Risk Factors Comparison 2024-04-01 to 2023-03-24 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled " Risk Factors. " These risks include, but are not limited to, the following: ~~•~~ ◦ **The Restructuring has changed, and is expected to continue to significantly change, our business, and may result in disruption to our continuing business.** ◦ We **are dependent on our strategic relationship with Medtronic for all of our revenue, with no sales or marketing capabilities of our own, and the loss of this partner would completely eliminate our revenue. We currently depend on revenue generated from a single business line (manufacturing Medtronic' s left- heart access portfolio) and for the foreseeable future will be significantly dependent on a limited number of products.** ◦ **Our business is not diversified. If our sole business line is disrupted, our business and results of operations would be adversely affected.** ◦ **If our distribution agreement with Medtronic terminates upon the occurrence of the Second Closing (as defined below) or for any other reason, and following the conclusion of the Net Sales Earnout (as defined below) period, we will** have ~~a history~~ **no sources** of **revenue.** ◦ **There are continued risks associated with the Restructuring, including our ability to complete the wind down and to manage the associated Restructuring and transition costs to realize the anticipated benefits, the impact of the Restructuring on our relationships with our employees, our major customers, distributors and vendors and unanticipated expenses and charges that may be incurred as a result of the Restructuring, such as litigation risks, including litigation regarding contract termination and employment and workers' compensation.** ◦ **Our ability to continue to have the liquidity necessary to service our debt, meet contractual payment obligations and fund our operations depends on many factors, including our ability to generate sufficient cash flow from operations or obtain other financing.** ◦ **If our Restructuring is not successful, our board of directors may decide to pursue a liquidation and dissolution of our business. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cashthat will need to be reserved for commitments and contingent liabilities, including under our 2022 Credit Agreement (as defined below).** ◦ **We historically had** net losses, and **our new business following** ~~we expect to continue to incur losses for at least~~ the **Restructuring** ~~next several years. If we ever achieve profitability, we~~ may not be **profitable** ~~able to sustain it. • We have a limited history operating as a commercial company; if we fail to effectively train our~~ **or continue to generate any revenue** ~~sales force, increase our sales and marketing capabilities or develop broad brand awareness in a cost- effective manner, our growth will be impeded, and our business will suffer~~ . ~~•~~ ◦ The commercial success of ~~our~~ **the** ~~products~~ **Products (as defined below), and thus our ability to generate revenue from Medtronic' s sales of the Products,** will depend upon attaining significant market acceptance of ~~these~~ -- **the** ~~products~~ **Products** among hospitals, physicians, patients and payors. ~~•~~ ◦ We **operate in a highly** ~~have significant international operations, and intend to further expand our business internationally, which exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. • We face significant competition~~ **competitive industry** , and if we **or the Products** are unable to compete ~~effectively~~ **successfully** , ~~we~~ **our sales to Medtronic** may **decline and** ~~not be able to achieve or~~ **our** ~~maintain significant market penetration or improve our results of operations. • If we are unable to manage the anticipated growth of our business, our future~~ revenue ~~and operating results~~ **from Medtronic' s sales of the Products to end- users** may be **reduced, and there would** ~~adversely affected. • We may not~~ be ~~able to develop, license or acquire new products, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have~~ a material adverse effect on our business ~~, financial condition~~ and results of operations. ~~•~~ ◦ Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business. ~~•~~ ◦ We depend upon third- party suppliers, including single- source suppliers, making us vulnerable to supply disruptions and price fluctuations. ◦ ~~• Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business. •~~ Defects or failures associated with ~~our~~ **the** ~~products~~ **Products** could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity ~~. ii • Coverage and adequate reimbursement may not be available~~ for ~~the procedures that utilize our products, which could diminish our sales or~~ **our business** ~~affect our ability to sell our products profitably~~ . ~~•~~ ◦ Regulatory compliance ~~, including compliance with U. S. federal and state fraud and abuse and other healthcare laws and regulations,~~ is expensive, complex and uncertain, and failure to comply could lead to enforcement actions against us and other negative consequences for our business. ◦ ~~• If we are unable to obtain and maintain patent protection or freedom to operate for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be adversely affected. • Our operations and financial results may be adversely impacted by the resurgence of COVID- 19 or another global pandemic. •~~ We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine **and Israel and Hamas** . Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine or **Gaza or** any other geopolitical tensions. ~~iii~~ ◦ **Our failure to maintain compliance with The Nasdaq Stock Market LLC' s (" Nasdaq ") continued listing requirements would result in the delisting of our common stock. If our common stock is delisted from Nasdaq and is traded over- the- counter, your ability to trade and the market price of our shares of common stock may**

be negatively impacted. PART I Item 1. Business. Overview **Historically** ~~We are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Despite several decades of effort by the incumbents in this field~~ , ~~the clinical and economic challenges associated with arrhythmia treatment continue to be a huge burden for patients, providers and payors. We are committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more effectively and efficiently. Through internal product development, acquisitions and global partnerships,~~ we ~~have established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products. Our goal is to provide our customers with a complete solution for catheter- based treatment of cardiac arrhythmias in each of our geographic markets. We design~~ **designed** , ~~manufacture~~ **manufactured** and ~~market~~ **marketed** a range of tools for catheter- based ablation procedures to treat various arrhythmias. ~~Cardiac ablation involves using high- energy radio frequency or extreme cold to target tissue in the heart that is responsible for triggering or sustaining an abnormal heart rhythm.~~ Our product portfolio ~~includes~~ **included** novel access sheaths, diagnostic and mapping catheters, conventional and contact ~~force~~ ablation catheters ~~(currently available only in our European markets)~~ , mapping and imaging consoles and accessories, as well as supporting algorithms and software programs. Our foundational ~~and most highly differentiated~~ product ~~is~~ **was** our AcQMap ~~imaging~~ **Imaging** and ~~mapping~~ **Mapping** ~~system~~ **System** , which **was designed** ~~offers a paradigm- shifting approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. With the ability~~ to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion **. In April 2022** , **we announced that we agreed to sell our left- heart access product portfolio to Medtronic and refinance existing debt with a new longer- term credit facility to recapitalize our business and fund our strategic growth priorities. Pursuant to the sale transaction, Medtronic paid upfront cash consideration of $ 50. 0 million (of which $ 4. 0 million was paid into an indemnity escrow account for a period of 18 months), and we became eligible for contingent cash consideration of up to $ 37. 0 million (of which we earned $ 20. 0 million on October 31, 2022 and $ 17. 0 million on December 31, 2022) plus a portion of Medtronic' s future net sales of the left- heart access product portfolio. In conjunction with the sale of our left- heart access product portfolio, we executed a distribution agreement with Medtronic (the " Distribution Agreement "), pursuant to which we agreed to manufacture and supply these left- heart access products to Medtronic as exclusive distributor of the product line for an initial term of up to four years at specified transfer prices. We will also continue to be eligible for earnout payments on Medtronic' s net sales of the left- heart access product portfolio through 2027. In November 2023, we announced, following an extensive strategic review by our board of directors, and in light of the current financing environment and the capital investments required to achieve leadership in the electrophysiology market, that we had determined to reallocate capital from our mapping and ablation business to the manufacturing of left- heart access products for Medtronic under the Distribution Agreement, which** we believe **will maximize the potential for future contingent cash consideration and cash flow. As part of this restructuring, we wound down our mapping and ablation businesses and no longer manufacture or distribute** our AcQMap **Mapping** System **, AcQMap 3D Mapping Catheter, AcQBlate Force- Sensing** ~~addresses the primary unmet need in electrophysiology procedures today. While multiple trials have established that cardiac ablation~~ **Ablation** ~~is effective when~~ **Catheter, AcQGuide Max 2. 0 Steerable Sheath, or associated accessories, though we continue to explore strategic alternatives for** ~~the~~ **these** ~~source~~ **businesses (including a potential sale** of **related assets). As a result** ~~the arrhythmia is accurately identified and successfully ablated, visualization~~ of **this restructuring, we rely solely on our strategic partnership** ~~various complex arrhythmias and creation of durable ablation lesions remains challenging~~ with ~~long, unpredictable procedure times~~ **Medtronic to generate revenue through (i) the manufacture of the left- heart access product portfolio for Medtronic at transfer prices specified under our Distribution Agreement** and **(ii) potential earnouts** ~~inconsistent outcomes. For example, data~~ from ~~large, multi~~ **Medtronic' s sales of the left** - ~~center trials of cardiac ablation have demonstrated that approximately~~ **heart access product portfolio to end- users. Left- Heart Access Portfolio Sale and Distribution Agreement On June** 30 **, 2022, we completed the first closing (the " First Closing ") of the sale of our left- heart access portfolio in accordance with the Asset Purchase Agreement with Medtronic executed on April 26, 2022 (the " Asset Purchase Agreement "), pursuant** to **which we sold to Medtronic our AcQCross ® line of sheath- compatible septal crossing devices, the AcQGuide ® MINI integrated crossing device and sheath, the AcQGuide FLEX steerable introducer with integrated transseptal dilator and needle and the AcQGuide ® VUE steerable sheaths (the " Products "). Pursuant to the Asset Purchase Agreement, Medtronic paid cash consideration of $** 50 ~~%~~ **. 0 million at the First Closing,** of ~~ablations~~ **which $ 4. 0 million was paid into an indemnity escrow account** for **a period of 18** ~~atrial fibrillation result in arrhythmia recurrence within the first 12~~ months ~~of~~ **following the First Closing, and acquired from us, among** ~~the~~ **other things, intellectual property rights to the Products and certain equipment used in the manufacturing of the Products. A second closing would occur on a date determined by Medtronic, but no later than the fourth anniversary of the First Closing, subject to the satisfaction of customary closing conditions (the " Second Closing "). At the Second Closing, Medtronic would acquire certain additional assets relating to the Products, primarily supplier agreements and permits and design and specification files required for Medtronic to become the manufacturer of record of the Products, for no additional consideration. Under the Asset Purchase Agreement, we also became eligible to receive contingent cash consideration of up to $ 37. 0 million plus a portion of Medtronic' s future net sales from the Products, as follows: (i) $ 20. 0 million upon our completion, to the reasonable satisfaction of Medtronic, of certain conditions set forth in the Asset Purchase Agreement relating to our becoming a qualified supplier of Medtronic for the Products, including demonstration of ISO 14971: 2019 compliance, completion of certain test method validations and compliance with certain other reporting requirements (the " OEM Earnout "); (ii) $ 17. 0 million upon the earlier of (A) the Second Closing or (B) our** initial **submission** ~~ablation procedure. Currently marketed mapping systems are not able to quickly and consistently identify the source of the arrhythmia in more complex cases, which can contribute to these unsatisfactory outcomes. Current competitive~~

~~mapping systems sequentially collect data point- by- point by contacting the heart surface at multiple locations throughout the chamber. This is a time- consuming process that often takes 15 to 20 minutes per map. Additionally, because contact- based mapping relies on a fixed timing reference to sequence the data points, it precludes these systems from being able to quickly and reliably identify the drivers and maintainers of unstable arrhythmias such as atrial fibrillation, many types of supraventricular tachycardias and certain ventricular arrhythmias. We designed our AcQMap System to improve procedure efficiency and outcomes by rapidly and accurately identifying ablation targets and confirming both ablation success and procedure completion. Our AcQMap System consists of our single- use AcQMap catheter as well as our console, workstation and proprietary software algorithms. With 48 ultrasound transducers interspersed between 48 biopotential electrodes, our innovative mapping catheter collects the data required to create a comprehensive map of the cardiac anatomy and electrical propagation pathways and patterns in under three minutes without contacting the chamber wall. Our proprietary software algorithms analyze the biopotential data and are collectively able to map any type of stable or unstable arrhythmia, including atrial fibrillation as well as all supraventricular tachycardias and ventricular arrhythmias. We believe that by creating high definition, clinically accurate activation maps of all types of arrhythmias, our AcQMap System offers physicians better decision- making tools to determine where to ablate. Similarly, we believe the speed and ease of creating a map makes it practical~~ for ~~physicians to iteratively map, treat, re- map and adjust additional therapy if and when needed. In the second half of 2022, we received U. S. Food and Drug Administration, or FDA, clearance and~~ Conformité Européenne Mark, or CE Mark, **certification of the Products under the European Union Medical Devices Regulation, or MDR, to the reasonable satisfaction of a third- party regulatory consultant, subject to certain other conditions as set forth in the Asset Purchase Agreement (the " Transfer Earnout "); and (iii) amounts equal to 100 %, 75 %, 50 % and 50 %, respectively, of quarterly Net Sales (as defined in the Asset Purchase Agreement) from sales of the Products achieved by Medtronic over each year over a four- year period beginning on the first full quarter after Medtronic' s first commercial sale of a Product and achievement of the OEM Earnout (the " Net Sales Earnouts "). On October 31, 2022, we achieved the OEM Earnout, and payment of $ 20. 0 million from Medtronic was received in November 2022. Further, on December 1, 2022, Medtronic qualified us as an original equipment manufacturer (" OEM ") and accordingly, we began to manufacture the Products exclusively** for **Medtronic under the Distribution Agreement. The Distribution Agreement has an initial term ending on the date of the Second Closing. If the Second Closing has not occurred on** ~~our~~ **or prior** ~~AcQMap 8. 5 software platform. This release provided significant enhancements~~ to ~~our industry~~ **the fourth anniversary of the First Closing, then the Distribution Agreement will automatically renew thereafter for successive one** ~~- unique~~ **year periods, unless either we or Medtronic provides notice of** non- **renewal at least 180 days before the end** ~~contact ultrasound- based anatomical reconstruction. AcQMap anatomies are now higher fidelity and easier to create in less time. AcQMap 8. 5 also provided additional workflow enhancements and troubleshooting tools to ensure cases could be run more efficiently. We have established a broad portfolio~~ of **the** ~~electrophysiology products that complements our AcQMap System. In addition to our AcQMap System, our commercial product portfolio includes a suite of access devices and full product lines of diagnostic and, in our European markets, ablation catheters. In our European markets, our portfolio provides our customers with a complete solution — from vascular access to diagnosis and treatment of arrhythmias. In the~~ **then** ~~United States, we are currently~~ -- **current** ~~seeking regulatory approval~~ **term. On December 31** , **2022, we achieved the Transfer Earnout** for ~~which we filed in 2022, for our ablation catheters to complement our portfolio of access and mapping devices. We also recently expanded our portfolio to include the AcQBlate ® FORCE gold- tip, irrigated, radiofrequency force sensing ablation catheters and Qubic Force control unit, or~~ **our submission** ~~AcQBlate Force Sensing Ablation System, which we commercialized following the December 2020 receipt of CE Mark approval in Europe. Biotronik SE & Co. KG, or Biotronik, had previously performed the BioConcept Study, which was used as the base data~~ for CE Mark **certification** ~~submission, and no additional clinical data was required for CE Mark approval. We also completed the AcQForce Flutter investigational device exemption, or IDE, trial for U. S. Food and Drug Administration Premarket Approval, or FDA PMA, in the United States during 2022 to seek a right atrial typical flutter indication. We currently anticipate FDA PMA and the U. S. commercial launch~~ of ~~our AcQBlate Force Sensing Ablation System in~~ the ~~second half of 2023. We will pursue CE Mark for our PFA system following the completion of the trial and satisfactory preparation of regulatory submission documents. We believe that our ability to offer a broad and differentiated product portfolio will support the adoption and utilization of our AcQMap System and drive an efficient business model. Once an AcQMap console and workstation is established in a customer account, our revenue from that account becomes predominantly recurring in nature and derived from the sale of our portfolio of disposable products~~ **Products under** ~~used with our system. We market and sell our electrophysiology products worldwide to hospitals and electrophysiologists that treat patients with arrhythmias. We have strategically developed a direct selling presence in~~ the ~~United States and select markets in Western Europe~~ **European** ~~where cardiac ablation is a standard~~ **Union MDR, to the reasonable satisfaction** of **a** ~~care and~~ third- party ~~reimbursement is~~ **regulatory consultant, and payment of $ 17. 0 million was received from Medtronic on January 14, 2023. The quarterly measurement period for the Net Sales Earnouts began on January 30, 2023, and such earnout payments began in January 2024 and** ~~well~~ **will** ~~- established~~ **continue quarterly each quarter thereafter until 2027** . In **2023, we earned $ 9. 4 million related to** ~~other~~ -- **the** ~~international markets~~ **Net Sales Earnouts** , ~~we leverage our partnership~~ with **$ 7** ~~Biotronik, a large multi- national, privately- held biomedical technology company with a leading portfolio across cardiac rhythm management, electrophysiology and vascular intervention, to sell and distribute our products~~ . **3 million paid in January 2024. Strategic Realignment and Restructuring** In **November 2023** ~~the United States and Western Europe~~ , our ~~target market is highly concentrated~~ **board of directors approved a strategic realignment of resources and corporate restructuring (the " Restructuring ")** . We **began implementation** ~~plan to leverage the concentrated nature~~ of **a shift in** ~~procedure volumes and the recurring nature of~~ our **business** ~~sales to drive an increasingly efficient commercial~~ model **to solely support** ~~. Our research and development activities are focused on advancing~~ the ~~field~~ **manufacturing and distribution** of **Medtronic** ~~electrophysiology by~~

~~increasing the AcQMap System~~ ' s **left- heart access** ~~utility and by seeking approval for additional labeled indications as well as by expanding our~~ product portfolio **under** ~~to further improve and simplify~~ the ~~entire procedural experience. Our~~ **Distribution Agreement, including to** ~~near~~ -- **earn potential Net Sales Earnouts. As part of the Restructuring, we wound down our mapping and ablation businesses and no longer manufacture or distribute our AcQMap Mapping System, AcQMap 3D Mapping Catheter, AcQBlate Force** ~~- term pipeline includes products~~ **Sensing Ablation Catheter, AcQGuide Max 2. 0 Steerable Sheath or associated accessories and are exploring strategic alternatives for these businesses (including a potential sale of related assets). We expect** that ~~broaden our clinical utility, improve~~ the ~~system' s workflow and user experience~~ **Restructuring will be substantially complete in the first quarter of 2024. As part of the Restructuring** , ~~and increase functionality and /~~ **we initiated a reduction in** ~~or~~ **our** ~~reduce~~ **workforce of approximately 160 employees, representing approximately 65 % of our employees, that is expected to be completed by the first quarter of 2024. In compliance with the Worker Adjustment and Retraining Notification Act, we provided pre- termination notices to affected employees and government authorities where required. We entered into retention arrangements with certain employees who remained with us to assist with the Restructuring and operation of our left- heart access distribution business. As of December 31, 2023, we have recognized $ 18. 6 million of the estimated $ 21. 0 million to $ 32. 0 million of pre- tax restructuring and exit- related charges, of which $ 0. 7 million of the estimated $ 2. 0 million to $ 3. 0 million represented cash expenditures for the payment of severance and related benefit** costs ~~across catheters~~ , ~~accessory devices, mapping systems and software~~ **$ 0 of the estimated $ 3** . ~~Our Market and Industry Cardiac arrhythmias,~~ **0 million to $ 4. 0 million represented cash expenditures** ~~or~~ **for** ~~heart rhythm disorders,~~ **the payment of retention bonuses to certain employees that** are **assisting with** ~~common and can occur when~~ the ~~heart beats~~ **Restructuring, less than $ 0. 1 million of the estimated $ 2. 0 million** ~~too~~ - **to** ~~rapidly, too slowly~~ **$ 5. 0 million represented cash expenditures** ~~or~~ **for other restructuring costs** ~~irregularly. If left untreated~~ , ~~arrhythmias can result in debilitating symptoms, heart failure, stroke~~ and **$ 18** ~~sudden cardiac death~~ . ~~Atrial fibrillation~~ **0 million of the estimated $ 14. 0 million to $ 20. 0 million represented non- cash pre- tax impairment charges in connection with the disposition of certain assets** , ~~or AF~~ **including inventory** , **fixed assets and intangibles. A majority of the non- cash charges was incurred in the fourth quarter of 2023, while the majority of the cash expenditures charges** is **expected** ~~the most common arrhythmia and is characterized by rapid and irregular activation of the heart. This irregular behavior increases the potential~~ to **be incurred in** ~~develop blood clots within the upper chambers of the heart, which can then~~ - **the** ~~circulate to~~ **first quarter of 2024. Overview of** ~~other~~ -- **the Products** ~~organs, leading to reduced blood flow and strokes.~~ We **Manufacture Historical Products Historically** ~~estimate that there were approximately 624~~ , **we designed** ~~000 cardiac ablation procedures globally for atrial fibrillation in 2021. Supraventricular tachycardias~~ , **manufactured** ~~or SVTs, are characterized by a rapid heartbeat in the upper chambers of the heart. These arrhythmias, which include atrial flutter and atrial tachycardia, among others, can arise organically or as a result of an~~ **and** ~~incomplete ablation for atrial fibrillation. These post AF ablation SVT procedures are considered to be " complex " SVT ablation procedures. We estimate there were approximately 494, 000 ablation procedures worldwide for SVTs in 2021. Moreover, the number of SVT procedures that fall under the complex category are expected to grow as a result of growth in AF ablation procedures. Ventricular arrhythmias affect the lower chambers of the heart and consist primarily of ventricular tachycardias, or VTs, and premature ventricular contractions, or PVCs. If left untreated, VTs and PVCs can lead to heart failure, ventricular fibrillation and sudden cardiac death. We estimate that there were approximately 116, 000 ablation procedures globally for ventricular arrhythmias in 2021. Currently~~ marketed ~~mapping systems rely on tissue contact and a fixed timing reference to collect and align data in the proper sequence. As a result, they are designed to map simple, stable and repetitive arrhythmias such as certain SVTs and VTs. Collecting a critical mass of data points to see even a stable rhythm is time consuming with contact mapping technologies, as data collection is sequential and by definition requires contact at all areas to fully map the heart. This time consuming, sequential data collection results in significant variability in the map quality and therefore the diagnostic relevance of the map in guiding therapy. Innovation in contact mapping systems therefore have been limited to enabling faster data collection via adding more sensors to contact mapping catheters. In addition, these technologies are not capable of mapping unstable or complex arrhythmias such as AF, certain VTs, PVCs or many types of SVTs, thereby generating an unmet need in the market for effective diagnostic and treatment alternatives. Our Solution We design, manufacture and market~~ a range of tools for catheter- based ablation procedures to treat various arrhythmias. Our foundational and most highly differentiated product ~~is~~ **was** our AcQMap ~~imaging~~ **Imaging** and ~~mapping~~ **Mapping** ~~system~~ **System** which ~~offers~~ **offered** a non- contact map paradigm- shifting approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. **We established a broad portfolio of electrophysiology products that complemented** ~~With the ability to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion, we believe~~ our AcQMap System ~~addresses the primary unmet need in electrophysiology procedures today~~ . ~~Overview of Our~~ **In addition to our** AcQMap System **, our commercial product portfolio included a suite of access devices and full product lines of diagnostic and, in our European markets, ablation catheters.** We ~~developed~~ **also launched the AcQBlate Force Sensing Ablation System following the December 2020 receipt of CE Mark approval in Europe. As part of the Restructuring, we wound down our mapping and ablation businesses and no longer manufacture or distribute** our AcQMap **Mapping** System **,** ~~to address the key challenges that electrophysiologists face during ablation procedures and remove the barriers to adopting ablation for complex arrhythmia procedures. Our~~ AcQMap **3D Mapping** ~~System consists of our AcQMap catheter~~ **Catheter** , **AcQBlate Force** ~~console and workstation. Our system uses a paradigm~~ - **Sensing Ablation** ~~shifting approach. With 48 ultrasound transducers interspersed between 48 biopotential electrodes, our innovative mapping catheter~~ **Catheter** ~~collects~~ **, AcQGuide Max 2. 0 Steerable Sheath or associated accessories. Current Products Following** the ~~data required~~ **Restructuring and the shift in our business model** to ~~create a comprehensive map~~ **solely supporting the manufacturing and distribution of the Products to Medtronic, we manufacture transseptal crossing devices and associated accessories, such as integrated transseptal dilators and needles, fixed- curve**

or steerable introducers, and steerable sheaths (i. e., the Products). These Products are used to access the left side, or left atrium, of the cardiac anatomy and ~~electrical propagation patterns~~ **are used in a range of medical applications, including in electrophysiology and structural heart procedures. The technology supports physicians during a critical component of** ~~and~~ **an** ~~pathways without contacting~~ **ablation or structural heart procedure. The transseptal crossing devices that we manufacture for Medtronic include versions that are length-, diameter- and tip- matched and designed to lock into the hub of sheaths used in many left- heart procedures. These devices enable mechanical septal crossing with a spring-loaded needle that can also be enhanced with concurrent delivery of radiofrequency energy. They streamline the procedural workflow by eliminating the need for wire and needle exchanges, as** ~~the~~ **they** ~~chamber wall~~ **incorporate a retained guidewire within the hollow crossing needle** . ~~This allows us to create comprehensive diagnostic maps~~ **The fixed-curve and steerable introducers are indicated for introducing various cardiovascular catheters into the heart, including the left side** of **the heart through the interatrial septum. They are designed to facilitate vascular access to the heart and** ~~the~~ **then** ~~chamber~~ **provide catheter positioning (fixed or variable) within the cardiac** anatomy **. The steerable sheaths are designed to facilitate handling and deliverability of interventional devices. We previously obtained U. S. Food and Drug Administration, or FDA, clearance for the Products in April 2021 and for additional configurations of the Products in June 2022 and submitted** ~~and~~ **an application for CE Mark** ~~electrical propagation patterns and pathways in~~ under ~~three~~ -- **the European Union MDR** ~~minutes. Our proprietary software algorithms analyze the biopotential data and are collectively able to map any type of stable or~~ **for** ~~unstable arrhythmia, including atrial fibrillation, as well as all supraventricular tachycardias and ventricular arrhythmias. Our AcQMap 8. 5 software platform, which we introduced in~~ the ~~second half of~~ **Products in December** 2022 ~~, offers significant enhancements to our industry unique non- contact ultrasound- based anatomical reconstruction enabling higher fidelity anatomies to be created in less time. Key Benefits of AcQMap~~ We believe the unique attributes of ~~our AcQMap System~~ **the Products that we manufacture for Medtronic** offer significant clinical benefits relative to the current standard of care. ~~Iterative Whole~~ **The Products are designed for patient safety and procedural efficiency, allowing for fewer steps than a traditional transseptal access workflow. The transseptal crossing devices contain a spring** ~~- Chamber Mapping Approach~~ **tensioned safety needle that only deploys when actuated. The matched integrated dilator and needle lock together** ~~With~~ **with introducers** ~~increased mapping speed and precision, electrophysiologists are empowered in real time to iteratively map, treat, re- map and adjust additional therapy~~ as **one unit for control and ease of use. The transseptal crossing devices incorporate a retained guidewire within the hollow crossing** ~~needed~~ - **needle** . This **design reduces exchanges and** allows physicians to ~~determine when~~ **reposition without requiring wire and needle exchanges. The elimination of guidewire and needle exchanges facilitates transseptal crossing procedures, as the optimal septal crossing** ~~ablation~~ -- **location and angle differ depending on the procedure so the ability to easily reposition without cumbersome catheter withdrawals and exchanges** is **important. Market** ~~complete, which we believe will drive more efficient~~ and ~~predictable procedures~~ **Industry Electrophysiology involves the diagnosing** and ~~better outcomes~~ **treating of abnormal electrical activities of the heart. Electrophysiology products include devices used by electrophysiologists and interventional cardiologists** for ~~a broader range of arrhythmias. Increased Mapping Accuracy Ultrasound technology allows us to create an anatomically accurate image of the heart chamber, and non- contact charge density mapping provides a more localized and sharper view of cardiac activation resulting in images with four times higher resolution than voltage- based maps produced by currently marketed contact- based mapping systems. We believe the combination of these two features allows electrophysiologists to reliably identify and ablate the source of the arrhythmia, which will help improve clinical outcomes and reduce the need for repeat procedures. Ability to Identify Multiple Complex Arrhythmias The AcQMap System is the only commercially available mapping system that can quickly and reliably map both stable and unstable rhythms, allowing electrophysiologists to see changes in conduction during the procedure and providing them~~ - **the** ~~with an optimal solution to better customize therapy. Demonstrated Clinical Outcomes Our UNCOVER AF post- market approval trial, which assessed the effectiveness of the AcQMap System in identifying patient-specific targets for ablation, demonstrated favorable freedom from AF outcomes. The results are particularly favorable in the context of other landmark trials in the electrophysiology space, including the STAR AF II trial, which evaluated a similar population of persistent AF patients. We believe the key differentiator in outcomes was the use of our AcQMap System to map and identify key ablation patterns and targets. Our Broad Portfolio We have established a broad portfolio of electrophysiology products that complements our AcQMap System. In addition to our AcQMap System, our commercial product portfolio includes a suite of access devices and full product lines of diagnostic and, in our European markets, ablation catheters. In our European markets, our portfolio provides our customers with a complete solution — from vascular access to diagnosis and~~ treatment ~~of arrhythmias. In the United States, we are currently seeking regulatory approval for our ablation catheters to complement our portfolio of access and mapping devices. We also recently expanded our portfolio to include the AcQBlate Force Sensing Ablation System, which we launched following the December 2020 receipt of CE Mark approval in Europe. We completed our IDE trial and filed for FDA PMA in the United States in 2022. We currently anticipate FDA PMA and the U. S. commercial launch of our AcQBlate Force Sensing Ablation Catheter and System in the second half of 2023. Our Growth Strategies We are committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more efficiently and effectively. We seek to establish our AcQMap System as the standard of care for mapping and diagnosis~~ of cardiac arrhythmias **, or heart rhythm disorders, which are common** and **can occur when the heart beats** ~~to too~~ ~~leverage~~ **rapidly, too slowly or irregularly. If left untreated, arrhythmias can result in debilitating symptoms, heart failure, stroke and sudden cardiac death. Atrial fibrillation, or AF, is the most common arrhythmia and is characterized by rapid and irregular activation of the heart. This irregular behavior increases the potential to develop blood clots within the upper chambers of the heart, which can then circulate to other organs, leading to reduced blood flow and strokes. Structural heart conditions involve defects or disorders in the heart' s structure —** its **valves, walls, chambers** ~~paradigm- shifting nature to drive adoption and utilization of our~~ - **or** ~~portfolio~~ **muscles. Structural heart**

products include those used by interventional cardiologists to treat defects of ~~differentiated~~ **the heart, such as valve stenosis (stiffness) and valve regurgitation (leaky valve). Surgical repair of the valve may be required in such circumstances. The Products we manufacture for Medtronic are used in** electrophysiology **and structural heart procedures. An estimated several hundred thousand transseptal crossings are performed annually during these procedures. The** ~~products~~ **Products support the challenging and critical step of accessing the left atrium during electrophysiology and structural heart procedures such as atrial fibrillation ablation procedures, left atrial appendage occlusions, and transcatheter mitral valve repairs. They simplify transseptal crossing for electrophysiologists and interventional cardiologists to improve workflow, add procedural efficiencies and help alleviate complexity during left heart procedures** . Our ~~growth~~ **Strategy Our strategy is to increase our value to our** ~~strategies~~ **strategic partner, Medtronic, as a contract manufacturer of the Products in the electrophysiology and structural heart markets such that Medtronic decides to continue to use us as a manufacturer of some or all of the Products at transfer prices. Important elements of our strategy** include **vigorously pursuing manufacturing improvements,** ~~: • utilizing our superior mapping technology~~ and **focusing on** ~~open platform to establish our presence within a geographically targeted base of customer accounts and physicians; • strategically positioning our commercial organization across targeted geographic regions to increase physician awareness and drive adoption; • maximizing console utilization and procedure volume growth in targeted geographic regions; • continuing to strategically expand our portfolio of products and broaden indications for existing products; • leveraging our strategic partnerships to efficiently~~ -- **efficient** ~~scale globally~~ **manufacturing, high quality** and **reliability so that** ~~broaden our product portfolio; and • continuing to build our clinical evidence base. Impact of COVID- 19 The markets~~ we ~~serve could~~ **are well positioned to capture manufacturing demands from Medtronic. For more information regarding these risks, please** see ~~continued impacts from COVID- 19 for the foreseeable future, and the emergence of new variants of COVID- 19 creates significant uncertainty as to how long COVID- 19 will continue to impact our business. The magnitude of the impact of the COVID- 19 pandemic on our productivity, results of operations and financial position and its disruption to our business and our clinical programs and timelines will depend, in part, on the length and severity of outbreaks, restrictions and other~~ -- **the** ~~measures designed~~ **section titled " Risk Factors — Risks Related** to ~~prevent~~ the ~~spread of COVID- 19 and on our ability to conduct business in the ordinary course. Corporate~~ Restructuring ~~In 2022, we completed an organizational workforce reduction and implemented additional cost reduction measures to reduce our operating expenses and optimize our cash resources~~ . **"** ~~The restructuring was the result of a detailed review of our strategic priorities, the external environment and cost structure, and is intended to sharpen our focus and strengthen our financial position. As part of the restructuring, we intend to prioritize maximizing console utilization and procedure volume growth in targeted geographic regions, as well as a more focused scope of product development initiatives.~~ Competition The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. ~~We~~ **Following the Restructuring, we** compete with **contract** manufacturers ~~and distributors~~ of cardiovascular medical devices **on the basis of our ability to perform our obligations as a manufacturer of the Products for Medtronic under the Distribution Agreement** . ~~Our~~ **We also face competition from Medtronic, which may determine to employ in- house capabilities to produce some or all of the Products. We believe that the principal competitive factors in the manufacturing services market are** ~~most~~ **cost** ~~significant~~ **; accelerated production time- to- market; higher efficiencies; global locations; rapid scale production; advanced technologies; quality; and improved pricing of components. In addition, because our revenue is dependent on Medtronic' s ability to sell the Products, we face indirect competition from Medtronic' s** competitors **for heart access products** in the electrophysiology field **, which we believe to** include Abbott Laboratories, Biosense Webster Inc. (a Johnson & Johnson Company), **and** Boston Scientific Corporation ~~and Medtronic, Inc. (" Medtronic")~~ . Many ~~of our~~ competitors **in the manufacturing services industry and the electrophysiology field** are large, well- capitalized companies with significantly greater market share and resources ~~than we have~~ . Therefore, they ~~can~~ **are able to** spend more on product development, **manufacturing,** marketing, sales and other product initiatives ~~than we can~~ . We **believe** ~~also compete with smaller medical device companies~~ that **the principal competitive factors in the electrophysiology field are** ~~have a single product or a limited range of products. Some of our competitors have~~ : ~~• significantly greater~~ name recognition; ~~• broader or deeper~~ relations with healthcare professionals, customers and third- party payors; ~~• more established~~ **quality and depth of** distribution networks; ~~• additional~~ **breadth of product** lines ~~of products~~ and the ability to offer rebates or bundle products to offer ~~greater~~ discounts or other incentives ~~to gain a competitive advantage~~ ; **capabilities** ~~• greater experience~~ in ~~conducting~~ research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and ~~• greater~~ financial and human resources for product development, **manufacturing,** sales and marketing and patent prosecution. ~~We believe that our proprietary AcQMap System offers a paradigm- shifting approach to mapping the drivers and maintainers of arrhythmias with unmatched speed and precision. With the ability to rapidly and accurately identify ablation targets and to confirm both ablation success and procedural completion, we believe our AcQMap System addresses the primary unmet need in electrophysiology procedures today. We have established a broad portfolio of electrophysiology products that complements our AcQMap System. We compete primarily on the basis that our products are designed to enable more physicians to treat more patients more efficiently and effectively. Our continued success depends on our ability to: • strategically develop innovative proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy- to- use for physicians; • obtain and maintain regulatory clearances or approvals; • demonstrate safety and effectiveness in our sponsored and third- party clinical trials; • expand our sales force within key geographic regions to increase physician awareness; • leverage our strategic partnerships and alliances to achieve distribution at a global scale and broaden our product portfolio; • obtain and maintain coverage and adequate reimbursement for procedures using our products; • attract and retain skilled research, development, sales and clinical personnel; • cost- effectively manufacture, market and sell our products; and • obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise~~

violating the intellectual property rights of others. Intellectual Property Our success depends in part on our ability to obtain, maintain, protect and enforce our intellectual property rights, including our patent rights, to preserve the confidentiality of our trade secrets, to operate without infringing, misappropriating or otherwise violating the intellectual property rights of others and to prevent others from infringing, misappropriating or otherwise violating our intellectual property rights. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect **our** the products and technology that we consider important to our business. We also rely on know- how and **the continued commercialization of the Products by Medtronic** continuing technological innovation to develop and maintain our competitive position . As of December 31, 2022 **2023** , our patent portfolio included 38 **42** solely owned or exclusively licensed U. S. patents and 23 **21** solely owned or exclusively licensed pending U. S. patent applications (including one **two** solely owned Patent Cooperation Treaty, or PCT, applications **application** and four **one** solely owned provisional U. S. patent applications). In addition, we solely owned or exclusively licensed 76 **60** issued patents and 51 **48** pending patent applications in jurisdictions outside the United States. Of our 74 **69** pending patent applications (U. S. and outside the U. S.), 2 **six** have been allowed. Of our 38 owned and exclusively licensed U **Following the Restructuring, we no longer intend to maintain pending patent applications** . **Our** S. patents , 36 U. S. patents cover our AcQMap mapping system. Such U. S. patents, and any U. S. patents that may in the future issue from such applications, are scheduled to expire between 2027 and 2041 without taking potential **2039. Further, pursuant to our sale of the Products to Medtronic, we no longer retain rights to any** patent **patents covering the Products** term extensions or adjustments into account, and assuming national phase entries are timely made upon our pending PCT application and timely payments of all applicable maintenance or annuity fees are made . For more information regarding the risks related to our intellectual property, please see the section titled " Risk Factors — Risks Related to Our Intellectual Property. " Manufacturing **Manufacture** and Supply We currently manufacture **the Products for Medtronic** our novel access sheaths, transseptal crossing tools, diagnostic and mapping catheters, ablation catheters, mapping and imaging consoles and accessories at our approximately 50, 800 square foot facility in Carlsbad, California. This facility provides approximately 15, 750 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. We believe our existing facility is sufficient to meet our current manufacturing needs and we believe that adequate additional space will be available if we require it. We stock inventory of raw materials, components and finished goods at our facility in Carlsbad and, to a limited extent, with our sales representatives who travel to our hospital customers' locations as part of their sales efforts . We rely on a single or limited number of suppliers for certain raw materials and components, and we generally have no long- term supply arrangements with our suppliers, as we generally order on a purchase order basis. **Government Regulation** Furthermore, we rely on third parties to manufacture certain products we offer our customers as part of our product portfolio, including Biotronik for diagnostic and ablation catheters, RF generators and irrigation pumps, and MedFact Engineering GmbH for robotic navigation enabled ablation catheters. In conjunction with the Asset Purchase Agreement (as defined below), we executed a distribution agreement with Medtronic (the" Distribution Agreement"), pursuant to which we manufacture and supply the Products (as defined below) to Medtronic as exclusive distributor of the product line for up to the next four years. Our manufacturing and distribution operations are subject to regulatory requirements of the FDA' s Quality System Regulation, or QSR, for medical devices sold in the United States, set forth in 21 CFR part 820, and the European Medical Device Directive 93 / 42 / EEC and amendments, or MDD, and the products **Products** comply to ISO 13485 for manufacturing for medical devices marketed in the European Union. In addition, the Carlsbad facility is licensed by the California Food and Drug Branch. We are also subject to applicable local regulations relating to the environment, waste management and health and safety matters including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances. Government Regulation U. S. Food and Drug Administration Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, preclinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post- marketing surveillance. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510 (k) of the FDCA, also referred to as a 510 (k) clearance, or approval from the FDA of a PMA application. Both the 510 (k) clearance and PMA processes can be resource intensive, expensive and lengthy, and require payment of significant user fees, unless an exemption is available. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Class I devices are deemed to be low risk and are subject to the general controls of the FDCA such as provisions that relate to adulteration, misbranding, registration and listing, notification, including repair, replacement, or refund, records and reports and good manufacturing practices. Most Class I devices are classified as exempt from premarket notification under Section 510 (k) of the FDCA, and therefore may be commercially distributed without obtaining 510 (k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, postmarket surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a premarket notification requesting permission to commercially distribute some Class II devices. Devices deemed by the FDA to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510 (k) device, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA application. However, there are some Class III devices for which the FDA has not yet called for a PMA. For these devices, the manufacturer must submit a

premarket notification and obtain 510 (k) clearance in order to commercially distribute these devices. The FDA can also impose sales, marketing or other restrictions on devices in order to assure that they are used in a safe and effective manner. The Investigational Device Process In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of trials deemed to present " non- significant risk " are deemed to have an approved IDE once certain requirements are addressed, and institutional review board, or IRB, approval is obtained. If the device presents a " significant risk " to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the trial protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA' s approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product' s safety and effectiveness, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA' s IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of trial sponsors and trial investigators. Clinical trials must further comply with the FDA' s good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The 510 (k) Clearance Process When a 510 (k) clearance is required, an applicant must submit a premarket notification to the FDA demonstrating that the proposed device is substantially equivalent to a predicate device, which is a previously cleared and legally marketed 510 (k) device or a device that was in commercial distribution before May 28, 1976. By regulation, a premarket notification must be submitted to the FDA at least 90 days before intent to market the device, and 510 (k) clearance must be received from the FDA prior to marketing the device. The Medical Device User Fee Amendments performance goals for a traditional 510 (k) clearance is 90 days. As a practical matter, however, clearance often takes longer, because the review clock is paused by the FDA to allow time to resolve any questions the FDA may have on the 510 (k). To demonstrate substantial equivalence, the manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics or different technological characteristics, and the information in the premarket notification demonstrates that the device is equally safe and effective and does not raise different questions of safety and effectiveness. The FDA may require further information including clinical data to make a determination regarding substantial equivalence. If the FDA determines that the device or its intended use is not substantially equivalent to a previously cleared device or use, the FDA will place the device into Class III. There are three types of 510 (k) s: traditional, special and abbreviated. Special 510 (k) s are typically for devices that are modified and the results of change evaluation can be sufficiently reviewed in a summary or risk analysis format. Abbreviated 510 (k) s are for devices that conform to special controls for the device type or to a recognized standard. The special and abbreviated 510 (k) s are intended to streamline review, and the FDA intends to process special 510 (k) s within 30 days of receipt. The PMA Process A PMA application under section 515 of the FDCA must be submitted to the FDA for Class III devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The PMA application process is much more demanding than the 510 (k) premarket notification process. A PMA is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use (s). After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel' s recommendations are important to the FDA' s overall decision making process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with QSR. The FDA also may inspect one or more clinical sites to assure compliance with the FDA' s regulations. Upon completion of the PMA application review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA' s belief that the PMA application is approvable and states what additional information the FDA requires or the post- approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA' s review clock is reset. Pervasive and Continuing Regulation After a device is placed on the market, numerous regulatory requirements continue to apply. These include: • the FDA' s QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; • labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off- label uses; • medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a

~~way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; • medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health; and • post- market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device. We~~ have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA and CDPH have broad post- market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Additionally, our Notified Body, DQS- MED, regularly inspects our manufacturing ~~, design~~ and operational facilities to ensure ongoing ISO 13485 compliance in order to maintain ~~our~~ CE Mark. **We** ~~Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: • warning letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recall or seizure of our products; • operating restrictions, partial suspension or total shutdown of production; • refusing our requests for 510 (k) clearance or premarket approval of new products, new intended uses or modifications to existing products; • withdrawing 510 (k) clearance or premarket approvals that have already been granted; and • criminal prosecution. Export of Our Products Export of products subject to the 510 (k) notification requirements, but not yet cleared to market, is permitted with FDA authorization provided certain requirements are met. Unapproved or uncleared products subject to the PMA requirements may be exported if the exporting company and the device meet certain criteria, including, among other things, that the device complies with the laws of the receiving country and has valid marketing authorization from the appropriate authority and that the company submits a " Simple Notification " to the FDA when it begins to export. Importantly, however, export of such products may be limited to certain countries designated by statutory provisions, and petitions may need to be submitted to the FDA to enable export to countries other than those designated in the statutory provisions. The petitioning process can be difficult, and the FDA may not authorize unapproved or uncleared products to be exported to countries to which a manufacturer wishes to export. Devices that are adulterated, devices whose label and labeling does not comply with requirements of the country receiving the product, and devices that are not promoted in accordance with the law of the receiving country, among others, cannot be exported. Foreign Government Regulation The regulatory review process for medical devices varies from country to country, and many countries also impose product standards, packaging requirements, environmental requirements, labeling requirements and import restrictions on devices. Each country has its own tariff regulations, duties, and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, criminal prosecution or other consequences. Our portfolio of products is regulated in the European Union as a medical device per either the Medical Device Directive (MDD) or the Medical Device Regulations (MDR). The MDD and MDR set out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE Mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the regulations within their jurisdiction. The means for achieving the requirements for the CE Mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks. The class of a product determines the conformity assessment required before the CE Mark can be placed on a product. Conformity assessments for our products were previously carried out as required by the MDD and are now performed in accordance with the MDR. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE Mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard. Our current CE Marks are issued by DQS- MED (Frankfurt, Germany). After the product has received the CE Mark and been placed on the market in the European Economic Area, or EEA, a manufacturer must comply with a number of regulatory requirements relating to: • registration of medical devices in individual EEA countries; • pricing and reimbursement of medical devices; • establishment of post- marketing surveillance and adverse event reporting procedures; • field safety corrective actions, including product recalls and withdrawals; and • interactions with physicians. Other International Laws In Europe, various countries have adopted anti- bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense. Violations of these anti- bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, the U. K. Bribery Act 2010 covers both public and private sector bribery, and prohibits the offer, provision or promise to give a financial or other advantage to induce or reward another individual to improperly perform their relevant functions or activities including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U. K. Bribery Act 2010. An individual found in violation of the U. K. Bribery Act 2010 faces imprisonment of up to ten years. In addition, individuals can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery. There~~ are also ~~international privacy laws that impose restrictions on~~ **subject to applicable local regulations relating to** the **environment, waste management and health and safety matters including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling,** collection, ~~use~~ **recycling** , **treatment** ~~storage, disclosure, transfer~~ and **remediation of hazardous substances. As of December 31, 2023,** ~~other~~ **there were no material capital expenditures** ~~processing of personal information, including health information. For example, the General Data Protection Regulation, or GDPR, imposes stringent data protection requirements, including,~~ for **environmental** ~~example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and~~

additional obligations regarding third- party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans. Domestic Government Regulation In the United States, there are local, state and national laws, directives and regulations that apply to the collection, use, storage, disclosure, transfer and other processing of personal information, including health information. For more information regarding the risks related to privacy laws that apply to us, please see " Risk Factors — Risks Related to Our Business and Products — We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing and cross- border transfer of personal information and our data privacy and security policies. " California Consumer Privacy Act The California Consumer Privacy Act, or CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and a new privacy law, the California Privacy Rights Act, or CPRA, which mostly took effect on January 1, 2023, significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. It remains unclear what, if any, further modifications will be made to the CCPA or CPRA, or how such legislation will be interpreted. Health Insurance Portability and Accountability Act The federal Health Insurance Portability and Accountability Act, or HIPAA, created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third- party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA and its implementing regulations established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. U. S. Federal, State and Foreign Fraud and Abuse Laws The federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. Violations of such laws could result in significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations. Anti- Kickback Statutes The U. S. federal Anti- Kickback Statute prohibits, subject to certain safe harbors, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for the furnishing or arranging for a good or service, or for the purchasing, leasing, ordering, or arranging for or recommending any good, facility, service or item for which payment may be made in whole or in part under federal healthcare programs such as the Medicare and Medicaid programs. The Anti- Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term " remuneration " expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Additionally, the intent standard under the Anti- Kickback Statute was amended under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act which is discussed below. Penalties for violations of the Anti- Kickback Statute include, but are not limited to, criminal, civil and / or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs and the curtailment or restructuring of operations. Various states have adopted laws similar to the Anti- Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors. In addition, many foreign jurisdictions in which we operate have similar laws and regulations. Federal False Claims Act The U. S. federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim, or the knowing use of false statements, to obtain payment from or approval by the federal government. Suits filed under the federal civil False Claims Act, known as " qui tam " actions, can be brought by any individual on behalf of the government. These individuals, sometimes known as " relators " or " whistleblowers, " may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend a case brought under the federal civil False Claim Act. If an entity is determined to have violated the federal civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government plus civil penalties for each separate false claim. Various states have adopted laws similar to the federal civil False Claims Act, and many of these state laws are broader in scope and apply to all payors and, therefore, are not limited to only those claims submitted to the federal government. Civil Monetary Penalties The federal Civil Monetary Penalties Statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, are for an

item or service that was not provided as claimed or is false or fraudulent. Open Payments The Affordable Care Act also includes a provision, commonly referred to as the Sunshine Act, which requires that any manufacturer of a covered device that provides payment or other transfer of value to a physician or teaching hospital, or to a third party at the request of a physician or teaching hospital, must submit to Centers for Medicare & Medicaid Services, or CMS, information about the payment or other transfer of value annually, with the reported information to be made public on a searchable website. Foreign Corrupt Practices Act The Foreign Corrupt Practices Act, or FCPA, prohibits any U. S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign government official, political party or candidate for the purpose of improperly influencing any act or decision of a foreign government entity to obtain or retain business. The FCPA also obligates companies whose securities are listed on a national securities exchange in the United States to comply with accounting provisions which require the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls - **control facilities** . **Although** U. S. Health Reform Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts our industry. The United States and some foreign jurisdictions are considering enacting or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is **no assurance that existing** significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals **environmental laws applicable** to further reform healthcare or **our operations** reduce healthcare costs may limit coverage of or lower reimbursement for - **or** the procedures associated with the use of our products **Products we** . The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and has affected medical device manufacturers -- **manufacture will** significantly. The Affordable Care Act provides incentives to programs that increase the federal government' s comparative effectiveness research and implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. On December 14, 2018, a Texas U. S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U. S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and held oral arguments on November 10, 2020. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID- 19 pandemic, suspended the 2 % Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third- party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third- party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and **operations, cash flows or** financial condition . Coverage and Reimbursement In both U. S. and non- U. S. markets , **we** our ability to successfully commercialize and achieve market acceptance of our products depends in significant part on the availability of adequate financial coverage and reimbursement from third- party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third- party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Third- party payors in the United States generally do not provide reimbursement **currently anticipate material capital expenditures** for **environmental** our products. Rather, we expect certain components of our AcQMap System to continue to be purchased by hospitals and other providers who will then seek reimbursement from third- party payors for the procedures performed using our products. Reimbursement systems in international markets vary significantly by country and by region within some

~~countries, and reimbursement approvals must be obtained on a country- by- country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government- managed healthcare systems that~~ control **facilities** ~~reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government- managed systems. While third- party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, third- party payor reimbursement policies may change in the future. Third- party payors are increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third- party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third- party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre- approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for procedures that utilize one or more products for which we receive regulatory clearance and approval, less favorable coverage policies and reimbursement rates may be implemented in the future. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products~~ . Human Capital Resources **As part of the Restructuring, we initiated a reduction in workforce of approximately 160 employees, representing approximately 65 % of our employees, that is expected to be completed by the first quarter of 2024. In compliance with the Worker Adjustment and Retraining Notification Act, we have provided pre- termination notices to affected employees and government authorities where required.** We **also entered into retention arrangements with certain employees** ~~are an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. We are committed to advancing the field of electrophysiology and our team is comprised of passionate, driven and dedicated professionals working to provide better tools for clinicians and making life better for the individuals~~ who ~~suffer from complex cardiac arrhythmias~~ **remained with us to assist with the Restructuring and operations of our left- heart access distribution business** . As of December 31, ~~2022~~ **2023** , we had ~~225~~ **233 employees, of which 230 are** full- time employees. **As of December 31, 2023, we have paid $ 0. 7 million of the estimated $ 2. 0 million to $ 3. 0 million in cash expenditures for the payment of severance and related benefit costs and $ 0 of the estimated $ 3. 0 million to $ 4. 0 million in cash expenditures for the payment of retention bonuses to certain employees that are assisting with the Restructuring. The majority of the cash expenditures charges are expected to be incurred in the first quarter of 2024.** We believe that the success of our business will depend, in part, on our ability to ~~attract and~~ retain qualified **personnel, especially our manufacturing** personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. Culture & Values We pride ourselves on being **a** ~~an innovative~~ company comprised of dedicated and talented **individuals** ~~industry leaders~~ working together to make a distinctive mark within the medical device industry. ~~Our team works diligently to fulfill the mission of bringing an advanced tool for identifying and mapping complex arrhythmias to physicians and hospitals in order to optimize and expand the success of cardiac ablation.~~ As employees of Acutus, we are: ~~•~~ ○ Accountable to patients, physicians and each other; ~~•~~ ○ Courageously pursuing continuous improvement; ~~•~~ ○ United as one team achieving excellence; ~~•~~ ○ Tenacious about ~~innovation~~ **quality** ; ~~•~~ ○ Uncompromising in integrity; and ~~•~~ ○ Science based- talent driven. Business Ethics & Compliance We are committed to conducting our business affairs with **Medtronic,** employees ~~, customers~~ , suppliers, competitors, the government, the public and our shareholders with honesty and integrity and in accordance with the highest ethical standards. We believe that one of our most valuable assets is our reputation for integrity, professionalism and fairness. We are focused on ensuring that our legal, compliance and risk mitigation policies and programs are designed to hold ourselves to the highest standards of business conduct ~~. Talent Attraction, Retention & Engagement We seek to identify, recruit and retain a dynamic and innovative team of professionals that is committed to improving the diagnosis and treatment of cardiac arrhythmias. As of December 31, 2022, 125 employees, or 56 % of our workforce, have been at Acutus for at least two years~~ . Compensation & Benefits We care about our employees, their career and overall wellbeing. We offer competitive salaries, comprehensive benefits, paid time off, holidays and an onsite health and wellness program. Company Information We were incorporated in Delaware on March 25, 2011 as Acutus Medical, Inc. Our principal executive offices and manufacturing facilities are located at 2210 Faraday Ave., Suite 100, Carlsbad, CA 92008, and our telephone number is (442) 232- 6080. Our website address is www. acutusmedical. com. The information on, or that may be accessed through, our website is not a part of this report and the inclusion of our website address in this report is an inactive textual reference only. " Acutus, " the " Acutus " logo, " Acutus Medical, " the " Acutus Medical " logo, " AcQMap, " the " AcQMap " logo, " AcQBlate, " the " AcQBlate " logo, " AcQGuide, " the " AcQGuide " logo **]** , " AcQRef, " the " AcQRef " logo, " SuperMap, " the " SuperMap " logo, " UNCOVER AF " and the " UNCOVER AF " logo are trademarks or registered trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this report are our property. Solely for convenience, our trademarks and trade names referred to in this report appear without the ™ or ® symbol, but those references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and trade names. Other trade names, trademarks and service marks appearing in this report are the property of their respective owners. We make our Annual Reports on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K and amendments to those reports available free of charge at our website as soon as reasonably practicable after they have been filed with the SEC. Implications of Being an Emerging Growth Company and a Smaller Reporting Company We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS

Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non- binding advisory vote on executive compensation or golden parachute arrangements. In addition, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company until the earliest of: (i) December 31, 2025; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $ 1. 235 billion; (iii) the last day of the fiscal year in which we are deemed to be a " large accelerated filer " as defined in Rule 12b- 2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non- affiliates exceeded $ 700. 0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period. We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non- voting common stock held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. Item 1A. Risk Factors. Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our consolidated financial statements and related notes before deciding whether to invest in shares of our common stock. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. Please also see the section titled " Cautionary Note Regarding Forward- Looking Statements. " **On November 8, 2023, we announced a strategic realignment of resources and corporate restructuring to reallocate capital from our mapping and ablation businesses to our left- heart access distribution relationship with Medtronic (i. e., the Restructuring), to maximize the potential for future earnouts and cash flow. The Restructuring involves streamlining our operations, including the winding down of our mapping and ablation businesses, as well as a significant reduction in our workforce. Our restructuring activities may divert management' s attention from our remaining business operations, which may result in adverse effects on our existing relationships with our partners and suppliers. If management is unable to successfully manage this transition and associated restructuring activities, or if we are required to take additional actions to support our business objectives, our expenses may be more than expected and may vary significantly from period to period and we may be unable to implement our new business strategy. There can be no assurance that we will avoid disruption in the business and be able to continue to manufacture at the levels required to earn the potential of the sales earnouts from Medtronic. As a result, our future financial performance, operations, and prospects may be negatively affected. Following the Restructuring, we are completely dependent on our sales to Medtronic, as our business model has shifted to solely supporting the manufacturing and distribution of the Products to Medtronic pursuant to the Distribution Agreement. As our sole line of business is manufacturing and distributing the Products to Medtronic, our sole revenue stream comes from the sale of Products to Medtronic at transfer prices specified in the Distribution Agreement and potentially earning the associated earnout payments we may become eligible to receive from Medtronic under the Asset Purchase Agreement, with earnout payments beginning in January 2024 and continuing quarterly each quarter thereafter until 2027. As we have no marketing or sales capabilities of our own, our success depends on Medtronic performing its obligations under the Distribution Agreement and continuing to market and successfully sell the Products to end- users. There can be no assurance that Medtronic will be able to, or will, perform its obligations under the Distribution Agreement, or continue to market and successfully sell the Products. A decision by Medtronic, whether motivated by marketing strategy, competitive conditions, financial difficulties or otherwise, to significantly decrease the number of Products purchased from us or to change their manner of doing business with us, could substantially reduce our revenue. The loss of Medtronic as a strategic partner, including as a result of Medtronic deciding to no longer market and sell the Products, would have a significantly negative effect on our overall operations and would likely completely eliminate our revenue. In addition, following our Restructuring, and for the foreseeable future thereafter, we depend on revenue generated from sales of a single line of products, the left- heart access Products, to a single party, Medtronic. To the extent that our production of the left- heart access Products or sales thereof by Medtronic are delayed or reduced, or the Products are not well- received by the market for any reason (including Medtronic' s failure to successfully market the Products), our revenue and cash flow would be adversely affected. Larger companies have the ability to manage their risk through diversification. Following the implementation of the Restructuring, including the winding down of our mapping and ablation businesses, our business lacks such diversification. The Restructuring reduces our ability to manage risk through diversification as we are solely reliant on our relationship with Medtronic to generate all our revenue. As a**

result, we could potentially be more impacted by factors affecting the medical technology industry in general and us in particular, than would be the case if our business was more diversified. If there is any disruption to our production, the Products, or Medtronic' s ability and willingness to sell the Products, our business, results of operations and financial condition could be adversely impacted. If our Distribution Agreement with Medtronic terminates upon the occurrence of the Second Closing or for any other reason, and following the conclusion of the Net Sales Earnout period, we will have no sources of revenue. Our sole revenue stream comes from the sale of Products to Medtronic at transfer prices specified in the Distribution Agreement and potentially earning the Net Sales Earnouts we may become eligible to receive from Medtronic under the Asset Purchase Agreement, with earnout payments beginning in January 2024 and continuing quarterly each quarter thereafter until 2027. The Distribution Agreement has an initial term ending on the date of the Second Closing. If the Second Closing has not occurred on or prior to the fourth anniversary of the First Closing, then the Distribution Agreement will automatically renew thereafter for successive one- year periods, unless either we or Medtronic provides notice of non- renewal at least 18- days before the end of the then current term. If our Distribution Agreement terminates upon the occurrence of the Second Closing or for any other reason, and following the conclusion of the Net Sales Earnout period, we will have no sources of revenue unless Medtronic decides to continue to use us as a manufacturer of some or all of the Products at transfer prices. We plan to continue to invest in our operations, vigorously pursue manufacturing improvements, and focus on efficient manufacturing, high quality and reliability so that we are well positioned to capture manufacturing demands from Medtronic. However, there can be no assurance that Medtronic will decide to continue to use us as a manufacturer of the Products. In such circumstances, we will have no sources of revenue and will plan to reduce our operations to those necessary to identify and explore strategic options, including the sale, license or other disposition of one or more of our remaining assets, technologies or products and wind down our business. We have **no intention of resuming any manufacturing or distribution activities. In the event that our board of directors determines that** a ~~limited history operating~~ **liquidation and dissolution of our business is the best method to maximize stockholder value, we would file proxy materials with the SEC, and schedule an extraordinary meeting of our stockholders to seek approval of such plan** as **required. As part of the Restructuring, we wound down our mapping and ablation businesses and no longer manufacture or distribute the AcQMap Mapping System, the AcQMap 3D Mapping Catheter, the AcQBlate Force- Sensing Ablation Catheter, the AcGuide Max 2. 0 Steerable Sheath, and associated accessories. We supported AcQMap procedures with** a **small group of therapy managers through November 30, 2023. In addition, the implementation of our corporate restructuring has reduced our workforce by approximately 65 %. We have incurred $ 16. 4 million out of an estimated $ 21- 32 million of pre- tax restructuring and exit- related charges, for associated employee severance and benefits, retention bonuses, other restructuring costs and the disposition of certain assets. We expect to incur additional costs until the Restructuring is complete, which may include additional severance, inventory liquidation, non- cash asset impairments and contract termination costs. The amount of actual restructuring, transition and impairment charges may materially exceed our estimates, when determined, due to various factors outside of our control, including the actual outcomes of discussions and negotiations (a number of which are currently ongoing) with the counterparties to the contracts we intend to terminate or modify. We could incur significant liability if we do not successfully negotiate wind down provisions or new terms. For example, on February 2, 2024, Biotronik SE & Co. KG (" Biotronik ") sent a Notice of Rescission and Termination (the " Notice ") to us. The Notice provides that Biotronik rescinds and terminates the Bi- Lateral Distribution Agreements entered into with us on May 11, 2020 (the " Bi- Lateral Distribution Agreements "), effective immediately, based on the alleged repudiation of our contractual obligations under the Bi- Lateral Distribution Agreements, and alleges damages in an amount to be quantified by Biotronik. Biotronik has separately alleged that we breached our contractual obligations to it under the License and Distribution Agreement entered into with us and VascoMed GmbH, Germany on July 2, 2019 (the " LDA "), as a result of the wind down of our mapping and ablation businesses and alleges further damages. On February 16, 2024, Biotronik and VascoMed GmbH, Germany (the " Biotronik Parties ") filed a Demand for Arbitration (the" Demand") against Acutus with the American Arbitration Association (who notified us of the Demand on February 29, 2024), alleging that we breached our contractual obligations under five agreements relating to the licensing, manufacturing, distribution and development of medical devices as a result of the wind down of our businesses. The Biotronik Parties allege that we breached, among other things, our obligations (i) to develop, manufacture, use and** ~~commercial~~ **commercialize** ~~company~~ **certain product lines under the LDA and the Manufacturing and Supply Agreement entered into on April 19, 2022 with Biotronik (the " MSA ")** ; ~~if we fail~~ **(ii)** to **distribute Biotronik products** ~~effectively train our sales force, increase our sales and marketing capabilities or develop broad brand -- and awareness in a cost~~ **manufacture and supply Acutus products under the Bi** - ~~effective manner~~ **Lateral Distribution Agreements** , **as applicable; and (iii) to use commercially reasonable efforts to perform and complete** our ~~growth~~ **responsibilities under the Feasibility and Development Agreement entered into on June 2, 2021 with Biotronik (the " F & DA "). The claim seeks, among other relief, $ 38. 0 million in damages, attorney' s fees, other expenses and costs. Our jurisdiction objection and any counterclaims are due on April 1, 2024. After that, the parties** will **appoint** ~~be impeded and~~ - **an** ~~our business~~ **arbitral tribunal and set a procedural timetable. We disagree with the Biotronik Parties' allegations. We intend to defend ourself vigorously and** will ~~suffer~~ **pursue all legal remedies available under applicable laws** . **Because** ~~We were incorporated in 2011, began commercializing our products in 2016 and became a publicly traded company in August 2020. Early versions~~ of **uncertainties with respect to** ~~our AcQMap System and certain related accessory products have been used in the United States since May 2018 and Western Europe since July 2016 in a limited, pilot launch capacity where our focus was on optimizing workflow and validating our value proposition. We fully commenced the launch of our commercial- grade console and software products in the first quarter of 2020. Accordingly, our limited commercialization experience and limited number of approved or~~

our Restructuring plans (including those described above) ~~cleared products make it difficult to evaluate our current business and assess our prospects. We also currently have limited sales and marketing experience. If we are unable to establish effective sales and marketing capabilities or if we are unable to commercialize any of our products~~ , we may not be able to ~~effectively generate product revenue, sustain revenue growth and compete~~ **complete the Restructuring in the timeframe** ~~effectively. In order to generate future growth, we plan to continue to expand and leverage our~~ **or on the terms** ~~sales and marketing infrastructure to increase our~~ **or** ~~customer base~~ **in the manner we expect. We may not realize, in full or in part, the anticipated benefits, savings** and ~~grow~~ **improvements in our cost structure from our realignment efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the Restructuring,** our business ~~. Identifying and recruiting qualified sales and marketing personnel and training them on our products~~ , ~~on applicable federal~~ **results of operations** and **financial condition would be adversely affected** ~~state laws and regulations and on our internal policies and procedures requires significant time~~ , ~~expense~~ and **we** ~~attention. It often takes several months or more before a sales representative is fully trained and productive. Our business~~ may be ~~harmed if our efforts to expand and train our sales force~~ **forced** ~~do~~ **to seek bankruptcy protection. In addition, the Restructuring involves numerous risks, including but** not **limited to: ◦ the inability of our remaining business to retain qualified personnel necessary to effectuate the Restructuring and run the remaining business; ◦ potential disruption of the operations of our remaining business and diversion of management' s attention from such business and operations; ◦ exposure to unknown, contingent or other liabilities, including litigation arising in connection with the Restructuring; ◦ negative impact on our business relationships, including but not limited to relationships with our old customers, suppliers, vendors, and employees; and ◦ unintended negative consequences from changes to our business profile. Our ability to continue to have the liquidity necessary to service our debt and meet financial covenants under our amended and restated credit agreement dated as of June 30, 2022, with related parties Deerfield Private Design Fund III, L. P. and Deerfield Partners, L. P. (collectively referred to as " Deerfield " or " Lenders ") and Wilmington Trust National Association (" Wilmington Trust ") as administrative agent (the " 2022 Credit Agreement ") depends on us generating sufficient cash, either through cash flows from operations or other financings. While we believe that cash on hand, distribution revenue from left- heart access Products to Medtronic and future earnouts will** generate ~~a corresponding increase in revenue,~~ **sufficient cash flows to service our debt** and **meet our obligations for the next twelve months, the foregoing expectation is dependent on a number of factors, including our ability to generate sufficient cash flow from operations, our ongoing ability to manage our operating obligations and the potential borrowing restrictions imposed by our Lenders based on their credit judgment. In the event that we are unable to timely service our debt** ~~our~~ **or** ~~higher fixed costs~~ **fund our other liquidity needs, we** may ~~slow~~ **need to refinance all** ~~our~~ **or** ~~ability~~ **a portion of our indebtedness before maturity, seek waivers of or amendments** to **our contractual obligations for payment,** reduce ~~costs in the face of a sudden decline in demand for~~ **or delay capital expenditures, liquidate inventory through additional discounting, sell material assets** ~~our~~ **or operations** ~~products. Any failure to hire, develop and retain talented sales and marketing personnel, to achieve desired productivity levels in a reasonable timeframe or to timely leverage our~~ **or** ~~fixed costs~~ **seek other financing opportunities. There can be no assurance that these options would be available to us and our inability to address our liquidity needs** could ~~have a material~~ **materially and** ~~adverse~~ **adversely** ~~effect~~ **affect** ~~on~~ **our operations and jeopardize** our business, **results of operations and** financial condition ~~and~~ **, including a default under the 2022 Credit Agreement which could** ~~results~~ **result in all amounts outstanding under such facility becoming immediately due and payable. If our Restructuring is not successful, our board** of **directors may decide to pursue a liquidation and dissolution of our business. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, including under our 2022 Credit Agreement. There can be no assurance that the Restructuring will be successful or that we will realize the anticipated benefits, including achievement of positive cash flow. If the Restructuring is not successful, our board of directors may decide to pursue an assignment for the benefit of creditors, a reorganization or a dissolution of the Company and liquidation of all our remaining assets. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our** operations. **The process** ~~Moreover, the members~~ of **liquidation may be lengthy, and we cannot make any assurances regarding the timing of completing such a process. If** our **board of** ~~direct~~ **directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, including any under our 2022 Credit Agreement, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. There is a substantial likelihood that no cash will be available to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves. In addition to our obligations to our Lenders and other creditors, our financial commitments and contingent liabilities may include: (i) personnel costs, including severance; (ii) contractual obligations to third parties; (iii) non- cancelable lease obligations; and (iv) potential litigation against us. As a result of the requirement to reserve for contingencies, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock [could] [would likely] lose all or a significant portion of their remaining investment in the event of a liquidation, dissolution or winding up. Risks Related to Our Business and the Products The commercial success of the Products, and thus our ability to generate revenue from Medtronic' s** sales

force are at **of the Products,** will **depend upon attaining significant** employees. The loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill technical expertise in replacement personnel, our revenue and results of operations could be materially harmed. Our ability to increase our customer base and achieve broader market acceptance of our the products **Products among hospitals** will also depend to a significant extent on our ability to expand our marketing efforts , as we plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost- effective manner is critical to achieving broad acceptance of our products and penetrating new customer accounts. Brand promotion activities may not generate patient or physician **physicians** awareness or increased revenue , **patients** and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand -- **and payors** . If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products. These factors also make it difficult for us to forecast our financial performance and growth, and such forecasts are subject to a number of uncertainties including our ability to successfully develop additional products that add functionality, to reduce the cost of products sold, to broaden our commercial portfolio offerings and obtain FDA 510 (k) clearance or PMA, and to successfully commercialize, market and sell, our planned or future products in the United States or in international markets. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer . Our success will depend **depends** , in part, on **Medtronic continuing to market and successfully sell the Products to end- users, which in turn depends on** the acceptance of our **the** products **Products** as safe, effective and, with respect to providers, cost- effective. We cannot predict how quickly, if at all, hospitals, physicians, patients or payors will accept our **the** products **Products** or, if accepted, how frequently they will be used. Our **The** products **Products** and planned or future products we may develop or market may never gain broad market acceptance for some or all of our **the** targeted indications. Hospitals, physicians, patients and payors must believe that our **the** products **Products** offer benefits over alternative treatment methods. To date, a substantial majority of our product sales and revenue have been derived from a limited number of customers who have adopted our AcQMap System and accompanying products. Our future growth and profitability largely depend **depends** on our **Medtronic' s** ability to increase physician awareness of **the** our system and our products **Products** and on the willingness of hospitals, physicians, patients or payors to adopt them. These parties may not adopt our **the** products **Products** unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses that our **the** products **Products** are safe, effective and, with respect to providers, cost- effective on a stand- alone basis and relative to competitors' products. Healthcare providers must believe that our **the** products **Products** offer benefits over alternative treatment methods. Even if we are able to raise awareness, physicians **Physicians** tend to be slow in changing their medical treatment practices and may be hesitant to select our **the** products **Products** for recommendation to their hospitals or patients for a variety of reasons, including: • long- standing relationships with competing companies and distributors that sell other products; • competitive responses and negative selling efforts from providers of alternative products; • lack of experience with our **the** products **Products** and concerns that we are relatively new to market ; • lack or perceived lack of sufficient clinical evidence, including long- term data, supporting safety or clinical benefits; and • time commitment and skill development that may be required to gain familiarity and proficiency with our **the** products **Products** . Physicians play a significant role in determining the course of a patient' s treatment, and as a result, the type of treatment that will be utilized and provided to a patient. We focus our sales, marketing and education efforts primarily on cardiac electrophysiologists. However, we cannot assure you that we will achieve broad market acceptance among these practitioners. For example, if electrophysiologists are not made aware of our products, they may not recommend ablation for their patients or the installation of our AcQMap System in their hospitals. In addition, some **Some** physicians may choose to utilize our **the** products **Products** on only a subset of their total patient population or may not adopt our **the** products **Products** at all. If we are **Medtronic is** not able to effectively demonstrate that the use of our **the** products **Products** is beneficial in a broad range of patients, adoption of our **the** products **Products** will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our **the** products **Products** will achieve broad market acceptance among hospitals and physicians. Additionally, even if our **the** products **Products** achieve market acceptance, they may not maintain that market acceptance over time if competing products, procedures or technologies are considered safer or more cost- effective or otherwise superior. Any failure of our **the** products **Products** to generate sufficient demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations. Our reputation among our current or potential customers, as well as among electrophysiologists, could also be negatively affected by safety or customer **end- user** satisfaction issues involving us or our **the** products **Products** , including product recalls. Any product recalls or other safety or customer **end- user** satisfaction issues relating to our reputation could negatively affect our **Medtronic' s** ability to establish or maintain broad adoption of our **the** products **Products** , which would harm our future prospects and have a material adverse effect on our business, financial condition and results of operations. In most cases, before a hospital can purchase our AcQMap console and workstation for the first time, our system must be approved for use by a hospital' s new product or value analysis committee or the staff of a hospital or health system. Such approvals could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations. We have significant international operations and intend to

further expand our business internationally, which exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. As of December 31, 2022, we have sold our products directly in the United States, Belgium, the Czech Republic, Denmark, France, Germany, Great Britain, Italy, the Netherlands, Sweden and Switzerland. Our business strategy includes plans for significant expansion in the countries in which we currently operate as well as other international markets and may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payors. During the years ended December 31, 2022 and 2021, 47 % and 52 %, respectively, of our revenue was generated from customers located outside of the United States, and we anticipate that international sales will continue to represent a substantial portion of our total sales in the future. For example, in May **Many** 2020, we entered into expansive bi- lateral distribution agreements with Biotronik (the" Bilateral Distribution Agreements"), pursuant to which Biotronik agreed to distribute our products in Germany, Japan, Mexico, Switzerland and multiple countries in Asia- Pacific, Eastern Europe, the Middle East and South America. In addition, some of our employees including those of our Belgium subsidiary, our suppliers and our other strategic partners are located outside of the United States. Doing business internationally involves a number of risks, including: • changes in a country' s or region' s political or economic conditions, including any potential impact resulting from the United Kingdom' s, or UK, exit from the European Union, commonly referred to as Brexit; • difficulties in developing effective marketing campaigns in unfamiliar foreign countries; • multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • obtaining regulatory approvals where required for the sale of our products in various countries; • requirements to maintain data and the processing of that data on servers located within such countries; • complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; • trade protection measures, customs clearance and shipping delays; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • natural disasters, political and economic instability including wars, terrorism, political unrest, outbreaks of disease or public health crises (including the impact of the COVID- 19 pandemic), boycotts, curtailment of trade and other market restrictions; • regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the FCPA, U. K. Bribery Act 2010 and comparable laws and regulations in other countries; • our reliance on international distributors who we do not control to effectively market and sell our products in full compliance with applicable laws; • differing protection of intellectual property; and • increased financial accounting and reporting burdens and complexities. We rely on shipping providers to deliver products to our customers and distributors globally. Labor, tariff or World Trade Organization- related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products, energy- related tie- ups, outbreaks of disease or public health crises (including the impact of the COVID- 19 pandemic) or other factors could disrupt or delay shipping or off- loading of our products domestically and internationally. Such disruptions or delays could materially and adversely affect our business, financial condition and results of operations. If one or more of these risks are realized, our business, financial condition and results of operations could be materially and adversely affected. We rely on our strategic relationship with Biotronik to enhance our product portfolio and to distribute our products in key international markets. We entered into expansive Bi- Lateral Distribution Agreements with Biotronik in May 2020 to round out our product portfolio with a full suite of diagnostic and ablation catheters, and to rapidly and efficiently establish a sales presence globally. Pursuant to our Bi- Lateral Distribution Agreements with Biotronik, we obtained a non- exclusive license to distribute a range of Biotronik' s therapeutic and diagnostic electrophysiology products and accessories in the United States, Canada, China, Hong Kong and multiple countries in Western Europe under our own private label. Biotronik has also agreed to distribute our products and accessories in Germany, Japan, Mexico, Switzerland and multiple countries in Asia- Pacific, Eastern Europe, the Middle East and South America. Accordingly, the Bi- Lateral Distribution Agreements significantly expand both our product portfolio and our international sales presence. If Biotronik is unable to successfully market and sell our products in these markets, or if we are unable to successfully market Biotronik' s products in the United States and geographies where we have or establish a direct selling presence, it could materially adversely impact our growth prospects in these markets and our relationship with Biotronik, which would harm our business, financial condition and results of operations. Our strategic alliance with Biotronik also includes cooperative arrangements with respect to regulatory approval and the commercialization, manufacture and marketing of our respective products in various geographic markets. While we will depend on Biotronik to sell our products in its designated territories and otherwise cooperate with us in our strategic alliance, we do not control the time and resources Biotronik devotes to such activities, and we may not have the resources available to satisfy expectations, which may adversely affect our relationship. Either party may terminate the Bi- Lateral Distribution Agreements with respect to a country if the other party does not meet specified purchase targets for that country following a specified ramp- up period. Any termination of the Bi- Lateral Distribution Agreements for this or other reasons could have a material adverse effect on our business, financial condition and results of operations. For example, recruiting and retaining qualified third- party distributors and training them in our technology and products requires significant time and resources. Further, if our relationship with Biotronik terminates, we may be unable to replace this relationship or develop a direct sales channel without disruption to our business. We may also seek to enter into additional strategic partnerships with other third parties in the future, including distribution arrangements. If we fail to develop new relationships with any other strategic partners we seek to engage, including in new markets, if we fail to manage, train or incentivize distributors effectively, or if we fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales and marketing efforts, our ability to generate revenue growth could suffer, which could have a material adverse effect on our business, financial condition and results of operations. Moreover, these strategic partnerships may be non- exclusive, and some of our strategic partners may also have cooperative relationships with certain of

~~our~~ competitors **in the manufacturing services** ~~. These relationships may not continue, may not be commercially successful or may require our expenditure of significant financial, personnel and administrative resources from time to time. If we are unable to leverage our existing and future strategic partnerships to achieve and maintain distribution at a global scale or establish and maintain a broad product portfolio, it could have a material adverse effect on our business, financial condition and results of operations. The medical device~~ industry ~~is intensely competitive, is subject to rapid change~~ and ~~is significantly affected by new product introductions and other market activities of industry participants. We compete with manufacturers and distributors of cardiovascular medical devices. Our most significant competitors in~~ the electrophysiology field ~~include Abbott Laboratories, Biosense Webster Inc. (a Johnson & Johnson Company), Boston Scientific Corporation and Medtronic, Inc.. Many of our competitors~~ are large, well- capitalized companies with significantly greater market share and resources ~~than we have~~. Therefore, they ~~can~~ **may be able to** spend more on product development, **manufacturing,** marketing, sales and other product initiatives ~~than we can~~. We ~~also~~ **believe that the principal** ~~compete~~ **competitive factors in the electrophysiology field are: name recognition; relations** with ~~smaller medical device companies that have a single~~ **healthcare professionals, customers and third- party payors; quality and depth of distribution networks; breadth of** product **lines and the ability to offer rebates** or **bundle** ~~a limited range of~~ products ~~. Some of~~ **to offer discounts** ~~our~~ **or** ~~competitors have: • continue to~~ **other incentives; capabilities in research and** ~~develop~~ **development** ~~innovative~~, ~~proprietary~~ **manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for** products **;** ~~that address significant clinical needs in a manner that is safe~~ and ~~effective~~ **financial and human resources** for ~~patients and easy- to- use for physicians; • increase the productivity of our sales force across key geographic markets; • leverage our strategic partnerships and alliances to achieve distribution at a global scale, to broaden our product portfolio and to enable and accelerate global connectivity; We can provide no assurance that we will be successful in developing new products or commercializing them in ways that achieve market acceptance. If we develop new products, sales of those products may reduce revenue generated from our existing products. Moreover, any significant delays in our product launches may significantly impede our ability to enter into or compete within a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a~~ product development, **manufacturing** ~~including during research and development~~, ~~clinical trials,~~ **sales and marketing and patent prosecution. Our success depends on our ability to: ◦ obtain and maintain** regulatory ~~review~~ **clearances or approvals; ◦ leverage our strategic relationship with Medtronic to sell Products to them and potentially earn earnouts under the Asset Purchase Agreement; ◦ retain skilled personnel** , **especially our** manufacturing **personnel;** and ~~marketing. Delays in~~ **◦ cost- effectively manufacture the** ~~product~~ **Products** ~~introductions~~ **. If we or the Products are not able to compete successfully, our sales to Medtronic may decline and our revenue from Medtronic' s sales of the Products to end- users may be reduced, and there** ~~could would have~~ **be** a material adverse effect on our business ~~, financial condition~~ and results of operations. **Our quarterly** ~~Any growth that we experience in the future could require us to expand our sales~~ and **annual results of** ~~marketing personnel and manufacturing~~ operations ~~and general and administrative infrastructure. In addition to the need to scale our organization~~ , ~~future growth will impose significant added responsibilities on management~~ including ~~the need to identify, recruit, train and integrate additional employees. We cannot assure you that any increases in scale- related improvements and quality assurance will be successfully implemented or~~ **our** ~~that appropriate personnel will be available to facilitate the growth of our business. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure and could require significant capital expenditures that may divert financial resources from other projects such as research and development of potential future products. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls and our reporting systems and procedures. If we are unable to manage our growth effectively, including by failing to implement necessary procedures, to transition to new processes or to hire necessary personnel, it may be difficult for us to execute our business strategy and our business could be adversely affected. Our success depends on our ability to develop, license or acquire and commercialize additional products and to develop new applications for our technologies in existing and new markets while improving the performance and cost- effectiveness of our existing products, in each case in ways that address current and anticipated customer requirements. We intend to develop and commercialize additional products through our research and development program and by licensing or acquiring additional products and technologies from third parties. Such success is dependent upon several factors including functionality, competitive pricing, ease of use, the safety and efficacy of our products and our ability to identify, select and acquire the rights to products and technologies on terms that are acceptable to us. The medical device industry is characterized by rapid technological change and innovation. New technologies, techniques or products could emerge that might offer better combinations of price and performance or better address customer requirements as compared to our current or future products. Competitors who may have greater financial, marketing and sales resources may be able to respond more quickly and effectively to new or changing opportunities, technologies, standards or customer requirements. Any new product we identify for internal development, licensing or acquisition may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. Due to the significant lead time and complexity involved in bringing a new product to market, we are required to make a number of assumptions and estimates regarding the commercial feasibility of a new product. These assumptions and estimates may prove incorrect, resulting in our introduction of a product that is not competitive at the time of launch. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. Our ability to mitigate downward pressure on our selling prices will be dependent upon our ability to maintain or increase the value we offer to hospitals, physicians, patients and payors. All new products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be~~

~~sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, be successfully commercialized or be widely accepted in the marketplace. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products, could adversely affect our business, financial condition and results of operations. Our ability to attract new customer accounts and increase~~ revenue ~~from existing customers depends in large part on our ability to enhance and improve our existing products and to introduce compelling new products. The success of any enhancement to our products depends on several factors~~ , ~~including our ability to drive increased installations of our AcQMap console and workstation in customer accounts, to accomplish timely completion and delivery, to formulate competitive pricing and to instill overall market acceptance. Any new product that we develop may not be introduced in a timely or cost- effective manner, may contain defects or may not achieve the market acceptance necessary to generate significant revenue. If we are unable to successfully develop, license or acquire new products, enhance our existing products to meet customer requirements or otherwise gain market acceptance, our business, financial condition and results of operations would be harmed. The typical development cycle of new medical device products can be lengthy and complicated and may require complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then such new technologies or products may be adversely impacted and our business and~~ operating results ~~may be harmed. Our quarterly and annual results of operations, including our revenue, profitability~~ and cash flow, may vary significantly in the future, and period- to- period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly and annual results include, without limitation: ~~•~~ ◦ the level of demand for ~~our~~ **the** ~~products~~ **Products**, which may vary significantly from period to period; ◦ ~~• the expenditures that we may incur to acquire, develop or commercialize additional products and technologies; • the timing and cost of clinical trials, including obtaining regulatory approvals or clearances for planned or future products; • the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein; •~~ the degree of competition in ~~our~~ **the electrophysiology** industry and any change in the competitive landscape of ~~our~~ **the electrophysiology** industry including consolidation among **market participants** ~~our competitors or future partners~~ ; ~~•~~ ◦ the coverage and reimbursement policies with respect to the procedures using ~~our~~ **the** ~~products~~ **Products** and potential future products that compete with ~~our~~ **the** ~~products~~ **Products** ; ~~•~~ ◦ the timing and ~~success or failure of clinical trials for our current or planned products or any future products we develop or competing products; • the timing of customer orders or medical procedures, the timing and number of installations of our AcQMap console and workstation, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold and the geographic mix of where products are sold; • the timing and~~ cost of, and level of investment in, ~~research,~~ development ~~,~~ **and** regulatory approval ~~and commercialization activities~~ relating to ~~our~~ **the** ~~products~~ **Products**, which may change from time to time; ~~•~~ ◦ the cost of manufacturing ~~our~~ **the** ~~products~~ **Products**, which may vary depending on the quantity of production and the terms of our agreements with third- party suppliers ~~and manufacturers~~ ; ~~•~~ ◦ the occurrence of natural disasters, outbreaks of disease or public health crises such as the COVID- 19 pandemic; ~~• the timing~~ and ◦ ~~nature of any future acquisitions or strategic partnerships; and •~~ future accounting pronouncements or changes in our accounting policies. Because our quarterly and annual results may fluctuate, period- to- period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. In addition, this variability and unpredictability could result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it may result in a decrease in the price of our common stock. We depend upon third- party suppliers including single- source suppliers, making us vulnerable to supply disruptions and price fluctuations. We rely on third- party suppliers to provide us with certain components of our products, some of which are single- source suppliers. In some cases, we do not have long- term supply agreements with, or guaranteed commitments from, our suppliers, including single- source suppliers. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. For example, the single- source supplier of raw materials for one of our **historical** products was unable to meet our shipment demands during late 2022, which impacted our ability to produce finished goods. Our suppliers may also cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in ~~our~~ **the** ~~products~~ **Products** would limit our ability to manufacture ~~our~~ **the** ~~products~~ **Products** and could have a material adverse effect on our business, financial condition and results of operations ~~. The success of our products depends in part on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our AcQMap System. However, physicians rely on their previous medical training and experience, and we cannot guarantee that all such physicians will have the necessary skills or training to effectively utilize our products. We do not control which physicians use our products or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to use our products. If physicians use our products in a manner that is inconsistent with their labeled indications, with components that are not~~

~~compatible with our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved by other physicians or in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products, which would have a material adverse effect on our business, financial condition and results of operations. Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as to significant costs and negative publicity~~ . Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of ~~our~~ **the** ~~products~~ **Products** caused by design flaws or manufacturing defects. In addition, component failures, design defects, off- label uses or inadequate disclosure of product- related information could also result in an unsafe condition or in the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, ~~our~~ **the** ~~products~~ **Products** and could result in significant costs, negative publicity and adverse competitive pressure. Furthermore, the reporting of product defects or voluntary recalls to the FDA or analogous regulatory bodies outside the United States could result in manufacturing audits, inspections and broader recalls or other disruptions to our manufacturing processes. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations. We provide a limited warranty that ~~our~~ **the** ~~products~~ **Products** are free of material defects and conform to specifications, and we offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on ~~our~~ **the** ~~products~~ **Products** . In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery and any recovery from such vendor or supplier may not be adequate. The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if ~~our~~ **the** ~~products~~ **Products** cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with ~~our~~ **the** ~~products~~ **Products** such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using ~~our~~ **the** ~~products~~ **Products** , even if ~~our~~ **the** ~~products~~ **Products** were not the actual cause of such injury or death. We may choose to settle any such claims even if we believe that such injuries were not due to failure of ~~our~~ **the** ~~products~~ **Products** . An adverse outcome of any such claim involving one of ~~our~~ **the** ~~products~~ **Products** could result in reduced market acceptance and demand for any or all of ~~our~~ **the** ~~products~~ **Products** and could harm our reputation ~~or brand 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 premarket notifications or applications for marketing~~ . Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations. Although we carry product liability insurance ~~, including for clinical trials and product marketing~~ , we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not continue to be available on acceptable terms, if at all. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses and reduce ~~product~~ **our** sales **to Medtronic** . If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. Product liability claims could cause us to incur significant legal fees and deductibles, and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results. Defending a suit regardless of its merit or eventual outcome could be costly, could divert management' s attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, in product recalls or in market withdrawals. We are required to file adverse event reports under MDR regulations with the FDA which are publicly available on the FDA' s website. We are required to file MDRs if ~~our~~ **the** ~~products~~ **Products we manufacture** may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and **Medtronic' s** future sales. See " — Risks Related to Government Regulation — If any of ~~our~~ **the** ~~products~~ **Products we manufacture** cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. " **Our operations** ~~In both U. S.~~ and ~~non- U. S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate~~ financial **results** ~~coverage and reimbursement from third- party payors including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third- party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Our products are purchased by hospitals and other providers who then seek reimbursement from third- party payors for the procedures performed using our products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country- by- country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many~~ **may** ~~international markets have government- managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government- managed systems. While third- party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, we can give no assurance that these third- party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, or permit hospitals and doctors to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using~~

~~our products will continue. If sufficient coverage and reimbursement is not available for the procedures using our products in either the United States or internationally, the demand for our products and our revenue will~~ be adversely **impacted** ~~affected. Furthermore, although we believe there is potential to improve on the current reimbursement profile for our products in the future, the overall amount of reimbursement available for procedures intended to diagnose and treat complex heart arrhythmias could remain at current levels or could decrease in the future. Failure~~ by ~~hospitals and other~~ -- **the** ~~users~~ **resurgence** of **COVID** ~~our products to obtain and maintain coverage and adequate reimbursement for the procedures using our products would materially adversely affect our business, financial condition and results of operations. Third~~ - **19** ~~party payors are also increasingly examining the cost effectiveness of products in addition to their safety and efficacy when making coverage and payment decisions. Third- party payors have also instituted initiatives to limit the growth of healthcare costs using, for~~ - **or another global pandemic** ~~example, price regulation or controls and competitive pricing programs. Some third- party payors also require demonstrated superiority on the basis of randomized clinical trials, or require pre- approval of coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction~~ . The markets we serve could see continued impacts from COVID- 19 for the foreseeable future, and the emergence of new variants of COVID- 19 creates significant uncertainty as to how long COVID- 19 will continue to impact our business. The magnitude of the impact of the COVID- 19 pandemic on our productivity, results of operations and financial position, and its disruption to our business ~~and our clinical programs and timelines~~ will depend, in part, on the length and severity of outbreaks, on restrictions and other measures designed to prevent the spread of COVID- 19 and on our ability to conduct business in the ordinary course. The uncertainty of future pandemics or resurgences of COVID- 19 could severely impact our business including: ~~•~~ ◦ significant interruptions to, or temporary closures of, our operations, including our manufacturing facility ~~or our commercial organization~~ ; ~~•~~ ◦ adverse effects on macroeconomic conditions as well as within the economies and financial markets of specific regions in which ~~our~~ **the** ~~products~~ **Products** are marketed **by Medtronic** ; ~~•~~ ◦ continued depressed demand for **the** ~~installations of our AcQMap console and workstation and for our disposable products~~ **Products** during a prolonged delay in physicians performing elective procedures using ~~our~~ **the** ~~products~~ **Products** , or due to focusing their resources elsewhere; ◦ ~~• continued or increased delays or difficulties in enrolling patients in our clinical trials or the interruption or delay of key clinical trial activities such as clinical trial site monitoring arising from limitations on access to trial sites or limitations on travel imposed or recommended by federal or state governments, employers and others; •~~ limitations in resources that would otherwise be focused on the conduct of our business, including because of sickness or the desire to avoid contact with large groups of people or as a result of government- imposed shelter- in- place or similar working restrictions; ~~• difficulties in recruitment of qualified sales~~ and ◦ ~~marketing personnel and mappers during a period in which we are seeking to significantly expand our commercial organization; and •~~ interruption in ~~global~~ shipping that may affect the shipment of ~~our~~ **the** ~~products~~ **Products to Medtronic** ~~or the transport of clinical trial materials~~ . U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the military conflict between Russia and Ukraine **and Gaza and Hamas** . Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine **and Israel** could lead to market disruptions including significant volatility in credit and capital markets. ~~Additionally~~ **Further** , Russia' s prior annexation of Crimea, ~~recent~~ recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so- called Donetsk People' s Republic and the so- called Luhansk People' s Republic, including an agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication payment system. Additional potential sanctions and penalties have also been proposed and / or threatened. ~~Russian~~ **In addition, the conflict in Gaza and surrounding areas has also created economic uncertainty and regional instability, including due to the risk of escalation into a wider regional conflict, and resulted in the imposition of sanctions targeting Hamas- affiliated individuals and entities. Such** military actions and the resulting sanctions could adversely affect the global economy and financial markets. Any of the above ~~-~~ mentioned factors could affect our business, prospects, financial condition and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10- K. ~~The continuing development of our products depends upon our maintaining strong working relationships with hospitals, physicians and other medical personnel. The research, development, marketing and sale of our current products and potential new and improved products for which we receive regulatory clearance or approval depend upon our maintaining working relationships with hospitals, physicians and other medical personnel. We rely on these relationships to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. For example, physicians assist us in clinical trials and in marketing and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships and continue to receive such advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations. At the same time, the medical device industry' s relationship with physicians is under increasing scrutiny by the U. S. Department of Health and Human Services Office of Inspector General, or OIG, the U. S. Department of Justice, or DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry' s relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other~~

~~government agencies could have a material adverse effect on our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below under " — Risks Related to Government Regulation. " We depend on our senior management team, and the loss of one or more key employees or an inability~~ **Inability** to ~~attract and~~ retain highly skilled employees **, especially manufacturing employees,** could harm our business. Our **manufacturing** ~~success depends largely on the continued services of key members of our executive management team and others in key management positions. We do not currently maintain key- person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, in developing our technologies and in implementing our business strategy. In addition, our research and development programs, clinical~~ operations ~~and sales and marketing efforts~~ depend on our ability to ~~attract and~~ retain ~~highly~~ skilled ~~scientists, engineers and sales~~ professionals **, especially manufacturing employees** . Competition for skilled personnel in our market is intense, and we have from time to time experienced, and we expect to continue to experience, difficulty in ~~hiring and~~ retaining employees with appropriate qualifications on acceptable terms, or at all. ~~Many~~ **Most** of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. **This is especially true as a result of the Restructuring.** If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees ~~often consider the~~ **are likely not to** value ~~of~~ the stock awards they receive in connection with their employment ~~. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees~~ . Furthermore, our common stock is currently trading at a price below the exercise price of most of our outstanding stock options. As a result, these ~~"~~ **"** underwater ~~"~~ **"** options are ~~less~~ **generally not** useful as a motivation and retention tool for our existing employees. If we ~~fail to attract new personnel or~~ fail to retain and motivate our current personnel, our business and future growth prospects would be harmed. **Changes to management, including turnover of our top executives, could have an adverse effect on our business. Our business has experienced significant executive management changes. In July 2023, we announced the departure of Charlie Piscitello, our Senior Vice President, Chief People Officer, which departure became effective July 14, 2023. In November 2023, we announced the departure of (i) David Roman, our President and Chief Executive Officer, and Kevin Mathews, our Senior Vice President, Commercial, which departures became effective January 7, 2024 and (ii) Tom Sohn, our Chief Administrative Officer, General Counsel and Secretary, which departure became effective February 6, 2024. In November 2023, we also announced the appointment of Takeo Mukai as our Chief Executive Officer, which appointment became effective January 8, 2024. In addition to his role as Chief Executive Officer, Mr. Mukai continues to serve as Chief Financial Officer. These leadership changes may be inherently difficult to manage and may hamper our ability to meet our financial and operational goals as new management becomes familiar with their roles and the business. Such changes may also result in added costs, uncertainty concerning our future direction, decreased employee morale, and the loss of personnel with deep institutional knowledge and industry relationships. Any of the foregoing could result in significant disruptions to our operations and impact our ability to execute on our business plans. Further, we have increased our dependency on the remaining members of our executive management team to facilitate a smooth transition in leadership roles. Since our executive officers are at- will employees, they could terminate their employment with us at any time, and any such departure could be particularly disruptive in light of the recent leadership changes. If we are unable to mitigate these or other similar risks, our business, results of operations and financial condition may be adversely affected.** Our results of operations could be materially harmed if we are unable to accurately forecast ~~customer~~ **Medtronic** demand for ~~our~~ **the** ~~products~~ **Products** and manage our inventory. We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub- assemblies, materials and finished ~~products~~ **Products** on hand. To ensure adequate inventory supply and manage our operations with our third- party manufacturers ~~and~~ suppliers, we forecast anticipated materials requirements and demand for ~~our~~ **the** ~~products~~ **Products** in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for ~~our~~ **the** ~~products~~ **Products** could be negatively affected by many factors, including our limited historical commercial experience, ~~rapid growth, failure to accurately manage our expansion strategy,~~ product introductions by competitors, an increase or decrease in ~~customer~~ **Medtronic** demand for ~~our~~ **the** ~~products~~ **Products** ~~, our failure to accurately forecast customer acceptance of new products~~ , unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of ~~customer~~ **Medtronic** demand ~~, including as a result of our introduction of product enhancements,~~ may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write- downs or write- offs, which could have a material adverse effect on our business, financial condition and results of operations. Conversely, if we underestimate ~~customer~~ **Medtronic** demand for ~~our~~ **the** ~~products~~ **Products** or our own requirements for components, subassemblies and materials, our third- party manufacturers and suppliers may not be able to deliver components, sub- assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to **Medtronic** ~~our customers~~ , any of which would damage our reputation, ~~customer~~ relationships and business. In addition, several components, sub- assemblies and materials incorporated into ~~our~~ **the** ~~products~~ **Products** require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us, or at all, and our third- party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet ~~customer~~ **Medtronic** demand for ~~our~~ **the** ~~products~~ **Products** and our business, our financial condition and our results of operations. The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business. We rely on suppliers, vendors, ~~outsourcing partners, consultants, alliance partners~~ and other third parties to ~~research, develop,~~ manufacture and ~~commercialize our~~ **supply certain components**

of the ~~products~~ **Products** . Using third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) ~~disputes may arise with respect to ownership of rights to technology developed with our partners; (vi)~~ changes in the cost of these purchases due to inflation, exchange rates, tariffs or other factors; and (~~vii~~ **vi**) disagreements could cause delays in, or termination of, the **manufacture and supply** ~~research, development or commercialization~~ of ~~our~~ **the** ~~products~~ **Products** or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may have a material adverse effect on our business, financial condition and results of operations. **The transfer** ~~Cost- containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability. In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate~~ pricing ~~arrangements with medical device companies and distributors and~~ **for our sale of Products to Medtronic under** ~~then~~ **the Distribution Agreement** ~~offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category- by- category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we~~ may not be ~~able~~ **sufficient** to **cover** ~~obtain new or~~ **our costs** ~~maintain existing contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins. While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue. We may not be able to achieve or maintain satisfactory pricing and margins for our products~~ . Manufacturers of medical devices have a history of price competition, and we can give no assurance that ~~we~~ **the transfer pricing for our sale of Products to Medtronic** will be ~~able~~ **sufficient** to **cover** ~~achieve satisfactory prices for our products or~~ **our costs** ~~maintain prices at the levels we have historically achieved~~ . Any decline in the amount that payors reimburse ~~our~~ customers for procedures involving the use of ~~our~~ **the** ~~products~~ **Products** could make it difficult for customers to continue using or adopting ~~our~~ **the** ~~products~~ **Products** and could create additional pricing pressure for us. If we are forced to lower the price we charge **Medtronic** for ~~our~~ **the** ~~products~~ **Products** , our revenue and gross margins will decrease ~~, which will adversely affect our ability to invest in and grow our business~~ . If we are unable to maintain our prices, or if our costs increase, for example, due to increased inflation and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business, financial condition and results of operations. ~~We have significant customer concentration with a limited number of customers accounting for a significant portion of our 2022 revenue. If we fail to retain these customers, our revenue could decline significantly. We currently derive a significant portion of our revenue from a relatively small number of customers. Our top three and top five customers accounted for 42 % and 50 % of our revenue in 2022, respectively. There are inherent risks whenever a large percentage of revenue is concentrated with a limited number of customers. Our revenue could fluctuate materially and could be materially and disproportionately impacted by purchasing decisions of these customers or any other significant customer. In the future, any of our significant customers may decide to purchase less than they have in the past, may alter their purchasing patterns at any time with limited notice or may decide not to continue to purchase our products at all, any of which could cause our revenue to decline and could have a material adverse effect on our business, financial condition and results of operations. If we do not diversify our customer base, we will continue to be susceptible to risks associated with customer concentration.~~ If our facility becomes damaged or inoperable or if we are required to vacate a facility, we may be unable to manufacture ~~our~~ **the** ~~products~~ **Products** or we may experience delays in production or an increase in costs, which could adversely affect our results of operations. We currently maintain our ~~research and development,~~ manufacturing ~~and administrative~~ operations in a building located in Carlsbad, California, and we do not have redundant facilities. Should our building be significantly damaged or destroyed by natural or man- made disasters such as earthquakes, fires (both of which are prevalent in California) or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our ~~research, development and~~ manufacturing would cease or be delayed **,** and our products may be unavailable. Because of the time required to authorize manufacturing in a new facility under federal, state and non- U. S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would not cover all damages, including losses caused by earthquakes or losses we may suffer due to ~~our~~ **the** ~~products~~ **Products** being replaced by competitors' products. The inability to perform our ~~research,~~ development and manufacturing activities if our facilities become inoperable, combined with our limited inventory of materials and components and manufactured ~~products~~ **Products** , may cause physicians to discontinue using ~~our~~ **the** ~~products~~ **Products** or harm our reputation **with Medtronic** , and we may be unable to re- establish **a good** ~~relationships~~ **relationship** with **Medtronic** ~~such physicians~~ in the future. Consequently, a catastrophic event at our current facility or any future facilities could have a material adverse effect on our business, financial condition and results of operations. ~~Furthermore, the current lease for our manufacturing facility expires at the end of 2027, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in~~

~~connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.~~ We have limited experience manufacturing ~~our~~ **the** ~~products~~ **Products** in commercial quantities, which could harm our business. Because we have only limited experience in manufacturing ~~our~~ **the** ~~products~~ **Products** in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following: ~~• our ◦~~ **an** intent to expand our manufacturing capacity, as a result of which our production processes may have to change; ~~•~~ ◦ key components of ~~our~~ **the** ~~products~~ **Products** are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components; if we experience a shortage or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays; ~~•~~ ◦ a delay in completing validation and verification testing for new controlled environment rooms at our manufacturing facility; ~~•~~ ◦ state and federal regulations including the FDA' s QSR for the manufacture of ~~our~~ **the** ~~products~~ **Products** , noncompliance with which could cause an interruption in our manufacturing; and ◦ ~~• attraction and~~ retention of qualified employees for our operations in order to significantly increase our manufacturing output. If we are unable to keep up with demand for ~~our~~ **the** ~~products~~ **Products** , ~~our growth could be impaired, and~~ market acceptance for ~~our~~ **the** ~~products~~ **Products** could be harmed and physicians may instead elect to use our competitors' products. Our inability to successfully manufacture ~~our~~ **the** ~~products~~ **Products** in sufficient quantities would materially harm our business. In addition, our manufacturing facility and processes and those of our third- party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators, could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results ~~. Technological change may adversely affect sales of our products and may cause our products to become obsolete. The medical device market is characterized by extensive research and development and rapid technological change. There can be no assurance that other companies, including current competitors or new entrants, will not succeed in developing or marketing products that are more effective than our products or that would render our products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Our failure to develop new products, applications or features could result from insufficient cash resources, high employee turnover, an inability to hire personnel with sufficient technical skills, a lack of other research and development resources or from other constraints. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our current or future competitors could have a material adverse effect on our business, financial condition and results of operations~~ . Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations. Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for ~~our~~ **the** ~~products~~ **Products from Medtronic, which may in turn reduce the price of the Products we charge Medtronic** . If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition and results of operations. ~~We have limited data and experience regarding the safety and efficacy of our products. Results of earlier trials may not be predictive of future clinical trial results, and planned trials may not establish an adequate safety or efficacy profile for such products and other planned or future products, which would affect market acceptance of these products. We have performed clinical trials with only limited patient populations. The long- term effects of using our products in a large number of patients have not been studied and the results of short- term clinical use of such products do not necessarily predict long- term clinical benefits or reveal long- term adverse effects. The results of clinical trials of our products conducted to date and ongoing or future trials and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed. Clinical development is a long, expensive and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining IRB approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new~~

indications for existing products, including: • enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays; • our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and / or preclinical testing which may be expensive and time- consuming; • trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities; • the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans; • the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do; • there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities; • there may be delays in obtaining IRB approvals or governmental approvals to conduct clinical trials at prospective sites; • the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory; • the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications; • we may have trouble in managing multiple clinical sites; • we may have trouble finding patients to enroll in our trials; • we may experience delays in agreeing on acceptable terms with third- party research organizations and trial sites that may help us conduct the clinical trials; and • we or regulators may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks. Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position. Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop new products or seek new indications. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, will need to be redesigned, will enroll an adequate number of patients on time or will be completed on schedule, if at all. The commencement and completion of clinical trials for future products or indications may be delayed, suspended or terminated as a result of many factors, including: • the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials; • the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site; • changes in regulatory requirements, policies and guidelines; • delays in reaching, or failure to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in patient enrollment and variability in the number and types of patients available for clinical trials; • the inability to enroll a sufficient number of patients in trials to observe statistically significant treatment effects in the trial; • having clinical sites deviate from the trial protocol or dropping out of a trial; • negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising; • safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks; • reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns; • regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others; • lower than anticipated retention rates of patients and volunteers in clinical trials; • our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, from deviating from the protocol or by dropping out of a trial; • delays relating to adding new clinical trial sites; • difficulty in maintaining contact with patients after treatment, resulting in incomplete data; • the quality of the products falling below acceptable standards; • the inability to manufacture sufficient quantities of our products to commence or complete clinical trials; and • exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors including a failure to conduct the clinical trial in accordance with regulatory requirements including the FDA' s current Good Clinical Practice, or GCP, regulations or our clinical protocols, an inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, an unforeseen safety issue or adverse side effect, a failure to demonstrate safety and effectiveness, a change in governmental regulation or administrative action or a lack of adequate funding to continue the clinical trial. In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a trial, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and / or stock- based compensation in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the trial result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the trial, then the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in a delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development. If we experience delays in the commencement or completion of any clinical trial of our products, or if any of our clinical trials are terminated, the commercial prospects of our products may be harmed, and our ability to generate revenue from sales may be delayed or materially diminished. We do not know whether any of our future preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, will slow down our product development and approval process and will jeopardize our ability to commence sales and generate associated revenue. Any of these occurrences may significantly harm our business, financial condition and results of operations. In addition, many of the factors that cause or lead to a delay in the commencement or completion of

~~clinical trials may also ultimately lead to the denial, suspension or revocation of expanded regulatory clearance or approval of our products. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products, or it could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products.~~ The sizes of the markets for **the** ~~our current and future products~~ **Products** have not been established with precision and may be smaller than we estimate. Our estimates of the total addressable markets for **the** ~~our current products~~ **Products** ~~and products under development~~ are based on a number of internal and third-party estimates, including, without limitation, the number of **transseptal crossings** ~~patients with cardiac arrhythmias and the assumed prices at which we can sell our products in markets~~ that **occur annually in electrophysiology and structural heart procedures** ~~have not been established or that we have not yet entered~~. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these estimates. As a result, our estimates of the total addressable market for **the** ~~our current or future products~~ **Products** may prove to be incorrect. If the actual number of patients who would benefit from ~~our~~ **the** ~~products~~ **Products**, the price at which we can sell **the** ~~products~~ **Products to Medtronic** or the total addressable market for ~~our~~ **the** ~~products~~ **Products** is smaller than we have estimated, it may impair our sales ~~growth~~ **to Medtronic** and have an adverse impact on our business. The use, misuse or off- label use of ~~our~~ **the** ~~products~~ **Products** may result in injuries that lead to product liability suits, which could be costly to our business. ~~Our~~ **The** ~~products~~ **Products** have been cleared by the FDA for **certain indicated uses** ~~the treatment of complex heart arrhythmias~~. If physicians expand the patient population in which they elect to use ~~our~~ **the** ~~products~~ **Products** that is outside of the intended use approved or cleared by the FDA, then the use, misuse or off- label use of ~~our~~ **the** ~~products~~ **Products** may result in outcomes and adverse events including stroke and death, potentially leading to product liability claims. **We** ~~Our products are not indicated for use in all patients with complex heart arrhythmias, and therefore cannot be marketed or advertised in the United States for certain uses without additional clearances from the FDA. However, we~~ cannot prevent a physician from using ~~our~~ **the** ~~products~~ **Products** for off- label applications or using components or products that are not ~~our~~ **compatible with the** ~~products~~ **Products**. ~~In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products~~. Complications resulting from the use of ~~our~~ **the** ~~products~~ **Products** off- label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. ~~Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties or seizures. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and / or other penalties against companies for alleged improper promotion and has investigated, prosecuted and / or enjoined several companies from engaging in off- label promotion. We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management' s attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results. We have acquired and may in the future seek to acquire or invest in additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. For example, in June 2019, we added an integrated product family of transseptal crossing and steerable introducer systems to our product portfolio through our acquisition of Rhythm Xience, and in July 2019, we acquired our AcQBlate Force Sensing Ablation System from Biotronik pursuant to a license agreement, or Biotronik License Agreement. However, we have limited experience in acquiring other businesses, products or technologies. The process of integrating an acquired company, business or technology may create unforeseen operating challenges, risks and expenditures, including that the acquisitions do not advance our corporate strategy, that we get an unsatisfactory return on our investment, that the acquisitions distract management, or that we may have difficulty: (i) integrating an acquired company' s accounting, financial reporting, management information and information security, human resource and other administrative systems to permit effective management; (ii) integrating the controls, procedures and policies at companies we acquire into our internal control over financial reporting; and (iii) transitioning the acquired company' s operations, suppliers and customers to us. It may take longer than expected to realize the full benefits from these acquisitions such as increased revenue, enhanced efficiencies or increased market share, or the benefit may ultimately be smaller than we expected. Moreover, if any of our acquisitions or investments increase our international operations, it would expose us to additional risks relating to operating outside the United States including increased operational and regulatory risks. Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of such acquisitions or investments, to incur unanticipated liabilities and may harm our business generally. If an acquired business, product or technology fails to meet our expectations or results in unanticipated costs and expenses, our business, financial condition and results of operations may suffer. We also cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost- effective and non- disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or to obtain the expected benefits of any acquisition or investment. In addition, under our amended and restated credit agreement dated as of June 30, 2022, with the lenders from time to time party thereto and Wilmington Trust National Association (" Wilmington Trust") as administrative agent (the" 2022 Credit Agreement"), we may require the prior written consent of such agents and the required lenders prior to consummating any acquisition or investment. Acquisitions could also result in dilutive issuances of equity or equity- linked securities, in the use of our available cash or in the incurrence of debt, whether to fund the upfront purchase price of the transaction or to fund deferred or contingent payments to which we agreed as~~

~~part of the transaction. For further information regarding our recent strategic transactions, see the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources. "~~ The terms of our 2022 Credit Agreement, require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. On June 30, 2022, we amended and restated our prior debt facility under the 2019 credit agreement with the 2022 Credit Agreement, which provided us with a senior term loan facility in aggregate principal amount of $ 35. 0 million **. On August 4, 2023, we entered into Amendment No. 1 (" Amendment No. 1 ") to the 2022 Credit Agreement with Deerfield. Pursuant to Amendment No. 1, the 2022 Credit Agreement was amended to decrease the amount of cash we are required to maintain pursuant to the minimum liquidity covenant in the 2022 Credit Agreement to $ 5, 000, 000 for a period of 18 months, at which point the amount required under the minimum liquidity covenant shall increase to $ 20, 000, 000 (or, if certain conditions are met, $ 10, 000, 000), in exchange for a fee paid by us. On November 8, 2023, we entered into Amendment No. 2 (" Amendment No. 2 ") to the 2022 Credit Agreement with Deerfield. Pursuant to Amendment No. 2, the 2022 Credit Agreement was amended to, among other things: (i) adjust and increase the amortization schedule such that payments commence on June 30, 2024 and are made 12, 24 and 36 months (i. e., the scheduled maturity date) following June 30, 2024; (ii) limit the business activities the Company may engage in; and (iii) require us to maintain a minimum liquidity of $ 10, 000, 000 at all times, in exchange for fees paid by us. On March 4, 2024, we entered into Waiver and Amendment No. 3 (" Amendment No. 3 ") to the 2022 Credit Agreement. Previously, on February 16, 2024, the Biotronik Parties filed the Demand against us with the American Arbitration Association, alleging that we breached our contractual obligations under five agreements relating to the licensing, manufacturing, distribution and development of medical devices as a result of the wind down of our businesses. Pursuant to Amendment No. 3, Deerfield has agreed to waive any Default or Event of Default (each defined in the 2022 Credit Agreement) that has arisen or may arise in connection with the Demand. In addition, pursuant to Amendment No. 3, among other things, (i) the 2022 Credit Agreement was amended such that (x) a Change in Control (as defined in the 2022 Credit Agreement) under the 2022 Credit Agreement would not be deemed to occur in the event our common stock ceases to be listed on Nasdaq (without a comparable re- listing) (a " Delisting ") and (y) exposure incurred in excess of $ 3. 0 million in respect of proceedings in relation to the Demand and / or related proceedings and / or between such parties is deemed an Event of Default (as defined in the 2022 Credit Agreement) under the 2022 Credit Agreement.** Our payment obligations under the 2022 Credit Agreement reduced cash available to fund working capital, capital expenditures, **manufacturing** ~~research and development~~ and general corporate needs. In addition, indebtedness under the 2022 Credit Agreement ~~bore~~ **bears** interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs. Our obligations under the 2022 Credit Agreement are secured by substantially all of our assets and the assets of our wholly- owned subsidiary. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the 2022 Credit Agreement contains customary affirmative and negative covenants restricting our activities, including limitations on: dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends or redeeming stock or making other distributions; making certain investments; liquidating our company; modifying our organizational documents; entering into sale- leaseback arrangements; and, engaging in certain other business transactions. In addition, we are required to maintain a minimum liquidity amount of $ ~~20~~ **10** . 0 million. Failure to comply with the covenants in the 2022 Credit Agreement, including the minimum liquidity covenant, could result in the acceleration of our obligations under the 2022 Credit Agreement, and, if such acceleration were to occur, would materially and adversely affect our business, financial condition and results of operations. We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our debt arrangement. The obligations under the 2022 Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory approvals and a material adverse change in our business, operations or other financial condition. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, Wilmington Trust may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. The 2022 Credit Agreement also provides for final payment fees ~~of an additional $ 1. 9 million~~ that are due upon prepayment, on the maturity date or upon acceleration, as well as prepayment penalties. Our outstanding indebtedness and any future indebtedness combined with our other financial obligations could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options ~~. Our results may be impacted by changes in foreign currency exchange rates. Our reporting currency is the U. S. dollar and our sales outside the United States are primarily denominated in Euros and British Pound Sterling. For the years ended December 31, 2022 and 2021, approximately 21 % and 27 %, respectively, of our sales were denominated in currencies other than U. S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States and Europe. If our operations in countries outside of the United States grows, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U. S. dollar increases relative to foreign currencies in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U. S. dollars. In addition, because we conduct business in currencies other than the U. S. dollar but report our results of operations in U. S. dollars, we also face~~

~~remeasurement exposure to fluctuations in currency exchange rates, which could hinder our ability to predict our future results and earnings and could impact our results of operations. We do not currently maintain a program to hedge exposures to non- U. S. dollar currencies. If we are unable to address these risks effectively, it could have a material adverse effect on our business, financial condition and results of operations~~ . Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, gross receipts, value added or similar taxes and may successfully impose additional obligations on us, and any such assessments or obligations could adversely affect our business, financial condition and results of operations. We have not historically collected sales and use, gross receipts, value added or similar taxes, although we may be subject to such taxes in various jurisdictions. One or more jurisdictions may seek to impose additional tax collection obligations on us, including for past sales. A successful assertion by a state, country or other jurisdiction that we should have been or should be collecting additional sales, use or other taxes on our services could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us ~~, discourage users from purchasing our products~~ or otherwise harm our business, results of operations and financial condition. Our ability to utilize our net operating loss carryforwards may be limited. As of December 31, ~~2022~~ **2023** , we had U. S. federal and state net operating loss, or NOL, carryforwards of approximately $ ~~390~~ **435** . ~~5~~ **8** million and $ ~~102~~ **128** . ~~6~~ **0** million, respectively. We may use these NOLs to offset against taxable income for U. S. federal and state income tax purposes. If not utilized, our U. S. federal NOLs (and our state NOLs in conforming states) arising in taxable years beginning before 2018 will begin to expire in 2031. Deductibility of U. S. federal NOLs arising in taxable years beginning after 2017 may be carried forward 20 years and are limited to 80 % of our taxable income before the deduction for such NOLs. Additionally, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U. S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 " ownership change " generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of a company' s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. Similar rules may apply under state tax laws. ~~We have not conducted a Section 382 study to determine whether the use of our NOLs is impaired. We may have previously undergone an " ownership change. "~~ In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future " ownership changes. " " Ownership changes " that have occurred in the past or that may occur in the future could result in the imposition of an annual limit on the amount of pre- ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U. S. federal and state income taxes during any year in which we have taxable net income than we would be entitled to retain if such NOLs were available as an offset against such income for U. S. federal and state income tax reporting purposes, which could adversely impact operating results. If we experience significant disruptions in our information technology systems, our business may be adversely affected. We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of ~~our~~ **the** ~~products~~ **Products** , as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to any number of unintentional events that could involve a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service **Medtronic** ~~our customers or disrupt our customers~~ ' **s** ability **to** use ~~our~~ **the** ~~products~~ **Products** for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or result in inappropriate disclosure of confidential or proprietary information, we could incur liability ~~, and the further development and commercialization of our products could be delayed or disrupted~~ . Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to security breaches, cyber- attacks and other related data and system disruptions. We cannot be certain that such potential losses will not exceed our policy limits, whether insurance will continue to be available to us on economically reasonable terms, or at all, or whether any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or ~~our customers' patients or~~ prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. **The information** ~~In the ordinary course of our business,~~ we ~~may become exposed to, or collect and store~~ **stored** , **historically includes** sensitive data **,** including procedure- based information **,** and legally protected health information, insurance information and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and

infrastructure, and that of our third- party billing and collections provider and other technology partners, may be vulnerable to cyber- attacks by hackers or viruses or breached due to employee error, malfeasance, social engineering (including phishing), ransomware, supply chain attacks and vulnerabilities through our third- party partners, credential stuffing, efforts by individuals or groups of hackers and sophisticated organizations including state- sponsored organizations, bug or security vulnerabilities in the software or systems on which we rely or other disruptions. We rely extensively on IT systems, networks and services including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and / or used by third parties or their vendors to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure by our workforce, by others with authorized access to our systems or by unauthorized persons could negatively impact operations. The ever- increasing use and evolution of technology including cloud-based computing creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third- party providers' systems, in portable media or in storage devices. We could also experience a business interruption, a theft of confidential information or the reputational damage from industrial espionage attacks, malware or other cyber- attacks, which may compromise our system infrastructure or lead to data leakage either internally or at our third- party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and we continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third- party providers' databases or systems that could materially and adversely affect our business, financial condition and results of operations. Additionally, we cannot be certain that any insurance coverage that we may maintain will be adequate or otherwise protect us with respect to claims, expenses, fines, penalties, business loss, data loss, litigation, regulatory actions or other impacts arising out of security breaches or other disruptions, or that such coverage will continue to be available on acceptable terms or at all. Any of these results could adversely affect our business, financial condition and results of operations. ~~We receive, generate and store significant and increasing volumes of sensitive information such as health information, insurance information and other potentially personally identifiable information. We face a number of risks relative to protecting this critical information including loss of access risk, inappropriate use or disclosure, inappropriate modification and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third- party vendors and subcontractors we use to manage this sensitive data. We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the different jurisdictions in which we operate, including comprehensive regulatory systems in the U. S. and Europe. Further, various states such as California, Massachusetts and Virginia have implemented privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. California enacted the CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may now bring enforcement actions for violations. The CCPA has been amended from time to time, and further, a new privacy law, the CPRA, was approved by California voters in the November 3, 2020 election. The CPRA mostly took effect on January 1, 2023 and significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. It remains unclear what, if any, further modifications will be made to the CCPA or CPRA, or how such legislation will be interpreted. This may potentially result in further uncertainty and require us to incur additional costs and expenses in efforts to comply. Certain other state laws impose similar privacy obligations and all 50 states have laws including obligations to provide notification of security breaches of computer databases that contain personal information to affected individuals, to state officers and to others. For example, the CCPA has prompted a number of proposals for new federal and state- level privacy legislation such as in Nevada, New Hampshire, Illinois and Nebraska. This legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, may require additional investment of resources in compliance programs, may impact strategies, and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. In addition, we may obtain health information from third parties (including hospitals) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act and regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA. The collection and use of personal data in the European Union are governed by the GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data such as health data, and additional obligations when we contract with third- party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union, or EU, to the United States and other third countries. In July 2020, the Court of Justice of the European Union issued a decision that struck down the EU- U. S. Privacy Shield framework, which provided companies with a mechanism to comply with data protection requirements when transferring personal data from the EU to the United States, and additionally called into question the validity of the European Commission' s Standard Contractual Clauses, on which U. S. companies rely to transfer personal data from Europe to the United States and elsewhere. In September 2020, the Swiss Federal Data Protection and Information Commissioner issued an opinion that stated it no longer~~

~~considers the Swiss- U. S. Privacy Shield adequate for the purposes of personal data transfers from Switzerland to the United States. These developments may result in European data protection regulators applying differing standards for, and requiring ad hoc verification of, transfers of personal data from Europe to the United States. To the extent that we engage in such transfers, if we are unable to implement safeguards to ensure that our transfers are lawful or if any safeguards upon which we rely are invalidated, we will face increased exposure to litigation, regulatory actions, fines and injunctions against data processing. If we are unable to engage in such transfers because there is no lawful mechanism to do so, the functionality or effectiveness of our products and services may decrease and our marketing efforts, plans and activities may be adversely impacted. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including biometric or health data. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with any European Union clinical trials or related to any employees in Europe. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and materially and adversely affect our business, financial condition and results of operations. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations which could increase our compliance costs and the risks associated with non- compliance. We cannot guarantee that we or our vendors may be in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy and cybersecurity policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. If we or our vendors fail to comply with the GDPR and the applicable national data protection laws of the European Union member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions which can result in monetary penalties of up to € 20. 0 million or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, and may result in restrictions on data processing and other administrative penalties. Further, in January 2021, following its exit from the EU, the United Kingdom transposed the GDPR into its domestic law with its own version of the GDPR (combining the GDPR and the UK Data Protection Act of 2018), or UK GDPR, which currently imposes the same obligations as the GDPR in most material respects and provides for fines of up to £ 17. 5 million or 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, for noncompliance. In addition, an actual or asserted violation of the GDPR or UK GDPR could result in regulatory investigation, reputational damage, orders to cease or change our processing of our data, enforcement notices and / or assessment notices for a compulsory audit. We also may face civil claims, including representative actions and other class action- type litigation where individuals have suffered harm, potentially resulting in our paying significant compensation or damages, or incurring other significant liabilities as well as associated costs, a diversion of internal resources and an infliction of reputational harm. Going forward, there is increasing risk for divergence in application, interpretation, and enforcement of the data protection laws as between the United Kingdom and the EEA. Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains uncertain. For example, on June 28, 2021, the European Commission announced a decision of " adequacy, " concluding that the United Kingdom ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the United Kingdom. This adequacy determination will automatically expire in June 2025 unless the European Commission renews or extends, and it may be modified or revoked in the interim. We may incur liabilities, expenses, costs and other operational losses under the GDPR, UK GDPR and privacy laws of the applicable EU Member States and the United Kingdom in connection with any measures we take to comply with them. Compliance with U. S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Penalties for violations of these laws vary. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data or, in some cases, impact our ability to operate in certain jurisdictions. In addition, we rely on third- party vendors to collect, process and store data on our behalf and we cannot guarantee that such vendors are in compliance with all applicable data protection laws and regulations. Our or our vendors' failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions which could include civil or criminal penalties, private litigation and / or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, that we failed to comply with data protection laws or that we breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.~~ Certain of our operating results and financial metrics may be difficult to predict as a result of seasonality. While we have not yet experienced significant seasonality in our results, it is not uncommon in our industry to experience seasonally weaker revenue during the summer months and end- of- year holiday season. We may be affected by seasonal trends in the future ~~, particularly as our business matures~~ . Additionally, this seasonality may be reflected to a much lesser extent, and sometimes may not be immediately apparent, in ~~our~~ **the** revenue **we generate from Medtronic** . To the extent we experience this seasonality, it may cause fluctuations in our operating results and financial metrics and make forecasting our future operating results and financial metrics more difficult **. Climate- related events and other such similar events could harm our business. Natural disasters, disease outbreaks and pandemics, power shortages, terrorism, political unrest, telecommunications failure, vandalism, geopolitical instability, war, climate-related events, and other events beyond our control could negatively impact our operations or otherwise harm our business. Such events may result in damage or loss of service to assets that our operations rely on, cause delays in Product availability, or result in losses of critical data, any of which may adversely impact our operations. In addition,**

the impacts of climate- related events on the global economy and our industry are rapidly evolving. Physical impacts of climate- related events (including but not limited to floods, droughts, more frequent or intense storms and wildfires), or chronic changes (such as droughts, heat waves or sea level changes) in climate patterns can adversely impact our operations, as well as the operations of our suppliers and Medtronic. Our facilities and offices may be adversely impacted by natural disasters, including those intensified by climate change. Our locations, and those of Medtronic and our suppliers, can be disrupted by droughts, extreme temperatures, fires, flooding and other climate change- related risks, as well as earthquakes, actions by utility providers, and other catastrophic events such as an actual or threatened public health emergency. If a catastrophic event occurs at or near any of our offices, or utility providers or public health officials take certain actions (e. g., shut off power to our facilities), our operations may be interrupted, which could adversely impact our business and results of operations. If a catastrophic event impacts a significant number of our suppliers, or our ability to manufacture the Products for Medtronic, our business and results of operations could be adversely impacted. Longer term physical impacts may also result in changing end- user preferences, which may adversely impact demand for certain of the Products. Transition impacts of climate- related events may subject us to increased regulations, reporting requirements, standards or expectations regarding the environmental impacts of our business. Failure to disclose accurate climate- related events information in a timely manner may also adversely affect our reputation, business, or financial performance . Risks Related to Our Financial Position and Need for Additional Capital We **historically** have incurred net losses since our inception in March 2011. For the ~~years~~ **year** ended December 31, ~~2022~~ **2023** ~~and 2021~~, ~~we~~ **continuing operations** had ~~a~~ net loss of $ ~~39~~ **11** ~~6~~ **9** million and ~~$ 117. 7 million, respectively, and we expect to continue to incur additional net losses~~ for ~~at least~~ the ~~next several years~~ **year ended** ~~. As a result of these losses, as of~~ December 31, 2022 **, continuing operations had net income of $ 28. 8 million,** and **our new business following the Restructuring may not be profitable or continue to generate any revenue. As of December 31,** ~~2021~~ **2023** , we had an accumulated deficit of $ ~~518~~ **600** ~~3~~ **0** million ~~and $ 478. 7 million, respectively~~. Our operations have been financed primarily by aggregate net proceeds from the sale of equity and debt securities, as well as other indebtedness. ~~Our~~ **Historically, our** losses and accumulated deficit have primarily been due to the significant investments we have made in our sales and marketing organization, clinical trials designed to provide clinical evidence of the safety and efficacy of our products and research and development and regulatory affairs to develop our products and support appropriate regulatory submissions. ~~We~~ **In the past, we** have also invested in acquisitions of businesses, products and technologies that we believe ~~complement~~ **complemented** or ~~expand~~ **expanded** our **historical** portfolio, ~~enhance~~ **enhanced** our technical capabilities or otherwise ~~offer~~ **offered** growth opportunities. In addition **, historically** , we have experienced negative gross margins ~~in recent periods~~ as a result of significant investments in our infrastructure to support our commercial launch and to enable our production volumes to scale **. On November 8, 2023, we announced a strategic realignment of resources and corporate restructuring to reallocate capital from our mapping and ablation businesses to our left- heart access distribution relationship with Medtronic (i. e., the Restructuring), to maximize the potential for future earnouts and cash flow. The Restructuring involves streamlining our operations, including the winding down of our mapping and ablation businesses,** as **well as a significant reduction in** our **workforce** ~~business grows~~. We ~~expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, as a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur operating losses and net losses for at least the next couple years, and we~~ cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future would make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations. In order to support our continued operations ~~and the growth of our business~~, we **need** ~~may seek~~ to raise additional capital, which ~~may~~ **will** not **likely** be available to us on acceptable terms, or at all. **Historically** ~~We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure~~ , **our** ~~commercial operations and research and development activities. Our~~ primary uses of capital **were** ~~are, and we expect will continue to be,~~ investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, **in the past,** we ~~have~~ acquired ~~, and may in the future seek to acquire or invest in,~~ additional businesses, products or technologies that we ~~believe~~ **believed** could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. **While** ~~For further information regarding our recent strategic transactions, see~~ the ~~section titled " Management' s Discussion~~ **Restructuring is intended to reduce our operating expenses** and ~~Analysis of Financial Condition~~ **optimize our cash resources by allowing us to focus exclusively on the manufacturing** and ~~Results~~ **distribution** of **the left- heart access Products to Medtronic and continue to generate revenue from such sales and potentially earn the associated earnout payments, we may need to raise additional capital to fund our** ~~Operations~~ **operations ,** ~~— Liquidity~~ and **such additional funding is not likely to be available on acceptable terms, or at all. Following the Restructuring, we expect our primary uses of** ~~Capital~~ **capital** ~~Resources. " Because of~~ **to be [investments in manufacturing and distributing** ~~these~~ -- **the left- heart access Products to Medtronic and related expenses, raw materials and supplies, legal** and other ~~factors~~ **regulatory expenses** , **general administrative costs** ~~we expect to continue to incur substantial net losses~~ and **working capital]** ~~negative cash flows from operations for at least the next several years~~ . Our future liquidity and capital funding requirements will depend on numerous factors, including: ~~•~~ ◦ **Medtronic' s success in selling the Products and** our ~~revenue growth~~ **ability to achieve earnouts pursuant to the Asset Purchase Agreement with Medtronic** ;

◦ ~~• our research and development efforts; • our sales and marketing activities; • our success in leveraging our strategic partnerships, including with Biotronik, as well as entrance into any other strategic partnerships or strategic transactions in the future; • our ability to raise additional funds to finance our operations; • the outcome, costs and timing of any clinical trial results for our current or future products; •~~ the emergence and effect of competing or complementary products; ◦ ~~• the availability and amount of reimbursement for procedures using our products; • our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make or may receive in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights; •~~ our ability to retain our current employees ~~and the need and ability to hire additional management and sales~~, ~~scientific and medical personnel~~ **especially our manufacturing employees** ; ~~• the terms~~ and ◦ ~~timing of any collaborative, licensing or other arrangements that we have or may establish; •~~ debt service requirements ~~; • the extent to which we acquire or invest in businesses, products or technologies; and • the impact of the COVID- 19 pandemic~~. If we determine to raise additional funds, we may do so through equity or debt financings, **if** ~~which may not be~~ available to us **at all** ~~on the timing needed or on terms that we deem to be favorable~~. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce or terminate ~~certain of~~ our **manufacturing** ~~product discovery~~ and ~~development~~ **distribution** activities ~~or future commercialization efforts. Moreover, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to products or technologies we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms~~. As of December 31, ~~2022~~ **2023** ~~and 2021~~, we had $ ~~70~~ **29** . 4 million ~~and $ 107. 9 million, respectively~~, in cash, cash equivalents **, restricted cash** and marketable securities. While we believe our existing cash, cash equivalents and marketable securities and anticipated cash **earnouts** generated from **Medtronic' s** sales of ~~our~~ **the** ~~products~~ **Products** will be sufficient to meet our anticipated cash needs for at least 12 months following the date of this Annual Report on Form 10- K, we cannot assure you that we will be able to generate sufficient liquidity as and when needed, or that revenue from **Medtronic' s** commercial sales will be adequate to fund our operating needs or achieve or sustain profitability. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. **The** ~~Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and result in other negative consequences for our business. Our~~ current ~~products~~ **Products that we manufacture** are subject to extensive regulation by the FDA in the United States, our Notified Body in the European Union and certain other non- U. S. regulatory agencies. Complying with these regulations is costly, time- consuming, complex and uncertain. Government regulations specific to medical devices are wide- ranging and include, among other things, oversight of: ~~•~~ ◦ product design, development, manufacture (including our suppliers) and testing; ◦ ~~• laboratory, preclinical and clinical trials; •~~ product safety and effectiveness; ~~•~~ ◦ product labeling; ~~•~~ ◦ product storage and shipping; ~~•~~ ◦ record keeping; ◦ ~~• premarket clearance or approval; • marketing, advertising and promotion; •~~ product sales and distribution; ~~•~~ ◦ product changes; ~~•~~ ◦ product recalls; and ~~•~~ ◦ post- market surveillance and reporting of deaths or serious injuries and certain malfunctions. ~~Before a new medical device or service or a new intended use for an existing product or service can be marketed in the United States, a company must first submit and receive either 510 (k) clearance or PMA from the FDA, unless an exemption applies. In the 510 (k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is substantially equivalent to a legally- marketed predicate device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed prior to May 28, 1976 (pre- amendments device), a device that was originally on the U. S. market pursuant to an approved PMA and later down- classified, or a 510 (k)- exempt device. To be substantially equivalent, the proposed device must have the same intended use as the predicate device and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA, the FDA must determine that a proposed device is safe and effective for its intended use based, in part on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. Either the 510 (k) or PMA process can be expensive, lengthy and unpredictable. We may not be able to obtain any necessary clearances or approval or may be unduly delayed in doing so, which will negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510 (k) clearance to market our products, our clearance can be revoked if safety or efficacy problems develop.~~ In order to sell ~~our~~ **the** ~~products~~ **Products** in member countries of the EEA, ~~our~~ **the** ~~products~~ **Products** must comply with the essential requirements of the **Medical Device Directive, or** MDD. Compliance with these requirements is a prerequisite to be able to affix the CE Mark to ~~our~~ **the** ~~products~~ **Products** , without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements, we must undergo a conformity assessment procedure which varies according to the type of medical device and its classification. Except for low- risk medical devices (Class I non- sterile, non-

measuring devices) where the manufacturer can issue an European Commission Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the MDD, a conformity assessment procedure requires the intervention by a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. If we fail to ~~remain~~ **be** in compliance with applicable European laws and directives, we would be unable to ~~continue to~~ affix the CE Mark to ~~our~~ **the** ~~products~~ **Products**, which would prevent ~~us~~ **Medtronic** from selling them within the EEA. Further, ~~all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials and clearance or gain approval from the FDA and non- U. S. regulatory agencies prior to commercial sale and distribution. Failure~~ **failure** to comply with applicable U. S. requirements regarding, for example, ~~promoting,~~ manufacturing or labeling ~~our~~ **the** ~~products~~ **Products**, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution ~~. The FDA can also refuse to clear or approve pending applications~~. Any enforcement action by the FDA and other comparable non- U. S. regulatory agencies could have a material adverse effect on our business, financial condition and results of operations. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state or international agencies, which may include any of the following actions: ~~•~~ ○ untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; ~~•~~ ○ unanticipated expenditures to address or defend such actions; ~~•~~ ○ customer notifications for repair, replacement or refunds; ~~•~~ ○ recall, detention or seizure of ~~our~~ **the** ~~products~~ **Products**; ~~•~~ ○ operating restrictions or partial suspension or total shutdown of production; ~~•~~ ○ refusing or delaying ~~our~~ requests for 510 (k) clearance or **Premarket Approval, or** PMA **,** of ~~new products or~~ modified products; ~~•~~ ○ operating restrictions; ~~•~~ ○ withdrawing 510 (k) clearances or PMA that have already been granted; ~~•~~ ○ refusal to grant export approval for ~~our~~ **the** ~~products~~ **Products**; or ○ **criminal prosecution.** If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations ~~. The FDA and the Federal Trade Commission, or FTC, also regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions~~. Our operations are subject to pervasive and continuing FDA regulatory requirements. Medical devices regulated by the FDA are subject to ~~" general~~ controls ~~"~~ which include: registration with the FDA; listing commercially distributed products with the FDA; complying with current Good Manufacturing Processes under QSR; filing reports with the FDA, and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; **and** reporting certain device field removals and corrections to the FDA ~~; and obtaining premarket notification 510 (k) clearance for devices prior to marketing. Some devices known as " 510 (k)- exempt " devices can be marketed without prior marketing- clearance or approval from the FDA. In addition to the " general controls, " some Class II medical devices are also subject to " special controls, " including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510 (k) clearance, most Class III devices are subject to PMA. As a company, we do not have prior experience in obtaining PMA~~. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices and product quality management. Such reviews and investigations may result in civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of ~~our~~ **the** ~~products~~ **Products**; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and could result in our incurring substantial unanticipated costs and the diversion of key personnel and management' s attention from their regular duties, any of which may have a material and adverse effect on our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future. ~~Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, Open Payments requires us to annually report to CMS payments and other transfers of value to all U. S. physicians and U. S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have spent and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition and results of operations.~~ Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of **the** ~~our planned or future products~~ **Products** and to manufacture ~~, market~~ and distribute ~~our~~ **the** ~~products~~ **Products to Medtronic** after clearance or approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval ~~,~~ **and** manufacture ~~and marketing~~ of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and ~~our~~ **the** ~~products~~ **Products we manufacture**. Any new regulations or revisions or reinterpretations of existing regulations may

impose additional costs or lengthen review times ~~of planned or future products~~. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations will change, and what the impact of such changes, if any, may be. In addition, on April 5, 2017, the European Parliament passed the **MDR** ~~Medical Devices Regulation~~ (Regulation 2017 / 745), which repeals and replaces the MDD. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i. e., without the need for adoption of EEA member state laws implementing them, in all EEA member states, and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The **MDR** ~~Medical Devices Regulation~~, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and to ensure a high level of safety and health while supporting innovation. The **MDR** ~~Medical Devices Regulation~~ took effect on May 26, 2021. The new regulations, among other things: ~~•~~ ○ strengthens the rules on placing devices on the market and reinforces surveillance once they are available; ~~•~~ ○ establishes explicit provisions on manufacturers' responsibilities for the follow- up of the quality, performance and safety of devices placed on the market; ~~•~~ ○ improves the traceability of medical devices throughout the supply chain to the end- user or patient through a unique identification number; ~~•~~ ○ sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and ~~•~~ ○ strengthens rules for the assessment of certain high- risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market. ~~These modifications may have an effect on the way we conduct our business in the EEA.~~ Any change in the laws or regulations that govern the clearance and approval processes relating to **the** ~~our current, planned and future products~~ **Products** could make it more difficult and costly to obtain clearance or approval for new **configurations, if any, of the** ~~products~~ **Products** ~~or~~ **and** to produce ~~, market~~ and distribute **the** existing ~~products~~ **Products**. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for ~~our~~ new **configurations, if any, of the** ~~products~~ **Products** would have an adverse effect on our ~~ability to expand our~~ business ~~. If we fail to comply with U. S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business operations and financial condition could be adversely affected. Healthcare providers and third- party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have obtained or will obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals and customers, we are exposed to broadly applicable anti- fraud and abuse, anti- kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of business conduct and ethics and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations. In the United States, we are subject to various state and federal anti- fraud and abuse laws, including, without limitation, the federal healthcare Anti- Kickback Statute and federal civil False Claims Act, federal data privacy and security laws and federal transparency laws related to payments and / or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. There are similar laws in other countries. Our relationships and our distributors' relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include: • the Anti- Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of items or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti- Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti- Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti- Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti- Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities such as reimbursement support programs, educational and research grants or charitable donations. Practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti- Kickback Statute. Our practices, such as trial periods or purchase of certain components of our mapping systems from customers, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti- kickback liability. CMS issued a final rule effective January 19, 2021 that created new safe harbors for, among other things, certain value- based arrangements and patient engagement tools that modified and clarified the scope of existing safe harbors for warranties and personal service agreements. The impact of the new safe harbor regulations on our operations is not yet clear; • federal civil and criminal false claims laws, including the federal civil False Claims Act, and the Civil Monetary Penalties Laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A~~

claim including items or services resulting from a violation of the Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government. These individuals, sometimes known as " relators " or, more commonly, as " whistleblowers, " may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non- reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings; • HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services; • HIPAA, as amended by the HITECH Act, and their implementing regulations, also impose obligations including mandatory contractual terms on covered entities subject to the rule such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and covered subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity or typically a business associate for purposes of HIPAA; • the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually, with certain exceptions, to the CMS information related to payments or other " transfers of value " made to physicians, as defined to include doctors, dentists, optometrists, podiatrists and chiropractors and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers are required to report information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse- midwives; and • analogous state and foreign law equivalents of each of the above federal laws such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third- party payor including commercial insurers; state laws that require medical device companies to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or to otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U. S. Congress continues to strengthen the arsenal of enforcement tools. The Bipartisan Budget Act of 2018, or BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti- Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have continued regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti- Kickback Statute, federal civil False Claims Act and HIPAA' s healthcare fraud and privacy provisions. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices, and financial arrangements with physicians, other healthcare providers and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti- Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil False Claims Act and the Civil Monetary Penalties Laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws. Achieving and sustaining compliance with applicable federal and state anti- fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws, we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Companies settling federal civil False Claims Act, Anti- Kickback Statute or the Civil Monetary Penalties Laws cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i. e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management' s attention from the operation of our business, and

may have a material adverse effect on our business, financial condition and results of operations. Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets. There have been and continue to be proposals by the federal government, state governments, regulators and third- party payors to control or manage the increased costs of healthcare and, more generally, to reform the U. S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition and results of operations. For example, in the United States in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. Implementation of the Affordable Care Act will impact existing government healthcare programs and will result in the development of new programs. There have been executive challenges to certain aspects of the Affordable Care Act. For example, President Trump signed executive orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. Legislation enacted in 2017, informally known as the Tax Cuts and Jobs Act, or TCJA, included a provision that repealed the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " Further, the BBA, among other things, amended the Affordable Care Act to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " On December 14, 2018, a Texas U. S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress as part of the TCJA. Additionally, on December 18, 2019, the U. S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On February 10, 2021, the Biden administration withdrew the federal government' s support for overturning the Affordable Care Act. On June 17, 2021, the U. S. Supreme Court dismissed the judicial challenge to the Affordable Care Act on procedural grounds without specifically ruling on the constitutionality of the Affordable Care Act. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, reexamining policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Further, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (" IRA 2022") which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA 2022 also eliminates the" donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law which, among other things, includes reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 up to 4 % in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, reduced Medicare payments to several providers including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We cannot assure you that the Affordable Care Act as currently enacted or as amended in the future will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm: • our ability to set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; and • the availability of capital. Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products which has resulted in several U. S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. While some of these measures may require additional authorization to become effective, Congress has indicated that it will continue to seek new legislative and / or administrative measures to control product costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing

~~including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. It is also possible that additional governmental action will be taken to address the COVID- 19 pandemic. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on our business, financial condition and results of operations~~ . If we fail to comply with the FDA' s QSR, or **other** FDA or ~~EU~~ **European Union** requirements ~~that pertain to clinical trials or investigations~~ , the FDA or the competent ~~EU~~ **European Union** authority could take various enforcement actions including halting our manufacturing operations, and our business would suffer. In the United States, as a manufacturer of a medical device, we are required to demonstrate and maintain compliance with the FDA' s QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical devices. The FDA enforces the QSR through periodic inspections and unannounced " for cause " inspections. We are subject to periodic FDA inspections to determine compliance with QSR and pursuant to the Bioresearch Monitoring Program, which may in the future result in the FDA issuing Form 483s ~~, including during the conduct of clinical trials~~ . Outside the United States, ~~our~~ **the** ~~products~~ **Products we manufacture** and **our** operations are also often required to comply with standards set by industrial standards bodies such as the International Organization for Standardization. Foreign regulatory bodies may evaluate ~~our~~ **the** ~~products~~ **Products** or the testing that ~~our~~ **the** ~~products~~ **Products** undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. Our failure to comply with FDA or local requirements that pertain to clinical trials / investigations, including GCP requirements and the QSR (in the United States), or failure to take satisfactory and prompt corrective action in response to an adverse inspection, could result in enforcement actions including a warning letter, adverse publicity, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing ~~our~~ **the** ~~products~~ **Products** , refusal to permit the import or export of ~~our~~ **the** ~~product~~ **Products** , prohibition on sales of ~~our~~ **the** ~~product~~ **Products** , a recall or seizure of ~~our~~ **the** ~~products~~ **Products** , fines, injunctions, civil or criminal penalties or other sanctions, any of which could cause our business and operating results to suffer. ~~Our global operations expose us to numerous and sometimes conflicting legal and regulatory requirements, and violation of these requirements could harm our business. We are subject to numerous and sometimes conflicting legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anti- corruption, import / export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti- competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time- consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our customers also could result in liability for significant monetary damages, fines and / or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and the allegation by our customers or distributors that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights. Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter- governmental disputes. Any of these changes could adversely affect our business.~~ The ~~imposition of new laws or regulations including potential trade barriers may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition and results of operations. Material modifications to our products~~ **Products** ~~may require new 510 (k) clearances, new CE Marks or other premarket approvals or may require us to recall or cease marketing our products and services until clearances are obtained. Material modifications to the intended use or technological characteristics of any of our products will require new 510 (k) clearances, new premarket approvals or new CE Mark grants, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer' s decision. Any modification to an FDA cleared device or service that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510 (k) clearance or possibly a new premarket approval. We may not be able to obtain additional 510 (k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products or services. In these circumstances, we may be subject to significant enforcement actions. Our products~~ may be subject to recalls after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation and adversely affect our business. The FDA and similar foreign

governmental authorities have the authority to require the recall of ~~our~~ **the** ~~products~~ **Products** because of any failure to comply with applicable laws and regulations or because of defects in design or manufacture. A government mandated or voluntary product recall by us **or Medtronic** could occur because of, for example, component failures, device malfunctions or other adverse events such as serious injuries or deaths or quality- related issues such as manufacturing errors or design or labeling defects. Any future recalls of ~~our~~ **the** ~~products~~ **Products** could divert managerial and financial resources, harm our reputation and adversely affect our business. If we initiate a correction or removal for one of ~~our devices~~ **the Products we manufacture** to reduce a risk to health posed by ~~the device~~ **such product**, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a ~~device~~ **product** recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and **Medtronic** ~~our customers~~ regarding the quality and safety of ~~our devices~~ **the Products**. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause ~~customers~~ **Medtronic** to delay purchase decisions or cancel orders **from us** and would harm our reputation. If any of ~~our~~ **the** ~~products~~ **Products we manufacture** cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable MDR regulations, which can result in voluntary corrective actions or agency enforcement actions. Under FDA MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving ~~our~~ **the** ~~products~~ **Products** also could result in future voluntary corrective actions such as recalls or customer notifications, or agency action such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition and results of operations. Our **strategic partner,** employees, independent contractors, consultants, ~~strategic partners, distributors~~ and vendors may engage in misconduct or other improper activities including noncompliance with regulatory standards and requirements. We are exposed to the risk that our **strategic partner,** employees, independent contractors, consultants ~~, strategic partners, distributors~~ and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales ~~, marketing and education programs~~. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally ~~. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials~~. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs including legal fees and the diversion of the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations. ~~Failure to comply with anti- bribery, anti- corruption and anti- money laundering laws including the FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations, could result in civil or criminal penalties, other remedial measures and legal expenses. As we grow our international presence, we are increasingly exposed to anti- corruption, trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The FCPA generally prohibits companies and their employees and third- party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action or otherwise obtain or retain business. In addition, the U. K. Bribery Act 2010 prohibits both domestic and international bribery as well as bribery across both private and public sectors. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. Violations of the FCPA, U. K. Bribery Act 2010 and anti- corruption laws could result in fines, criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Violations would also negatively affect our business and reputation, financial condition and results of operations. In addition, our solutions may be subject to U. S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our solutions, or our failure to obtain any required import or export authorization for our solutions when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory~~

~~requirements regarding the export of our solutions may create delays in the introduction of our solutions in international markets or, in some cases, prevent the export of our solutions to some countries altogether. Furthermore, U. S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U. S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our solutions by, or in our decreased ability to export our solutions to, existing or potential customers with international operations. Any decreased use of our solutions or limitation on our ability to export or sell access to our solutions would likely adversely affect our business. We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the U. K. Bribery Act 2010, export control and economic sanctions laws and other anti- corruption, anti- money- laundering and anti- terrorism laws and regulations. We cannot assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in prohibited conduct for which we may be held responsible. Violations of the FCPA, the U. K. Bribery Act 2010, export control and economic sanctions laws or other anti- corruption, anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.~~ Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability. Our ~~research and development and~~ manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third- party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future, or have not occurred in the past, as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and results of operations. ~~Our~~ **We are a contract manufacturer, and our lack of any meaningful registered intellectual property means we rely solely on our manufacturing processes for our** success ~~depends in~~ **. We are a contract manufacturer of the Products for Medtronic, and our business is** ~~large~~ **largely** ~~part on~~ **dependent upon** our ~~ability~~ **manufacturing processes and know- how. Pursuant** to ~~obtain~~ **our sale of the Products to Medtronic, we no longer retain any patents covering the Products, and we no longer have** ~~and~~ **an** ~~maintain~~ **intellectual property position that is protected by meaningful registered intellectual property. The lack of strong** patent and other intellectual property protection **increases** ~~in the United States and other countries with respect to~~ our ~~products~~ **vulnerability** and ~~technology we develop~~ **sole dependence on our manufacturing processes for our success** . We ~~seek~~ **are required** to **indemnify Medtronic for** ~~protect our position by in- licensing~~ intellectual property ~~relating to our~~ **claims in respect of the** ~~products~~ **Products under** ~~and filing patent applications in the United States and abroad related to our technologies and products that are important to our business. We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret and other~~ -- **the Asset Purchase** ~~intellectual property rights to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on obtaining and maintaining patents, preserving our trade secrets, maintaining the security of our data and know- how and obtaining other intellectual property rights. We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, our trade secrets, data and know- how could be subject to unauthorized use, misappropriation or disclosure to unauthorized parties despite our efforts to enter into confidentiality agreements~~ -- **Agreement** ~~with our employees~~ , ~~consultants, contractors, clients~~ and ~~other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. In addition, the patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard~~ as ~~proprietary. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output such as our employees, consultants, contractors, collaborators, vendors and other third parties, any of whom may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain,~~

maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in- licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As a result , the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in- license may be challenged, narrowed or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed, in which case our competitors and other third parties may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Given that patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents. In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Our other intellectual property including our trademarks could also be challenged, invalidated, infringed and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks, in which case we could be forced to re- brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands and suffer other competitive harm. Third parties may also adopt trademarks similar to ours which could harm our brand identity and lead to market confusion. We may in the future also be subject to claims by our former employees, consultants or contractors asserting an ownership right in our patents or patent applications as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants, contractors and any other partners or collaborators who have access to our proprietary know- how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. Failure to obtain and maintain patents, trademarks and other intellectual property rights necessary to our business, and failure to protect, monitor and control the use of our intellectual property rights, could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our patents, trademarks, data, technology and other intellectual property, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Furthermore, our owned and in- licensed patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in- licensed patent rights and technology was funded in part by the U. S. government. As a result, the government may have certain rights, or march- in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents including a non-exclusive license authorizing the government to use the invention for non- commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march- in rights to use or allow third parties to use our licensed technology. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U. S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Moreover, a portion of our intellectual property has been acquired from one or more third parties. While we have conducted diligence with respect to such acquisitions, and because we did not participate in the development or prosecution of much of the acquired intellectual property, we cannot guarantee that our diligence efforts identified and / or remedied all issues related to such intellectual property, including potential ownership errors, potential errors during prosecution

~~of such intellectual property and potential encumbrances that could limit our ability to enforce such intellectual property rights We~~ may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell **the** ~~and market our products~~ **Products to Medtronic and Medtronic' s ability to sell the Products to end- users** . The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U. S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover ~~our~~ **the** ~~products~~ **Products** ~~, or that we may be accused of misappropriating third parties' trade secrets~~ . Additionally, ~~our~~ **the** ~~products~~ **Products** include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and / or export ~~our~~ **the** ~~products~~ **Products** ~~or~~ to ~~use~~ **Medtronic, or Medtronic' s ability to sell and / or export the** ~~product~~ **Products** ~~names~~ **to end- users** . Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of ~~our~~ **the** ~~products~~ **Products** . Moreover, in recent years, individuals and groups that are non- practicing entities, commonly referred to as " patent trolls, " have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or " invitations to license, " or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management' s attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party' s patent or trademark or of misappropriating a third party' s trade secret, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our ~~customers or~~ business partners in connection with litigation and to obtain licenses or refund ~~subscription~~ fees, which could further exhaust our resources **. For example, under our Asset Purchase Agreement with Medtronic, we are required to indemnify Medtronic against the risk of intellectual property claims related to the Products. We may be responsible for claims that the Products we supply use, infringe, misappropriate or otherwise violate third party intellectual property rights** . Even if we believe a third party' s intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability or priority of ~~patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents and our ability to invalidate the asserted~~ patents. A court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to ~~commercialize any~~ **sell the** ~~products~~ **Products to Medtronic** ~~or technology we may develop~~ and ~~any~~ **Medtronic' s ability to sell** ~~other~~ ~~--~~ **the** ~~products~~ **Products to end** ~~or technologies covered by the asserted third~~ ~~-~~ **users** ~~party patents~~ . In order to successfully challenge the validity of any such U. S. patent in federal court, ~~we would need to~~ **the presumption of validity must be** overcome ~~a presumption of validity~~ . ~~As this~~ **This** burden is a high one requiring ~~us to present~~ clear and convincing evidence as to the invalidity of any such U. S. patent claim, **and** there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof. Further, if patents, trademarks or trade secrets are successfully asserted against us **or Medtronic** , this may harm our business and result in injunctions preventing us from developing, manufacturing or selling ~~our~~ **the** ~~products~~ **Products to Medtronic or them from selling the Products to end- users** , or result in obligations to pay license fees, damages, attorney fees and court costs, which could be significant. In addition, if ~~we are~~ **a party is** found to willfully infringe third- party patents or trademarks or to have misappropriated trade secrets, ~~we~~ **that party** could be required to pay treble damages in addition to other penalties. ~~Although~~ **Our rights to develop, manufacture and distribute the Products to Medtronic are subject, in part, to the terms and conditions of licenses granted to us by Medtronic. We rely, in part, upon licenses to certain** patent **rights** ~~, trademark, trade secret~~ and **proprietary technology from Medtronic that** ~~other intellectual property disputes in the medical device area~~ ~~--~~ **are important** ~~have often been settled through licensing~~ or ~~similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain~~ necessary ~~licenses on satisfactory terms, if at all. In addition, if any license we obtain is non- exclusive, we may not be able~~ to ~~prevent our competitors and other~~ ~~--~~ **the development** ~~third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain necessary licenses~~ , ~~we may not be able to redesign our products to avoid infringement. Any of these events could materially and adversely affect our business, financial condition and results of operations. Similarly, interference or derivation proceedings provoked by third parties or brought by the U. S. Patent and Trademark Office, or USPTO, may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings such as reexamination, inter partes review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from~~ manufacturing ~~our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations. Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Any claims we assert against~~

~~perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an~~ **and** ~~alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may raise challenges to the validity of certain of our owned or in- licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, may construe the patent' s claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and / or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer' s competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition and results of operations. Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or~~ distribution ~~activities~~ **of the Products to Medtronic** . We may not have ~~sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition and results of operations. Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others. We rely, in part, upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our products and technology. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. In addition, we may not have~~ the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering ~~the~~ **such** technology ~~that we license from third parties~~ . Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our ~~licensors~~ **licensor, Medtronic,** ~~fail~~ **fails** to prosecute, maintain, enforce and defend such patents, or ~~lose~~ **loses** rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop ~~and commercialize~~ **, manufacture or distribute** any of ~~our~~ **the** ~~products~~ **Products** that are the subject of such licensed rights could be adversely affected. ~~Our licensors may have relied on third- party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in- license. This could materially and adversely affect our business, financial condition and results of operations. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could materially and adversely affect our business, financial condition and results of operations. We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in- licenses. We may need to obtain additional licenses from our existing licensors or otherwise acquire or in- license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established~~

~~companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially and adversely affect our business, financial condition and results of operations.~~ If we are unable to protect the confidentiality of our other proprietary information **covering the Products**, our business and competitive position may be harmed. **We** ~~In addition to patent protection, we~~ also rely on other proprietary rights, including protection of trade secrets and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or are unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, contractors, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know- how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know- how or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. The laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited in the United States and abroad, which could ~~affect our ability to expand in domestic and international markets or~~ require costly efforts to protect ~~our~~ **the** technology. To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use ~~our~~ **the** ~~products~~ **Products** ~~or technology~~, or develop similar technology. Our competitors could purchase ~~our~~ **the** ~~products~~ **Products from Medtronic** and attempt to replicate some or all of the competitive advantages ~~we derive~~ **derived the** ~~from our development efforts or~~ design around ~~our~~ **any** protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of ~~our~~ **the** ~~products~~ **Products** ~~, brand~~ -- **and** ~~and~~ **our** business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of ~~our~~ **the** ~~products~~ **Products** and harm our business ~~, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets, and agreement terms that address non- competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases~~. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time- consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations. ~~Obtaining and maintaining~~ **Maintaining** patent protection **for the Products** depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and ~~our~~ patent protection **for the Products** could be reduced or eliminated ~~for~~ **by Medtronic' s** non- compliance with these requirements **, which could have a material adverse effect on our business, financial condition and results of operations**. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications will be due to the USPTO and foreign patent agencies over the lifetime of **such** ~~our owned or licensed~~ patents ~~and~~ **or patent** applications. **We** ~~In certain circumstances, we~~ rely on **Medtronic** ~~our licensing partners~~ to pay these fees due to U. S. and non- U. S. patent agencies **for patents in respect of the Products**. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent ~~or patent application~~, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent ~~or patent application~~ include, but are not limited to, failure to respond to official actions within

prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If ~~we~~ **Medtronic** ~~fail~~ **fails** to maintain the patents ~~and patent applications~~ covering ~~our~~ **the** ~~products~~ **Products**, we may not be able to stop a competitor from marketing products that are the same as or similar to ~~our~~ **the** ~~products~~ **Products**, which could have a material adverse effect on our business, financial condition and results of operations ~~. We may not be able to protect our intellectual property rights throughout the world. A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or trade names in foreign countries where we do not have any patents or patent applications and where legal recourse may be limited or unavailable. This may have a significant commercial impact on our foreign business operations. Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and, further, may export otherwise infringing products to territories where we have patent and trademark protection but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, many countries, including India, China and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws~~. We may be subject to claims that we or our employees, consultants or contractors have wrongfully used, disclosed or otherwise misappropriated the intellectual property of a third party, including trade secrets or know- how, or are in breach of non- competition or non- solicitation agreements with our competitors or claims asserting an ownership interest in intellectual property we regard as our own **or otherwise transferred to Medtronic**. Many of our employees, consultants and contractors were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, used, disclosed or otherwise misappropriated intellectual property, including trade secrets or other proprietary information of their former employers or our competitors or potential competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own **or transferred to Medtronic** based on claims that our employees, consultants or contractors have breached an obligation to assign inventions to another employer, to a former employer or to another person or entity. Litigation may be necessary to defend against such claims, and it may be necessary ~~or we may desire~~ to enter into a license to settle any such claim; however, there can be no assurance that ~~we~~ **a license** would be ~~able to obtain~~ **obtained** ~~a license~~ on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. For example, a court could prohibit us from using technologies or features that are essential to ~~our~~ **the** ~~products~~ **Products** if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employer. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. An inability to incorporate technologies or features that are important or essential to ~~our~~ **the** ~~products~~ **Products** could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling ~~our~~ **the** ~~products~~ **Products to Medtronic or Medtronic from selling the Products to end- users**. Any litigation or the threat thereof may adversely affect our ability to ~~hire~~ **maintain** employees ~~or contract with independent sales representatives~~. A loss of key personnel or their work product could hamper or prevent our ability to ~~commercialize our~~ **manufacture the** ~~products~~ **Products for Medtronic**, which could have an adverse effect on our business, financial condition and results of operations. We may be subject to claims challenging the inventorship of ~~our~~ **the** patents **we transferred to Medtronic** and other intellectual property **in respect of the Products**. We or **Medtronic** ~~our licensors~~ may be subject to claims that former consultants, contractors or other third parties have an interest in **the** ~~our owned or in- licensed~~ patents, trade secrets or other intellectual property **in respect of the Products that we transferred to Medtronic** as an inventor or co- inventor. While it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives

or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we **or Medtronic** may be forced to bring claims against third parties or defend claims that they may bring against us **or Medtronic** to determine the ownership **the** ~~of what we regard as our~~ intellectual property. **Under our Asset Purchase Agreement with Medtronic, we are required to indemnify Medtronic against the risk of intellectual property claims related to the Products. We may be responsible for claims that the Products we supply use, infringe, misappropriate or otherwise violate third party intellectual property rights.** If we or **Medtronic** ~~our licensors~~ fail in defending any such claims, in addition to paying monetary damages, we **or Medtronic** may lose valuable intellectual property rights such as exclusive ownership of, or right to use, intellectual property that is important to ~~our~~ **the** ~~products~~ **Products** . Any such events could have a material adverse effect on our business, financial condition and results of operations. ~~Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy- Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a " first- to- invent " system to a " first- inventor- to- file " system, that allow third- party submission of prior art to the USPTO during patent prosecution and that set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings including post- grant review, inter partes review and derivation proceedings. Under a first- inventor- to- file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular the first to file provisions, became effective in 2013. Accordingly, it is not clear what impact, if any, the Leahy- Smith Act will have on the operation of our business. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected. We rely on trademarks, service marks, trade names and brand names to distinguish our products from the products of our competitors, and we have registered or applied to register these trademarks. Our registered or unregistered trademarks, service marks, trade names and brand names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. Additionally, we cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.~~ Risks Related to Our Common Stock **Our failure to maintain compliance with Nasdaq' s continued listing requirements would result in the delisting of our common stock. Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On May 1, 2023, we received a letter from the Listing Qualifications Department (the " Staff ") of Nasdaq indicating that, based upon the closing bid price of our common stock, for the prior 30 consecutive business days, we were not in compliance with the $ 1. 00 minimum bid price requirement set forth in Nasdaq Listing Rule 5450 (a) (1) for continued listing on The Nasdaq Global Market (the " Bid Price Requirement "). Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A), we were granted 180 calendar days, or until October 30, 2023, to regain compliance with the Bid Price Requirement. On October 19, 2023, we applied to transfer our securities from The Nasdaq Global Market to The Nasdaq Capital Market. On October 27, 2023, we received a letter from the Staff notifying us that we were eligible for an additional 180- calendar day period, or until April 29, 2024, to regain compliance with the Bid Price Requirement and approving our application to list our securities on The Nasdaq Capital Market. Our securities were transferred to The Nasdaq Capital Market at the opening of business on October 31, 2023. Our continued compliance with the Bid Price Requirement is dependent on our share price and there can be no assurance that we will continue to satisfy Nasdaq' s minimum financial and other requirements in future periods. We currently do not intend to take steps to regain compliance with the Bid Price**

Requirement. Accordingly, we expect our common stock to be delisted from Nasdaq and start trading in the over- the- counter markets April 29, 2024. The perception among investors that we are at heightened risk of a deficiency under the Bid Price Requirement and of subsequent delisting could negatively affect the market price of our securities and trading volume of our common stock. Additionally, any delisting determination, if made following the notification of a deficiency and expiration of any applicable cure period, could seriously decrease or eliminate the value of an investment in our common stock. While an over- the- counter market could offer some level of liquidity for our common stock, our common stock would likely have: limited availability of market quotations; reduced liquidity; a determination that it is a " penny stock " under SEC rules, subjecting brokers trading our common stock to more stringent rules on disclosure and the class of investors to which the broker may sell the common stock; and limited news and analyst coverage. If our common stock is delisted from Nasdaq and is traded on the over- the- counter market, the application of the " penny stock " rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a " penny stock " as any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than $ 5. 00 per share, subject to certain exceptions. If our common stock is delisted from Nasdaq and is traded on the over- the- counter market at a price of less than $ 5. 00 per share, our common stock would be considered a penny stock. Unless otherwise exempted, the SEC' s penny stock rules require a broker- dealer, before a transaction in a penny stock, to deliver a standardized risk disclosure document that provides information about penny stock and the risks in the penny stock market, the current bid and offer quotations for the penny stock, the compensation of the broker- dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer' s account. Further, prior to a transaction in a penny stock, the penny stock rules require the broker- dealer to provide a written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser' s agreement to the transaction. If applicable in the future, the penny stock rules may restrict the ability of brokers- dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock is no longer a penny stock. The market price for our common stock has been volatile, it may decline regardless of our operating performance, and an active trading market may not be sustained in our common stock. The market price of our common stock has been volatile, and it may fluctuate or decline substantially due to a number of factors such as those listed in the section " Risks Related to Our Business and Strategy " and the following: • actual or anticipated changes or fluctuations in our operating results; • the failure by our ~~customers~~ **end- users** to obtain coverage at reimbursement levels that would be sufficient to support product sales to our ~~customers~~ **end- users** ; • unanticipated serious safety concerns related to the use of ~~our~~ **the** ~~products~~ **Products** ; • the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections; • announcements by us or our competitors of new products, significant acquisitions, strategic partnerships, joint venture, capital commitments or other transactions; • industry or financial analyst or investor reaction to our press releases, and other public announcements and filings with the SEC; • rumors and market speculation involving us or other companies in our industry; • future sales or expected future sales of our common stock; • price and volume fluctuations in the overall stock market from time to time; • changes in operating performance and stock market valuations of other medical device companies generally, or those in our industry in particular; • our cash position; • sales of shares of our common stock by us or our shareholders; • failure of industry or financial analysts to maintain coverage of us, changes in financial estimates by any analysts who follow our company or our failure to meet these estimates or the expectations of investors; • actual or anticipated developments in our business or our competitors' businesses or the competitive landscape generally; • our inability to obtain adequate supplies and components for ~~our~~ **the** ~~products~~ **Products** or inability to do so at acceptable prices; • litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors; • accusations that we have violated a law or regulation; • recalls of ~~our~~ **the** ~~products~~ **Products** ; • developments or disputes concerning our intellectual property rights, ~~our solutions~~ **the Products** or third- party proprietary rights; • any delay in any regulatory filings for **the** ~~our planned or future products~~ **Products** and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such ~~products~~ **Products** ; • adverse regulatory decisions including failure to receive regulatory approval or clearance of **the** ~~our planned and future products~~ **Products** or to maintain regulatory approval or clearance for **the** ~~our existing products~~ **Products , as applicable** ; • changes in laws or regulations applicable to ~~our~~ **the** ~~products~~ **Products** ; • announced or completed acquisitions of businesses or technologies by ~~us or~~ our competitors; • breaches of, or failures relating to, security, privacy or data protection; • new laws or regulations or new interpretations of existing laws or regulations applicable to our business; • any major changes in our management or our board of directors; • changes in accounting principles; • ineffectiveness of our internal controls; • actual or anticipated changes in healthcare policy and reimbursement levels; • general economic conditions including increased inflation and slow or negative growth of our markets; and • other events or factors including those resulting from war, incidents of terrorism or responses to these events. We also cannot assure you that a trading market for our common stock will be maintained. The stock markets, and securities of medical device companies in particular, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many medical device companies. Stock prices of many medical device companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. We ~~may~~ **are and will continue to** be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock has been volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We and certain of our current officers have been named as defendants in two putative securities class action lawsuits filed by putative stockholders in the United States District Court for the Southern District of California on February 15, 2022 and March 23, 2022 (case numbers 22CV206 and 22CV0388). The plaintiffs allege that the defendants violated Section 10 (b) of the Exchange Act and Rule 10b- 5 and Section 20 (a) of the Exchange Act. The

complaints allege that the defendants made false and misleading statements about our business, prospects and operations. The putative claims are based upon statements made in filings made by us with the SEC, press releases and on earnings calls between May 13, 2021 and November 11, 2021. The lawsuits seek, among other relief, a determination that the alleged claims may be asserted on a class- wide basis, unspecified compensatory damages, attorney' s fees, other expenses and costs. On July 19, 2022, the court consolidated the two actions, appointed a lead plaintiff and appointed lead counsel for the proposed class. On September 16, 2022, the lead plaintiff filed a consolidated amended complaint. ~~We~~ **The defendants** thereafter filed a motion to dismiss **. On September 27, 2023, the court granted the defendant' s motion to dismiss in its entirety, but gave plaintiffs leave to file an amended complaint. On October 27, 2023, the plaintiffs filed a second amended complaint asserting similar claims. The defendants thereafter filed a motion to dismiss. We are defending the action** . While we are defending the actions, due to the complex nature of the legal and factual issues involved in these matters, the outcome is not presently determinable. If these matters were to proceed beyond the pleading stage, we could be required to incur substantial costs and expenses to defend these matters and / or be required to pay substantial damages or settlement costs, which could materially adversely affect our business, financial condition and results of operations. We may also be the target of this type of litigation in the future. Securities litigation against us, including the putative class actions described above, could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. ~~The issuance of additional shares of our common stock in connection with our financings, acquisitions, investments, share incentive plans or otherwise will dilute all other stockholders. Our amended and restated certificate of incorporation authorizes us to issue up to 260, 000, 000 shares of our common stock and up to 5, 000, 000 shares of preferred stock with such rights and preferences as included in our amended and restated certificate of incorporation. Subject to compliance with applicable rules and regulations, we may issue common stock or securities convertible into common stock from time to time in connection with our financing, acquisition, investment, equity incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline.~~ We currently do not intend to declare dividends on our common stock in the foreseeable future and, as a result, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates. We currently do not expect to declare any dividends on our common stock in the foreseeable future. Instead, we anticipate that all of our earnings, if any, in the foreseeable future will be used to provide working capital to support our operations ~~and~~ **so that we are well positioned** to ~~finance the growth~~ **capture manufacturing demands from Medtronic. We plan to manage** and **foster** ~~development of~~ our ~~business~~ **strategic relationship with Medtronic so that it continues to use us to manufacture the Products at transfer prices** . Any determination to declare or pay dividends in the future will be at the discretion of our board of directors, subject to applicable laws and dependent upon a number of factors including our earnings, capital requirements and overall financial conditions. In addition, our ability to pay dividends on our common stock is currently limited by the covenants of our 2022 Credit Agreement and may be further restricted by the terms of any future debt or preferred securities. Accordingly, your only opportunity to achieve a return on your investment in our company may be if the market price of our common stock appreciates and you sell your shares at a profit. The market price for our common stock may never exceed, and may fall below, the price that you pay for such common stock. We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors. We are an emerging growth company as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including: ~~•~~ ○ no requirement for our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act; ~~•~~ ○ reduced disclosure obligations regarding executive compensation in our periodic reports and Annual Report on Form 10- K; and ~~•~~ ○ exemptions from the requirements of holding non- binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2025. Our status as an emerging growth company will end as soon as any of the following takes place: ~~•~~ ○ the last day of the fiscal year in which we have more than $ 1. 235 billion in annual revenue; ~~•~~ ○ the last day of the fiscal year in which we qualify as a " large accelerated filer, " with at least $ 700 million of equity securities held by non- affiliates; ~~•~~ ○ the date on which we have issued, in any three- year period, more than $ 1. 0 billion in non- convertible debt securities; or ~~•~~ ○ December 31, 2025, the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering or IPO. We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates. Our directors, executive officers and principal stockholders and their respective affiliates have substantial influence over us and could delay or prevent a change in corporate control; our principal stockholders may have interests that conflict with your interests as an investor in our common stock. As of December 31, ~~2022~~ **2023** , our directors, executive officers and holders of more than 5 % of our common stock beneficially owned, as a group, approximately ~~22~~ **18** . ~~0~~ **1** % of our common stock. As of December 31, ~~2022~~ **2023** , funds affiliated with certain of our directors also held all of the 6, 666 outstanding shares of our Series A Common Equivalent Preferred Stock, convertible into up to 6, 665, 841 shares of our common stock (which conversion is subject to certain beneficial ownership limitations set forth in our Certificate of Designation

of Preferences, Rights and Limitations of the Series A Common Equivalent Preferred Stock). In addition, as of December 31, ~~2022~~ **2023**, we had $ ~~36~~ **34**. ~~8~~ **5** million remaining in aggregate principal amount of outstanding long- term debt under our 2022 Credit Agreement with certain entities affiliated with Deerfield Management Company, **L. P.,** of which one entity is a ~~5~~ **9. 1** % holder of our common stock. Our principal stockholders, in the aggregate, will continue to have substantial influence over the outcome of matters submitted to our stockholders for approval including the election of directors and any matter related to the merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, in the aggregate, will continue to have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership may have the effect of: ~~•~~ delaying, deferring or preventing a change in corporate control; ~~•~~ impeding a merger, consolidation, takeover or other business combination involving us; or ~~•~~ discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The interests of our principal stockholders may conflict with your interests as a stockholder. You should carefully consider these potential conflicts of interest before deciding whether to invest in shares of our common stock. Provisions in our organizational documents and agreements with third parties could delay or prevent a change of control. Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider to be in its best interest, including attempts that might result in a premium over the market price of our common stock. These provisions include the following: ~~•~~ establish a classified board of directors so that not all members of our board of directors are elected at one time; ~~•~~ authorize the issuance of " blank check " preferred stock that our board of directors could use to implement a stockholder rights plan; ~~•~~ permit the board of directors to establish the number of directors and fill any vacancies and newly- created directorships; ~~•~~ provide that directors may only be removed for cause; ~~•~~ require super- majority voting to amend some provisions in our certificate of incorporation and bylaws; ~~•~~ eliminate the ability of our stockholders to call special meetings of stockholders; ~~•~~ prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; ~~•~~ provide that the board of directors is expressly authorized to make, alter or repeal our bylaws; ~~•~~ restrict the forum for certain litigation against us to Delaware; and ~~•~~ establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings. These provisions could make it more difficult for a third party to acquire us, even if the third party' s offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. In addition, our ~~agreements~~ **LDA** with Biotronik ~~contain~~ **contains** provisions that may have the effect of delaying, deterring or preventing a change in control transaction involving us. Under the **LDA** ~~Biotronik License Agreement~~, if we undergo a change in control with certain competitors of the Biotronik Parties (as defined therein), our exclusive license to our AcQBlate Force Sensing Ablation System in the United States would convert to co- exclusive licenses with the Biotronik Parties, certain milestone payments would become immediately due and payable (regardless of achievement) **,** and we would be required to pay up to $ 25. 0 million to the Biotronik Parties (to the extent such amount has not already been paid as unit- based royalties). **As a result** ~~In addition, the non- distributing party~~ of **our Restructuring, Biotronik** ~~each Bi- Lateral Distribution Agreement~~ has ~~the right~~ **alleged that we breached our contractual obligations** to ~~terminate~~ **it under** the **LDA and alleges damages. We disagree with Biotronik' s allegations. We intend** ~~agreement in the case of a change in control of either party, whereas the distributing party of each Bi- Lateral Distribution Agreement has the right in certain circumstances~~ to **defend ourself vigorously and will pursue all legal remedies available under applicable laws** ~~terminate the agreement in the case of a change in control of the non- distributing party~~. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another ~~State~~ **state** court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction: ~~•~~ any derivative action or proceeding brought on our behalf; ~~•~~ any action asserting a claim of breach of fiduciary duty; ~~•~~ any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and ~~•~~ any action asserting a claim against us that is governed by the internal- affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U. S. federal courts have exclusive jurisdiction. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the **Securities Act of 1933, as amended, or** Securities Act. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive- forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the

Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Our board of directors is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval. Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value. ~~Our failure to maintain compliance with Nasdaq' s continued listing requirements could result in the delisting of our common stock. Our common stock is currently listed on the Nasdaq Global Select Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On both June 22, 2022 and November 2, 2022, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC (" Nasdaq") notifying us that, for the last 30 consecutive business days, the closing bid price of our common stock has not been maintained at the minimum required closing bid price of at least $ 1. 00 per share as required for continued listing on the Nasdaq Global Select Market pursuant to Listing Rule 5450 (a) (1) (the " Minimum Bid Price Rule"). In both instances, on July 26, 2022 and January 10, 2023, respectively, we received a letter from Nasdaq notifying us that we had regained full compliance with the Minimum Bid Price Rule, and that the matter was closed. Our continued compliance with the Minimum Bid Price Rule is dependent on our share price and there can be no assurance that we will continue to satisfy Nasdaq' s minimum financial and other requirements in future periods. The perception among investors that we are at heightened risk of a deficiency under the Minimum Bid Price Rule and of subsequent delisting could negatively affect the market price of our securities and trading volume of our common stock. Additionally, any delisting determination, if made following the notification of a deficiency and expiration of any applicable cure period, could seriously decrease or eliminate the value of an investment in our common stock. While an alternative listing on an over- the- counter exchange could maintain some degree of a market in our common stock, we could face substantial material adverse consequences including, but not limited to: limited availability for market quotations for our common stock; reduced liquidity with respect to our common stock; a determination that our common stock is a" penny stock" under SEC rules, subjecting brokers trading our common stock to more stringent rules on disclosure and the class of investors to which the broker may sell the common stock; and limited news and analyst coverage.~~ General Risk Factors Our quarterly operating results fluctuate and may fall short of prior periods, our projections or the expectations of securities analysts or investors, which could materially adversely affect our stock price. Our operating results have fluctuated from quarter to quarter at points in the past, and they may do so in the future. Therefore, results of any one quarter are not a reliable indication of results to be expected for any other quarter or for any year. If we fail to increase our results over prior periods, to achieve our projected results or to meet the expectations of securities analysts or investors, our stock price may decline, and the decrease in the stock price may be disproportionate to the shortfall in our financial performance. Results may be affected by various factors including those described in these risk factors. We maintain a forecasting process that seeks to plan ~~sales~~ **revenue generated** and align expenses. If we do not control costs or appropriately adjust costs to actual results, or if actual results differ significantly from our forecast, our financial performance could be materially adversely affected. Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank (SVB), where we maintain certain accounts, was placed into receivership with the Federal Deposit Insurance Corporation (FDIC), which resulted in all funds held at SVB being temporarily inaccessible by SVB' s customers. If other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash, cash equivalents and investments to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC' s insurance limit. Any delay in our ability to access our cash, cash equivalents and investments (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause us to need to seek additional capital sooner than planned. Economic conditions may adversely affect our business. Adverse worldwide economic market and geopolitical conditions including, but not limited to, recession, inflation, deflation, consumer credit activity, consumer debt levels, fuel and energy costs, interest rates, tax rates and policy, unemployment trends, the impact of natural disasters such as pandemics, civil disturbances, terrorist activities and acts of war, including the ~~recent~~ Russian invasion of Ukraine **and Israel- Hamas conflict** and those related to the COVID- 19 pandemic, may negatively impact our business. A significant change in the liquidity or financial condition of our ~~customers~~ **sole partner, Medtronic,** could cause unfavorable trends in ~~their~~ **its** purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition and results of operations. Litigation and other legal proceedings may adversely affect our business. From time to time **,** we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, we and certain of our current officers have been named as defendants in two putative securities class action lawsuits filed by putative stockholders in the United States District Court for the Southern District of California on

February 15, 2022 and March 23, 2022 (case numbers 22CV206 and 22CV0388). Plaintiffs allege that the defendants violated Section 10 (b) of the Exchange Act and Rule 10b- 5, and Section 20 (a) of the Exchange Act. The complaints allege that the defendants made false and misleading statements about our business, prospects and operations. The putative claims are based upon statements made in filings made by us with the SEC, press releases and on earnings calls between May 13, 2021 and November 11, 2021. The lawsuits seek, among other relief, a determination that the alleged claims may be asserted on a class-wide basis, unspecified compensatory damages, attorney' s fees, other expenses and costs. On July 19, 2022, the court consolidated the two actions, appointed a lead plaintiff and appointed lead counsel for the proposed class. On September 16, 2022, the lead plaintiff filed a consolidated amended complaint. We thereafter filed a motion to dismiss. **On September 27, 2023, the court granted the defendant' s motion to dismiss in its entirety, but gave plaintiffs leave to file an amended complaint. On October 27, 2023, the plaintiffs filed a second amended complaint asserting similar claims. The defendants thereafter filed a motion to dismiss. We are defending the action.** While we are defending the actions, due to the complex nature of the legal and factual issues involved in these class action matters, the outcome is not presently determinable. If these matters were to proceed beyond the pleading stage, we could be required to incur substantial costs and expenses to defend these matters and / or be required to pay substantial damages or settlement costs, which could materially adversely affect our business, financial condition and results of operations **. In addition, on February 2, 2024, Biotronik sent a Notice to us. The Notice provides that Biotronik rescinds and terminates the Bi- Lateral Distribution Agreements, effective immediately, based on the alleged repudiation of our contractual obligations under the Bi- Lateral Distribution Agreements, and alleges damages in an amount to be quantified by Biotronik. Biotronik has separately alleged that we breached our contractual obligations to it under the LDA, as a result of the wind down of our mapping and ablation businesses and alleges further damages. On February 16, 2024, the Biotronik Parties filed the Demand against Acutus with the American Arbitration Association (who notified us of the Demand on February 29, 2024), alleging that we breached our contractual obligations under five agreements relating to the licensing, manufacturing, distribution and development of medical devices as a result of the wind down of our businesses. The Biotronik Parties allege that we breached, among other things, our obligations (i) to develop, manufacture, use and commercialize certain product lines under the LDA and the MSA; (ii) to distribute Biotronik products and manufacture and supply Acutus products under the Bi- Lateral Distribution Agreements, as applicable; and (iii) to use commercially reasonable efforts to perform and complete our responsibilities under the F & DA. The claim seeks, among other relief, $ 38. 0 million in damages, attorney' s fees, other expenses and costs. Our jurisdiction objection and any counterclaims are due on April 1, 2024. After that, the parties will appoint an arbitral tribunal and set a procedural timetable. We disagree with the Biotronik Parties' allegations. We intend to defend ourself vigorously and will pursue all legal remedies available under applicable laws** . Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and / or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation ~~and brand image~~ , undermine **Medtronic** ~~our~~ **or** ~~customers~~ **our end- user** ' **s** confidence and reduce long- term demand for ~~our~~ **the** ~~products~~ **Products** , even if the regulatory or legal action is unfounded or not material to our operations ~~. If securities analysts do not publish research or reports about our business or if they downgrade our stock or our sector, our stock price and trading volume could decline. The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business or industry. We do not control these analysts. Furthermore, if one or more of the analysts who do cover us downgrade our stock or our industry or the stock of any of our competitors, or publish inaccurate or unfavorable research about our business or industry, the price of our stock could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline. In addition, if we fail to meet the expectations of any analysts that covers us, our stock price could decline~~ . The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain qualified board members. We are **currently** subject to the reporting and corporate governance requirements of the Exchange Act, the listing requirements of Nasdaq and other applicable securities rules and regulations, including the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act. 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, particularly after we are no longer an emerging growth company as defined in the JOBS Act. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal control over financial reporting. In order to improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management' s attention may be diverted from other business concerns, which could harm our business, financial condition, results of operations and prospects ~~. Although we have already hired additional personnel to help comply with these requirements, we may need to further expand our legal and finance departments in the future, 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 spend** ~~intend to invest~~ resources to comply with evolving

laws, regulations and standards, and this ~~investment~~ may result in increased general and administrative expense 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, regulatory authorities may initiate legal proceedings against us and our business and prospects may be harmed. As a result of disclosure of information in the filings required of a public company, our business and financial condition have become more visible, which may result in threatened or actual litigation including by competitors and other third parties. If such claims are successful, our business, financial condition, results of operations and prospects could be materially harmed, 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 materially harm our business, financial condition, results of operations and prospects. Our status as a public company and these new rules and regulations make it more expensive for us to obtain director and officer liability insurance, which may require us 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 members of our board of directors, particularly to serve on our audit committee and compensation committee. ~~In addition, as a result of our disclosure obligations as a public company, we have reduced strategic flexibility and are under pressure to focus on short- term results, which may materially and adversely affect our ability to achieve long- term profitability.~~