, we might not be able to pursue our growth strategy. Our future success will depend upon the continued service of Dr. Branislav Vajdic and other members of our key management team and our technical contributors. Though no individual is indispensable, the loss of the services of these individuals could have a material adverse effect on our business, operations, revenues or prospects. We do not currently maintain key man life insurance on the lives of these individuals. We will not be profitable unless we can demonstrate that our products can be manufactured at low prices. To date, we have focused primarily on research and development of the first versions of our software and hardware products, as well as other technologies we plan to introduce in our eco- system, and

their proposed marketing and distribution. Consequently, we have little experience in manufacturing these products on a commercial basis. We plan to manufacture our products through third- party manufacturers. We can offer no assurance that either we or our manufacturing partners will develop efficient, automated, low- cost manufacturing capabilities and processes to meet the quality, price, engineering, design and production standards or production volumes required to successfully mass market our products, especially at the low- cost levels we require to absorb the cost of near free distribution of our products pursuant to our proposed business plan. Even if we or our manufacturing partners are successful in developing such manufacturing capability and processes, we do not know whether we or they will be timely in meeting our product commercialization schedule or the production and delivery requirements of potential customers. A failure to develop such manufacturing processes and capabilities could have a material adverse effect on our business and financial results. If we or our suppliers fail to achieve or maintain regulatory approval of manufacturing facilities, our growth could be limited and our business could be harmed. In order to maintain compliance with FDA and other regulatory requirements, our development and manufacturing facilities must be periodically re- evaluated and qualified under a quality system to ensure they meet production and quality standards. Suppliers of components and products used to manufacture our devices must also comply with FDA regulatory requirements, which often require significant resources and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers do not maintain regulatory approval for our manufacturing operations, our business could be adversely affected. Our dependence on a limited number of suppliers may prevent us from delivering our devices on a timely basis. We currently rely on a limited number of suppliers of components for our prototype devices. If these suppliers became unable to provide components in the volumes needed or at an acceptable price, we would have to identify and qualify acceptable replacements from alternative sources of supply. The process of qualifying suppliers is lengthy. Delays or interruptions in the supply of our requirements could limit or stop our ability to provide sufficient quantities of devices on a timely basis or meet demand for our devices or services, which could have a material adverse effect on our business, financial condition and results of operations. We rely significantly on information technology and any failure, inadequacy, or security lapse of that technology, including any cybersecurity incidents, could harm us. We believe that companies have been increasingly subject to a wide variety of security incidents, cyberattacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state- sponsored attack. Cyber threats may be generic, or they may be custom- crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent and much harder to detect and defend against. Several key areas of our business depend on the use of information technologies, including production, manufacturing, marketing, and logistics, as well as clinical and regulatory matters. We also utilize systems that allow for the secure storage and transmission of proprietary or confidential information regarding our customers, employees, and others, including personal information. Despite our efforts to prevent such behavior, third parties may nonetheless attempt to hack into our systems and obtain data relating to our pre- clinical studies, clinical trials, patients using our VCG technology and our telehealth ECG collection device or other information relating to us or our business. If we fail to maintain or protect our information systems and data integrity effectively, we could have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with physicians, and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences and reputational damages. While we have invested in the protection of data and information technology, there can be no assurance that our efforts or those of our third- party collaborators, if any, or manufacturers, to implement adequate security and quality measures for data processing would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or to prevent data from being stolen or corrupted in the event of a security breach. Any such loss or breach could harm our business, operating results, and financial condition. **For a discussion of our management of cybersecurity risks, see Item 1C," Cybersecurity- Risk Management" and"- Governance."** We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future. As a public company, we are subject to the reporting requirements of the Exchange Act, and the Sarbanes- Oxley Act. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal controls over financial reporting. We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. We are continuing to develop and refine our internal controls over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a- 15 (f) under the Exchange Act. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our staff. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified to date include (i) lack of formal risk assessment under COSO framework (ii) policies and procedures which are not adequately documented, (iii) lack of proper approval processes, review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and ~~ineffective review processes over period end financial disclosure and~~ reporting and (v) insufficient **number of staff to maintain optimal** segregation of duties **and levels of oversight. Starting in third quarter of 2023, we have undertaken specific remediation actions to address the material weaknesses in our financial reporting. We are establishing more robust processes related to the review of complex accounting transactions, the preparation of account reconciliations and the**

review of journal entries. These remediation actions included hiring a Controller in July 2023, who we believe has extensive experience in developing and implementing internal controls and executing plans to remediate control deficiencies . We will be required to expend time and resources to further improve our internal controls over financial reporting. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock. Our independent registered public accounting firm is not required to audit the effectiveness of our internal control over financial reporting until after we are no longer an" emerging growth company " as defined in the JOBS Act and meet other requirements. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results, and cause a decline in the market price of our common stock. Risks Related to Economic Conditions We maintain our cash at financial institutions, often in balances that exceed federally insured limits. Our cash is held in accounts at U. S. banking institutions that we believe are of high quality. Cash held in non- interest- bearing and interest- bearing operating accounts may exceed the Federal Deposit Insurance Corporation (" FDIC ") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. ~~The FDIC took control of one such banking institution, Silicon Valley Bank (" SVB "), on March 10, 2023 and as a result, we stood to lose approximately $ 0. 6 million. The FDIC also took control of Signature Bank (" Signature Bank ") on March 12, 2023 we do not hold any accounts at this bank. The Federal Reserve on March 13, 2023 announced that account holders would not bear the loss of SVB' s collapse. Thus, we do not view the risk as material to our financial condition. However, as the FDIC continues to address the situation with SVB, Signature Bank and other similarly situated banking institutions, the risk of loss in excess of insurance limitations has generally increased. Any material loss that we may experience in the future could have an adverse effect on our ability to pay our operational expenses or make other payments and may require us to move our accounts to other banks, which could cause a temporary delay in making payments to our vendors and employees and cause other operational inconveniences.~~ Changes in tax laws or regulations may increase tax uncertainty and adversely affect results of our operations and our effective tax rate. We are subject to taxes in the United States and in the future expect to be subject to certain foreign jurisdictions. Due to economic and political conditions, tax rates in various jurisdictions, including the United States, may be subject to change. Our future effective tax rates could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws or their interpretation. In addition, we may be subject to income tax audits by various tax jurisdictions. Although we believe our income tax liabilities are reasonably estimated and accounted for in accordance with applicable laws and principles, an adverse resolution by one or more taxing authorities could have a material impact on the results of our operations. Escalating global trade tensions, ~~and~~ the ~~conflict between~~ Russia and Ukraine **war** , ~~and~~ **the Israel- Hamas war,** the adoption or expansion of tariffs and trade restrictions **and economic disruption and uncertainty resulting therefrom** could negatively impact us. The ~~current military conflict between~~ Russia and Ukraine **war and Israel- Hamas war** could lead to disruption, instability and volatility in global markets and industries that could negatively impact our operations and could adversely affect our business and / or our supply chain, business partners or customers in other countries beyond Russia and Ukraine. The U. S. government and other governments in jurisdictions in which we operate have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. It is not possible to predict the broader consequences of this conflict, which could include sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, partners or customers. More specifically, while it is difficult to anticipate the impact the sanctions announced to date may have on our Research and Development team is largely based in Belgrade, Serbia any further sanctions imposed or actions taken by the U. S. or other countries, and any retaliatory measures by Russia in response, such as restrictions on energy supplies from Russia to countries in the region, could increase our costs, reduce our sales and earnings or otherwise have an adverse effect on our operations. Natural disasters and other events beyond our control could materially adversely affect us. Natural disasters or other catastrophic events may cause damage or disruption to our operations, international commerce and the global economy, and thus could have a strong negative effect on us. Our business operations are subject to interruption by natural disasters, fire, power shortages, pandemics and other events beyond our control. Such events could make it difficult or impossible for us to deliver our products and services to our customers and could decrease demand for our products and services. ~~The ongoing~~ **Our business and operations, and the operations of our suppliers and customers, have been, and may in the future be adversely affected by epidemics, pandemics or other public health crises such as the** COVID- 19 pandemic ~~continues~~ **outbreak. We may face risks related** to ~~present operational,~~ health **epidemics** ~~, labor, logistics~~ and **pandemics or** other **outbreaks** ~~challenges, and it is difficult to assess the ultimate impact~~ of ~~the~~ **communicable diseases. The** COVID- 19 pandemic **and governments' measures taken in response had a significant**

adverse impact, both direct and indirect, on our business ~~, financial condition~~ and ~~cash flows. The World Health Organization declared the COVID- 19 outbreak a pandemic in 2020. Based~~ on ~~current COVID- 19 trends,~~ the **broader economy. We may in** ~~Department of Health and Human Services is planning for~~ the ~~federal~~ **future experience, weakened demand from certain customers as a result of a** ~~Public~~ **public** ~~Health~~ **health crisis** ~~Emergency for COVID- 19~~ , **which could adversely affect our revenues. For example** ~~declared under Section 319 of the Public Health Service Act~~ , ~~to expire~~ **healthcare providers have,** at ~~the end of the day~~ **times, deferred elective medical procedures in order to focus** on **combating** ~~May 11, 2023. There are many variables and uncertainties regarding~~ the COVID- 19 pandemic, **which significantly reduced demand** ~~including the emergence, contagiousness and threat of new and different strains of the virus and their severity; the effectiveness of treatments or~~ **for certain of** ~~vaccines against the virus or~~ **our** ~~its new strains; travel restrictions, business closures~~ **medical products. We also faced difficulty sourcing some materials** and ~~other measures that are~~ **components necessary to fulfill** ~~or~~ **our** ~~may be imposed in affected areas or countries by governmental authorities;~~ **developmental requirements due to suppliers' capacity constraints and shipping and transportation** disruptions **during** ~~in the supply chain; an increasingly competitive labor market due to a sustained labor shortage or increased turnover caused by~~ the COVID- 19 pandemic ~~;~~ **. These disruptions adversely affected our ability to meet our schedules. If we are not able to mitigate similar disruptions effectively in future epidemics, pandemics or other public health crisis, our ability to manufacture our products or meet our customers' schedules would be adversely affected, possibly materially, and our business could be harmed. In addition, efforts to find alternate sources of supply may** ~~increased~~ **increase** ~~logistics~~ **our** costs ~~; additional costs due to remote working arrangements, adherence to social distancing guidelines and other COVID- 19 related challenges. Further, there remain increased risks of cyberattacks on information technology systems used in remote working environment; increased privacy- related risks due to processing health- related personal information; absence of workforce due to illness; and other factors that are currently unknown or considered immaterial. It is difficult to assess the ultimate impact of the COVID- 19 pandemic on our~~ **or** ~~business~~ **lower the quality of our product, which could negatively affect our profitability** , financial condition and **business** ~~cash flows~~ . Risks Related to Our Industry The industry in which we operate is highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or are otherwise more attractive, we may be unable to compete effectively with other companies. The medical technology industry is characterized by intense competition and rapid technological change, and we will face competition on the basis of product features, clinical outcomes, price, services and other factors. Competitors may include large medical device and other companies, some of which have significantly greater financial and marketing resources than we do, and firms that are more specialized than we are with respect to particular markets. Our competition may respond more quickly to new or emerging technologies, undertake more extensive marketing campaigns, have greater financial, marketing and other resources than ours or may be more successful in attracting potential customers, employees and strategic partners. Our competitive position will depend on multiple, complex factors, including our ability to achieve regulatory clearance and market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory approvals for products under development and protect our intellectual property. In some instances, competitors may also offer, or may attempt to develop, alternative systems that may be delivered without a medical device or with a medical device superior to ours. The development of new or improved products, processes or technologies by other companies may render our products or proposed products obsolete or less competitive. The entry into the market of manufacturers located in low- cost manufacturing locations may also create pricing pressure, particularly in developing markets. Our future success depends, among other things, upon our ability to compete effectively against current technology, as well as to respond effectively to technological advances or changing regulatory requirements, and upon our ability to successfully implement our marketing strategies and execute our research and development plan. Our research and development efforts are aimed, in part, at solving increasingly complex problems, as well as creating new technologies, and we do not expect that all of our projects will be successful. If our research and development efforts are unsuccessful, our future results of operations could be materially harmed. We face competition from other medical device companies that focus on similar markets. We face competition from other companies that have longer operating histories and may have greater name recognition and substantially greater financial, technical and marketing resources than us. Many of these companies also have FDA or other applicable governmental approval to market and sell their products, and more extensive customer bases, broader customer relationships and broader industry alliances than us, including relationships with many of our potential customers. Increased competition from any of these sources could result in our failure to achieve and maintain an adequate level of customers and market share to support the cost of our operations. Unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects. The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical experiences and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market' s view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be completed in a timely or cost- effective manner or result in a commercially viable product. Failure to successfully complete these trials or procedures in a timely and cost- effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent clinical analysis. In addition, results from our already completed clinical trials or procedures may not be supported by actual long- term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long- term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks. Intellectual property litigation and

infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products. The medical device industry in which we operate is characterized by extensive intellectual property litigation and, from time to time, we might be the subject of claims by third parties of potential infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert the time and effort of our management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in our payment of significant monetary damages and / or royalty payments, or it could negatively impact our ability to sell current or future products in the affected category and could have a material adverse effect on business, cash flows, financial condition or results of operations. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to obtaining intellectual property protections we rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We will seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We will seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or intellectual property assignment agreements with our employees and consultants. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. In general, any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition. If we are unable to protect our proprietary rights, or if we infringe on the proprietary rights of others, our competitiveness and business prospects may be materially damaged. We have filed for and were granted a number of utility patents in the U. S as well as through PCT covering international markets. We will continue to seek patent protection for our inventions and may seek patent protection for our proprietary designs if warranted. Seeking patent protection is a lengthy and costly process, and there can be no assurance that patents will be issued from any pending applications, or that any claims allowed from existing or pending patents will be sufficiently broad or strong to protect our designs or our proprietary technology. There is also no guarantee that any patents we hold will not be challenged, invalidated or circumvented, or that the patent rights granted will provide competitive advantages to us. Our competitors have developed and may continue to develop and obtain patents for technologies that are similar or superior to our technologies. In addition, the laws of foreign jurisdictions in which we develop, manufacture or sell our products may not protect our intellectual property rights to the same extent, as do the laws the United States. Adverse outcomes in legal disputes regarding patent and other intellectual property rights could result in the loss of our intellectual property rights, subject us to significant liabilities to third parties, require us to seek licenses from third parties on terms that may not be reasonable or favorable to us, prevent us from manufacturing, importing or selling our products, or compel us to redesign our products to avoid infringing third parties' intellectual property. As a result, we may be required to incur substantial costs to prosecute, enforce or defend our intellectual property rights if they are challenged. Any of these circumstances could have a material adverse effect on our business, financial condition and resources or results of operations. Dependence on our proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may result in our payment of significant monetary damages or impact offerings in our product portfolios. Our long- term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or may lose access to technologies critical to our products. Also, our currently pending industrial design patent or any future patents applications may not result in issued patents, and issued patents are subject to claims concerning priority, scope and other issues. Furthermore, to the extent we do not file applications for patents domestically or internationally, we may not be able to prevent third parties from using our proprietary technologies or may lose access to technologies critical to our products in other countries. Enforcement of federal and state laws regarding privacy and security of patient information may adversely affect our business, financial condition or operations. The use and disclosure of certain health care information by health care providers and their business associates have come under increasing public scrutiny. Recent federal standards under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish rules concerning how individually- identifiable health information may be used, disclosed and protected. Historically, state law has governed confidentiality issues, and HIPAA preserves these laws to the extent they are more protective of a patient' s privacy or provide the patient with more access to his or her health information. As a result of the implementation of the HIPAA regulations, many states are considering revisions to their existing laws and regulations that may or may not be more stringent or burdensome than the federal HIPAA provisions. We must operate our business in a manner that complies with all applicable laws, both federal and state, and that does not jeopardize the ability of our customers to comply with all applicable laws. We believe that our operations are consistent with these legal standards. Nevertheless, these laws and regulations present risks for health care providers and their business associates that provide services to patients in multiple states. Because these laws and regulations are recent, and few have been interpreted by government regulators or courts, our interpretations of these laws and regulations may be incorrect. If a challenge to our activities is successful, it could have an adverse effect on our operations, may require us to forego relationships with customers in certain states and may restrict the territory available to us to expand our business. In addition, even if our interpretations of HIPAA and other federal and state laws and regulations are correct, we could be held liable for unauthorized uses or disclosures of patient information as a result of inadequate systems and controls to protect this information or as a result

of the theft of information by unauthorized computer programmers who penetrate our network security. Enforcement of these laws against us could have a material adverse effect on our business, financial condition and results of operations. We may become subject, directly or indirectly, to federal and state health care fraud and abuse laws and regulations and if we are unable to fully comply with such laws, the Company could face substantial penalties. Although not affected at this time, our operations may in the future become directly or indirectly affected by various broad state and federal health care fraud and abuse laws, including the Federal Healthcare Programs' Anti- Kickback Statute and the Stark law, which among other things, prohibits a physician from referring Medicare and Medicaid patients to an entity with which the physician has a financial relationship, subject to certain exceptions. If our future operations are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and results of operations could be adversely affected. We may be subject to federal and state false claims laws which impose substantial penalties. Many of the physicians and patients whom we expect to use our services will file claims for reimbursement with government programs such as Medicare and Medicaid. As a result, we may be subject to the federal False Claims Act if we knowingly " cause " the filing of false claims. Violations may result in substantial civil penalties, including treble damages. The federal False Claims Act also contains " whistleblower " or " qui tam " provisions that allow private individuals to bring actions on behalf of the government alleging that the defendant has defrauded the government. In recent years, the number of suits brought in the medical industry by private individuals has increased dramatically. Various states have enacted laws modeled after the federal False Claims Act, including " qui tam " provisions, and some of these laws apply to claims filed with commercial insurers. We are unable to predict whether we could be subject to actions under the federal False Claims Act, or the impact of such actions. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the False Claims Act, could adversely affect our results of operations. Risks Related To Common Stock The price of our Common Stock and Warrants may be subject to wide fluctuations. A consistently active trading market for our Common Stock and Warrants does not exist and may not develop or be maintained. You may not be able to sell your shares quickly or at the current market price if trading in our stock is not active. You may lose all or a part of your investment. The market price of our Common Stock and Warrants may be highly volatile and subject to wide fluctuations in response to a variety of factors and risks, many of which are beyond our control. In addition to the risks noted elsewhere in this prospectus, some of the other factors affecting our stock price may include: • variations in our operating results; • announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments; • announcements by third parties of significant claims or proceedings against us; • future sales of our Common Stock or other equity securities; • any delay in our regulatory filings for our product and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; • adverse results or delays in clinical trials; • our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; • adverse regulatory decisions, including failure to receive regulatory approval of our product; • changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals; • adverse developments concerning our manufacturers; • our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; • our inability to establish collaborations if needed; • additions or departures of key scientific or management personnel; • introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • our ability to effectively manage our growth; • the size and growth of our initial target markets; • our ability to successfully treat additional types of indications or at different stages; • actual or anticipated variations in annual and quarterly operating results; • our cash position; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • changes in the market valuations of similar companies; • overall performance of the equity markets; • sales of our Common Stock by our stockholders in the future; • trading volume of our Common Stock; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our or our licensee' s technologies; • significant lawsuits, including patent or stockholder litigation; • general political and economic conditions, including war and its unknown impact on our Serbia development team; and • other events or factors, many of which are beyond our control. We are an " emerging growth company, " and any decision on our part to comply with certain reduced disclosure requirements We are an " emerging growth company " as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but (i) not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, (ii) not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board (the " PCAOB "), requiring mandatory audit firm rotation or a supplement to the auditor' s report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, (iii) not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, (iv) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (v) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $ 1. 24 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement; (iii) the date on which we have issued more than $ 1. 0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated

filer. We cannot predict if investors will find our securities less attractive if we choose to rely on these exemptions. If some investors find our securities less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our securities and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to stockholders of such companies. Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7 (a) (2) (B) of the Securities Act of 1933, as amended (the " Securities Act "), for complying with new or revised accounting standards. We have opted for taking advantage of the extended transition period for complying with new or revised accounting standards pursuant to Section 107 (b) of the Jobs Act. **We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors. We are a smaller reporting company under Rule 12b- 2 of the Securities Exchange Act of 1934. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.** Future sales and issuances of our Common Stock or rights to purchase Common Stock, including pursuant to our equity incentive plans and other equity securities could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell Common Stock or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Common Stock or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Common Stock. Our Certificate of Incorporation authorizes the issuance of 100, 000, 000 shares of Common Stock and 10, 000, 000 shares of Preferred Stock. Initially, the aggregate number of shares of our Common Stock that may be issued pursuant to stock awards under our 2022 Equity Incentive Plan (" 2022 Plan ") is 1, 900, 000 shares **, increased to 5, 900, 000 shares at the last shareholders' meeting**. As of December 31, ~~2022~~ **2023**, there are ~~747~~ **849**, ~~364~~ **171** shares available for issuance under the 2022 Plan. The number of shares available for issuance under the 2022 Plan will be increased on the first day of each fiscal year beginning with the 2023 fiscal year by five percent (5 %) of the total number of shares of common stock outstanding on the last day of the immediately preceding fiscal year as defined in the Plan. Further increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline. Nasdaq Capital Market, may delist our Common Stock if we fail to comply with ongoing listing standards. Nasdaq Capital Market requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our Common Stock and Warrants. If we fail to meet these continued listing requirements, our Common Stock or Warrants may be subject to delisting. If our Common Stock or Warrants are delisted and we are not able to list such Common Stock and Warrants on another national securities exchange, we expect our securities would be quoted on an over- the- counter market; However, if this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our Common Stock and Warrants and reduced liquidity for the trading of our securities. In addition, in the event of such delisting, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution. Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities, our ability to estimate future expenses and acceptance of our products in the market. There are no significant commitments for future financing of the commercial phase of our telehealth Product and other future products. In the future, our securities may be offered to other investors at a price lower than the price per share paid by our investors, or upon terms which may be deemed more favorable than previously offered. In addition, the issuance of securities in any future financing using our securities may dilute an investor' s equity ownership. Moreover, we may issue other equity securities with derivative features to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders, including the investors in this offering. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and / or may have to curtail certain, if not all, of our business objectives and plans. If our shares become subject to the penny stock rules, it would become more difficult to trade our shares. The SEC has adopted regulations, which generally define " penny stock " to be an equity security that has a market price of less than $ 5. 00 per share, subject to specific exemptions. The market price of our Common Stock is less than $ 5. 00 per share and therefore may be a " penny stock. " Brokers and dealers effecting transactions in " penny stock " must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability

of brokers or dealers to sell our Common Stock and may affect your ability to sell shares of our Common Stock in the future. Liability of directors for breach of duty is limited under Delaware law. Our certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any: • breach of their duty of loyalty to us or our stockholders; • act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; • unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or • transaction from which the directors derived an improper personal benefit. These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission. Our bylaws provide that we will indemnify for our directors and officers to the fullest extent permitted by law, and may indemnify employees and other agents. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding. We entered into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for any and all expenses (including reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by such directors or officers or on his or her behalf in connection with any action or proceeding arising out of their services as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request provided that such person follows the procedures for determining entitlement to indemnification and advancement of expenses set forth in the indemnification agreement. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. In so far as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future and, as such, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, and any future loan arrangements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our Common Stock. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.