Risk Factors Comparison 2024-04-16 to 2023-03-31 Form: 10-K

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~~There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Annual Report on Form 10- K, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and / or operating results could be materially adversely affected. The risks and uncertainties described below include forward- looking statements and our actual results may differ from those discussed in these forward- looking statements. Risk Factor Summary Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading " Risk Factors " and should be carefully considered, together with other information in this Annual Report on Form 10- K and our other filings with the SEC before making investment decisions regarding our common stock. ● There is substantial doubt about our ability to continue as a going concern. ● Because we are an early commercialization stage company with one product in commercialization process, we expect to incur substantial additional operating losses. ● Our PURE EP System and other product candidates are in continued development and may not be successfully developed or commercialized. ● We expect to derive our revenue from sales of our PURE EP System and other products we may develop. If we fail to generate revenue from these sources, our results of operations and the value of our business will be materially and adversely affected. ● We may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights. ● We may be unable to develop our existing or future technology. ● We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development. ● We have completed one clinical trial of our product. The results of additional clinical studies may not support the usefulness of our technology. ● The medical device industry is subject to stringent regulation and failure to obtain regulatory approval will prevent commercialization of our products. ● We, and our third- party manufacturer (s), are, and will be, subject to extensive regulation by the FDA. ● The market for our technology and revenue generation avenues for our products may be slow to develop, if at all. ● Our estimate of the size of our addressable market may prove to be inaccurate. ● The EP market is highly competitive. ● If we do not effectively manage changes in our business, these changes could place a significant strain on our management and operations. ● Our strategic business plan may not produce the intended growth in revenue and operating income. ● We currently have limited sales, marketing or distribution operations and will need to expand our expertise in these areas. ● Our product development program depends upon third- party researchers, including Mayo, who are outside our control and whose negative performance could materially hinder or delay our pre- clinical testing or clinical trials. ● We may face risks associated with future litigation and claims. ● The Company has concluded that there is a material weakness in its internal control over financial reporting, which, if not remediated, could materially adversely affect its ability to timely and accurately report its results of operations and financial condition. The accuracy of the Company' s financial reporting depends on the effectiveness of its internal controls over financial reporting. ● If we do not obtain protection for our intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing products. ● If we infringe upon the rights of third parties, we could be prevented from selling products and forced to pay damages and defend against litigation. ● We depend on our collaboration with Mayo Clinic for the research and development of additional advanced features of PURE EP ™ System. If this collaboration is not successful, we may not be able to realize the market potential of such features and may not have rights to use any such developed advanced features. ● If we fail to comply with our obligations under our license agreements, we could lose the rights to intellectual property that is important to our business. ● We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers. ● Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non- compliance with these requirements. ● The market price for our common stock may fluctuate significantly, which could result in substantial losses by our investors. ● Although our shares of common stock are now listed on The Nasdaq Capital Market, we currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock. ● If we cannot continue to satisfy the continuing listing criteria of the Nasdaq Capital Market, the exchange may subsequently delist our common stock. ● Future sales of our common stock in the public market or other financings could cause our stock price to fall. ● If we sell additional equity or debt securities to fund our operations, it may impose restrictions on our business. Risks Related to Our Business and Industry There is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has issued an opinion on our consolidated financial statements included in this Annual Report on Form 10- K that states that the consolidated financial statements were prepared assuming we will continue as a going concern. Our consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have used cash in our operating activities for the past few years. As of and for the year ended December 31, 2022, we had a net loss of $ 27. 3 million and net cash used in operating activities of $ 21. 7 million. Our consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We also cannot~~

be certain that additional financing, if needed, will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations. There remains substantial doubt about our ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued. To date, we have experienced negative cash flow from development of our technology, as well as from the costs associated with building a sales force to market our product and services. We expect to incur substantial net losses for the foreseeable future in order to further develop and commercialize our product. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our product. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability. Because of the numerous risks and uncertainties associated with further development and commercialization of our technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable, and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization in the medical device industry. We may never successfully commercialize our technology and our business may fail. We are an early commercialization stage company and we expect to incur substantial additional operating expenses over the next several years as our marketing, commercialization, and customer development along with additional research and development increase for our PURE EP System and other product candidates. The amount of our future losses and when, if ever, we will achieve profitability are uncertain. Our products that have generated minimal commercial revenue, and, although we expect to generate revenues this year from the commercial sale of our PURE EP System, may not be able to generate sufficient revenues to fund our operating expenses, if any. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: ● successful completion of the pre- clinical and clinical development of our products; ● obtaining necessary regulatory approvals from the FDA or other regulatory authorities; ● establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and ● raising sufficient funds to finance our activities. We might not succeed at all, or at any, of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected. Although our main product candidate, the PURE EP System, received FDA 510 (k) clearance from FDA, we are currently conducting clinical trials and may conduct additional clinical trials, which may require substantial further capital expenditure, to establish the safety and efficacy data needed to obtain acceptance by the medical community and coverage by third- party payors. The continued development of the PURE EP System, and / or any other product candidates we may develop, is dependent upon our ability to obtain sufficient additional financing. However, even if we are able to obtain the requisite financing to fund our development program, we cannot assure you that our current or future product candidates will be successfully developed or commercialized. Our failure to develop, manufacture, receive regulatory approval for, or successfully commercialize any of our product candidates could result in the failure of our business and a loss of all of your investment in our company. As of December 31, 2022, our cash and cash equivalents were approximately $ 0. 4 million. Based on our currently expected level of operating expenditures, we do not expect that our existing cash and cash equivalents will be sufficient to fund our operations in the near future. Our revenue is generated from sales of our PURE EP System, for which we made first commercial sale in February 2021, and other products we may develop. Future sales of these products, if any, will be subject to, among other things, commercial and market uncertainties that may be outside our control. If we fail to generate our intended revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected. Until PURE EP System or another product of ours become commercially viable, we will have to fund all of our operations and capital expenditures from cash on hand, public or private equity offerings, debt financings, bank credit facilities or corporate collaboration and licensing arrangements. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We also may decide to raise additional funds before we require them if we are presented with favorable terms for raising capital. If we seek to sell additional equity or debt securities, obtain a bank credit facility or enter into a corporate collaboration or licensing arrangement, we may not obtain favorable terms for us and / or our stockholders or be able to raise any capital at all, all of which could result in a material adverse effect on our business and results of operations. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities, all of which could have an adverse impact on our business and results of operations. Our product, the PURE EP System, may not deliver the levels of accuracy and reliability needed to make it a successful product in the marketplace, and the development of such accuracy and reliability may be indefinitely delayed or may never be achieved. In addition, we may experience delays in the development of our technology for other reasons, including failure to obtain necessary funding and failure to obtain all necessary regulatory approvals. Failure to develop this or other technology could have an adverse material effect on our business, financial condition, results of operations and future prospects. We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development. The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following: ● the FDA or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold; ● patients do not enroll in a clinical study or results from patients are not received at the expected rate; ● patients discontinue participation in a clinical

study prior to the scheduled endpoint at a higher than expected rate; ● patients experience adverse events from a product we develop; ● third- party clinical investigators do not perform the studies in accordance with the anticipated schedule or consistent with the study protocol and good clinical practices or other third- party organizations do not perform data collection and analysis in a timely or accurate manner; ● third- party clinical investigators engage in activities that, even if not directly associated with our studies, result in their debarment, loss of licensure, or other legal or regulatory sanction; ● regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the preclinical or clinical studies; ● changes in governmental regulations or administrative actions; ● the interim results of the preclinical or clinical study, if any, are inconclusive or negative; and ● the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety. If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future. Preclinical studies and clinical trials are expensive and difficult to design and implement and any delays or prolongment in our preclinical and clinical studies will require additional capital. There is no assurance that we will be able to acquire additional capital to support our studies. The failure to obtain additional capital would have a material adverse effect on the Company. In November 2019, we commenced our first clinical study with PURE EP System and completed the clinical trial as of September 2021. Conducting clinical trials is a long, expensive, and uncertain process that is subject to delays and failure at any stage. Clinical trials can take months or years. The commencement or completion of any of our subsequent clinical trials may be delayed or halted for numerous reasons, including: ● the FDA may not approve a clinical trial protocol or a clinical trial, or may place a clinical trial on hold; ● subjects may not enroll in clinical trials at the rate we expect, or we may not follow up on subjects at the rate we expect; ● subjects may experience unexpected adverse events; ● third- party clinical investigators may not perform our clinical trials consistent with our anticipated schedule or the clinical trial protocols and good clinical practices, or other third- party organizations may not perform data collection and analysis in a timely or accurate manner; ● interim results of any of our clinical trials may be inconclusive or negative; ● regulatory inspections of our clinical trials may require us to undertake corrective action or suspend or terminate the clinical trials if investigators find us to be in violation of regulatory requirements; or ● governmental regulations or administrative actions may change and impose new requirements, particularly with respect to reimbursement. Results of pre- clinical studies do not necessarily predict future clinical trial results and previous clinical trial results may not be repeated in subsequent clinical trials. We may experience delays, cost overruns and project terminations despite achieving promising results in pre- clinical testing or early clinical testing. In addition, the data obtained from clinical trials may be inadequate to support a device' s approval or clearance, or to demonstrate safety and efficacy to the extent required to obtain third- party coverage and / or reimbursement. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct, or results inadequate to demonstrate the safety and effectiveness of the product candidate. The FDA may also require additional pre- clinical studies or clinical trials that could further delay clearance or approval of any product candidates we may develop in the future and / or the PURE EP System to the extent we seek clearance / approval for different indications than that for which it is currently cleared. If we are unsuccessful in receiving FDA clearance approval of a future product candidate, or a product' s clearance or approval is withdrawn, we would not be able to commercialize the product (s) in the U. S., which could seriously harm our business. Moreover, we face similar risks in other jurisdictions in which we may sell or propose to sell our products. Medical devices are subject to extensive and rigorous regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act, by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Under the Federal Food, Drug, and Cosmetic Act and associated regulations, manufacturers of medical devices must comply with certain regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging and distribution of medical devices. In addition, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U. S., and the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized and can prevent or limit further marketing of a product based on the results of these post- market evaluation programs. The process of obtaining marketing clearance or approval from the FDA for new products could take a significant period of time, require the expenditure of substantial resources, involve rigorous pre- clinical and clinical testing, require changes to the products and result in limitations on the indicated uses of the product. In addition, if we seek regulatory approval in non- U. S. markets, we will be subject to further regulatory approvals that may require additional costs and resources. There is no assurance that we will obtain necessary regulatory approvals in a timely manner, or at all. To obtain 510 (k) clearance for a medical device, a pre- market notification must be submitted to the FDA demonstrating that the device is " substantially equivalent " to a previously cleared " predicate " device. A new device is substantially equivalent to a predicate device " at least as safe and effective " as the predicate. The FDA considers a device substantially equivalent to a predicate if it has the same intended use as the predicate and has either: (i) the same technological characteristics as the predicate or (ii) different technological characteristics from the predicate, but the information submitted to the FDA does not raise new questions of safety or effectiveness or demonstrates that the device is at least as safe and effective as the predicate. We received 510 (k) clearance to market our current lead product, the PURE EP System in the U. S. However, if we intend to market the PURE EP System for additional medical uses or indications, we may need to submit additional 510 (k) applications to the FDA that are supported by satisfactory clinical trial results specifically for the additional indication. Clinical trials necessary to support 510 (k) clearance or PMA approval for any future product candidates, or any new indications for use for our PURE EP System, would be expensive and could require the enrollment of large numbers of suitable patients who could be difficult to identify and recruit. Delays or failures in any necessary clinical trials could prevent us from commercializing any modified product or new product candidate and could adversely affect our business, operating results and prospects. The results of our initial clinical trials may not provide sufficient evidence to allow the FDA to grant us such additional marketing clearances and even additional trials requested by the FDA may not result in our obtaining 510 (k) marketing clearance for our product. The failure to obtain FDA marketing clearance for

any additional indications for the PURE EP System or any other of our future products would have a material adverse effect on our business. In addition to the pre- market regulations, once a device is approved or cleared for the applicable indications for use, numerous FDA regulations apply, including but not limited to those relating to manufacturing, labeling, packaging, advertising, and record keeping. Notably, these regulations apply to us, as well as our contract manufacturer (s). Even if regulatory approval or clearance of a product is obtained, the approval or clearance may be subject to limitations on the uses for which the product may be marketed or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the product. Any such requirements could reduce our revenues, increase our expenses, and render the product not commercially viable. If we fail to comply with the applicable regulatory requirements, or if previously unknown problems with any approved commercial products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other negative consequences, including: ● restrictions on our products, manufacturers or manufacturing processes; ● warning letters and untitled letters; ● civil penalties and criminal prosecutions and penalties; ● fines; ● injunctions; ● product seizures or detentions; ● import or export bans or restrictions; ● voluntary or mandatory product recalls and related publicity requirements; ● suspension or withdrawal of regulatory approvals; ● total or partial suspension of production; and ● refusal to approve pending applications for marketing approval of new products or of supplements to approved applications. Regulations are constantly changing, and in the future our business may be subject to additional regulations that increase our compliance costs. We believe we understand the current laws and regulations to which our products will be subject in the future. However, federal, state and foreign laws and regulations relating to the sale of our products are subject to future changes, as are administrative interpretations of regulatory agencies. If we fail to comply with such federal, state or foreign laws or regulations, we may fail to obtain regulatory approval for our products and, if we have already obtained regulatory approval, we could be subject to enforcement actions, including injunctions preventing us from conducting our business, withdrawal of clearances or approvals and civil and criminal penalties. In the event that federal, state, and foreign laws and regulations change, we may incur additional costs to seek government approvals, in addition to the clearance from the FDA in order to sell or market our products. If we are slow or unable to adapt to changes in existing regulatory requirements or the promulgation of new regulatory requirements or policies, we or our licensees may, following approval, lose marketing approval for our products which will impact our ability to conduct business in the future. The market for our products may be slower to develop or smaller than estimated or it may be more difficult to build the market than anticipated. The medical community may resist our products or be slower to accept them than we anticipate. Revenues from our products may be delayed or costs may be higher than anticipated which may result in our need for additional funding. We anticipate that our principal route to market will be through commercial distribution partners. These arrangements are generally non- exclusive and have no guaranteed sales volumes or commitments. The partners may be slower to sell our products than anticipated. Any financial, operational or regulatory risks that affect our partners could also affect the sales of our products. In the current economic environment, hospitals and clinical purchasing budgets may exercise greater restraint with respect to purchases, which may result in purchasing decisions being delayed or denied. If any of these situations were to occur this could have a material adverse effect on our business, financial condition, results of operations and future prospects. While our addressable market size estimate for the EP market was made in good faith and is based on assumptions and estimates we believe to be reasonable, this estimate may not be accurate. If our estimates of the size of our addressable market are not accurate, our potential for future growth may be less than we currently anticipate, which could have a material adverse effect on our business, financial condition, and results of operations. If we seek to market our products in foreign jurisdictions, we may need to obtain regulatory approval in these jurisdictions. In order to market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval procedures vary among countries (except with respect to the countries that are part of the European Economic Area) and can involve additional clinical testing. The time required to obtain approval may differ from that required to obtain FDA approval. Should we decide to market our products abroad, we may fail to obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority, including obtaining CE Mark approval, does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may be unable to file for, and may not receive, necessary regulatory approvals to commercialize our products in any foreign market, which could adversely affect our business prospects. In addition, a new Medical Device Regulation was published in 2017, which includes additional premarket and post- market requirements, as well as potential product reclassifications or more stringent commercialization requirements that could delay or otherwise adversely affect our clearances and approvals. There are a number of groups and organizations, such as healthcare, medical device and software companies in the EP market that may develop a competitive offering to our products. The largest companies in the EP market are GE, Johnson & Johnson, Boston Scientific, Siemens, Medtronic, and Abbott. All of these companies have significantly greater resources, experience and name recognition than we possess. There is no assurance that they will not attempt to develop similar or superior products, that they will not be successful in developing such products or that any products they may develop will not have a competitive advantage over our products. Moreover, our product may not be viewed as superior to existing technology or new technology from our competitors and as a result we may not be able to justify expected selling price our product, which may have a material adverse effect on market acceptance of our product. In addition, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products that we believe we currently possess. Should a superior offering come to market, this could have a material adverse effect on our business, financial condition, results of operations and future prospects. We rely on key officers, consultants and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace. We are highly dependent on our officers, consultants and scientific and medical advisors because of their expertise and experience in medical device development. We do not have " key person " life insurance policies for any of our officers.

Moreover, if we are unable to obtain additional funding, we will be unable to meet our current and future compensation obligations to such employees and consultants. In light of the foregoing, we are at risk that one or more of our consultants or employees may leave our company for other opportunities where there is no concern about such employers fulfilling their compensation obligations, or for other reasons. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our results of operations. We may fail to attract and retain qualified personnel. We expect to rapidly expand our operations and grow our sales, research and development and administrative operations. This expansion is expected to place a significant strain on our management and will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies, research and academic institutions, government entities and other organizations for qualified personnel in the areas of our activities. Many of these companies, institutions and organizations have greater resources than we do, along with more prestige associated with their names. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our marketing and development activities, and this could have a material adverse effect on our business, financial condition, results of operations and future prospects. **If we do not effectively manage changes in our business, these changes could place a significant strain on our management and operations.** Our ability to grow successfully requires an effective planning and management process. The expansion and growth of our business could place a significant strain on our management systems, infrastructure and other resources. To manage our growth successfully, we must continue to improve and expand our systems and infrastructure in a timely and efficient manner. Our controls, systems, procedures and resources may not be adequate to support a changing and growing company. If our management fails to respond effectively to changes and growth in our business, including acquisitions, there could be a material adverse effect on our business, financial condition, results of operations and future prospects **. Our strategic business plan may not produce the intended growth in revenue and operating income** . Our strategies ultimately include making significant investments in sales and marketing programs to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected. We may also fail to secure the capital necessary to make these investments, which will hinder our growth. In addition, as part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the operations, technologies, services and products of the acquired companies and the diversion of management' s attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations **. We currently have limited sales, marketing or distribution operations and will need to expand our expertise in these areas** . We currently have limited sales, marketing or distribution operations. We have begun implementing a market development program and are in the process of building such operations in connection with the commercialization of PURE EP System, and we are expanding our expertise in sales, marketing and distribution operations for commercial growth. To increase internal sales, distribution and marketing expertise and be able to conduct these operations, we have begun to invest in and will have to invest significant amounts of financial and management resources. In developing these functions ourselves, we could face a number of risks, including: ● we may not be able to attract and build an effective marketing or sales force; ● the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and ● there are significant legal and regulatory risks in medical device marketing and sales that we have never faced, and any failure to comply with applicable legal and regulatory requirements for sales, marketing and distribution could result in an enforcement action by the FDA, European regulators or other authorities that could jeopardize our ability to market our planned products or could subject us to substantial liability. Our product development program depends upon third- party researchers, including Mayo Clinic, who are outside our control and whose negative performance could materially hinder or delay our pre- clinical testing or clinical trials. We do not have the ability to conduct all aspects of pre- clinical testing or clinical trials ourselves. We depend upon independent investigators and collaborators, such as commercial third- parties, government, universities and medical institutions, to conduct our pre- clinical and clinical trials under agreements with us. For our first clinical trial for the PURE EP System, titled " Novel Cardiac Signal Processing System for Electrophysiology Procedures (PURE EP 2. 0 Study) " which commenced in November 2019, we rely on third parties, including TCARF and Mayo Clinic to conduct the patient cases. In addition, we are party to various license agreements with Mayo, pursuant to which we rely on research and development information, materials, technical data, unpatented inventions, trade secrets, know- how and supportive information of Mayo to develop, make, have made, use, offer for sale, sell, and import licensed products. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. The failure of any of these outside collaborators to perform in an acceptable and timely manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical and laboratory practices, or pre- clinical testing or clinical trial protocols, could cause a delay or otherwise adversely affect our pre- clinical testing or clinical trials, our success in obtaining regulatory approvals and, ultimately, the timely advancement of our development programs. In addition, these collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position

would be harmed. If healthcare providers are unable to obtain sufficient reimbursement or other financial incentives from third-party healthcare payers related to the use of our products, their adoption and our future product sales will be materially adversely affected. Widespread adoption of the PURE EP System, and any other products we may develop in the future, by the medical community is unlikely to occur without a financial incentive from third- party payors for the use of these products. Third- party payors include but are not limited to governmental programs such as Medicare and Medicaid, commercial health insurers and private payors, workers' compensation programs, and other organizations. Currently, the PURE EP System does not receive separate reimbursement from any third- party payor. Instead, healthcare providers typically receive reimbursement for the procedure in which our product is used. Future regulatory action by CMS or other governmental agencies, or unfavorable clinical data, among other things, may impact coverage and / or reimbursement policies for procedures performed using our products. If healthcare providers are unable to obtain adequate coverage of, or reimbursement for, procedures performed using our products, or if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly **. We may face risks associated with future litigation and claims** . We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, personal injury and product liability matters. Due to the uncertainties of litigation, we can give no assurance that we will prevail on any claims made against us in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results. The risk that we may be sued on product liability claims is inherent in the development and commercialization of medical devices. Specifically, we believe we will be subject to product liability claims or product recalls, particularly in the event of false positive or false negative reports, because we plan to develop and manufacture medical diagnostic products. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Product liability claims could be asserted directly by consumers, health- care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our current or future clinical trials, products to be sold, and other aspects of our business. A product recall or a successful product liability claim or claims that exceed our planned insurance coverage could have a material adverse effect on us. In addition, insurance coverage is becoming increasingly expensive and we may not be able to maintain current coverage, or expand our insurance coverage to include future clinical trials or the sale of new products or existing products in new territories, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. In the event of an award against us during a time when we have no available insurance or insufficient insurance, we may sustain significant losses of our operating capital. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations, as well as impair our reputation in the medical and investment communities. Our business is subject to cybersecurity risks. Our operations are increasingly dependent on information technologies and services. Threats to information technology systems associated with cybersecurity risks and cyber incidents or attacks continue to grow, and include, among other things, storms and natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error, and complications encountered as existing systems are maintained, repaired, replaced, or upgraded. Risks associated with these threats include, among other things: ● theft or misappropriation of funds; ● loss, corruption, or misappropriation of intellectual property, or other proprietary, confidential or personally identifiable information (including supplier, or employee data); ● disruption or impairment of our and our business operations and safety procedures; ● damage to our reputation with our potential customers and the market; ● exposure to litigation; ● increased costs to prevent, respond to or mitigate cybersecurity events. Although we utilize various procedures and controls to mitigate our exposure to such risk, cybersecurity attacks and other cyber events are evolving and unpredictable. Moreover, we have no control over the information technology systems of our suppliers, and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period time. We presently maintain insurance coverage to protect against cybersecurity risks. However, we cannot ensure that it will be sufficient to cover any particular losses we may experience as a result of such cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations. We may be subject, directly or indirectly, to U. S. federal and state healthcare laws, including fraud and abuse, false claims, and privacy laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation and enforcement. If we are unable to, or have not fully complied with such laws, we could face substantial penalties. We are subject, directly or indirectly, to various U. S. federal and state healthcare laws and regulations. These laws include fraud and abuse laws, such as the federal Anti- Kickback Statute, federal False Claims Act, and federal Foreign Corrupt Practices Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject, directly or indirectly, to patient privacy regulations by both the federal government and the states in which we conduct our business. The healthcare laws that may affect our ability to operate include, but are not limited to, the following. ● The federal Anti- Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. ● The federal physician self- referral law, commonly referred to as the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, if the physician or an immediate family member has a financial relationship with the entity

providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition. ● Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits may be filed under the federal False Claims Act by the government or by an individual on behalf of the government (known as " qui tam " actions). Such individuals, commonly known as " relators " or " whistleblowers, " may share in any amounts paid by the entity to the government in fines or settlement. ● The federal transparency requirements under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, including the provision known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare, Medicaid, or the Children' s Health Insurance Program (CHIP) to record any information related to payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, and to report this data annually to CMS for subsequent public disclosure. Manufacturers must also disclose investment interests held by physicians and their family members. ● The federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies. ● Federal criminal statutes created through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. ● Other federal and state fraud and abuse laws, prohibitions on self-referral and kickbacks, fee- splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, transparency, reporting, and disclosure requirements, which may extend to services reimbursable by any third- party payer, including private insurers. ● State and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that could potentially harm consumers. Additionally, we may be subject to state equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U. S. states have adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. Several states impose marketing restrictions or require medical device companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement we could be subject to penalties. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of fraud and abuse laws may be punishable by criminal and / or civil sanctions, including penalties, fines and / or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U. S. government. In addition, private individuals have the ability to bring actions on behalf of the U. S. government under the False Claims Act as well as under the false claims laws of several states. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our existing or future business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Any such actions instituted against us could have a significant adverse impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending against such actions, we may nonetheless be subject to substantial costs, reputational harm and adverse effects on our ability to operate our business. In addition, the approval and commercialization of any of our products outside the United States will also likely subject us to non- U. S. equivalents of the healthcare laws mentioned above, among other non- U. S. laws. If any of our employees, agents, or the physicians or other providers or entities with whom we do business are found to have violated applicable laws, we may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, or, if we are not subject to such actions, we may suffer reputational harm for conducting business with persons or entities found, or accused of being, in violation of such laws. Any such events could adversely affect our ability to operate our business and our results of operations. In addition, to the extent we commence commercial operations overseas, we will be subject to the federal Foreign Corrupt

Practices Act and other countries' anti- corruption / anti- bribery regimes, such as the U. K. Bribery Act. The federal Foreign Corrupt Practices Act prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the federal Foreign Corrupt Practices Act and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and results of operations. We could be adversely affected if healthcare legislation or reform measures substantially change the market for medical care or healthcare coverage in the U. S., negatively affecting our business or revenue for PURE EP or future products. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, commonly referred to as the " Healthcare Reform Law, " includes a number of rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law- making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U. S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and medical devices, and imposing additional taxes, fees, and rebate obligations on medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U. S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law' s provisions were designed to encourage providers to find cost savings in their clinical operations. Medical devices represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding medical devices. This attention may result in our products we may commercialize or promote, including our current commercial products, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us. These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children' s Health Insurance Program), creation of government- sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U. S. could impact the reimbursement for medical devices, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for our approved medical devices, products we currently commercialize or promote, or any product we may commercialize or promote is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations. Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U. S. federal government, which may force significant additional changes to the healthcare system in the U. S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including those products currently being developed by us or our development or commercialization partners or any product we may commercialize or promote, including our current commercial products), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any medical device or any product we may commercialize or promote, including our current commercial products, or for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations. Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the Healthcare Reform Law and judicial challenges have continued for over a decade. However, as of the Supreme Court' s ruling ordering the dismissal of, arguably, the most promising case challenging the Healthcare Reform Law to- date in June 2021, it appears that the Healthcare Reform Law will remain in- effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business. Additionally, the Biden administration has introduced various measures in recent years, focusing on healthcare and medical- product pricing, in particular. It remains to be seen how these measures will affect our business and there is uncertainty as to what other healthcare programs and regulations may be implemented or changed at the federal and / or state level in the U. S., but, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and / or successfully commercialize products in the U. S. in the future. For example, any changes that reduce, or impede the ability of healthcare providers to obtain reimbursement for medical procedures in which the products we currently, or intend to, commercialize are used, or that reduce medical procedure volumes, could adversely affect our operations and / or future business plans. The financial impact of U. S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for medical devices affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U. S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, pricing, and marketing of medical device products. In addition, third- party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products. ~~The COVID- 19 pandemic may adversely affect our business. In an effort to contain and mitigate the spread of COVID- 19, many countries, including the United States, have imposed unprecedented restrictions on travel, quarantines, and other public health safety~~

~~measures. Such government- imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID- 19 cases. The COVID- 19 pandemic may adversely impact our business plan as our clinical studies may be delayed as hospitals in the impacted regions may shift their resources to patients affected by the disease. The rapidly evolving nature of the circumstances is such that it is impossible, at this stage, to determine the full and overall impact the COVID- 19 pandemic may have, but it could disrupt production and cause delays in the supply and delivery of products used in our research and development efforts, adversely affect our employees, and disrupt our operations, all of which may have a material adverse effect on our business. In addition, the pandemic may have an adverse effect on the ability of regulatory bodies to review submissions in a timely manner, grant approvals or supervise our candidates and products, and may further divert the attention and efforts of the medical community to coping with the coronavirus and disrupt the marketplace in which we operate and may have a material adverse effects on our operations. Patient enrollment in future clinical trials could be slowed, delayed, or suspended due to the pandemic as well. Moreover, the COVID- 19 pandemic has created significant economic uncertainty and volatility in the credit and capital markets. Management plans to secure the necessary financing through the issue of new equity and / or the entering into of strategic partnership arrangements; however, there is no assurance that our management will be able to obtain such financing on reasonable terms or at all. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations. In addition, a significant resurgence of COVID- 19 or other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.~~ As a smaller reporting company, we are subject to scaled disclosure requirements that may make it more challenging for investors to analyze our results of operations and financial prospects. Currently, we are a " smaller reporting company, " as defined by Rule 12b- 2 of the Exchange Act. As a " smaller reporting company, " we are able to provide simplified executive compensation disclosures in our filings and have certain other decreased disclosure obligations in our filings with the SEC, including being required to provide only two years of audited financial statements in annual reports. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects. Furthermore, we are a non- accelerated filer as defined by Rule 12b- 2 of the Exchange Act, and, as such, are not required to provide an auditor attestation of management' s assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404 (b) of the Sarbanes- Oxley Act. Because we are not required to, and have not, had our auditor' s provide an attestation of our management' s assessment of internal control over financial reporting, a material weakness in internal controls may remain undetected for a longer period. **The Company has concluded that there is a material weakness in its internal control over financial reporting, which, if not remediated, could materially adversely affect its ability to timely and accurately report its results of operations and financial condition. The accuracy of the Company' s financial reporting depends on the effectiveness of its internal controls over financial reporting.** Internal controls over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. Failure to maintain effective internal controls over financial reporting, or lapses in disclosure controls and procedures, could undermine the ability to provide accurate disclosure (including with respect to financial information) on a timely basis, which could cause investors to lose confidence in the Company' s disclosures (including with respect to financial information), require significant resources to remediate the lapse or deficiency, and expose it to legal or regulatory proceedings. In connection with the audit of its December 31, ~~2022~~ **2023** financial statements, the Company' s management identified inadequate identification, recording and reporting of stock based compensation due under consulting or other third- party contracts entered into by the Company, but not yet ratified by the Company' s Board of Directors which resulted in deficiencies, which, in aggregate, amounted to a material weakness in the Company' s internal control over financial **reporting. Other material weaknesses along with stock based compensation identified were the lack of segregation of duties and ineffective review processes over period end financial disclosure and** reporting. The Company' s remediation efforts are ongoing and it will continue its initiatives to implement and document policies, procedures, and internal controls. Remediation of the identified material weakness and strengthening the internal control environment will require a substantial effort throughout 2023 and beyond, as necessary, and the Company will test the ongoing operating effectiveness of the new and existing controls in future periods. The material weakness cannot be considered completely remediated until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. The Company cannot guarantee that it will be successful in remediating the material weakness it identified or that its internal control over financial reporting, as modified, will enable it to identify or avoid material weaknesses in the future. The Company cannot guarantee that its management will be successful in identifying and retaining appropriate personnel; that newly engaged staff or outside consultants will be successful in identifying material weaknesses in the future; or that appropriate personnel will be identified and retained prior to these deficiencies resulting in material and adverse effects on the Company' s business. There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected. The ongoing internal control provisions of Section 404 of the Sarbanes- Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that

there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision- making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost- effective control system, misstatements due to error or fraud may occur and not be detected. In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us and adversely affect how our stock trades. This could in turn negatively affect our ability to access equity markets for capital. Risks Related to Our Intellectual Property **If we do not obtain protection for our intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing products.** We intend to rely on a combination of patents, trade secrets, and nondisclosure and non- competition agreements to protect our proprietary intellectual property. Our **owned** patent portfolio now includes ~~25~~ **36** (issued / allowed) issued utility patents (~~18~~ **24** utility patents where BioSig is at least one of the applicants). ~~Thirty four~~ **Twenty five** additional U. S. and foreign utility patent applications are pending covering various aspects of our PURE EP System for recording, measuring, calculating and displaying of electrocardiograms during cardiac ablation procedures (**25** ~~thirty four~~ U. S. and foreign utility patent applications where either BioSig, Mayo, or both is at least one of the applicants). ~~Two of these pending~~ **We also have one** U. S. patent **and one U. S. Pending** ~~applications~~ **application** ~~are~~ directed to artificial intelligence (AI). We also have 30 issued worldwide design patents, which cover various features of our display screens and graphical user interface for enhanced visualization of biomedical signals (30 design patents where BioSig is at least one of the applicants). Finally, ~~of the 34 patent applications mentioned above,~~ we have licenses to ~~7~~ **12 (issued / allowed)** patents and ~~13~~ **9** additional worldwide utility patent applications from Mayo Foundation for Medical Education and Research that are pending (~~7~~ **12 issued / allowed** patents and ~~13~~ **9** applications where only Mayo is the applicant). These patents and applications are generally directed to electroporation and stimulation. We plan to file additional patent applications in the U. S. and in other countries as we deem appropriate for our products. Our applications have and will include claims intended to provide market exclusivity for certain commercial aspects of the products, including the methods of production, the methods of usage and the commercial packaging of the products. However, we cannot predict: ● the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents; ● if and when such patents will be issued, and, if granted, whether patents will be challenged and held invalid or unenforceable; ● whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or ● whether we will need to initiate litigation or administrative proceedings which may be costly regardless of outcome. Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. Patent rights are territorial, and patent protection extends only to those countries where we have issued patents. Filing, prosecuting and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Many countries, however, do not protect intellectual property to the same extent as the U. S. or Europe, and their litigation processes differ. Competitors may successfully challenge or avoid our patents, or manufacture products in countries where we have not applied for patent protection. Changes in the patent laws in the U. S. or other countries may diminish the value of our patent rights. As a result of these and other factors, the scope, validity, enforceability, and commercial value of our patent rights are uncertain and unpredictable. Indeed, several companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for ~~Biosig~~ **BioSig** to stop the infringement, misappropriation or other violation of ~~Biosig~~ **BioSig** ' s intellectual property rights generally. Proceedings to enforce ~~Biosig~~ **BioSig** ' s intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of ~~Biosig~~ **BioSig** ' s business, could put ~~Biosig~~ **BioSig** ' s patents at risk of being invalidated or interpreted narrowly and ~~Biosig~~ **BioSig** ' s patent applications at risk of not issuing and could provoke third parties to assert claims against ~~Biosig~~ **BioSig** . ~~Biosig~~ **BioSig** may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. The patent positions of medical device companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. A third- party may submit prior art, or we may become involved in opposition, derivation, reexamination, inter partes review, post- grant review, supplemental examination, or interference proceedings challenging our patent rights or the patent rights of our licensors or development partners. The costs of defending or enforcing our proprietary rights in these proceedings can be substantial, and the outcome can be uncertain. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the

scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged. Furthermore, our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product, particularly in litigation in countries other than the U. S. that do not provide an extensive discovery procedure. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time- consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know- how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, it is our policy to require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know- how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know- how or other proprietary information is disclosed, the value of our trade secrets, know- how and other proprietary rights would be significantly impaired and our business and competitive position would suffer. Given the fact that we may pose a competitive threat, competitors, especially large and well- capitalized companies that own or control patents relating to electrophysiology recording systems, may successfully challenge our current and planned patent applications, produce similar products or products that do not infringe our future patents, or produce products in countries where we have not applied for patent protection or that do not respect our patents. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know- how, the value of our intellectual property may be greatly reduced. Patent protection and other intellectual property protection are important to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate **. If we infringe upon the rights of third parties, we could be prevented from selling products and forced to pay damages and defend against litigation** . Our commercial success also depends upon our ability, and the ability of any third party with which we may partner, to develop, manufacture, market and sell our products, if approved, and use our patent- protected technologies without infringing the patents of third parties. We may not have identified all patents, published applications or published literature that affect our business by blocking our ability to commercialize our products, by preventing the patentability of one or more aspects of our products to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products. For example, we (or the licensor of a product to us) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U. S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U. S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may be required to: ● obtain licenses, which may not be available on commercially reasonable terms, if at all; ● abandon an infringing product candidate; ● redesign our product candidates or processes to avoid infringement; ● cease usage of the subject matter claimed in the patents held by others; ● pay damages; and / or ● defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of our financial and management resources. We may not have sufficient resources to bring these actions to a successful conclusion. Any of these events could substantially harm our earnings, financial condition and operations. We depend on our collaboration with Mayo Clinic for the research and development of additional advanced features of PURE EP ™ System. If this collaboration is not successful, we may not be able to realize the market potential of such features and may not have rights to use any such developed advanced features. On March 15, 2017, we entered into a know- how license agreement with Mayo Foundation for Medical Education and Research (" Mayo Clinic "), effective December 2, 2016, and as amended whereby we were granted an exclusive license, with the right to sublicense, certain know how and patent applications in the fields of signal processing, physiologic recording, electrophysiology recording, electrophysiology software and autonomics to develop, make and offer for sale. The agreement expires ten years from the effective date. In furtherance of this collaboration, we subsequently entered into four additional agreements whereby we were granted exclusive licenses, with the right to sublicense additional Mayo Clinic patents and know- how. Pursuant to these agreements, Mayo Clinic retains ownership of the licensed intellectual property and any developed intellectual property. Mayo Clinic also retains the right to prosecute and enforce the developed intellectual property. If our agreements with Mayo Clinic terminate, our access to technology and intellectual property licensed to us by Mayo Clinic may be restricted or terminate entirely, which may delay our continued development of such advanced features utilizing the Mayo Clinic' s technology or intellectual property or require us to stop development of those product candidates completely. Additional risks posed by this collaboration include: ● Mayo Clinic may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our advanced features or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related

proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property; ● Mayo Clinic may own or co- own intellectual property covering our advanced features that results from our collaboration with them, and in such cases, we may not have the exclusive right or any right to commercialize such intellectual property or such product candidates or research programs; or ● We may be prevented from enforcing or defending any intellectual property that we contribute to or that arises out of the collaboration, if Mayo Clinic refuses to cooperate with such action. Our collaboration with Mayo Clinic is made subject to the rights of the U. S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between Mayo Clinic and the U. S. government. Additionally, to the extent there is any conflict between our agreements with Mayo Clinic and applicable laws or regulations, applicable laws and regulations will prevail. Some, and possibly all, of the developed intellectual property rights relating to our advanced features may have been developed in the course of research funded by the U. S. government. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh- Dole Act of 1980. Government rights in certain inventions developed under a government- funded program include a nonexclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if the U. S. government determines that adequate steps have not been taken to commercialize the invention, that government action is necessary to meet public health or safety needs, that government action is necessary to meet requirements for public use under federal regulations, or that the right to use or sell such inventions is exclusively licensed to an entity within the U. S. and substantially manufactured outside the U. S. without the U. S. government' s prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e. g., manufacturing substantially all of the invention in the U. S.). The U. S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U. S. government may acquire title in any country in which a patent application is not filed within specified time limits. Additionally, certain inventions are subject to transfer restrictions during the term of these agreements and for a period, thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U. S. government or third parties pursuant to the Bayh- Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business. The U. S. government has not exercised any of these rights or provided us with any notice of its intent to exercise any of these rights with respect to any of the intellectual property licensed to us by Mayo Clinic. We are not aware of any instance in which the U. S. government has ever exercised any such rights with respect to any technologies or other intellectual property developed under funding agreements with the U. S. government. **If we fail to comply with our obligations under our license agreements, we could lose the rights to intellectual property that is important to our business.** Our current license agreements impose on us various development obligations, payment of royalties and fees based on achieving certain milestones as well as other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. In addition, if the licensor fails to enforce its intellectual property, the licensed rights may not be adequately maintained. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing our products or possible future products covered by the licensed intellectual property. Any of these events could materially adversely affect our business, prospects, financial condition and results of operation. **We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.** Our employees may have been previously employed at other companies in the industry, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product (s), which would materially adversely affect our commercial development efforts **. Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non- compliance with these requirements** . Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and / or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know- how which could have a material adverse effect on our business, prospects, financial condition and results of operation. Risks Related to our Common Stock The **market price for our common stock may fluctuate significantly, which could result in substantial losses by our investors. The** stock market in general, and Nasdaq in particular, as well as biotechnology companies, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as: ● announcements of technological innovations, new products or product enhancements by us or others; ● actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business,

operations or prospects; • announcements of significant strategic partnerships, out- licensing, in- licensing, joint ventures, acquisitions or capital commitments by us or our competitors; • conditions or trends in the biotechnology industry; • changes in the economic performance or market valuations of other biotechnology companies; • general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition; • purchase or sale of our common stock by stockholders, including executives and directors; • volatility and limitations in trading volumes of our common stock; • changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of our common stock by stockholders; • our cash position; • announcements and events surrounding financing efforts, including debt and equity securities; • changes in earnings estimates or recommendations by security analysts, if our common stock is covered by analysts; • the addition or departure of key personnel; • disputes and litigation related to intellectual property rights, proprietary rights, and contractual obligations; • changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and • other events or factors, many of which may be out of our control. These factors and any corresponding price fluctuations may materially and adversely affect the market price of our common stock and result in substantial losses by our investors. Further, the stock market in general, and the market for technology companies in particular, has experienced extreme price and volume fluctuations in the past. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Moreover, the COVID- 19 pandemic has resulted in significant financial market volatility and uncertainty in recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock. Price volatility of our common stock might be worse if the trading volume of our common stock is low. In the past, following periods of market volatility, stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful. Future sales of our common stock could also reduce the market price of such stock. Moreover, the liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but by delays in the timing of transactions and reduction in security analysts' and the media' s coverage of us, if any. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock. In addition, without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate its investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future **. Although our shares of common stock are now listed on The Nasdaq Capital Market, we currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock** . Although our shares of common stock are now listed on The Nasdaq Capital Market under the symbol " BSGM, " trading volume in our common stock has been limited and an active trading market for our shares of common stock may never develop or be maintained. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered. **Our failure to meet the continued listing requirements of** Nasdaq **could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets. Our common stock is listed on the Nasdaq Capital Market. If we fail to satisfy the continued listing** ~~requires~~ **requirements** ~~us to meet certain financial~~ **of Nasdaq, such as minimum bid price, shareholders' equity** , public float **and other requirements** , **Nasdaq may take steps to delist our common stock. Such a delisting would have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any delisting materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities. In the event of a delisting, we would attempt to take actions to restore our compliance with Nasdaq' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum** bid price ~~and liquidity standards~~ **requirement or prevent future** ~~on~~ **non - compliance with Nasdaq' s** ~~an ongoing basis in order to continue the~~ listing **requirements. On March 5, 2024, we received a letter from the Listing Qualifications Department** of ~~our~~ **Nasdaq (the " Staff ") stating that the Company has not regained compliance with Listing Rule 5550 (a) (2) because the Company' s** common stock **did not meet the** ~~. Generally, we must maintain a~~ minimum ~~amount~~ **bid price** of **$ 1. 00 per share required for continued listing on The Nasdaq Capital Market, and the Company is not eligible for a second 180 day cure period under Rule 5810 (c) (3) (A) (2) because the Company does not comply with the $ 5, 000, 000 minimum** stockholders' equity **initial listing requirement for The Nasdaq Capital Market, and that accordingly, Nasdaq would delist the Company' s common stock unless the Company requested** ~~and~~ **an appeal of this determination. On March 11, 2024, the Company submitted a request for a hearing before the Nasdaq Hearings Panel to appeal the Staff' s delisting determination. On March 12, 2024, we received a letter from the Staff stating that based upon the Staff' s review of the Company and pursuant to Listing Rule 5101, the Staff believes that the Company no longer has an operating business and is a " public shell, " and that the continued listing of its securities is no longer warranted, in view of work force reductions and resignations of members of the board of directors and officers (see below). The letter further stated that the Company no longer meets the requirement of Rule 5550 (b) (2) to maintain** a

minimum ~~number~~ **Market Value** of **Listed** ~~holders of our securities~~ **Securities of $ 35 million, if none of the other standards set forth in Rule 5550 (b) is met** . ~~If~~ **The Staff stated that the foregoing matters serve as an additional basis for delisting the Company' s common stock from The Nasdaq Stock Market, and that the Hearings Panel will consider this matter in rendering a determination regarding the Company' s continued listing on The Nasdaq Capital Market. We intend have appealed the foregoing determinations. The requested hearing before the Hearings Panel will be held on May 7, 2024. On April 15, 2024, the closing price of our Common Shares reported on the Nasdaq Capital Market was $ 1. 10. We may need to seek to effect a reverse stock split of our common stock in order to attempt to comply with the Nasdaq minimum bid price requirements, which could occur in the near term, but requires stockholder approval, of which there can be no assurance. We may be unable to complete a reverse stock split, and even if** we ~~fail~~ **do, we may still be unable** to meet ~~any of~~ **the minimum bid price requirement, and we may be unable to meet** ~~the~~ **other** ~~continuing~~ **applicable Nasdaq** listing requirements, **including maintaining minimum levels of stockholders' equity or market values of** our common stock ~~may be subject to delisting~~ . If our common stock is delisted and we are not able to list our common stock on another national securities exchange, we expect our securities would be quoted on an over- the- counter market ~~. If this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future~~ . There can be no assurance that an active trading market for our common stock will develop or be sustained. **Future sales of our common stock in the public market or other financings could cause our stock price to fall.** Sales of a substantial number of shares of our common stock in the public market, the perception that these sales might occur or other financings, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act unless these shares are owned or purchased by " affiliates " as that term is defined in Rule 144 under the Securities Act. In addition, shares of common stock issuable upon exercise of outstanding options, restricted stock units and shares reserved for future issuance under our incentive stock plan will be eligible for sale in the public market to the extent permitted by applicable vesting requirements and, in some cases, subject to compliance with the requirements of Rule 144. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. **If we sell additional equity or debt securities to fund our operations, it may impose restrictions on our business.** In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which may impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to such restrictions, our business, financial condition and results of operations could be materially adversely affected. Our stockholders may experience substantial dilution as a result of the exercise of outstanding options or warrants to purchase shares of our common stock, or upon conversion of our Series C preferred stock into shares of our common stock. As of ~~March 30~~ **April 15** , ~~2023~~ **2024** , we have outstanding options to purchase ~~4~~ **543** , **479** ~~616, 151shares~~ --- **shares** of common stock, ~~430~~ **763** , ~~835~~ **333** restricted stock units and have reserved ~~4~~ **259** , **968** ~~052, 945~~ shares of our common stock for further issuances pursuant to our 2023 Long- Term Incentive Plan. In addition, as of ~~March 30~~ **April 15** , ~~2023~~ **2024** , we may be required to issue ~~511~~ **267** , ~~297~~ **508** shares of our common stock for issuance upon conversion of outstanding convertible Series C preferred stock which includes accrued dividends as of ~~March 30~~ **April 15** , ~~2023~~ **2024** , and ~~8~~ **2** , ~~867~~ **878** , ~~786~~ **734** shares of our common stock for issuance upon exercise of outstanding warrants. Should all of these shares be issued, you would experience dilution in ownership of our common stock and the price of our common stock will decrease unless the value of our company increases by a corresponding amount. The interests of our controlling stockholders may not coincide with yours and such controlling stockholders may make decisions with which you may disagree. As of ~~March 30~~ **April 15** , ~~2023~~ **2024** , ~~three~~ **two** of our stockholders beneficially owned over 19. ~~4~~ **78** % of our common stock. As a result, these stockholders may be able to influence the outcome of matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company and make some future transactions more difficult or impossible without the support of our controlling stockholders. The interests of our controlling stockholders may not coincide with our interests or the interests of other stockholders. Delaware law and our Amended and Restated Certificate of Incorporation and By- laws contain anti- takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable. Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders. In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a " business combination " with an " interested stockholder " for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85 % of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have

the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2 / 3 % of the outstanding voting stock which is not owned by the interested stockholder. Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price. Risks Related to our Series C Preferred Stock Our Series C Preferred Stock contains covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business. Covenants in the certificate of designation for our Series C Preferred Stock impose operating and financial restrictions on us. These restrictions prohibit or limit our ability to, among other things: ● incur additional indebtedness; ● permit liens on assets; ● repay, repurchase or otherwise acquire more than a de minimis number of shares of capital stock; ● pay cash dividends to our stockholders; and ● engage in transactions with affiliates. As of ~~March 31~~ **April 16** , ~~2023~~ **2024** , we were in compliance with all covenants of the Series C Preferred Stock. These restrictions may limit our ability to obtain financing, withstand downturns in our business or take advantage of business opportunities. Moreover, debt financing we may seek may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable. In addition, the certificate of designation for our Series C Preferred Stock requires us to redeem shares of our Series C Preferred Stock, at each holder' s option and for an amount greater than their stated value, upon the occurrence of certain events, including our being subject to a judgment of greater than $ 100, 000 or our initiation of bankruptcy proceedings. The holders of our Series C Preferred Stock are entitled to receive a dividend, which may be increased if we do not comply with certain covenants. The holders of the Series C Preferred Stock are entitled to a 9 % annual dividend on the $ 1, 000 per share stated value of our Series C Preferred Stock, which is payable in cash or, subject to the satisfaction of certain conditions, in pay- in- kind shares. The dividend may be increased to a 18 % annual dividend if we fail to comply with certain covenants, including our being subject to a judgment of greater than $ 100, 000 or our initiation of bankruptcy proceedings. As a result of the payment of dividends related to our Series C Preferred Stock, we may be obligated to pay significant sums of money or issue a significant number of shares of our common stock, which could negatively affect our operations or result in the dilution of the holders of our common stock, respectively. The terms of our Series C Preferred Stock contain anti- dilution provisions that may result in the reduction of the conversion prices in the future. The terms of our Series C Preferred Stock contain anti- dilution provisions, which provisions require the lowering of the conversion price to the purchase price of future offerings. If in the future we issue securities for less than the conversion of our Series C Preferred Stock then in effect, we will be required to further reduce the relevant conversion prices. The terms of our Series C Preferred Stock prohibit us from paying dividends in the future on our common stock. As a result, any return on investment may be limited to the value of our common stock. The terms of our Series C Preferred Stock prohibit us from paying dividends in the future on our common stock, absent consent from the holders representing a super- majority of the outstanding shares of our Series C Preferred Stock and a certain investor. Because we will likely not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates. General Risk Factors The liability of our directors and officers is limited. The applicable provisions of the Delaware General Corporation Law and our Amended and Restated Certificate of Incorporation and By- laws limit the liability of our directors to us and our stockholders for monetary damages for breaches of their fiduciary duties, with certain exceptions, and for other specified acts or omissions of such persons. In addition, the applicable provisions of the Delaware General Corporation Law and of our Amended and Restated Certificate of Incorporation and By- laws provide for indemnification of such persons under certain circumstances. In the event we are required to indemnify any of our directors or any other person, our financial strength may be harmed. Negative publicity or unfavorable media coverage could damage our reputation and harm our operations. In the event that the marketplace perceives our products as not offering the benefits which we believe they offer, we may receive negative publicity. This publicity may result in litigation and increased regulation and governmental review. If we were to receive such negative publicity or unfavorable media attention, whether warranted or unwarranted, our ability to market our products would be adversely affected. We may be required to change our products and services and become subject to increased regulatory burdens, and we may be required to pay large judgments or fines and incur significant legal expenses. Any combination of these factors could further increase our cost of doing business and adversely affect our financial position, results of operations and cash flows. 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. We currently have new research coverage by securities and industry analysts. 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 would likely decline. If one or more of these analysts cease coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline. We are subject to financial reporting and other requirements that place significant demands on our resources. We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes- Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. **ITEM 1B –**

UNRESOLVED STAFF COMMENTS