Risk Factors Comparison 2025-03-06 to 2024-03-01 Form: 10-K

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We operate in a rapidly changing environment that involves many risks that could materially affect our business, financial condition or future results, and some of which are beyond our control. The occurrence of any of these risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. In evaluating the Company and its business, you should carefully consider the information included under Part I, Item 1A " Risk Factors " in this Annual Report. Risk Factors Summary The following is a summary of the risk factors that could materially affect our business, financial condition, or future results, all of which are more fully described below. This summary should be read in conjunction with the " Risk Factors " described below and should not be relied upon as a complete summary of the material risks facing our business. Risks Relating to Our Business and Financial Condition ● **Our dependence on a limited number of products, and disruptions in our ability to sell these products. ● Dependence upon the integrity of our supply chain and third- party suppliers for certain raw materials and components. ● Failure to protect our information technology infrastructure which could adversely affect our business and operating results. ●** The strict adherence to regulatory requirements governing medical devices during the manufacturing process and that of suppliers. ● ~~Successful development and commercialization of enhanced products or new products to remain competitive. ● Our dependence on a limited number of products, and disruptions in our ability to sell these products. ● Dependence upon the integrity of our supply chain, including multiple single- source suppliers. ● Our reliance on third- party suppliers for certain of our raw materials and components. ● Securities class action litigation or derivative litigation. ●~~ Our markets are very competitive, and we sell certain of our products in a mature market. ● We manufacture and store our products at a single facility in Florida. ● ~~Our inability to collect on our accounts receivables from our customers. ●~~ Failure to maintain relationships with **IDNs** ~~Integrated Delivery Networks~~ and **GPOs** ~~Group Purchasing Organizations. ● Cost- containment efforts of our customers and purchasing groups. ● A failure in our efforts to access and educate clinicians, anesthesiologists, radiologists, and hospital administrators regarding the advantages of our products~~ . ● The lengthy sales cycle for medical devices could delay our sales. ● Our reliance on distributors to sell our products outside the U. S. ● **Successful development and commercialization of enhanced or new products to remain competitive. ●** Our dependency on our founder, Chairman, President and Chief Executive Officer, Roger Susi ~~. ● Failure to attract and retain the talent required for our business. ● Sufficiency of our internal and external sources of liquidity~~ . ● Inability to scale our operations or adequately manage generational upgrades to our own products. ● **Our engagement in related party transactions** ~~Difficulties associated with integrating acquisitions of technologies, products, and businesses~~ . ● Difficulties associated with accurately forecasting our business performance. ● Inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with **U. S. generally accepted accounting principles (" U. S.** GAAP **")** . ● Changes in effective tax rates or ~~adverse outcomes resulting~~ **results** from examination of ~~our~~ income or other tax returns. ● **The development** ~~Our engagement in related party transactions. ● We are subject to various privacy~~ and ~~consumer protection laws~~ **increased use of Artificial Intelligence presents operational risks and challenges that could damage our reputation or materially harm our business** . Risks Related to Our Industry ● Changes in government regulations or U. S. healthcare policy could force us to make modifications to how we develop, manufacture, market, and price our products **which may have a material adverse effect on our financial condition and results of operations** . ● Failure to obtain, or experience significant delays in obtaining, FDA clearances or other necessary approvals to commercially distribute new products. ● Risks associated with doing business outside of the U. S. ● We may incur product liability losses or become subject to other lawsuits related to our products, business, and insurance coverage could be inadequate or unavailable to cover these losses. ~~21 ● Defects or failures associated with our products and / or our quality control systems.~~ ● Our products or product types, or MR imaging could be subject to negative publicity. ● Healthcare fraud and abuse regulations could potentially result in significant liability, require us to change our business practices and / or restrict our operations in the future. ● Impact of violations of the U. S. Foreign Corrupt Practices Act and similar worldwide anti- bribery laws. ● We and our suppliers and customers are required to obtain regulatory approvals and maintain compliance with regulations applicable to medical devices and infusion pumps. ~~● Our operations are subject to environmental laws and regulations.~~ Risks Relating to our Intellectual Property ● Protection of ~~our~~ **confidential** intellectual property **, unpatented trade secrets, and proprietary technology** . ● Uncertainties associated with timely patent reviews and approvals. ● We may become involved in patent litigation or other intellectual property proceedings relating to our current and future products. ~~● Disclosure of confidential or proprietary information, unpatented trade secrets, know- how, confidential and proprietary technology.~~ Risks Related to Ownership of Our Common Stock ● Significant fluctuations and volatility of our common stock ~~. ●~~ ● Use of capital to repurchase shares of our common stock ~~and~~ **,** need or choice to raise additional capital in the future **, payment of dividends, or reduction or cessation of expected dividends. ● The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain executive management and qualified Board members** . ● The ability of Roger Susi, who serves as our Chairman of the Board ~~of Directors~~ , President and Chief Executive Officer, to exert significant influence over matters subject to stockholder approval due to his significant minority ownership. ● ~~Payment of dividends, or a reduction or cessation of expected dividends. ● The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain executive management and qualified board members. ● Failure to develop and maintain adequate internal controls or to implement new or improved~~

~~controls. ●~~ Impact of being a public company on our competitive environment and our risk of potential litigation ~~. ● Impact from our~~ **or** involvement in securities class action litigation, if any. **21** ● Impact of securities or industry analysts' failing to initiate research coverage of our stock, downgrading our stock, or discontinuing coverage. ~~22~~ ● Our charter documents and Delaware law have provisions that may discourage an acquisition of us by others and may prevent attempts by our stockholders to replace or remove our current management. Risks Relating to Our Business and Financial ConditionOur financial performance is significantly dependent on a limited number of products, and disruptions in our ability to sell these products may have a material adverse effect on our business. Our current revenue and profitability are significantly dependent on the sale of the MRidium 3860 MRI compatible IV infusion pump system, the 3880 MRI compatible patient vital signs monitoring system (both Class II medical devices) and the ongoing sale of related disposables and services. There can be no guarantee that in the future, the FDA will not impact our ability to commercially distribute. The FDA could require us to cease shipment of our products, notify health professionals and others that the devices present unreasonable risk or substantial harm to public health, order a recall, repair, replacement, or refund of the devices, detain or seize adulterated or misbranded medical devices, or ban the medical devices. The FDA may also issue warning letters or untitled letters, refuse future requests for 510 (k) submission or premarket approval, revoke existing 510 (k) clearances or premarket approvals previously granted, impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us. As inflationary measures have affected the greater market in the last ~~two~~ **several** years, we have considered the effects of inflation on our business operations and financial results. We have assessed that inflation has not had a material impact on our revenues, expenses, assets, liabilities, or cash flows for the current reporting period. We have also evaluated our exposure to future inflationary risk and concluded that it is not significant based on our current business model and market conditions. We have mitigated the impact of inflation on our cost of goods sold by continued operational efficiency. Our products could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to: ● entrance of new competitors into our markets; ● technological advancements of MRI scanners; ● technological developments such as new imaging modalities which render MRI procedures obsolete or reduce the instances where MRI imaging is utilized; ● loss of key relationships with suppliers, **IDNs** ~~integrated delivery healthcare systems~~, **GPOs** ~~group purchasing organizations~~, distributors, or direct end- user customers; ● manufacturing or supply interruptions; ● product liability claims; ● our reputation and product market acceptance; ● loss of existing regulatory approvals or the imposition of new requirements to maintain such approvals; and ● product recalls or safety alerts. Any major factor adversely affecting the sale of our products or services would cause our revenues to decline and have a material adverse impact on our business, financial condition, and our common stock. ~~23We have significant international sales as well as international supply chain links and we face risks related to health epidemics that could adversely affect our revenue. Our~~ **22Our** ~~business could be adversely impacted by the effects of various health epidemics. With respect to our sales, in the past, some customers implemented heightened security policies that inhibited the ability of our domestic sales force and international distributors to access hospitals for purposes of selling our products. This caused delays of orders for our products and negatively affected our revenues. These heightened security policies and delays of orders may be reinstated or continue. Our materials suppliers could also be disrupted by epidemic related conditions, possibly resulting in disruption to our supply chain. If our suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. In addition, a significant health epidemic could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products which could have a material adverse effect on our business, operating results and financial condition. Our~~ continued success depends on the integrity of our supply chain **and unaffiliated third** ~~, including multiple single source~~ **party** suppliers **for certain of our raw materials and components**, the disruption of which could negatively impact our business. Many of the component parts of our products are obtained through supply agreements with **unaffiliated** third parties. Some of these parts require our partners to engage in complex manufacturing processes and involve long lead times or delivery periods. Considering our dependence on third- party suppliers, several of which are single- source suppliers, we are subject to inherent uncertainties and risks related to their ability to produce or deliver parts on a timely basis, to comply with product safety and other regulatory requirements and to provide quality parts to us at a reasonable price ~~. For example, we are dependent upon a single vendor for the ultrasonic motor at the core of our devices. If this vendor fails to meet our volume requirements, which we anticipate will increase over time, or if the vendor becomes unable or unwilling to continue supplying motors to us, this would impact our ability to supply our devices to customers until a replacement source is secured. Our executed agreement with this vendor, which renewed in March 2024, provides that the price at which we purchase products from the vendor is determined by agreement from time to time or should material costs change. Although we have had a long history of stable pricing with this supplier, this provision may make it difficult for us to continue to receive motors from this vendor on favorable terms or at all if we do not agree on pricing in the future. In such event, it could materially and adversely affect our commercial activities, operating results, and financial condition~~. In the near term, we do not anticipate finding alternative sources for our primary suppliers ~~, including single source suppliers~~. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, or manufacture or deliver such materials later than anticipated, we could experience protracted delays or interruptions in the supply of materials which would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results, and financial condition. ~~Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of raw materials, parts, or finished products, could result in an interruption in the supply of certain products and a decline in our sales. We rely on third- party suppliers for certain of our raw materials and components. We rely on unaffiliated third- party suppliers for certain raw materials and components necessary for the manufacturing and operation of our products.~~ Certain ~~of those~~ raw materials and components are proprietary products of those unaffiliated third- party suppliers

and are specifically cited in our applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until an appropriate application amendment is approved by the regulatory agency. **If our material suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of raw materials, parts, or finished products, could result in an interruption in the supply of certain products and a decline in our sales.** ~~24Among -~~ **Among** the reasons we may be unable to obtain these raw materials and components include, but are not limited to: ● a supplier' s inability or unwillingness to continue supplying raw materials and / or components; ● regulatory requirements or action by regulatory agencies or others, including changes in international trade treaties and / or tariffs; ● adverse financial or other strategic developments at or affecting the supplier, including bankruptcy; ● unexpected demand for or shortage of raw materials or components; ● failure of the supplier to comply with quality standards which results in quality and product failures, product contamination and / or recall; ● discovery of previously unknown or undetected imperfections in raw materials or components; ● labor disputes or shortages, including from natural disasters and the effects of health emergencies or pandemics; and ● political instability and actual or anticipated military or political conflicts. These events could negatively impact our ability to satisfy demand for our products, which could have a material adverse effect on our products' use and sales and our business and results of operations. We may experience these or other shortages in the future resulting in delayed shipments, supply constraints, contract disputes and / or stock- outs of our products. **23A cyber security incident or failure to protect our information technology infrastructure could be disruptive to our business, compromise confidential data, cause reputation harm, adversely affect our business and operating results, subject us to litigation and federal and state governmental inquiries.** We **collect** ~~have been subject to securities class action litigation~~ and ~~derivative litigation,~~ **store sensitive business** and ~~we may be subject to similar or~~ other **information** ~~litigation in the future. In 2014~~ , ~~following adverse action by the FDA~~ **including intellectual property and trade secrets, on** ~~or~~ **our** ~~volatility in~~ **networks. Our business operations are dependent upon the secure maintenance of this information. Despite the implementation of security measures, our information technology systems and those of our vendors and customers are vulnerable to attack and damage from computer viruses, malware, denial of service attacks, unauthorized access,** ~~our -~~ **or** ~~stock price~~ **other harm** , ~~securities class action litigation has been brought against us~~ **including from threat actors seeking to cause disruption to our business** . ~~There can be no assurance~~ **We face risks related to the protection of information** that we **maintain- or engage a third- party to maintain on our behalf- including unauthorized access, acquisition, use, disclosure, or modification of such information. Cyberattacks are increasing in their frequency, sophistication, and intensity and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. Beyond external criminal activity, systems that access or control access to our services and databases may be compromised as a result of human error, fraud or malice on the part of employees or third parties, or may result from accidental technological failure. A material cyberattack or security incident could cause interruptions in our operations and could also damage our reputation, financial condition, and results of operations. If threat actors are able to circumvent or breach our security systems, they could steal any information located therein or cause serious and potentially long- lasting disruption to our operations. Security breaches or attempts thereof could also damage our reputation and expose us to a risk of litigation, sanctions, and / or monetary loss. We also face risks associated with security breaches affecting third parties that conduct business with us or our customers and others who interact with our data. While we maintain insurance that covers certain security incidents, we may not carry appropriate insurance or maintain sufficient coverage to compensate for damage from all events and related potential liability. We are subject to diverse laws and regulations relating to data privacy and security, such as federal and state data protection regulations, including the California Consumer Privacy Act, as amended, and European data privacy laws, including the General Data Protection Regulation. Complying with these numerous and complex regulations is expensive and difficult, and failure to comply with these regulations could result in regulatory scrutiny, civil liability and related fines, or damage to our reputation. In addition, any security breach or attempt thereof could result in liability for stolen assets or information, additional costs associated with repairing any system damage, incentives offered to clients or other business partners to maintain business relationships after a breach, and implementation of measures to prevent future breaches, including organizational changes, deployment of additional personnel and protection technologies, increased employee training, and engagement of third- party experts and consultants. The costs incurred to remediate any security incident could be substantial. In addition, we cannot assure you that any of our third- party service providers with access to our sensitive or confidential information, or to that of our customers and / or employees,** will not **experience** ~~face other securities~~ **security breaches** ~~litigation in the future. With respect to any litigation, our -~~ **or attempts thereof, which** ~~insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuits. A decision adverse to our interests on these actions or resulting from these matters could result in the payment of substantial damages and~~ could have a **corresponding** ~~material adverse~~ effect on our business ~~, financial condition, and our common stock. Regardless of the outcome, these claims may result in injury to our reputation, significant costs, diversion of management' s attention and resources, and loss of revenue. There is no assurance that our internal and external sources of liquidity will at all times be sufficient for our cash requirements. We must have sufficient sources of liquidity to fund our working capital requirements, our capital improvement plans, to return cash to shareholders via stock repurchases and / or dividends and execute on our strategic initiatives. A decline in operating results could limit our generation of capital resources and cause financial stresses if we are unable to increase revenues or adjust our costs appropriately to changes in revenue. Further, future new product launches or~~

~~investments in other growth initiatives may demand increased working capital before any long- term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, which cannot at all times be assured. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plan, pursuing additional financing to the extent available, reducing capital expenditures, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity and other potential 25actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position~~ . The manufacture of our products requires strict adherence to regulatory requirements governing medical devices and if we or our suppliers encounter problems our business could suffer. The manufacture of our products must comply with strict regulatory requirements governing Class II medical devices in the U. S. and other regulatory requirements in foreign locations. Problems may arise during manufacturing, quality control, storage, or distribution of our products for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, manufacturing quality concerns, or problems with raw materials, electromechanical, software and other components, supplier issues, and natural disasters. If problems arise during production, the affected products may have to be discarded. Manufacturing problems or delays could also lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, voluntary recalls, corrective actions, or product liability related ~~costs~~ **24costs** may also be incurred. Should we encounter difficulties in the manufacture of our products or be subject to a product recall, our business could suffer materially. Our markets are very competitive, and we sell certain of our products in a mature market. The market for our 3880 MRI compatible patient vital signs monitoring system is well- developed and sales growth for our monitor could be slower than we anticipate. Our vital signs monitoring system could face difficult competition, including competitors offering lower prices, which could have an adverse effect on our revenue and margins. Our competitors may have certain advantages, which include the ability to devote greater resources to the development, promotion, and sale of their products. Consequently, we may need to increase our efforts, and related expenses for research and development, marketing, and selling to maintain or improve our position. We may not realize the per unit revenue we have planned for and expect. Continued sales to our existing customers are expected to be significant to our revenue in the future, and if our existing customers do not continue to purchase from us, our revenue may decline. We manufacture and store our products at a single facility in Florida. We manufacture and store our products at a single facility in Winter Springs, Florida **, which is also the location of our principal executive offices** . If by reason of fire, hurricane, or other natural disaster, or for any other reason, the facility is destroyed or seriously damaged or our access to it is limited, our ability to provide products to our customers would be seriously interrupted or impaired completely and our operating results and financial condition would be materially and negatively affected. Our **insurance** ~~inability to collect on our accounts receivables from customers~~ may ~~have~~ **not cover our losses in** ~~an~~ **any** ~~adverse effect on~~ **particular case. In addition, regardless of the level of insurance coverage, damage to our facility may harm** our business **,** ~~operations and~~ financial condition **,** ~~. We market our products to end users in the United States and to distributors internationally. Sales to end users in the United States are generally made on open credit terms. Management maintains an~~ **and** ~~allowance~~ **operating results. Our manufacturing facility in Winter Springs, Florida, is our only manufacturing facility, and if it is damaged orrendered inoperable or inaccessible due to political, social or economic upheaval or due to natural or other disasters, itwould be difficult or impossible** for ~~potential credit losses. From~~ **us to manufacture our product for a period of** time ~~to time~~ , **which** ~~we have had, and~~ may **lead to a loss of** ~~in the future have, accounts receivables from one or more affiliated~~ customers ~~that accounted for 10 percent or more of our gross accounts receivable. As a result, we may be exposed to a certain level of concentration of credit risk. If a major customer experiences financial difficulties, the effect on us could be material and have an~~ **and** ~~adverse effect on~~ **significant impairment of** our ~~business,~~ financial condition ~~,~~ and **operating** results ~~of operations~~ . **If** ~~Additionally, the recent health pandemic has and may continue to cause delays in payments from customers, which may adversely impact our future results of operations and liquidity. 26If~~ we fail to maintain relationships with **IDNs** ~~Integrated Delivery Networks~~ and **GPOs** ~~Group Purchasing Organizations~~ , sales of our products could decline. Our ability to sell our products to U. S. hospitals, acute care facilities and outpatient imaging centers depends in part on our relationships with **IDNs** ~~Integrated Delivery Networks~~ and ~~Group Purchasing Organizations (“~~ GPOs ~~”)~~ . Many existing and potential customers for our products are members of GPOs. GPOs negotiate pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO’ s affiliated hospitals and other members. We pay the GPOs an administrative fee in the form of a percentage of the volume of products sold to their affiliated hospitals and other members. If we are not an approved provider selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products. Should a GPO negotiate a sole source or bundling contract covering a future or current competitor’ s products, we may be precluded from making sales of our competing products to members of that GPO for the duration of the contractual arrangement. For example, even if we have an existing contract with a GPO for sales of our MRidium 3860 MRI compatible IV infusion pump, we may encounter difficulties in selling, or be unable to sell, our 3880 MRI compatible patient vital signs monitoring system to that GPO’ s affiliated hospitals and other members, which may result in a longer sales cycle or an inability to sell. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition, and results of operations. In the future, if another competitive supplier emerges, and we fail to keep our relationships and develop new relationships with GPOs, our competitive position would likely suffer. ~~Cost- containment efforts of our~~

~~customers and purchasing groups could adversely affect our sales and profitability. Our MRI compatible medical devices are considered capital equipment by many potential customers, and hence changes in the budgets of healthcare organizations and the timing of spending under these budgets and conflicting spending priorities, such as spending related to the recent health pandemic, may have a significant effect on the demand for our products and related services. Any decrease in expenditures by these healthcare facilities could decrease demand for our products and related services and reduce our revenue. Additionally, changes to reimbursement policies by third- party payors could also decrease demand for MR procedures and hence also for our products and related services and reduce our revenue. Any failure in our efforts to access and educate clinicians, anesthesiologists, radiologists, and hospital administrators regarding the advantages of our products could significantly limit our product sales. We believe our future success will require us to educate a sufficient number of clinicians, anesthesiologists, radiologists, hospital administrators and other purchasing decision- makers about our products and the costs and benefits of our products. If we fail to demonstrate the safety, reliability and economic benefits of our products to hospitals and acute medical facilities, our products may not be adopted, and our expected and actual sales would suffer.~~ The lengthy sales cycle for medical devices could delay our sales. The decision- making process of customers is often complex and time- consuming. Based on our experience, we believe the period between initial discussions with customers regarding our products and a customer' s purchase of our ~~products~~ **25products** have varied widely and have historically ranged between three and six months in duration. Sales cycles can also be delayed because of capital budgeting procedures. Moreover, even if one or two units are sold to a hospital, we believe that it will take additional time and experience with our products before other medical professionals routinely use them for other procedures and in other departments of the hospital. Such time would delay potential sales of additional units and disposable products or additional optional accessories to that medical facility or hospital. These delays could have an adverse effect on our business, financial condition, and results of operations. ~~27Because -~~ **Because** we rely on distributors to sell our products outside of the U. S., our revenues could decline if our existing distributors do not continue to purchase products from us or if our relationship with any of these distributors is terminated. We rely on distributors for all our sales outside the U. S. and hence do not have direct control over foreign sales activities. These distributors also assist us with regulatory approvals and the education of physicians and government agencies. Our revenues outside the U. S. ~~have recently~~ **in fiscal year 2024** represented approximately ~~20~~ **17** percent of our net revenues. If our existing international distributors fail to sell our products or sell at lower levels than we anticipate, we could experience a decline in revenues or fail to meet our forecasts. We cannot be certain that we will be able to attract new international distributors nor retain existing ones that market our products effectively or provide timely and cost- effective customer support and service. None of our existing distributors are obligated to continue selling our products. If we do not successfully develop and commercialize enhanced products or new products that remain competitive, we could lose revenue opportunities and customers, and our ability to achieve growth would be impaired. The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long- term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for MRI compatible infusion, therapeutic, diagnostic and safety products and services. The research and development process is time- consuming and costly and may not result in products or applications that we can successfully commercialize. If we do not successfully adapt our technology, products, and applications, we could lose revenue opportunities and customers. In addition, we may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business. We are highly dependent on our founder, Chairman **of the Board of Directors** , President and Chief Executive Officer, Roger Susi. We believe that Mr. Susi will continue to play a significant role in the development of new products. Our current and future operations could be adversely impacted if we were to lose his services. Accordingly, our success will be dependent on appropriately managing the risks related to maintaining his continued services, including having a succession plan. ~~If we fail to attract and retain the talent required for our business, our business could be materially harmed. Competition for highly skilled personnel is often intense in the medical device industry, including in the MRI compatible medical device segment. If our current employees with experience in the MRI compatible device industry leave our company, we may have difficulty finding replacements with an equivalent amount of experience and skill, which could harm our operations. Our future success will also depend in part on our ability to identify, hire and retain additional personnel, including executives, skilled engineers to develop new products and sales and production staff.~~ We ~~may not be successful in attracting, integrating, or retaining qualified personnel to meet our current growth plans or future needs. Our productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively. Any one of our executive officers or other key employees could terminate his or her relationship with us at any time. The loss of one or more of our executive officers or key employees, and any failure to have in place and execute an effective succession plan for key executive officers, could significantly delay or prevent us from achieving our business and / or development objectives and could materially harm our business. Changes in our executive management team may also cause disruptions in, and harm to, our business. We may also have difficulty finding and retaining qualified Board members. Any failure to do so could be perceived negatively and could adversely affect our business. Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product. 28We ~~~~may be unable to scale our operations successfully. We are working to expand our size and scale via more penetration of existing markets and the launch of new complementary products and updates to existing products. This growth, if it occurs as planned, will place significant demands on our management and manufacturing capacity, as well as our financial, administrative, and other resources. We cannot guarantee that any of the personnel, systems, procedures ~~and ~~**,** controls **and new facilities** we put in place will be adequate to support the manufacture and distribution of our products. Our operating results will depend substantially on the ability of our officers and key employees to manage changing business conditions and to implement and improve our financial and administrative systems and manage other resources. If we are unable to respond to and manage

changing business conditions, or the scale of our products, services, and operations, then the quality of our services, our ability to retain key personnel and our business could be harmed. In February 2023, we purchased 26 acres of land in Orlando, Florida **and continue construction** on ~~which we plan to build~~ an expanded facility to increase capacity. Any failure to successfully **complete** ~~construct~~ **construction** and operate such a facility expansion might limit our ability to grow as we expect. We do not plan to retain the current Winter Springs, Florida leased facility once the larger facility is fully operational. ~~We~~ **26We** engage in related party transactions, which result in a conflict of interest involving our management. We have engaged in the past, and continue to engage, in related party transactions, particularly between our ~~company~~ **Company** and Roger Susi and his affiliates. The only significant ongoing related party transaction is the lease agreement between our ~~company~~ **Company** and Susi, LLC, an affiliate of Roger Susi, with respect to our current sole production and headquarters facility in Winter Springs, Florida. Related party transactions that present difficult conflicts of interest, could result in disadvantages to our ~~company~~ **Company** , and may impair investor confidence, which could materially and adversely affect us. Related party transactions could also cause us to become materially dependent on related parties in the ongoing conduct of our business, and related parties may be motivated by personal interests to pursue courses of action that are not necessarily in the best interests of our ~~company~~ **Company** and our stockholders. The **newly constructed, larger** ~~purchase of land and the planned expanded~~ facility **, expected to be occupied in mid- 2025,** will reduce **our** related party transaction exposure by the eventual termination of the **current** lease with Susi, LLC ~~. Any acquisitions of technologies, products, and businesses may be difficult to integrate, could adversely affect our relationships with key customers, and / or could result in significant charges to earnings. We periodically evaluate potential acquisitions of technologies, products and businesses that are complementary to our products and that could accelerate our growth. However, our company has never completed an acquisition and there can be no assurance that we will be successful in finding any acquisitions in the future. The process of identifying, executing, and realizing attractive returns on acquisitions involves a high degree of uncertainty. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies, and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock~~ . The environment in which we operate makes it difficult to accurately forecast our business performance. Significant changes and volatility in most aspects of the current business environment, including financial markets, customer behavior, speed of technological, regulatory, and competitive changes, and the recent health pandemic, make it increasingly difficult for us to predict our revenues and earnings into the future. Our quarterly sales and profits depend substantially on the volume and timing of orders fulfilled during the quarter, and such orders are difficult to forecast. Product demand is dependent upon the capital spending budgets of our customers and prospects as well as government funding policies and matters of public policy as well as product and economic cycles that can affect the spending decisions of these entities. As a result, any revenue, earnings or financial guidance or outlook which we have given or might give may turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues, earnings, and financial information at the time we give such guidance, based on then- current conditions, there is a significant risk that such guidance or outlook will turn out to be incorrect. Historically, companies that have overstated their operating guidance have suffered significant declines in their stock price when such **lesser** results are announced to the public. ~~29There~~ -- **There** are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with **U. S.** GAAP. Furthermore, portions of **U. S.** GAAP require the use of fair value models which are variable in application and methodology from appraiser to appraiser. Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position, and operating results. The preparation of financial statements in conformity with **U. S.** GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such assumptions and estimates include those related to revenue recognition, accruals for product returns, allowances for doubtful accounts, valuation of inventory, impairment of intangibles and long- lived assets, accounting for leases, accounting for income taxes and stock- based compensation and allowances for uncertainties. These factors are also influenced by regular changes to **U. S.** GAAP, some of which are material to many companies. These changes introduce risk to our financial reporting processes due to implementation and internal control implications. We base the aforementioned estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " Our actual operating results may differ and fall below our assumptions and the financial forecasts of securities analysts and investors, resulting in a significant decline in our stock price. Changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results. **In July 2024, the Company received notice of examination from the U. S. Internal Revenue Service (the " IRS ") for the tax year ended December 31, 2021.** We **are currently complying with the taxing authority and believe our tax position for the year under review was appropriate and have not accounted for any proposed adjustments at this time. 27We** are subject to the continuous examination of our income tax returns by the ~~Internal Revenue Service, or~~ IRS ~~,~~ and other tax authorities. It is possible that tax authorities may disagree with certain positions we have taken, and any adverse outcome of such a review or audit could have a negative effect on our financial position and operating results. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes, but the determination of our provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded in our financial statements and may materially affect our financial results in the period or periods for which such determination is made. There can be no assurance that the outcomes from continuous examinations will not have an adverse effect on our business, financial condition, and results of operations. ~~We are~~ **The constant growth and development of**

technology, including the increased use of Artificial Intelligence, presentsrisks and challenges to our operations that could give rise to legal or regulatory action, damage our reputation or otherwise materially harm of our business. Emerging technology is a consistent subject **of new** ~~to various privacy and consumer protection~~ laws ~~. Our privacy policy is posted on our~~ **or regulations** ~~website,~~ and ~~any failure by us or our vendor or other business partners~~ **evolving interpretations and applications of laws and regulations. If we fail** to comply with ~~it~~ **these laws, we may be subject to penalties, fines or criminal or civil liability. The development and use of Artificial Intelligence (" AI ") presents new risks and challenges that can impact** ~~or~~ **our** ~~with federal, state,~~ **operations if we incorporate AI into** ~~or~~ **our operations, or if used by our third-party vendors. While we aim to develop and use AI responsibly and attempt to mitigate ethical and legal issues presented by its use, we may ultimately be unsuccessful in identifying or resolving issues before they arise. AI technologies are complex and rapidly evolving and the technologies that we develop or use may ultimately be flawed. If our AI technologies fail to operate as anticipated or not perform as specified, including any biases or errors in the outputs of AI, patient care may be affected, legal claims may be asserted against us and our reputation may be harmed. Moreover, AI technology is subject to rapidly evolving domestic and** international **laws and regulations, which could impose significant costs and obligations on the Company. For example, in 2023 the Biden Administration issued a new, executive order on safe, secure and trustworthy AI, including transparency requirements for AI and other predictive algorithms that are part of certified health information technology. Some states have adopted or are considering additional measures regarding the use of AI within the health care industry. Emerging regulations may pertain to data** privacy, data protection ~~or security laws or regulations~~ **, and the ethical use of AI, as well as clarifying intellectual property considerations. Our use of AI** could ~~result in~~ **give rise to legal or** regulatory ~~or litigation- related actions~~ **action** ~~against us~~, ~~legal~~ **increased scrutiny or** liability, ~~fines, damages~~ **damage** ~~, and other costs~~ **our reputation or otherwise materially harm our business** . **Additionally, if we fail to keep pace** ~~Substantial expenses and operational changes may be required in connection~~ with **various AI technological developments** ~~maintaining compliance with such laws~~ , ~~and in particular certain emerging privacy laws are still subject to a high degree of uncertainty as to their interpretation and application. For example, in May 2018, the General Data Protection Regulation (the " GDPR ") began to fully apply to the processing of personal information collected from individuals located in the European Union. The GDPR has created new compliance obligations and has significantly increased fines for noncompliance. Although we take steps to protect the security of our customers' personal information, we may be required to expend significant resources to comply with data breach requirements if third parties improperly obtain and use the personal information of our customers or~~ **our competitive position** ~~we otherwise experience a data loss with respect to customers' personal information. A breach of our network security~~ and ~~systems could have negative consequences for our~~ business **results may benegatively impacted** ~~and future prospects, including possible fines, penalties and damages, reduced customer demand for our products, and harm to our reputation and brand~~ . ~~30Risks~~ -- **Risks** Related to Our IndustryWe are subject to substantial government regulation that is subject to change and could force us to make modifications to how we develop, manufacture, market, and price our products. The medical device industry is regulated extensively by governmental authorities, principally the FDA in the U. S. and corresponding state and foreign regulatory agencies. The majority of our manufacturing processes are required to comply with quality systems regulations, including current good manufacturing practice requirements that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. Failure to comply with applicable medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspensions of production, refusal of the FDA or other regulatory agencies to grant pre- market clearances or approvals for our products, withdrawals, or suspensions of future or current clearances or approvals and criminal prosecution. In addition, our products are subject to pre- clearance requirements by the FDA and similar international agencies that govern a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales, and distribution. Compliance with these regulations is time consuming, burdensome, and expensive for us. The failure to obtain, or the loss or suspension of any such pre- approval, would negatively affect our ability to sell our products and harm our anticipated revenues. ~~Foreign~~ **28Foreign** governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we sell our products in foreign countries, we may be subject to more rigorous regulation in the future. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenue. If we fail to obtain, or experience significant delays in obtaining, FDA clearances or other necessary approvals to commercially distribute new products, our ability to maintain profitability or grow will suffer. Our current products are Class II medical devices and hence require regulatory pre- market approval by the FDA and other federal and state authorities prior to their sale in the U. S. Similar approvals are required by foreign governmental authorities for sale of our products outside of the U. S., including the EU. We are responsible for obtaining the applicable regulatory approval for the commercial distribution of our products. As part of our strategy, we plan to seek approvals for new or improved MRI compatible products. The process of obtaining approvals is costly and time consuming, and there can be no assurance that we will obtain the required approvals on a timely basis, or at all. Failure to receive approvals for new products will hurt our ability to grow. We are subject to risks associated with doing business outside of the U. S. Sales to customers outside of the U. S. **were** ~~have recently been~~ approximately ~~20~~ **17** percent of our net revenues **in 2024** and we expect that non- U. S. sales will contribute to future growth. A majority of our international sales originate from Europe and Japan, and we also make sales in Canada, Hong Kong, Australia, Mexico and certain parts of the Middle East. The risks associated with operations outside the U. S. include: ● foreign regulatory and governmental requirements that could change and restrict our ability to manufacture and sell our products; ● possible failure to comply with anti- bribery laws such as the U. S. Foreign Corrupt Practices Act and similar anti- bribery laws in other jurisdictions; ● foreign currency fluctuations that can impact our financial statements when foreign denominations **, particularly the Japanese yen,** are translated into U. S. dollars; ~~31~~ ● different local product preferences and product

requirements, which might increase with increasing nationalism; ● trade protection and restriction measures under international trade treaties and via tariffs, and import or export licensing requirements; ● difficulty in establishing, staffing and managing non- U. S. operations; ● failure to maintain relationships with distributors, especially those who have assisted with foreign regulatory or government clearances; ● uncertainties regarding judicial systems and procedures, changes in labor, environmental, health and safety laws; ● healthcare crises or epidemics; ● potentially negative consequences from changes in or interpretations of tax laws, including U. S. state and foreign tax jurisdiction responses to recent changes in U. S. federal tax laws **and tariff practices** ; ● political instability and actual or anticipated military or political conflicts, including instability related to war and terrorist attacks, such as Russia' s invasion of Ukraine, and **conflict in** ~~to political matters, such as~~ the ~~U. K.' s Brexit~~ **Middle East; 29 ● longer payment cycles** ; ● economic instability, inflation, deflation, recession or interest rate fluctuations; ● potential disruption in supply chains; and ● minimal or diminished protection of intellectual property. These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition. We may incur product liability losses or become subject to other lawsuits related to our products, business, and insurance coverage could be inadequate or unavailable to cover these losses. Our business is subject to potential product liability risks that are inherent in the design, development, manufacture and marketing of our medical devices and disposable products. We carry third- party product liability insurance coverage to protect against such risks, but there can be no assurance that our policy is adequate. In the ordinary course of business, we may become the subject of product liability claims and lawsuits alleging that our products have resulted or could result in an unsafe condition or injury to patients. Any product liability claim brought against us, with or without merit, could be costly to defend and could result in settlement payments and adjustments not covered by or in excess of our product liability insurance. We currently have third- party product liability insurance with maximum coverage of $ 5, 000, 000; however, such coverage requires a substantial deductible that we must pay before becoming eligible to receive any insurance proceeds. The deductible amount is currently equal to $ 50, 000 per occurrence and $ 150, 000 in the aggregate. We will have to pay for defending product liability or other claims that are not covered by our insurance. These payments could have a material adverse effect on our profitability and financial condition. Product liability claims and lawsuits, safety alerts, recalls or corrective actions, regardless of their ultimate outcome, could have a material adverse effect on our business, financial condition, reputation and on our ability to attract and retain customers. In addition, we may not be able to obtain insurance in the future on terms acceptable to us or at all. ~~32Defects or failures associated with our products and / or our quality control systems could lead to the filing of adverse event reports, recalls or safety alerts and negative publicity and could subject us to regulatory actions. Safety problems associated with our products could lead to a product recall or the issuance of a safety alert relating to such products and result in significant costs and negative publicity. An adverse event involving one of our products could require us to file an adverse event report with the FDA. Such disclosure could result in reduced market acceptance and demand for all our products and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals or clearances. We may also voluntarily undertake a recall of our products or temporarily shut down production lines based on internal safety, quality monitoring and testing data. To avoid future product recalls we have made and continue to invest in our quality systems, processes, and procedures. We will continue to make improvements to our products and systems to further reduce issues related to patient safety. However, there can be no assurance our efforts or systems will be sufficient. Future quality concerns, whether real or perceived, could adversely affect our operating results.~~ Our products or product types, or MR imaging could be subject to negative publicity, which could have a material adverse effect on our financial position and results of operations and could cause the market value of our common stock to decline. The market' s perception of our products could be harmed if any of our products or similar products offered by others in our industry become the subject of negative publicity due to a product safety issue, withdrawal, recall, or are proven or are claimed to be harmful to patients. The harm to market perception may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. Our products are designed for use around MRI scanners. MRI has been an important imaging diagnostic for some time now, however, should traditional MRI technology change materially or decline in usage due to new technologies or concerns about costs or efficacy of MR imaging, our products would suffer as MRI usage and installations declined. Such a matter may also have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. U. S. healthcare policy and changes thereto, including the Patient Protection and Affordable Care Act, may have a material adverse effect on our financial condition and results of operations. Our medical devices and business activities are subject to rigorous regulation by the FDA and other federal, state and international governmental authorities. These authorities and members of Congress have been increasing their scrutiny over the medical device industry. **The current government administration has not indicated whether it will continue to scrutinize our industry as closely as it has in** ~~In recent years, Congress, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services and the Department of Defense have issued subpoenas and other~~ -- **the** ~~requests~~ **past. Any new regulations** ~~for~~ - **or** ~~information to medical device manufacturers~~ **statutory provisions could result in delays or increased costs during the periods of product development** , **clinical trials and** ~~primarily related to financial arrangements with healthcare providers,~~ regulatory **review and approval, as well as increased costs to assure** compliance ~~and marketing and product promotional practices~~ . Furthermore, certain state governments have enacted ~~legislation~~ **30legislation** to limit and / or increase transparency of interactions with healthcare providers, pursuant to which we are required by law to disclose payments and other transfers of value to healthcare providers licensed by certain states. ~~We anticipate~~ **In addition, with the current political climate, funding adjustments** that **change** ~~the government will continue to scrutinize our~~ - **or impact Medicare** ~~industry closely, and any new regulations~~ or **Medicaid** ~~statutory provisions could result in delays or increased costs during the periods of product development, clinical trials and regulatory review and approval,~~ as well as ~~increased costs~~ **general**

uncertainties regarding these programs may impact a hospitals ability to ~~assure compliance~~ **honor payment obligations** . ~~33We~~ **We** are subject to healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future. We and our customers are subject to various U. S. federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti- kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment, and exclusion from participation in healthcare programs such as Medicare and Medicaid, and Veterans' Administration health programs and health programs outside the U. S. These laws and regulations are broad in scope and are subject to evolving interpretations, which could require us to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our sales, profitability, and financial condition. Furthermore, since many of our customers rely on reimbursement from Medicare, Medicaid, and other governmental programs to cover a substantial portion of their expenditures, if we or our customers are excluded from such programs as a result of a violation of these laws, it could have an adverse effect on our results of operations and financial condition. We have developed and implemented business practices and processes to train our personnel to perform their duties in compliance with healthcare fraud and abuse laws and conduct informal oversight to detect and prevent these types of fraud and abuse. However, we lack formal written policies and procedures at this time. If we are unable to formally document and implement the controls and procedures required in a timely manner or we are otherwise found to be in violation of such laws, we might suffer adverse regulatory consequences or face criminal sanctions, which could harm our operations, financial reporting, or financial results. We could be adversely affected by violations of the U. S. Foreign Corrupt Practices Act and similar worldwide anti- bribery laws. The U. S. Foreign Corrupt Practices Act and similar worldwide anti- bribery laws generally prohibit companies and their intermediaries from making improper payments to non- U. S. officials for the purpose of obtaining or retaining business. We intend to adopt policies for compliance with these anti- bribery laws, which often carry substantial penalties. We cannot assure you that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees, or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. We and our suppliers and customers are required to obtain regulatory approvals ~~to comply~~ **and maintain compliance** with regulations applicable to medical devices, including infusion pumps, and these approvals could result in delays or increased costs in developing new products **, subject us to sanctions and could adversely affect our business** . In December 2014, the FDA issued guidance entitled " Infusion Pumps Total Product Life Cycle. " This guidance established substantial additional pre- market requirements for new and modified infusion pumps. Through this guidance, the FDA indicated more data demonstrating product safety will be required for future 510 (k) submissions for infusion pumps, including the potential for more clinical and human factors data. The process for obtaining regulatory approvals to market infusion pumps and related accessories have become more costly and time consuming. The impact of this guidance is likely to result in a more time consuming and costly process to obtain regulatory clearance to market infusion pumps. In addition, new requirements could result in longer delays for the clearance of new products, modification of existing infusion pump products or remediation of existing products in the market. Future delays in the receipt of, or failure to obtain, approvals could result in delayed or no realization of product revenues. ~~34We and our suppliers and customers are required to maintain compliance with regulations applicable to medical devices, including infusion pumps, and it could be costly to comply with these regulations and to develop compliant products and processes. Failure to comply with these regulations could subject us to sanctions and could adversely affect our business. Even~~ **31Even** if ~~we are~~ able to obtain approval for introducing new products to the market, we and our suppliers may not be able to remain in compliance with **the** applicable FDA and other material regulatory requirements once clearance or approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling, off- label marketing, advertising and post- marketing reporting, adverse event reports and field alerts. Compliance with these FDA requirements is subject to continual review and is monitored through periodic inspections by the FDA. ~~For example, the FDA conducted routine inspections of our facility in Winter Springs, Florida in June 2019. The FDA issued a Form 483 on June17, 2019 resulting from an inspection of our facility between June 11 and June 17, 2019, that identified three observations. These observations were related to procedural and documentation issues associate, vendor requirements and complaint investigation. We submitted responses to the Form 483 in July 2019 in which we described our proposed corrective and preventative actions to address each of the observations. We received an acknowledgement letter from the FDA, on October 1, 2019, noting the proposed corrective and preventative actions were reviewed and appeared adequate.~~ In addition, manufacturing flaws, component failures, design defects, off- label uses by practitioners, or inadequate disclosure of product related information could result in an unsafe condition or the injury or death of a patient. All these events could harm our sales, margins and profitability in the affected periods and may have a material adverse effect on our business. Any adverse regulatory action or action taken by us to maintain appropriate regulatory compliance, with respect to these laws and regulations could disrupt our business and have a material adverse effect on our sales, profitability, and financial condition. Furthermore, an adverse regulatory action with respect to any of our products or operating procedures or to our suppliers' manufacturing facilities could materially harm our reputation in the marketplace. ~~Our operations are subject to environmental laws and regulations, with which compliance is costly and which exposes us to penalties for non- compliance. Our business, products, and product candidates are subject to federal, state, and local laws and regulations relating to the protection of the environment, worker health and safety and the use, management, storage, and disposal of hazardous substances, waste, and other regulated materials. These environmental laws and regulations could require us to pay for environmental remediation and response costs at third- party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations.~~ Risks Relating to our Intellectual PropertyOur success depends on our ability to protect our intellectual property **,**

unpatented trade secrets, know- how, confidential and proprietary information, and technology . We intend to rely on a combination of patents, trademarks, trade secrets, know- how, license agreements and contractual provisions to establish and protect our proprietary rights to our technologies and products. We cannot guarantee that the steps we have taken or will take to protect our intellectual property rights will be adequate or that they will deter infringement, misappropriation, or violation of our intellectual property. We may fail to secure patents that are important to our business, and we cannot guarantee that any pending U. S. trademark or patent application, if ultimately issued, will provide us some relative competitive advantage. Litigation may be necessary to enforce our intellectual property rights and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expenses and may not adequately protect our intellectual property rights. In addition, the laws of some of the countries in which our products may in the future be sold may not protect our products and intellectual property to the same extent as U. S. laws, or at all. We may be unable to protect our rights in ~~35trade --~~ **trade** secrets and unpatented proprietary technology in these countries. If our trade secrets become known, we may lose our competitive advantages. Even if we are able to secure necessary patents in the U. S., we may not be able to secure necessary patents and trademarks in foreign countries in which we sell our products or plan to sell our products. In 2013, the U. S. transitioned to a " first inventor to file " system for patents in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to a patent. We may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. ~~Our unpatented trade secrets, know- how, confidential and proprietary information, and technology may be inadequately protected.~~ We rely on unpatented trade secrets, know- how and technology. This intellectual property is difficult to protect, especially in the medical device industry, where much of the information about a product must be submitted to regulatory authorities during the clearance process. We seek to protect trade secrets, confidential information, and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other ~~breaches~~ **32breaches** of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, ~~board~~ **Board** members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us. If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know- how, we would not be able to effectively assert our trade secret protections against them, which could have a material adverse effect on our business. There can be no assurance of timely patent review and approval ~~to~~ **that would** minimize competition and **allow us to** generate sufficient revenues. There can be no assurance that the **U. S.** Patent and Trademark Office will have sufficient resources to review our patent applications in a timely manner. Consequently, even if our patent applications are ultimately successful, our patent applications may be delayed, which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition, and operations. ~~36We~~ **We** may become involved in patent litigation or other intellectual property proceedings relating to our current and future product clearances, which could result in liability for damages or delay or stop our development and commercialization efforts. The medical device industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties (which may have substantially greater resources than we have) initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following: ● stop selling, making, or using products that use the disputed intellectual property; ● obtain a license from the intellectual property owner to continue selling, making, licensing, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all; ● pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing; ● pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; or ● redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and / or infeasible. ~~If~~ **33If** any of the foregoing events occur, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. As the number of participants in our industry grows, the possibility of intellectual property infringement claims against us increases. Furthermore, the costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial.

Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time. In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult, and time- consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time- consuming and could divert our management' s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business. There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement (s) have not been finally resolved by the courts (i. e., an " at- risk launch "). The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. An adverse decision could have a material adverse effect ~~37on~~ **on** our business, financial position and results of operations and could cause the market value of our common stock to decline. In addition, we may indemnify our customers and distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. ~~We may be subject to claims that we, our board members, employees, or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information. As is commonplace in the medical device industry, some of our board members, employees and consultants are or have been associated with other medical device companies that compete with us. For example, Mr. Susi and a number of our other employees are former employees of other medical device firms. While associated with such other companies, these individuals may have been exposed to research and technology similar to the areas of research, technology, sales methodology, pricing models and other such matters in which we are engaged. We may become subject to future claims that we, our employees, board members, or consultants have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims. We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non- executive directors because they have a fiduciary duty of confidentiality as directors. There is the possibility that any of our former board members, employees, or consultants who are currently or who may be employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.~~ Risks Related to Ownership of Our Common StockOur common stock price has been and will likely continue to be subject to significant fluctuations and volatility, and you may be unable to sell your shares at a fair price, or at all. Our stock could be subject to wide fluctuations in price in response to various factors, including the following: ● ~~a~~ **sales of large blocks of our stock or** lack of liquidity in the public trading of our common stock; ● the commercial success or failure of our key products; ● delayed or reduced orders from our customers; ● **negative developments concerning our sources of manufacturing or** manufacturing or supply interruptions; ● changes or developments in laws or regulations applicable to our products and product candidates; ● introduction of competitive products or technologies; **34** ● poorly executed acquisitions or acquisitions whose projected potential is not realized; ● actual or anticipated variations in quarterly operating results; ~~38~~ ● failure to meet or exceed our own estimates and projections or the estimates and projections of securities analysts or investors; ● new or revised earnings estimates or guidance by us or securities analysts or investors; ● varying economic and market conditions in the U. S.; ● negative developments impacting the medical device industry in general and changes in the market valuations of companies deemed similar to us ~~; ● negative developments concerning our sources of manufacturing supply~~ ; ● disputes or other developments relating to patents, trademarks or other proprietary rights; ● litigation or investigations involving us, our industry, or both; ● issuances of debt, equity or convertible securities at terms deemed unfavorable by the market; ● major catastrophic events; ● ~~sales of large blocks of our stock; ●~~ changes in our Board of Directors, management or key personnel; or ● the other factors described in this " Risk Factors " section. Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results, fluctuations in our share price and investors' perception of our business. If we fail to meet or exceed such expectations, our business and stock price could be materially adversely affected. Any use of capital to repurchase shares of our common stock, **need to** or **choice to raise future capital,** the election to continue **, reduce or cease** to pay a regular cash dividend, could have a material adverse effect on our stock price and our business. Our Board of Directors has historically authorized stock repurchase programs and, pursuant to these authorizations, we have used a significant amount of cash to repurchase shares of common stock of our ~~company~~ **Company** . **If** ~~During 2016 and 2017, we repurchased 779, 135 shares of our common stock for approximately $ 11. 8 million. While those stock repurchase programs have expired, should~~ our Board of Directors authorize another stock repurchase program, there can be no assurance that we will be able to repurchase shares on favorable terms or, if we do repurchase shares, that such repurchases will increase ~~shareholder~~ **stockholder** value. Stock repurchases now are burdened with a ~~Federal~~ **federal** excise tax which diminishes their attraction to deliver returns to ~~shareholders~~ **stockholders** . In ~~December~~ **February** ~~2023~~ **2025** , our Board of Directors declared a ~~special~~ **regular quarterly** cash dividend of $ 0. ~~48~~ **17** per share ~~and the initiation of a regular quarterly dividend of $ 0. 15 per share. The special cash dividend and the first quarterly dividend are payable on January 12, 2024, to shareholders of record at the close of business on~~

~~December 18, 2023~~ . Even though our ~~board~~ **Board** of ~~directors~~ **Directors** has approved the payment of a regular quarterly cash dividend on the Company' s common stock, there can be no assurance as to whether or when we may pay dividends on our common stock in the future. Future dividends, if any, will be declared and paid at the discretion of the ~~Company' s board~~ **Board** of ~~directors~~ **Directors** and will depend on a number of factors ~~. Similarly, on February 2, 2023, the Board of Directors declared a special cash dividend of $ 1. 05 per share on the Company' s common stock. On February 21, 2023, we paid $ 13, 222, 907 to shareholders of record at the close of business on February 13, 2023~~ . In the future, the Board of Directors may elect to allocate capital based on our continued ability to generate cash from operations, our capital needs to support normal operations, and making investments ~~that are 39aimed~~ -- **aimed** at supporting growth, rather than paying cash dividends. These capital allocation decisions could have a material adverse effect on our stock price. If the Board of Directors chose to **reduce or** omit a dividend and ~~retained~~ -- **retain** future earnings for the operation and expansion of our business, realization of a gain on your investment will depend solely on the appreciation of the price of our common stock, which may never occur. ~~Additionally~~ **35Additionally** , if we use a significant portion of our capital to repurchase shares or pay cash dividends, our financial flexibility will be reduced, and we may not be able to execute on other strategic initiatives or tolerate periods of operating losses. If we repurchase shares on unfavorable terms or if our use of capital to repurchase shares or pay cash dividends inhibits our ability to pursue other strategic initiatives or tolerate periods of operating losses, it could have a material adverse effect on our stock price and our business. ~~We may need or choose to raise additional capital in the future, which could result in dilution to our stockholders and adversely affect stock price.~~ While we believe that our cash and investment balances and prospective cash flow from our operations will provide us with adequate capital to fund operations for at least the next 12 months from the date of the issuance of the financial statements included herein, we may need or choose to raise additional funds prior to that time. We may seek to sell additional equity or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. The sale of additional equity or ~~convertible~~ debt securities could result in additional dilution to our stockholders. If additional funds are raised through the issuance of debt securities or preferred stock, these securities could have rights that are senior to holders of common stock and any debt securities could contain covenants that would restrict our operations. The sale of such securities could hurt demand for our common stock and cause our share price to decline. ~~Roger Susi, who serves as our Chairman of the Board of Directors, President and Chief Executive Officer, owns a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval. Mr. Susi, our founder, who serves as our Chairman of the Board of Directors, President and Chief Executive Officer, and his affiliates, beneficially own approximately 36 percent of our outstanding common stock. Mr. Susi may be able to significantly influence matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions, or other extraordinary transactions. He may also have interests that differ from yours and may vote in a way with which you disagree, and which may be adverse to your interests. This concentration of ownership may have the effect of promoting, delaying or deterring a change of control of our company.~~ The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain executive management and qualified ~~board~~ **Board** members. As a public company, we are subject to the reporting requirements of the ~~Securities~~ Exchange Act ~~of 1934, as amended (" Exchange Act ")~~ , the Sarbanes-Oxley Act **of 2002** , the Dodd- Frank **Wall Street Reform and Consumer Protection** Act, the listing requirements of ~~the~~ Nasdaq ~~Stock Market~~ and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. As a result, management' s attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may need to hire more employees in the future or engage outside consultants to monitor and advise us regarding compliance, which will increase our costs and expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We may need to invest in additional ~~40resources~~ -- **resources** to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. We believe that being a public company and compliant with these rules and regulations has made it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and qualified members of our Board of Directors, particularly to serve on the Board of Directors' audit committee (the " Audit Committee ") and compensation committee (the " Compensation Committee "). **Roger Susi** ~~As a result of being a public company~~ , **who serves as** ~~we are obligated to establish and maintain adequate internal controls. Failure to develop and maintain adequate internal controls or~~ **our** ~~to implement new~~ **Chairman of the Board of Directors, President and Chief Executive Officer, owns a significant percentage of** ~~or~~ **our** ~~improved controls could have a material adverse effect~~ **stock and will be able to exert significant influence over matters subject to stockholder approval. Mr. Susi, our founder, who serves as our Chairman of the Board of Directors, President and Chief Executive Officer, and his affiliates, beneficially** ~~on~~ **own approximately 36 percent** ~~our business, financial position and results~~ of ~~operations and could cause the market value of~~ our **outstanding** common stock ~~to decline~~ **as of December 31, 2024** . ~~Ensuring~~ **Mr. Susi may**

be able to significantly influence matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions, or other extraordinary transactions. He may also have 36interests that ~~we~~ **differ from yours and may vote in a way with which you disagree, and which may be adverse to your interests. This concentration of ownership may** have ~~adequate internal financial and accounting~~ **the effect of promoting, delaying or deterring a change of** ~~controls -~~ **control** ~~and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort. Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability~~ of ~~financial reporting and the preparation of financial statements in accordance with GAAP. During the evaluation and testing process, if we identify one or~~ **our Company** ~~more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls are effective. We are required to disclose significant changes made in our internal controls and procedures on a quarterly basis. Our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed, or operating. Our remediation efforts may not enable us to avoid a material weakness in the future~~ . Our business practices are more visible as a public company, and this could impact our competitive environment and ~~our~~ risk of potential litigation **or involvement in securities class action litigation that could adversely affect our business and could subject us to significant liabilities** . As a result of disclosure of information in filings required of a public company, our business and financial condition are more visible than a privately- held company, potentially exposing us to new competition and threatened or actual litigation, including by competitors and other third parties. New competition could result in reduced sales of our products and adversely impact our profitability. If lawsuits prevail against us, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results ~~. We may and have become involved in securities class action litigation that could divert management' s attention from our business and adversely affect our business and could subject us to significant liabilities~~ . The stock markets have from time- to- time experienced significant price and volume fluctuations that have affected the market prices of small capitalization medical device companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this " Risk Factors " section, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities **, whatever the cause** . We have become, and may in the future, become involved in this type of litigation. Litigation is expensive and could divert management' s attention and resources from our primary business, which could adversely affect our operating results. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require us to make significant payments. Such payment could have a material impact on how investors view our ~~company~~ **Company** and result in a decline in our stock price. ~~41~~ **If securities or industry analysts fail to initiate research coverage of our stock, downgrade our stock, or discontinue coverage, our trading volume might be reduced, and our stock price could decline. The trading market for our common stock depends, in part, on the research reports that securities or industry analysts publish about our business. If securities or industry analysts do not commence or continue coverage of our Company, the trading market for our stock may not be robust and the price of our stock could likely be negatively impacted. In the event securities or industry analysts initiate coverage, and later downgrade our stock or discontinue such coverage, our stock price could decline. Our charter documents and Delaware law have provisions that may discourage an acquisition of us by others and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our charter documents, as well as provisions of the Delaware General Corporation Law (" DGCL "), could depress the trading price of our common stock by making it more difficult for a third party to acquire us at a price favorable to our stockholders. These provisions include: ● authorizing the issuance of " blank check " preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval to defend against a takeover attempt; and ● establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. We are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This 37**