Risk Factors Comparison 2024-02-16 to 2023-02-22 Form: 10-K

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The following discussion of risk factors contains forward- looking statements. These risk factors may be important to understanding other statements in this report. The following information should be carefully considered in addition to the other information set forth in this report, including the Management' s Discussion and Analysis of Financial Conditions and Results of Operations section and Consolidated Financial Statements and accompanying notes. If any of the risks or uncertainties described below actually occur or continue to occur, our business, reputation, financial condition, results of operations, future prospects and stock price could be materially and adversely affected. The risks below are not the only risks we face and additional risks not currently known to us or that we presently deem immaterial may emerge or become material at any time and may negatively impact our business, reputation, financial condition, results of operations, future prospects or stock price. The order in which these factors appear should not be construed to indicate their relative importance or priority. Risk Factors Summary The following is a summary of the principal risks that could adversely affect our business, operations, financial results and stock price. Commercial Execution and Product Performance Risks • Failure to achieve widespread market acceptance domestically may harm operating results. • Competition from existing and new products and procedures may decrease our market share. • Clinical data may be negative, or our trials may not satisfy requirements of regulatory authorities, slowing or reversing the rate of adoption or reducing use of our products by the medical community. • ~~Our success depends, in part, on the adoption of the EPi- Sense device for the treatment of Afib following 2021 FDA pre- market approval of this product. • We may be unable to promptly train sufficient numbers of physicians in the use of our products, resulting in slower market acceptance. •~~ Reliance on independent distributors to sell our products in some international markets could adversely impact our sales. Industry Condition Risks • A prolonged downturn in macroeconomic conditions may materially adversely affect our business. • Rising healthcare costs may result in efforts by government and private payors to contain or reduce healthcare spending, including **reimbursement** for procedures that utilize our products. • Adverse changes in governmental and third **-** party payors' policies toward coverage and reimbursement for surgical procedures would harm our ability to promote and sell our products. Operational Risks • Unfavorable publicity relating to our business or industry could negatively impact our operations. • Reliance upon single and limited source third- party suppliers and service providers could harm our business if such third parties cannot provide materials or products or perform services for us in a timely manner. • Our manufacturing operations are highly centralized and ~~any~~ disruption could harm our business ~~. • Our business could be negatively impacted if we fail to successfully integrate acquisitions~~ . • If we fail to properly manage our anticipated growth, our business could suffer. • If we cannot retain our skilled and experienced officers and other employees, or recruit, hire, train and integrate sufficient additional qualified personnel, our business may suffer. • Disruptions of critical information systems or material breaches in the security of our systems could harm our business, customer relations and financial condition. • Our insurance may not cover our indemnification obligations and other liabilities associated with our operations. Legal & Compliance Risks • We could face substantial penalties if we do not fully comply with federal, state and foreign regulations. • We may be subject to fines, injunctions and penalties if we fail to comply with extensive FDA regulations. • Unless and until we obtain additional FDA approval for our products, we will not be able to promote ~~most of~~ them **for treatment of Afib and / or** to prevent stroke **,** and our inability to maintain or grow our business could be harmed. We may be subject to fines, injunctions and penalties if we are found to be promoting our products for unapproved or off- label uses. • Modifications to our products may require new clearances or approvals by FDA; failure to obtain such clearances or approvals where required could result in a recall of the modified products and limitation on future sales until cleared or approved. • If we or our third- party vendors fail to comply with extensive FDA regulations relating to the manufacturing of our products we may be subject to fines, injunctions and penalties. • Any adverse finding, judgement, settlement or enforcement action against us as a result of the current qui tam lawsuit could negatively affect our business. • The use of products we sell may result in injuries or other adverse events that lead to product liability claims. • Our ability to compete in the marketplace could be affected if our intellectual property rights fail to provide meaningful commercial protection for our products. • Litigation and administrative proceedings over patent and other intellectual property rights are common in our industry, and any litigation or claim against us may cause us to incur substantial costs. • We are subject to various regulatory and other risks related to selling our products internationally which could harm our revenue. • Any allegation or determination of wrongdoing under the Foreign Corrupt Practices Act or other anti- corruption laws could have a material adverse effect on our business. • Compliance with European Union medical device regulation may limit our ability to sell our products in European markets. Financial Risks • Our quarterly financial results are likely to fluctuate significantly. • We have a history of net losses, and we may never become profitable ~~. • Our income tax expense could increase and adversely impact cash flows if our federal tax net operating loss and general business credit carryforwards expire or are limited~~ . • Governmental authorities may question our intercompany transfer pricing policies or change their laws in a manner that could increase our effective tax rate. • Our goodwill may become impaired which could adversely affect our financial performance. • We may take inventory- related charges as a result of inaccurate forecasting or estimates of product life cycles which would negatively affect our gross margins and results of operations. • We are subject to credit risk from our accounts receivable related to our sales. • We may be unable to comply with the covenants of our Loan Agreement. Common Stock Risks • We may fail to achieve our publicly announced guidance about our business which could cause a decline in our stock price. • Securities analysts may discontinue coverage for our common stock or issue reports which could have a negative impact on the market price of our common stock. • Our common stock may experience extreme fluctuations in the price and trading volume causing our stockholders to lose some or all

of their investment. • The sale of material amounts of common stock could encourage short sales by third parties and depress the price of our common stock causing our stockholders to lose part or all of their investment. • Stockholder ownership of our common stock may be diluted if we sell common stock in a capital raising transaction or issue shares in a future acquisition. • Anti- takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could inhibit a change in control or a change in management that stockholders consider favorable. • Our stockholders must rely on stock appreciation for any return on investment as we do not expect to pay dividends in the foreseeable future. If our products do not achieve widespread market acceptance in the United States, our operating results will be harmed, and we may not achieve or sustain profitability. Our success depends in large part on the medical community' s acceptance of our products in the United States, which is the largest revenue market in the world for medical devices. Our ablation and LAAM product sales in the United States generate the majority of our revenue. We expect that sales of these products will continue to account for a majority of our revenue for the foreseeable future and that our future revenue will depend on the increasing acceptance by the medical community of our products as standard of care for treating Afib, managing the LAA and managing pain with Cryo Nerve Block therapy. The U. S. medical community' s acceptance of our products will depend upon our ability to demonstrate the safety and efficacy, advantages, long- term clinical performance and cost-effectiveness of our products. In addition, acceptance of products for the treatment of Afib is dependent upon, among other factors, the level of awareness and education of the medical community about the surgical treatment of Afib and the existence, effectiveness and safety of our products. Market acceptance and adoption of our products for the treatment of Afib also depends on the level of health insurer (including Medicare) reimbursement to physicians and hospitals for procedures using our products. Negative publicity resulting from incidents involving our products, or similar products could have a significant adverse effect on the overall acceptance of our products. If we encounter difficulties growing the market for our products in the U. S., we may not be able to increase our revenue enough to achieve or sustain profitability, and our business and operating results will be seriously harmed. Competition from existing and new products and procedures may decrease our market share and may cause our revenue to decline, and could adversely affect our operating results. The medical device industry, including the market for the treatment of Afib, is highly competitive, is subject to rapid technological change and can be significantly affected by new product introductions and promotional activities. There is no assurance that our products will compete effectively against drugs, catheter- based ablation, implantable devices, other surgical ablation devices, other products or techniques to occlude the left atrial appendage or other products and techniques to manage post- operative pain. Our products may become obsolete prior to the end of their anticipated useful lives, or we may introduce new products or next- generation products prior to the end of the useful life of our current products, either of which may require us to dispose of existing inventory and related capital equipment and / or write off their value or accelerate their depreciation. In addition, other products may be sold at lower prices. Due to the size of our markets, we anticipate that new or existing competitors may develop competing products, procedures and / or clinical solutions. There are few barriers to prevent new entrants or existing competitors from developing products to compete directly with ours. Companies also compete with us to attract qualified scientific ~~and ,~~ technical **and commercial** personnel as well as funding. Most of our competitors and potential competitors have greater financial, manufacturing, marketing and research and development capabilities than we have, and may obtain FDA approval or clearance for their products. **In 2023, Medtronic announced the FDA clearance of the PendutureTM Left Atrial Appendage Exclusion System.** The introduction of new products, procedures or clinical solutions, or our competitors obtaining FDA approvals or clearances **, such as Medtronic' s Penditure device** , may result in price reductions, reduced margins, loss of market share, or may render our products obsolete, which could adversely affect our revenue and future profitability. Any clinical data that is generated regarding our products may not be positive, and our current and planned clinical trials may not satisfy the requirements of the FDA or other regulatory authorities. Our clinical trials are expensive to conduct, typically taking many years to complete and have uncertain outcomes. Delays in patient enrollment or failure of patients to consent or continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. Conducting successful clinical studies may require the enrollment of large numbers of clinical sites and patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites; and the ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. Our products will be measured on their efficacy ~~which is dependent on the number of patients that experience Afib, stroke, or continued arrhythmias such as IST, following treatment with our products and the number of patients that have serious complications resulting from ablations or LAA exclusion using our products~~ . We cannot provide any assurance that the data collected during our clinical trials will be compelling to the medical community because it may not be scientifically meaningful, may identify unexpected safety concerns, and may not demonstrate that procedures utilizing our products are an attractive option when compared against data from alternative procedures and products. Negative data could affect the use of our products and harm our business and prospects. Conversely, positive results from clinical trial experience should not be relied upon as evidence that any of our products will gain market acceptance or that they will satisfy regulatory requirements for product approval. There can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future study results. We may be required to demonstrate with substantial evidence through well- controlled clinical trials that our product candidates are either (i) safe and effective for use in a diverse population for their intended uses or (ii) are substantially equivalent to predicate devices under section 510 (k) of the Food, Drug and Cosmetic Act (FDCA). Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other regulatory authorities despite

having progressed through initial clinical trials. Our devices and products may not be approved or cleared even though clinical or other data, in our view, are adequate to support an approval or clearance. The FDA or other regulatory authorities may: • disagree with our trial design and our interpretation of data from preclinical studies and clinical trials; • change requirements for the approval or clearance of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial; • approve or clear a product candidate for fewer or more limited indications or uses than we request; • grant approval or clearance contingent on the performance of costly post- marketing clinical trials; or • not approve the labeling claims necessary or desirable for the successful commercialization of our product candidates. These factors would affect the rate and extent to which our products are adopted in the medical community. ~~On April 29, 2021, we announced FDA approval of the EPi- Sense System to treat patients diagnosed with long- standing persistent Afib. Our success depends, in part, on the medical community' s acceptance of this and other of our products in the United States. We expect that our future revenue will depend on the increasing acceptance by the medical community of our products as standard of care for treating Afib. The U. S. medical community' s acceptance of the EPi- Sense System and other of our products will depend upon our ability to demonstrate long- term clinical performance and advantages and cost- effectiveness of our products. In addition, acceptance of products for the treatment of Afib is dependent upon, among other factors, the level of awareness and education of the medical community about the surgical treatment of Afib and the existence, effectiveness and safety of our products. Market acceptance and adoption of our products or procedures for the treatment of Afib, including but not limited to the EPi- Sense System, also depends on the level of health insurer (including Medicare) reimbursement to physicians and hospitals for procedures using our products. Negative publicity resulting from incidents involving our products, or similar products, could have a significant adverse effect on the overall acceptance of our products. Market acceptance could be delayed by lack of physician willingness to attend training sessions by the time required to complete this training, or by restrictions on our ability to provide training. If we are unable to gain and / or maintain such support, training services and collaboration, our ability to grow the market for our products may be impacted and we may not be able to increase our revenue enough to achieve or sustain profitability, and our business and operating results may be seriously harmed. Our success is dependent on our ability to train surgeons in the safe and effective use of our products. Restrictions on our ability to train surgeons, or unwillingness of surgeons to participate in such training, could reduce the market acceptance of our products. Our research and development efforts and our marketing strategy depend heavily on obtaining support, physician training assistance and collaboration from experienced physicians at leading commercial and research hospitals, particularly in the U. S. and Europe. We deliver training on the safe and effective use of our products consistent with their FDA (or equivalent regulatory body) approved or cleared indications. While we train providers in the safe and effective use of our products, we do not train them to use any of our products specifically to treat Afib unless the product is FDA- approved specifically for the treatment of Afib. In order for surgeons to learn to use our products, they must attend training sessions to familiarize themselves with the products, and they must be committed to learning the technology. Further, surgeons must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use the products. Continued market acceptance could be delayed by lack of surgeon willingness to attend training sessions, by the time required to complete this training or by restrictions on our ability to provide training. If we are unable to gain and / or maintain such support, training services and collaboration, our ability to market our products and, as a result, our financial condition, results of operations and cash flow, could be materially and adversely affected.~~ We rely on independent distributors to market and sell our products in certain markets outside of the United States, and a failure of our independent distributors to successfully market our products or any disruption in their ability to do so may adversely impact our sales. We depend on independent third- party distributors to sell our products in certain markets outside of the United States, and if these distributors do not perform, we may be unable to maintain or increase international revenue. We intend to grow our business outside of the United States, and to do so, we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell our products. Independent distributors may terminate their relationship with us or devote insufficient sales efforts to our products. We are not able to control our independent distributors, and they may not be successful in marketing our products. In addition, many of our independent distributors outside of the United States initially obtain and maintain foreign regulatory approval for sale of our products in their respective countries. Our failure to maintain our relationships with our independent distributors outside of the United States, or our failure to recruit and retain additional skilled independent distributors in these locations, could have an adverse effect on our operations. Turnover among our independent distributors, even if replaced, may adversely affect our short- term financial results while we transition to new independent distributors or direct sales personnel. The ability of these independent distributors to market and sell our products could also be adversely affected by unexpected events, including, but not limited to, power failures, nuclear events, local economic and political conditions, natural or other disasters and war or terrorist activities. In addition, the ability of our independent distributors to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired or our independent distributors could experience a significant change in their liquidity or financial condition, all of which could impair their ability to distribute our products and eventually lead to distributor turnover, and may adversely impact our sales. Industry Conditions Risks A prolonged downturn in macroeconomic conditions in which we operate may materially adversely affect our business. A prolonged economic downturn as a result of the collateral effects of inflationary pressures, increases in interest rates, slower economic activity, a future outbreak of COVID- 19 or a similar infectious disease, among other factors, may adversely impact our business. Specifically, impacts to procedure volumes and hospital staffing may result in reductions of our revenue and materially and adversely affect our results of operations and cash flows. ~~We may experience diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites. Key clinical trial activities, such as clinical trial site monitoring, subject visits and study procedures, may be interrupted. We may also encounter interruption or delays in the operations of FDA or other regulatory authorities, which may impact review and approval timelines.~~ Geopolitical issues around the world have impacted the global supply chain and could materially adversely affect global economic growth, disrupt

discretionary spending habits and generally decrease demand for our products and services. Our customers' ability to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired, resulting in a decrease in sales **. We may experience diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites. We may also encounter interruption or delays in the operations of FDA or other regulatory authorities, which may impact review and approval timelines** . We are unable to predict the extent to which current or future worldwide economic conditions may impact our business. Healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payors to keep, contain or reduce healthcare costs. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs, combined with closer scrutiny of such costs, could lead to patients being unable to obtain approval for payment from these third- party payors. The cost containment measures that healthcare providers are instituting both in the U. S. and internationally could harm our business. Some healthcare providers in the U. S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer elective surgical procedures, eliminating incremental procedure costs or by requiring the use of the least expensive devices possible, which could adversely affect the demand for our products or the price at which we can sell our products. Some healthcare providers have sought to consolidate and create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services has become and will continue to become more intense. This has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important marketing segments. Third- party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the use of our products is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical procedures would also harm our ability to promote and sell our products. Payors continue to review their policies and can, without notice, deny coverage for treatments that include the use of our products. Because each third- party payor individually approves coverage and reimbursement, obtaining these approvals may be time- consuming and costly. In addition, third- party payors may require us to provide scientific and clinical support for the use of our products. Adverse changes in coverage and reimbursement for surgical procedures could harm our business and reduce our revenue. FDA does not regulate the practice of medicine. Physicians may use our products in circumstances where they deem it medically appropriate, such as for the treatment of Afib or the reduction in stroke risk, even though FDA may not have approved or cleared our products to be marketed specifically for those indications. Some payors may deny coverage or payment for the use of our products for indications not specifically approved or cleared by FDA. Often, these denials can be overcome through an appeals process, but there is no guarantee of success in these cases. Our revenue generated from sales outside of the United States is also dependent upon coverage and reimbursement within prevailing foreign healthcare payment systems. Foreign healthcare payors generally do not provide the same level of reimbursement for sole- therapy minimally invasive procedures utilizing ablation devices and related products as payors in the United States. In addition, healthcare cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we sell our products, and these efforts are expected to continue. To the extent that the use of our devices has historically received reimbursement under a foreign healthcare payment system, such reimbursement, if any, has typically been significantly less than the reimbursement provided in the United States. If coverage and adequate levels of reimbursement from governmental and third- party payors outside of the United States are not obtained and maintained, sales of our products outside of the United States may decrease, and we may fail to achieve or maintain significant sales outside of the United States. We may experience unfavorable publicity relating to our business or our industry. This publicity could have a negative impact on our **sales, our** ability to attract and retain customers ~~, our sales~~ , clinical studies involving our products, our reputation and our stock price. We may experience a negative impact on our business from newspaper articles or other media reports relating to, among other things, our compliance with FDA regulations for medical device reporting, adverse patient and clinical outcomes, potential impact to our business from competitors or emerging technology and concerns over disclosure of financial relationships between us and our consultants. We believe that such publicity would potentially have a negative impact on our **business, results of operations and financial condition and our** clinical studies ~~, business, results of operations and financial condition~~ , or cause other adverse effects, including a decline in the price of our stock. We rely upon single and limited source third- party suppliers and third- party service providers, making us vulnerable to supply problems and price fluctuations which could harm our business. We rely on single and limited source third- party vendors for the manufacture and sterilization of components used in our products. For example, we rely on one vendor to manufacture ~~several of~~ our RF ~~generators~~ **generator** , as well as separate vendors to manufacture our EPi- Sense System and related RF generator. It would be a time consuming and lengthy process to secure these products from an alternative supplier. We have significant concentrations with a limited number of vendors. Additionally, our devices are sterilized prior to use using ethylene oxide at third- party sterilizers. Recently, certain sterilization facilities have experienced mandated temporary closures due to concerns over the impact of emissions of ethylene oxide from such facilities, and the Environmental Protection Agency has proposed regulations aimed at reducing hazardous air pollutants. We also rely on third parties to handle our warehousing and logistics functions for European and several **other** international markets on our behalf. Our reliance on outside manufacturers, sterilizers and suppliers also subjects us to risks that could harm our business, including: • we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms; • we may have difficulty timely locating and qualifying alternative suppliers or sterilizers; • switching components may require product redesign and new submissions to FDA which would increase our costs and could significantly delay production or, if FDA refuses to approve the changes, completely eliminate our ability to sell our products; • future regulatory actions to modify sterilization processes may cause sterilizers to close, even on a temporary basis, or require new regulatory approvals for us to use, creating lost sterilization capacity and delays; • our suppliers manufacture products for a range of customers, and

fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and • our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements. Identifying and qualifying additional or replacement suppliers or sterilizers for any of the components used in our products or replacement of warehousing and logistics providers, if required, may not be accomplished quickly and could involve significant additional costs. Any interruption or delay in the supply of components, materials, sterilization or warehousing and logistics, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products and could therefore have a material adverse effect on our business, financial condition and results of operations. Our manufacturing operations are **highly centralized** ~~currently conducted at a single location~~ , and ~~any~~ disruption at our manufacturing ~~facility~~ **facilities** could increase our expenses and decrease our revenue. Our manufacturing operations are **highly centralized to our corporate headquarters** ~~currently conducted at a single location in Ohio~~ . While we take precautions **, such as** ~~and are in process of~~ qualifying a second building **for manufacturing** ~~on our Ohio campus~~ , we do not maintain a backup manufacturing facility **outside of our Ohio campus** , making us dependent on the current ~~facility~~ **facilities** and production workers for the continued operation of our business. A natural or other disaster could damage or destroy our manufacturing equipment and cause substantial delays in our manufacturing operations, which could lead to additional expense and decreased revenue due to lack of supply. The insurance we maintain may not be adequate to cover our losses. With or without insurance, damage to our ~~facility~~ **facilities** or our other property due to a natural disaster or casualty event could have a material adverse effect on our business, financial condition and results of operations ~~. We may enter into significant acquisitions in the future. Acquisitions have inherent uncertainties and involve risks and difficulties in integrating that may adversely affect our business, results of operations and financial condition. All acquisitions involve inherent uncertainties, which may include, among other things, our ability to: • successfully identify targets for acquisition; • negotiate reasonable terms; • properly perform due diligence and determine significant risks associated with a particular acquisition; • properly evaluate target company management capabilities; and • successfully transition and integrate the acquired company into our business and achieve the desired performance. We may acquire businesses with unknown liabilities, contingent liabilities or internal control deficiencies. We have plans and procedures in place to conduct reviews of potential acquisition candidates for compliance with applicable regulations and laws prior to acquisition. Despite these efforts, realization of any of these liabilities or deficiencies may increase our expenses, adversely affect our financial position through the initiation, pendency or outcome of litigation or otherwise, or cause us to fail to meet our public financial reporting obligations. We have consummated three significant acquisitions since 2013 and in the future may continue to invest a substantial amount of capital in acquisitions. We continue to evaluate potential acquisition opportunities to support, strengthen and grow our business. There can be no assurance that we will be able to locate suitable acquisition candidates, acquire possible acquisition candidates, acquire such candidates on commercially reasonable terms, or integrate acquired businesses successfully in the future. In addition, any governmental review or investigation of our proposed acquisitions, such as by the Federal Trade Commission, may impede, limit or prevent us from proceeding with an acquisition. Future acquisitions may require us to incur additional debt and contingent liabilities, which may adversely affect our business, results of operations and financial condition. The process of integrating acquired businesses into our existing operations may result in operating, contract and supply chain difficulties, such as the failure to retain customers or management personnel. Such difficulties may divert significant financial, operational and managerial resources from our existing operations and make it more difficult to achieve our operating and strategic objectives~~ . We may experience periods of rapid growth and expansion, which could place a significant strain on our personnel, information technology systems and other resources. In particular, the increase in our direct sales force requires significant management and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. To achieve our revenue goals, we must successfully increase production output as required by customer demand. In the future, we may experience difficulties in increasing production, including problems with production yields and quality control, component supply and shortages of qualified personnel. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenues and adversely impact our operating results. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer. We depend on our officers and other skilled and experienced personnel to operate our business effectively. If we are not able to retain our current employees or recruit, hire, train and integrate additional qualified personnel, our business will suffer and our future revenue and profitability will be impaired. We are highly dependent on the skills and experience of our President and Chief Executive Officer, Michael H. Carrel, and certain other officers and key employees. We do not have any insurance in the event of the death or disability of key personnel. Our officers and key employees, with the exception of our President and Chief Executive Officer, do not have employment agreements, and they may terminate their employment and work elsewhere without notice and without cause or good reason. Currently we have non- compete agreements with our officers and other employees. Due to the specialized knowledge of each of our officers with respect to our products and our operations and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. The announcement of the loss of one or more of our key personnel could negatively affect our stock price. We depend on our scientific and technical personnel for successful product development and innovation, which are critical to the success of our business. In addition, to succeed in the implementation of our business

strategy, our management team must rapidly execute our sales strategy, obtain expanded FDA clearances and approvals, achieve market acceptance for our products and further develop products, while managing anticipated growth by implementing effective planning, manufacturing and operating processes. Managing this growth will require us to attract and retain additional management and technical personnel. We rely primarily on direct sales employees to sell our products in the United States and in Europe, and failure to adequately train them in the use and benefits of our products will prevent us from achieving our market share and revenue growth goals. We have key relationships with physicians that involve procedure, product, market and clinical development and training. ~~If~~ **Our business could be negatively impacted if** any of these physicians end their relationship with us ~~, our business could be negatively impacted~~ . We cannot assure you that we will be able to attract and retain the personnel and physician relationships necessary to grow and expand our business and operations. If we fail to identify, attract, retain and motivate these highly skilled personnel and physicians, we may be unable to continue our development and sales activities. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Like **many** other companies, we experience attempts to gain unauthorized access to our systems and information on a regular basis **, and a number of our employees work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities** . Despite our security measures, including employee training, our information technology and infrastructure are vulnerable to cyber- attacks, malicious intrusions, breakdowns, destruction, loss of data privacy, breaches due to employee error, malfeasance or other disruptions. Cyber- attacks are becoming more sophisticated and frequent, and our systems could be the target of malware, ransomware and other cyber- attacks. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. We can give no assurances that these measures and efforts will prevent interruptions or breakdowns. If we are unable to detect or prevent a security breach or cyber- attack or other disruption from occurring, then we could incur losses or damage to our data, or inappropriate disclosure of our confidential information or that of others ~~;~~ **. We have cyber- insurance coverage that may not cover all possible events,** and ~~we~~ **this insurance is subject to deductibles and coverage limitations. We** could sustain damage to our reputation and customer and employee relationships, suffer disruptions to our business and incur increased operating costs including costs to mitigate any damage caused and protect against future damage, and be exposed to additional regulatory scrutiny or penalties and to civil litigation and possible financial liability, any of which could have a material adverse effect on our business, operating margins, revenues and competitive position. We also rely in part on information technology to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements **. In addition, some of our software systems are cloud- based data management applications, hosted by third- party service providers whose security and information technology systems are subject to similar risks. The failure to protect either our or our service providers' information technology infrastructure could disrupt our operations** . If our information technology systems do not effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, human error or cyber incident, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations could be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness with which we report our operating results. We maintain insurance designed to provide coverage for ordinary risks associated with our operations and our ordinary indemnification obligations, which we believe to be customary for our industry. The coverage provided by such insurance may not be adequate for claims we may make or may be contested by our insurance carriers. If our insurance is not adequate or available to pay liabilities associated with our operations, or if we are unable to purchase adequate insurance at reasonable rates in the future, our business, financial condition, results of operations or cash flows may be materially adversely impacted. We spend considerable time and money complying with federal, state and foreign regulations in addition to FDA regulations, and, if we do not fully comply with such regulations, we could face substantial penalties. We are subject to extensive regulation by the federal government and foreign countries in which we conduct business. The laws that affect our ability to operate our business in addition to the FDCA and FDA regulations 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, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs; • the Federal False Claims Act, which prohibits submitting a false claim or causing the submission of a false claim to the government; • Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid; • state consumer protection, fraud and business practice laws, including the California Consumer Privacy Act (" CCPA "), which among other things, requires disclosures to California consumers and provides consumers new abilities to opt out of certain sales of personal information; • state laws that prohibit the practice of medicine by non- doctors and by doctors not licensed in a particular state, and fee- splitting arrangements between doctors and non- doctors, as well as state law equivalents to the Anti- Kickback Statute and the Stark Law, which may not be limited to government- reimbursed items; • federal and state healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act (HIPAA) which protects medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting reasonably necessary to accomplish the intended purpose; • laws and regulations, such as the General Data Protection Regulation in the European Union, that govern collection, use, disclosure, transfer and storage of personal data that we may collect from our employees, consultants or in conjunction with clinical trials; • the Federal Trade Commission Act and similar laws regulating

advertising and consumer protection; and • similar and other regulations outside the United States. Healthcare fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a law has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations. Our manufacturing operations and research and development activities involve the use of biological materials and hazardous substances and are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of and human exposure to hazardous substances. Our research and development and manufacturing operations may produce biological waste materials, such as animal tissues and certain chemical waste. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in compliance with environmental laws and regulations. Compliance with these laws and regulations may be expensive, and non- compliance could result in substantial liabilities. In addition, we cannot eliminate the risk of accidental contamination or injury to third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed any applicable insurance coverage we may have. Our manufacturing operations may result in the release, discharge, emission or disposal of hazardous substances that could cause us to incur substantial liabilities, including costs for investigation and remediation. If our ~~past or present~~ operations are found to be in violation of any of the laws described above or the other governmental regulations to which we, our distributors or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare, Medicaid and other government programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully or clearly interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management' s attention from the operation of our business and damage our reputation. If we fail to comply with the extensive FDA regulations relating to our business, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and promote our products may be hurt. Our products are classified by FDA as medical devices and, as such, are subject to extensive regulation by FDA and numerous other federal, state and foreign governmental authorities. FDA regulations, guidance, notices and other issuances specific to medical devices are broad and regulate numerous aspects of our business. Compliance with FDA, state and other regulations can be complex, expensive and time- consuming. FDA and other authorities have broad enforcement powers. Furthermore, changes in the applicable governmental regulations could prevent further commercialization of our products and technologies and could materially harm our business. If a serious failure to comply with applicable regulatory requirements was determined, it could result in enforcement action by FDA or other state or federal agencies, including the U. S. Department of Justice (USDOJ), which may include any of the following sanctions, among others: • warning letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recall or seizure of our products; • operating restrictions, partial suspension or total shutdown of production; • suspension or termination of our clinical trials; • refusing or delaying our pending requests for 510 (k) clearance or PMAs, new intended uses or modifications to existing products; • withdrawing 510 (k) clearance or PMAs that have already been granted; and • criminal prosecution. If any of these events were to occur, we could lose customers and our production, product sales, business, results of operations and financial condition would be harmed. We are also subject to medical device reporting regulations that require us to file reports with FDA if our products may have caused or contributed to a death or serious injury or, in the event of product malfunction, that if such malfunction were to recur, would likely cause or contribute to a death or serious injury. There have been incidents, including patient deaths, which have occurred during or following procedures using our products that we have not reported to FDA because we determined that our products did not malfunction and did not cause or contribute to the outcomes in these incidents. If FDA disagrees with us, however, and determines that we should have submitted reports for these adverse events, we could be subject to significant regulatory fines or other penalties. In addition, the number of medical device reports we make, or the magnitude of the problems reported, could cause us or FDA to terminate or modify our clinical trials or recall or cease the sale of our products, and could hurt commercial acceptance of our products and harm our reputation with customers. Unless and until we obtain additional FDA approval for our products, we will not be able to promote ~~most of~~ them **for the treatment of Afib and / or** to prevent stroke, and our ability to maintain and grow our business could be harmed. We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off- label, uses. Our business and future growth depend on the continued use of our products for the treatment of Afib. Unless the products are approved or cleared by FDA specifically for the treatment of Afib or prevention of stroke, we may not make claims about the safety or effectiveness of our products for such uses. In order to obtain additional FDA approvals to promote our products for the treatment of Afib or reduction in stroke risk, we will need to demonstrate in clinical trials that our products are safe and effective for such use. Development of sufficient and appropriate clinical protocols to demonstrate quality, safety and efficacy may be required and we may not adequately develop such protocols to support approval. We cannot assure you that any of our clinical trials will be completed in a timely manner or successfully or that the results obtained will be acceptable to FDA. We, FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. These limitations present a material risk that FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing and / or support activities, though

designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the FDCA. We also face the risk that FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities. Investigations concerning the promotion of unapproved uses and related issues, are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. Although our Isolator Synergy System and EPi- Sense System have received FDA approval for the treatment of some forms of Afib in certain procedures, we have not received FDA clearance or approval to promote our other products for the treatment of Afib or the prevention of stroke. Unless and until we obtain FDA clearance or approval for the use of our other products to treat Afib or prevent stroke, we, and others acting on our behalf, may not claim in the U. S. that such products are safe and effective for such uses or otherwise promote them for such uses. Similar restrictions also exist outside of the U. S. There is no assurance that future clearances or approvals of our products will be granted or that current or future clearances or approvals will not be withdrawn. Failure to obtain a clearance or approval or loss of an existing clearance or approval, could hurt our ability to maintain and grow our business. Modifications to our products may require new clearances or approvals or may require us to cease promoting or to recall the modified products until such clearances or approvals are obtained and FDA may not agree with our conclusions regarding whether new clearances or approvals were required. Any modification to a 510 (k)- cleared device **or PMA- approved device** that would constitute a change in its intended use, design or manufacture could require a new or supplemental 510 (k) clearance or, possibly, submission and FDA approval of a PMA application **or PMA supplement** . FDA requires every medical device company to make the determination as to whether a 510 (k) must be filed, but FDA may review any medical device company' s decision. We have made modifications to our products and concluded that such modifications did not require us to submit a new or supplemental 510 (k). FDA may not agree with our decisions regarding whether submissions were required. If FDA were to disagree with us and require us to submit a 510 (k), PMA or a PMA supplement for then- existing modifications, we could be required to cease promoting or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects. If we or our third- party vendors fail to comply with extensive FDA regulations relating to the manufacturing of our products or ~~any~~ component ~~part~~ **parts** , we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be hurt. Our manufacturing facilities and the manufacturing facilities of any of our third- party component manufacturers, critical suppliers or third- party sterilization facilities are required to comply with FDA' s QSR, which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of the products we sell. FDA may evaluate our compliance with the QSR, among other ways, through periodic announced or unannounced inspections which could disrupt our operations and interrupt our manufacturing. If in conducting an inspection of our manufacturing facilities or the manufacturing facilities of any of our third- party component manufacturers, critical suppliers or third- party sterilization facilities, an FDA investigator observes conditions or practices believed to violate the QSR, the investigator may document their observations on a Form FDA- 483 that is issued at the conclusion of the inspection. A manufacturer that receives an FDA- 483 may respond in writing and explain any corrective actions taken in response to the inspection observations. FDA will typically review the facility' s written response and may re-inspect to determine the facility' s compliance with the QSR and other applicable regulatory requirements. Failure to take adequate and timely corrective actions to remedy objectionable conditions listed on an FDA- 483 could result in FDA taking administrative or enforcement actions. Among these may be FDA' s issuance of a Warning Letter to a manufacturer, which informs the manufacturer that FDA considers the observed violations to be of " regulatory significance " that, if not corrected, could result in further enforcement action. FDA enforcement actions, which include seizure, injunction and criminal prosecution, could result in total or partial suspension of a facility' s production and / or distribution, product recalls, fines, suspension of FDA' s review of product applications and FDA' s issuance of adverse publicity. Thus, an adverse inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse inspections could also delay FDA approval of our products and could have an adverse effect on our production, sales and financial condition. We and any of our third- party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to the sterilization of our products or facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. ~~Any interruption~~ **Interruption** or delay in the manufacture of the product or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products and could, therefore, have a material adverse effect on our business, financial condition and results of operations. We are currently defending against a lawsuit brought under the False Claims Act, and any adverse finding, judgement, or enforcement action could materially and adversely affect our business, financial condition or results of operations. As previously disclosed, on December 11, 2017, the Company received a Civil Investigative Demand (CID) from the **US Department of Justice (** USDOJ **)** stating that it was investigating the Company to determine whether the Company has violated the False Claims Act, relating to the promotion of certain medical devices related to the treatment of atrial fibrillation for off- label use and submitted or caused to be submitted false claims to certain federal and state health care programs for

medically unnecessary healthcare services related to the treatment of Afib. The Company provided the USDOJ with documents and answers to the written interrogatories, and cooperated with the investigation. In 2021, USDOJ informed the Company that the investigation resulted from a lawsuit by a private individual, or" relator", brought on behalf of the United States and various state and local governments under the qui tam provisions of the federal and similar state and local laws. Although the USDOJ and all of the state and local governments declined to intervene, the relator continues to pursue the lawsuit. During the third quarter of 2022, the relator filed a Fourth Amended Complaint, which dropped allegations of off- label promotion and now alleges that the Company paid illegal kickbacks to healthcare providers in exchange for using or referring the Company' s products, in violation of the federal Anti- Kickback Statute and various comparable state and local laws. While the Company is contesting the case, it is not possible to predict when the lawsuit will be resolved, the outcome of the lawsuit or its potential impact on the Company. While the Company believes its practices are lawful, there can be no assurance that the lawsuit will not result in findings of violations of federal laws that could lead to the imposition of damages, fines, penalties, restitution, other monetary liabilities, sanctions, settlements or changes to the Company' s business practices or operations that could have a material adverse effect on the Company' s business, financial condition or results of operations, or eliminate altogether the Company' s ability to operate its business. The use of products we sell may result in injuries or other adverse events that lead to product liability suits, which could be costly to our business or our customers' businesses. The use of our products may result in a variety of serious complications, including damage to the heart, nerves, internal bleeding, death, paralysis or other adverse events. Serious complications are commonly encountered in connection with surgical procedures. If products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components, are misused or are associated with serious injuries or deaths, we may become subject to costly litigation by our customers or their patients. We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. We could be required to pay damages that exceed our insurance coverage, and such amounts could be significant. Any product liability claim, with or without merit, could also result in an increase in our insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future. Any product liability claim, even a meritless or unsuccessful one, would be time- consuming and expensive to defend and could result in the diversion of our management' s attention from our business and result in adverse publicity, withdrawal of clinical trial participants, injury to our reputation and loss of revenue. Any of these events could negatively affect our financial condition. Our intellectual property rights may not provide meaningful commercial protection for our products, which could enable third parties to use our technology or methods, or very similar technology or methods, and could reduce our ability to compete. Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Although we have taken steps to protect our intellectual property and proprietary technology, we cannot assure you that third parties will not be able to design around our patents or, if they do infringe upon our technology, that we will be successful in or will have sufficient resources to pursue a claim of infringement against those third parties. We believe that third parties may have developed or are developing products that could infringe upon our patent rights. Any pursuit of an infringement claim by us may involve substantial expense or diversion of management attention. In addition, although we have generally entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements may be breached, may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Additionally, as is common in the medical device industry, some of these individuals were previously employed at other medical equipment or biotechnology companies, including our competitors. Although no claims are currently pending against us, we may be subject to claims that these individuals have used or disclosed trade secrets or other proprietary information of their former employers. The laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Foreign countries generally do not allow patents to cover methods for performing surgical procedures. If our intellectual property does not provide significant protection against foreign or domestic competition, any current or future competitors could compete more directly with us, which could result in a decrease in our revenue and market share. All of these factors may harm our competitive position. The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights and any litigation or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Any patent dispute, even one without merit or an unsuccessful one, would be time- consuming and expensive to defend and could result in the diversion of our management' s attention from our business and result in adverse publicity, the disruption of development and marketing efforts, injury to our reputation and loss of revenue. Litigation also puts our patent applications at risk of being rejected and our patents at risk of being invalidated or interpreted narrowly and may provoke third parties to assert claims against us. Any of these events could negatively affect our financial condition. In the event of a patent dispute, if a third - party' s patents were upheld as valid and enforceable, and we were found to be infringing, or found to be inducing infringement by others, we could be prevented from selling our products unless we were able to obtain a license to use technology or ideas covered by such patent or are able to redesign our system to avoid infringement, or we may be ordered to pay substantial

damages to the patent holders. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our products, we may be unable to sell our products and our business could suffer. We sell our products outside of the United States, and we are subject to various regulatory and other risks relating to international operations, which could harm our revenue and profitability. Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory requirements in each jurisdiction where we operate or have sales. Our failure, or the failure of our distributors, to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or our distributors have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Moreover, if political or economic conditions deteriorate in these countries, or if any of these countries are affected by a natural disaster or other catastrophe, our ability to conduct our international operations or collect on international accounts receivable could be limited and our costs could be increased, which could negatively affect our operating results. Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including, but not limited to: • export restrictions and controls relating to technology; • pricing pressure that we may experience internationally; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • political and economic instability; • consequences arising from natural disasters and other similar catastrophes, such as hurricanes, tornados, earthquakes, floods and tsunamis; • potentially adverse tax consequences, tariffs and other trade barriers; • the need to hire additional personnel to promote our products outside of the United States; • international terrorism and anti- American sentiment; • fluctuations in exchange rates for future sales denominated in foreign currency, which represent a portion of our sales outside of the United States; and • difficulty in obtaining and enforcing intellectual property rights. Our exposure to each of these risks may increase our costs and require significant management attention. We cannot assure you that one or more of these factors will not harm our business. Due to the global nature of our business, we may be exposed to liabilities under the Foreign Corrupt Practices Act and various other anti-corruption laws, and any allegation or determination that we violated these laws could have a material adverse effect on our business. Our business practices in foreign countries must comply with anti- corruption laws, including the Foreign Corrupt Practices Act (FCPA), the UK Anti- Bribery Act of 2010 and other U. S. and foreign anti- corruption laws, which prohibit companies from engaging in bribery including corruptly or improperly offering, promising, or providing money or anything else of value to foreign officials and certain other recipients. In addition, the FCPA imposes certain books, records and accounting control obligations on public companies and other issuers. We operate in parts of the world in which corruption can be common and compliance with anti- bribery laws may conflict with local customs and practices. Our global operations face the risk of unauthorized payments or offers being made by employees, consultants, sales agents and other business partners outside of our control or without our authorization. We have a compliance program in place designed to reduce the likelihood of potential violations of the FCPA and other U. S. and foreign anti- bribery and anti- corruption laws. It is our policy to implement safeguards (including mandatory training) to prohibit these practices by our employees and business partners with respect to our operations. However, irrespective of these safeguards, or as a result of monitoring compliance with such safeguards, it is possible that we or certain other parties may discover or receive information at some point that certain employees, consultants, sales agents, or other business partners may have engaged in corrupt conduct for which we might be held responsible. Violations of the FCPA or other foreign anti- corruption laws may result in restatements of, or irregularities in, our financial statements as well as severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In some cases, companies that violate the FCPA may be debarred by the U. S. government and / or lose their U. S. export privileges. Changes in anti- corruption laws or enforcement priorities could also result in increased compliance requirements and related costs which could adversely affect our business, financial condition and results of operations. In addition, the U. S. or other governments may seek to hold us liable for successor liability FCPA violations or violations of other anti- corruption laws committed by companies in which we invest or that we acquired or will acquire. Compliance with developing European Union medical device regulations may limit our ability to maintain sales of our products in European markets or to introduce new products into European markets. Many foreign countries where we market or may market our products have regulatory bodies and restrictions similar to those of FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance and the requirements may differ. In particular, marketing of medical devices in the EU is subject to compliance with the Medical Device Directive 93 / 92 / EEC (MDD). A medical device may be placed on the market within the EU only if it conforms to certain " essential requirements " and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. In May 2017, the EU adopted a new Medical Device Regulation (EU) 2017 / 745 (MDR), which repealed and replaced the MDD effective May 26, 2021. The MDR clearly envisages, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations with respect to clinical data for devices and pre- market regulatory review of high- risk devices. The MDR also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2021 , may continue to be placed on the market ~~for the~~

~~remaining validity of the certificate,~~ until ~~May 26, 2024~~ **2027** ~~at~~ **or 2028, depending on device classification, as long as** ~~the~~ **those** ~~latest~~ **devices meet the requirements of 2017 / 745 as amended by EU 2023 / 607** . After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU. If we fail to comply with the new MDR, we may not be able to continue to sell existing products in the EU or introduce new products for sale in the EU, either of which could materially harm our results of operations and financial condition. Our quarterly financial results are likely to fluctuate significantly because **the pace of adoption of** our ~~sales prospects~~ **products by clinicians** are uncertain. Due to differing rates of adoption of our devices, our quarterly operating results may fluctuate significantly. Current worldwide economic conditions, natural disasters and other factors discussed in this " Risk Factors " section also may impact our sales results, causing our quarterly operating results to be difficult to predict and may fluctuate significantly from quarter to quarter or from prior year to current year periods. These fluctuations may also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year. Even though we reported net income of $ 50, 199 in 2021, we have a history of net losses, including net losses of $ **30, 438 in 2023, and $** 46, 466 in 2022 ~~, and $ 48, 155 in 2020~~ . As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~326~~ **357** , ~~619~~ **057** . Our net losses have resulted principally from costs and expenses relating to sales, training and promotional efforts, research and development, clinical trials, seeking regulatory clearances and approvals and general operating expenses. We expect to continue to incur substantial expenditures and to potentially incur additional operating losses in the future as we further develop and commercialize our products. If sales of our products do not continue to grow as we anticipate, we may not be able to achieve profitability. Our expansion efforts may prove to be more expensive than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and accumulated deficit. ~~Our federal tax net operating loss (NOL) and general business credit carryforwards generated or acquired may expire or will be limited because we experienced an ownership change of more than 50 percent, which could result in greater future income tax expense and adversely impact future cash flows. Section 382 of the Internal Revenue Code of 1986 imposes limitations (Section 382 limitation) on a company' s ability to use net operating loss and general business credit carryforwards if a company experiences a more- than- 50- percent ownership change over a three- year testing period. Additionally, in connection with acquisitions, acquired NOLs are also subject to Section 382 limitation. The Section 382 limitations could limit the availability of our net operating loss and general business credit carryforwards to offset any future taxable income, which may increase our future income tax expense and adversely impact future cash flows. Federal net operating losses generated prior to 2018 are also subject to expiration under current IRS regulations. We have total federal income tax net operating loss carryforwards that began to expire in 2020 and federal and state research and development credit carryforwards that began to expire in 2022. We have available federal net operating loss and research and development credit carryforwards, subject to expiration, of $ 331, 169 and $ 13, 205 as of December 31, 2022. We also have various state net operating losses and research and development credit carryforwards with varying expirations.~~ Governmental authorities may question our intercompany transfer pricing policies or change their laws in a manner that could increase our effective tax rate or otherwise harm our business. As a U. S. company doing business in international markets through subsidiaries, we are subject to foreign tax and intercompany transfer pricing laws, including those relating to the flow of funds between the parent and subsidiaries. If tax authorities challenge our intercompany transfer pricing, our operations may be negatively impacted and our effective tax rate may increase. Tax rates vary from country to country and if regulators determine that our profits in one jurisdiction should be increased, we might not be able to fully offset any associated increase in tax expense in the other jurisdiction, which would increase our effective tax rate. Additionally, the Organization for Economic Cooperation and Development, or OECD, has issued certain proposed guidelines regarding base erosion and profit sharing including minimum taxation. As these guidelines are formally adopted by the OECD, it is possible that separate taxing jurisdictions in which we operate may also adopt some form of these guidelines. In such case, we may need to change our approach to intercompany transfer pricing in order to maintain compliance under the new rules. Our effective tax rate may increase or decrease, including changes in minimum taxation, depending on the current location of global operations at the time of the change. Finally, we might not always be in compliance with all applicable customs, exchange control, value added tax and transfer pricing laws despite our efforts to be aware of and to comply with such laws. In such case, we may need to adjust our operating procedures and our business could be adversely affected. If our goodwill becomes impaired, it could materially reduce the value of our assets and reduce our net income or increase our net loss for the year in which the impairment occurs. As of December 31, ~~2022~~ **2023** , we had $ 234, 781 in goodwill ~~related to acquisitions~~ , which represents ~~the~~ purchase price we paid in excess of the fair value of the net assets we acquired. The Financial Accounting Standards Board' s (FASB) Accounting Standards Codification (ASC) 350, " Goodwill and Other Intangible Assets " requires that goodwill be tested for impairment at least annually (absent any impairment indicators). We may have future impairment adjustments to our recorded goodwill. Any finding that the value of our goodwill has been impaired would require us to record an impairment charge which could materially reduce the value of our assets and reduce our net income or increase our net loss for the year in which the impairment charge occurs and increase our accumulated deficit. An inability to forecast future revenue or estimate life cycles of products may result in inventory- related charges that would negatively affect our gross margins and results of operations. To mitigate the risk of supply interruptions, we may choose to maintain additional inventory of our products or component parts. Managing our inventory levels is important to our cash position and results of operations and is challenging in the current economic environment. As we grow and expand our product offerings, managing our inventory levels becomes more difficult, particularly as we expand into new product areas and bring product enhancements to market. While we rely on our personnel and information technology systems for inventory management, our personnel and information technology systems may fail to adequately perform these functions or may experience an interruption. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Conversely, inadequate inventory levels may make it difficult for us to meet

customer product demand, resulting in decreased revenue. An inability to forecast future revenue or estimated life cycles of products may result in inventory- related charges that would negatively affect our gross margins and results of operations and increase our accumulated deficit. We are subject to credit risk from our accounts receivable related to our sales, which include sales into countries outside the United States that may experience economic turmoil. The majority of our accounts receivable arise from sales in the United States. However, we also have significant receivable balances from customers within the European Union and Asia. Our accounts receivable in the United States are primarily due from public and private hospitals. Our accounts receivable outside the United States are primarily due from public and private hospitals and from independent distributors. Our historical write- offs of accounts receivable have not been significant. We monitor the financial performance and credit worthiness of our customers so that we can properly assess and respond to changes in their credit profile. Our independent distributors operate in certain countries where economic conditions continue to present challenges to their businesses, and, thus, could place the amounts due to us at risk. These distributors are owed amounts from public hospitals that are funded by their governments. Adverse financial conditions in these countries may negatively affect the length of time that it will take us to collect associated accounts receivable or impact the likelihood of ultimate collection. ~~Our Loan~~ **We may be unable to comply with the covenants of our Credit** Agreement ~~with Silicon Valley Bank (" SVB ")~~ **. The Credit Agreement entered into on January 5, 2024,** contains **specific financial covenants and** a minimum liquidity ~~covenant~~ **requirement** , ~~dividend~~ **along with other terms** ~~restrictions~~ **restricting indebtedness, liens, investments and acquisitions, asset dispositions, certain payments** and other customary ~~terms~~ **representations and warranties. The Credit Agreement contains mandatory prepayment provisions which require prepayment of amounts outstanding (i) upon the receipt of proceeds from the issuance of any non- permitted indebtedness and (ii) when there is** ~~and~~ **an** ~~conditions~~ **Availability shortfall, as defined** . The occurrence of an event of default could result in ~~an increase to the applicable interest rate by 3. 0 %, an acceleration of all obligations,~~ an obligation to repay all obligations in full and a right by ~~SVB~~ **our lenders** to exercise all remedies available to them. If we are unable to pay those amounts, ~~SVB~~ **our lenders** could proceed against the collateral granted to it pursuant to the ~~Loan~~ **Credit** Agreement, and we may in turn lose access to **both our collateral and** our current source of borrowing availability. We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price. We provide financial guidance about our business and future operating results. In developing this guidance, our management makes certain assumptions and judgments about our future operating performance, including rate of adoption of our products, projected hiring to support our growth, continued increase of our market share, potential impact from competitive devices and therapies, and stability of the macro- economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control ~~,~~ and ~~which~~ could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, the market price of our common stock could decline. Securities analysts may not continue, or additional securities analysts may not initiate, coverage for our common stock or may issue negative reports. This may have a negative impact on the market price of our common stock. Several securities analysts provide research coverage of our common stock. Some analysts have already published statements that do not portray our technology, products or procedures using our products in a positive light and others may do so in the future. If we are unable to educate those who publicize such reports about the benefits we believe our business provides, or if one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us, our business or our markets. If sufficient securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. It may be difficult for companies such as ours, with a smaller market capitalization, to attract and maintain sufficient independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock. The price and trading volume of our common stock may experience extreme fluctuations and our stockholders could lose some or all of their investment. Because we operate within the medical device segment of the healthcare industry, our stock price is likely to be volatile. The market price of our common stock ~~may have and~~ has had ~~a history of~~ **and may continue to have** substantial fluctuation due to a variety of factors, including, but not limited to those risk factors described in the " Risk Factors " section herein. These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. We believe the quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. The market prices of the securities of medical device companies, particularly companies like ours without consistent revenue and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of these particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management' s attention and resources and harm our ability to grow our business. The sale of material amounts of common stock could encourage short sales by third parties and depress the price of our common stock. As a result, our stockholders may lose all or part of their investment. The downward pressure on our stock price caused by the sale of a significant number of shares of our common stock or the perception that such sales could occur by any of our significant stockholders could cause our stock price to decline, thus allowing short sellers of our stock an opportunity to take advantage of any decrease in the value of our stock. The presence of short sellers in our common stock may further depress the price of our common stock. Some of our directors and executive officers have entered into, or may enter into, Rule 10b5- 1 trading plans

pursuant to which they may sell shares of our stock from time to time in the future. Actual or potential sales by these insiders, including those under a prearranged Rule 10b5- 1 trading plan, could be interpreted by the market as an indication that the insider has lost confidence in our stock and adversely impact the market price of our stock. Sales of common stock by us in a capital raising transaction or our issuances of shares in an acquisition may dilute stockholder ownership of common stock and cause a decline in the market price of our common stock. We may need to raise capital in the future to fund our operations or new initiatives or reduce or pay in full our indebtedness. If we raise funds by issuing equity securities, our stock price may decline and our existing stockholders may experience significant dilution. Furthermore, we may enter into capital raising transactions or issue shares in acquisitions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock. Provisions in our certificate of incorporation and bylaws could delay or prevent a change of control or change in management that would provide a premium to the market price of common stock. These provisions include those: • authorizing the issuance without further approval of " blank check " preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt; • prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; • limiting the ability of stockholders to call special meetings of stockholders; • prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders; and • establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings. In addition, Section 203 of the Delaware General Corporation Law limits business combination transactions with 15 % stockholders that have not been approved by our board of directors. These provisions and others could make it difficult for a third party to acquire us, or for members of our board of directors to be replaced, even if doing so would be beneficial to our stockholders. Because our board of directors is responsible for appointing the members of our management team, these provisions could, in turn, affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, stockholders may lose an opportunity to realize a premium on shares of common stock or the market price of our common stock could decline. We do not expect to pay dividends in the foreseeable future. As a result, stockholders must rely on stock appreciation for any return on investment. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, stockholders will have to rely on capital appreciation, if any, to earn a return on investment in our common stock. Furthermore, pursuant to our credit facility, we are currently subject to restrictions on our ability to pay dividends and we may in the future become subject to other contractual restrictions on, or prohibitions against, the payment of dividends.