Risk Factors Comparison 2025-03-31 to 2024-04-01 Form: 10-K

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

Investing in our common stock involves a..... of risk factors that follow.) Risks Related to Our Financial Position and Need for Additional Capital ● We will be required to raise additional funds to finance our operations and continue as a going concern; We may not be able to do so when necessary, and / or the terms of any financings may not be advantageous to us. ● Our business has a history of losses, will incur additional losses, and may never achieve profitability. Risks Related to Our Internal Controls ● We have identified material weaknesses in our internal control over financial reporting. These material weaknesses could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner. ● Compliance with Sarbanes- Oxley Act Section 404 could have a material adverse impact on our business. Risks Related to Our Business and Products ● We will not be able to reach profitability unless we are able to achieve our product expansion and growth goals; our VIVO launch plans require significant investment in infrastructure and sales representatives. ● Our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators. ● We have entered into joint marketing agreements with respect to our products, and may enter into additional ~~join~~ **joint** marketing agreements ~~,~~ that will reduce our revenues from product sales. ● Royalty agreements with respect to LockeT, the surgical vessel closing pressure device, will reduce any future profits from this product. ● If we experience significant disruptions in our information technology systems, our business may be adversely affected. ● Litigation and other legal proceedings may adversely affect our business. ● If we make acquisitions or divestitures, we could encounter difficulties that harm our business. ● Failure to attract and retain sufficient qualified personnel could also impede our growth. ● Our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs. ● We may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do. ● Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms. ● If hospitals, physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any. ● The recent coronavirus outbreak (" COVID- 19 ") adversely affected our financial condition and results of operations **,** and we cannot provide any certainty as to whether there will be future impacts from COVID- 19 or another pandemic. ● A variety of risks associated with marketing our products internationally could materially adversely affect our business. ● ~~23~~ The impact of the military conflicts in Ukraine and Israel, and the actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have affected, and may continue to affect, our business and results of operations, including our supply chain. ● If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates. ● We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements. ● Our ability to use our net operating loss **carry** ~~carryforwards~~ ----- **forwards** may be limited. ● We may have to make milestone payments under the Settlement Agreement we entered into with the Department of Justice (" DOJ "). Risks Related to Government Regulation and our Industry ● We are subject to pervasive and continuing regulation by the FDA and other regulatory agencies. Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business. ● Changes in trade policies among the U. S. and other countries, in particular the imposition of new or higher tariffs, could place pressure on our average selling prices as our customers seek to offset the impact of increased tariffs on their own products. Increased tariffs or the imposition of other barriers to international trade could have a material adverse effect on our revenues and operating results. ● Product clearances and approvals can often be denied or significantly delayed. ● Although we have obtained regulatory clearance for our VIVO and LockeT products in the U. S. and certain non- U. S. jurisdictions, our business plans include expanding uses for our products, which will require additional clearances; and even after clearance is obtained, our products remain subject to extensive regulatory scrutiny. ● If we or our suppliers fail to comply with the FDA' s Quality System Regulation, or QSR, or any applicable state equivalent, our operations could be interrupted, and our potential product sales and operating results could suffer. ● Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business. ● If any of our products 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. ● 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. Risks Related to our Intellectual Property ● If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any products we may develop, and our technology may be adversely affected. ~~24Risks~~ -- **Risks** Related to Ownership of Our Common Stock Including Volatility **, Anti- takeover Provisions, the Impact of Future Sales and Potential Dilution CATHETER PRECISION, INC. PART I ITEM 1. BUSINESS Overview The registrant (together with our consolidated operating subsidiary, the " Company " or "**

Catheter ”) was incorporated under the name “ Ra Medical Systems, Inc. ” as a Delaware corporation in July 2018. A predecessor had been incorporated in California in September of 2002, but was reincorporated in 2018 in connection with our initial public offering. The Company was initially formed to develop, commercialize and market ~~and~~ an excimer laser- based platform for use in the treatment of vascular and dermatological immune- mediated inflammatory diseases, including the DABRA product line. On January 9, 2023, the Company merged with Catheter Precision, Inc., or “ Old Catheter ”, a privately- held Delaware corporation (the “ Merger ”), and the business of Old Catheter became a wholly owned subsidiary of the Company, which today is our only operating subsidiary. Following the Merger, we discontinued the Company’ s legacy lines of business and the use of any of its DABRA- related assets. For further information about these historical lines of business, see “ Item 1. Business ” of the Company’ s Form 10- K for the fiscal year ended December 31, 2021. Since the Merger, we have shifted the focus of our operations to Old Catheter’ s product lines. Accordingly, our current activities primarily relate to Old Catheter’ s historical business which comprises the design, manufacture and sale of new and innovative medical technologies focused in the field of cardiac electrophysiology, or “ EP. ” Our two primary products include the VIVO System and LockeT. The VIVO System, which is an anacronym for View into Ventricular Onset System (“ VIVO ” or “ VIVO System ”) is a non- invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to EP procedures. Our newest product, LockeT, is a suture retention device indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure. LockeT is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently. On January 24, 2025, we acquired PeriKard, LLC., a development stage company developing a kit of tools to enable physicians to more easily gain access to the pericardial space of the heart. It is intended that the kit will have both a better needle system and a better drainage system than current alternatives. The pericardium is the thin, fluid filled, sac that surrounds the heart. The pericardium is made up of an outer layer of tissue that holds the heart in place within the chest, protects it from inflammation, and acts as a barrier to infection. It also prevents the heart from stretching out and filling with too much blood which could constrict the heart and impede normal heart function in which case, access to the pericardium is needed to drain the excess fluid. Access is also desirable for ablation to treat arrhythmias outside the heart wall. PeriKard is currently in the product development phase. Additional future royalty cash payments may be due to the seller equal to 10 % of aggregate future net sales activity of PeiKard’ s pericardial access kits, to the extent the product is successfully commercialized, for five years from the acquisition’ s closing date. Our product portfolio also includes the Amigo ® Remote Catheter System, or Amigo, a robotic arm that serves as a catheter control device. Prior to 2018, Old Catheter marketed Amigo. We own the intellectual property related to Amigo, and this product is under consideration for future research and development of a generation 2 product. We continue to evaluate potential product acquisitions from time to time that might prove complementary to our current portfolio. Electrophysiology Market Overview EP is one of healthcare’ s largest sectors and rapidly growing. The EP market includes well known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x- ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense- Webster (J & J) and Boston Scientific Corp. Population growth, increasing rates of heart disease and the rising cost of healthcare are driving growth in the EP markets. In September 2024, the Heart Failure Society of America (" HFSA") reported in the Journal of Cardiac Health that approximately 6. 7 million Americans over the age of 20 currently live with heart failure, forecast to rise to 8. 7 million by 2030. The proportion of younger patients (aged 35- 64) is rising faster than that of older patients driven in part by increasing obesity and hypertension rates amount younger patients, and the overall lifetime risk of heart failure for Americans has risen to 24 %. Within the EP market, we focus our products that address the catheter ablation market. The catheter ablation market was $ 3. 5 billion in 2022 and is estimated by Global Market Insights to grow to $ 14. 5 billion in 2032. This market includes medical devices used for atrial and ventricular ablation procedures. Within the last 10 years, ventricular ablation has become a fast- growing treatment option due to updated treatment guidelines, improved technology and raising incidence rates. However, the exact number of ventricular ablations performed is not well documented. The ventricular ablation market is estimated by Global Market Insights to grow at a rate of 14. 5 % CAGR through 2032. Over a ten- year period, one study in Australia demonstrated a growth of 18 % for ventricular tachycardia. Of note, this surpassed the growth rate of atrial fibrillation (12. 7 %) which has historically been the largest incidence of cardiac arrhythmias. The Heart Rhythm Society, or HRS, Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias, published in May 2019 recommends catheter ablation in preference to anti arrhythmic drugs or in the situation where anti arrhythmic therapy has failed or is not tolerated. The guidelines also recommend ablation for reducing recurrent ventricular tachycardia, or VT, and implantable cardioverter- defibrillator shocks. Existing Treatments and Methods for Catheter Ablations Traditionally, the first line of treatment for cardiac arrhythmias is medication. However, this is often not a permanent fix and many patients eventually need a catheter ablation. In September 2024, the New England Journal of Medicine published clinical trial results which compared the number of adverse events in patients treated with catheter ablation versus patients treated with drug therapy. The trial found that patients treated with catheter ablation had suffered 50 % fewer adverse events at the median follow- up period of 4. 3 years than patients treated with drug therapy. Catheter Ablation Procedure Overview An electrophysiologist stands next to the patient’ s bed near the patient’ s groin. A catheter or catheters are inserted into the femoral vein (located at the groin) and navigated into the right side of the heart. Depending on the type of arrhythmia, the catheter is inserted into the atrium or the ventricle. Once inserted, a diagnostic catheter is used in conjunction with

an invasive (traditional) mapping system to create a map of the patient' s heart. This allows the physician to see the individual patient' s cardiac structures and size. Once the map is created, the physician begins to " pace map. " This process requires the physician to move the catheter from spot to spot to determine the electrical conduction at different areas to determine if the tissue in that area is responsible for the arrhythmia. Once the area is located, the physician will provide a form of energy (radiofrequency, cryo, etc.) to ablate the tissue in that spot. Treatment Challenges for Ventricular Arrhythmias Treatment of ventricular arrhythmias with cardiac ablations is a relatively new treatment option. As a result, we believe that the patient population is underserved, the condition is not as well understood, and the available techniques and technologies are limited when compared to the atrial ablation options. Ablation locations within the ventricle are very difficult to identify. Often, patients are ~~Highly~~ highly ~~Concentrated~~ symptomatic (dizzy, breathing difficulties, etc.) but the arrhythmia is infrequent. When this happens, it is hard to predict when the patient will be having an " active " arrhythmia. Because of this, the physician may not be able to identify the location even when using medication to induce the arrhythmia. Without confirmation during invasive mapping, the patient is removed from the electrophysiology lab without the ablation procedure being performed and the patient is required to return at a later date and try again for a successful outcome. Even when a patient has frequent ventricular arrhythmias, the process of pace- mapping often takes 4 – 5 hours to identify the location for ablation, which can increase the likelihood of patient complications due to the extended time under anesthesia. Lastly, many patients with untreated ventricular arrhythmias cannot tolerate anesthesia well, thus invasive mapping may not be an option for them. Treatment Challenges for Atrial Arrhythmias Catheter ablation for atrial arrhythmias is more standardized and " advanced " than for ventricular ablations, thus less pace mapping is required. Instead, a procedure called Pulmonary Vein Isolation (" PVI ") is performed for atrial fibrillation, and a single line is ablated for atrial flutter. In pulmonary vein isolation, tiny scars are created in the left upper chamber of the heart in the area where the four lung (pulmonary) veins connect. Despite steady improvement in the tools available to perform effective procedures, there is clear study evidence that catheter based atrial fibrillation treatment technology can become more effective. According to a study entitled " Long Term Outcomes of Catheter Ablation of Atrial Fibrillation: A Systematic Review and Meta- Analysis " published in the Journal of the American Heart Association on March 18, 2013, which looked at multiple individual studies covering over 6, 000 patients, " single procedure freedom from atrial fibrillation at long term follow up was 53. 1 %. " The same study found " with multiple procedures performed, the long- term success rate was 79. 8 %. " Ineffective treatment may result in patients undergoing two or more EP procedures to achieve relief from atrial fibrillation at an estimated cost in the range of $ 20, 000 or more per procedure. Specific reasons have not been proven for the lower success rate of initial ablation procedures. However, there is growing evidence that better results occur if the treating EP physician is able to make better lesions by maintaining stable contact force of the catheter against the heart wall, thereby reliably delivering the energy required to eliminate the abnormal rhythms. Variation in catheter contact force occurs as the physician attempts to manually position and hold the catheter tip in a stable position during cases lasting 2 to 3 hours in order to perform typically over 100 ablations of the cardiac anatomy. Large multi- national medical device companies, such as Medtronic, Inc., Boston Scientific Corp., Abbott Laboratories, St. Jude Medical, Inc. and the Biosense Webster division of Johnson & Johnson, among others, continue to invest heavily to develop and introduce new devices and technologies to improve patient outcomes. Included among these are force- sensing catheters, including the Biosense SmartTouch TM catheter, which provide a continuous readout of the contact force between the catheter and the heart wall. Our Vivo System is focused on the controlled delivery of these catheter technologies to enhance both the performance of ablation procedures and the ease and safety for the physicians who perform them. Our Products VIVO ™ System Our lead product, VIVO, is an FDA- cleared and CE marked product that utilizes non- invasive inputs to locate the origin of ventricular arrhythmias. VIVO has been used in more than 1, 000 procedures in leading U. S. and European hospitals. VIVO is a non- invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to electrophysiology procedures. The VIVO system has achieved a CE Mark allowing it to be sold in the European Union and has been placed at several hospitals in Europe. FDA 510 (k) Clearance in the United States was received in June 2019. The VIVO software is provided on an off- the- shelf laptop, and the system includes a 3D camera. In addition, the system can only be used with a disposable component, the VIVO Positioning Patches, which are required for each procedure. The VIVO software contains proprietary algorithms that are based on standard EP principles. However, the accuracy of the algorithms is improved because it does not use generalized assumptions and instead uses patient specific information. VIVO uses standard clinical inputs such as a CT or MRI and a 12 lead ECG, both of which are routinely gathered for most EP procedures, allowing VIVO to seamlessly integrate into the workflow. A 3D photograph is obtained of the patient' s torso after the ECG leads are in place and all of these clinical inputs are combined to generate a 3D map of the patient' s heart with a location of the earliest onset of the ventricular arrhythmia. VIVO Workflow VIVO Clinical Use and Studies To date, VIVO has been used in more than 1, 000 procedures, by more than 30 physicians in 11 countries. Initial clinical work was completed with the first- generation software, which resulted in FDA 510 (k) Clearance in June 2019. The U. S. multi- center study enrolled 51 patients from 5 centers. Of note, the Principal Investigator and center to have the highest enrollment was Johns Hopkins University in Baltimore, Maryland. This study was conducted to evaluate the accuracy of VIVO as compared to invasive mapping systems (current prevailing method for determining arrhythmia origins). VIVO met all study endpoints and correctly matched the predicted arrhythmia origin in 44 / 44 patients (100 %; primary endpoint) and correctly matched paced sites in 225 / 226 locations (99. 56 %; secondary endpoint). In some instances, this study showed that VIVO has better predictability for arrhythmia origin than a physician' s manual review of a 12 lead ECG. While conducting the initial clinical study for FDA submission, we developed generation 2 in parallel with a goal to

have this version complete and ready to submit upon 510 (k) clearance of generation 1. We successfully achieved this goal and received CE Mark and FDA 510 (k) Clearance for generation 2 in 2020. Additional clinical work has occurred with generation 2. Until recently, this data has been single center, physician- initiated research and has resulted in peer reviewed clinical science at electrophysiology conferences and in journals. Three physicians, at different centers in the UK conducted a feasibility study for Stereotactic Ablative Radiotherapy, or SABR, and published their data on nine patients. SABR is an ablation technique utilizing non- invasive methods akin to proton therapy for cancer treatment. To do a complete non- invasive ablation, accurately predicting the ablation location non- invasively is key to procedural success, and VIVO was utilized for this purpose. Non- invasive ablation is a new technique and requires additional data, but it is showing promise and has generated excitement within the EP community. If accepted for wide- spread treatment, this would allow for previously un- ablatable patients to receive lifesaving treatments. In October 2021 the first patient was enrolled in the VIVO EU Registry. This registry aims to gather data about how VIVO is used in real-world settings, outside of a rigorous clinical study. The registry enrolled 125 patients across Europe and the UK and collected information about different workflows and applications for VIVO. Enrollment of 125 patients was completed in June 2023. The study required a 12- month follow- up and data collection was completed in late 2024. This data serves multiple purposes including fulfilling European regulatory requirements for on- going data collection, publication of multi- center data, and future development of studies and improvements to the VIVO technology. The EU registry data demonstrated that approximately 60 % of physicians used VIVO pre- procedurally to improve procedural workflow and that VIVO is 94. 33 % accurate. This data is planned for publication submission in early Q2 2025. The physician-initiated study at Coventry Hospital in the UK completed enrollment and follow- up of 50 patients in Q4 2024. This study focused on outcomes of re- entrant ventricular tachycardia procedures when using VIVO pre- procedurally. These patients have hearts that are not structurally normal and have scarred tissue present in the ventricle. This data will be used for publication and to support an FDA submission to expand the current labeling of the existing product in Q2 2025. The Coventry data shows that the VIVO non- invasive mapping system was able to accurately map the ventricular tachycardia sight of origin in scar development dependent ventricular tachycardia and identify the relevant myocardial scar. Procedural success was seen in 90 % of patients at mean follow up of 7. 3 ± 4. 7 months. LockeT, a suture retention device, is a sterile, Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to distributors. In May 2023, Catheter submitted LockeT for CE Mark approval. CE Mark approval is expected in the first half of 2025, at which time initial international shipments to distributors will begin. LockeT is indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure and is intended to temporarily secure sutures, aid clinicians in locating and removing sutures efficiently and promote hemostasis. Clinical studies for LockeT began during 2023. The five phases of the current studies are planned to show the product' s effectiveness and benefits, including faster wound closure, earlier ambulation, potentially leading to faster hospital discharge, and lower costs for the healthcare provider and / or insurance payor. This data is intended to aid our marketing efforts and expand our indications for use with the FDA. See License and Other Agreements below. The Phase I- First in Man Feasibility Study was completed in 2023 and showed that the device works for its intended purpose and that there were no safety events, and gathered initial data to support Phase II submission to Institutional Review Board (IRB). This data has been presented as an abstract at several conferences including Western Atrial Fibrillation Symposium in February 2024 and American Heart Association in March 2024. This data was also accepted and published in August 2024 in the Journal of Cardiovascular Electrophysiology. Phase II completed enrollment of 97 patients in late 2024. This phase compared manual compression (standard of care) to LockeT. This data has been drafted into a manuscript and is currently undergoing revisions and journal submission is planned for the first half of 2025. The journal for submission has not yet been determined. Phase III was submitted to the IRB in December 2024. The study was approved by the IRB in January 2025. This study is collecting retrospective data, and as such, data collection has already been completed. The manuscript is currently in draft form and under review for planned journal submission in the first half of 2025. The aim of this study is to evaluate the safety profile of LockeT as compared to another vascular closure device when closing large bore access sites for left atrial appendage occlusion procedures. Phase IV was submitted to the IRB in December 2024. The study was approved by the IRB in January 2025. This study aims to evaluate the effectiveness of LockeT, a novel external compression device, for large- bore venous vascular access site hemostasis following electrophysiologic pulsed field ablation procedures. This study is planned to begin enrollment by April 2025 and take 6 months to complete. Thus, the anticipated completion date is October 2025. Phase V was submitted to IRB in February 2025. The goal of this study is to compare the safety and effectiveness of LockeT for small bore vascular closure compared to Vascade, a vascular closure device. It is anticipated that approval from the IRB will be provided by April 1, 2025, at which point enrollment will commence. Study duration is expected to be 9 months, with enrollment conclusion by end of Q4 2025. Our Solutions Adoption of our VIVO System by electrophysiologists is expected to enhance their ability to diagnose and treat cardiac arrhythmias. Non- invasive mapping prior to the ablation procedure provides a solution for patients that could not be ablated previously. First, many patients with VT do not tolerate anesthesia well. By providing a non- invasive solution to determine the ablation location, physicians are better able to understand where the arrhythmia originates and how easily one can access the ablation location, minimizing the amount of time that the patient may need to be anesthetized, and allowing many patients the ability to have an ablation that otherwise could not. Second, many patients are highly symptomatic, but do not have PVCs often. In these situations, the patients are often brought in for ablation procedures only to have no arrhythmia and sent home time and time again. In these instances, the physicians can monitor the patient prior to hospitalization and obtain information about the arrythmia. In this way, the patient can still proceed to an ablation

procedure without having PVCs on the day of surgery. Non- invasive mapping also enables planning prior to the start of the procedure. This enables the physicians to better understand where they are targeting, which enables them to make advanced decisions about where they are navigating the catheter and which catheter (s) they are using, reducing both procedure time and cost. Surgery patients who are offered the LockeT device are expected to benefit from faster wound closure, more comfort than manual compression and earlier ambulation, potentially leading to early hospital discharge and lower costs for the healthcare provider and / or insurance payor. Our Strategy Our goal is to become a leading developer and marketer of electrophysiology products which provide patients, hospitals, and physicians with novel technologies and solutions to improve procedural outcomes and the lives of patients with cardiac arrhythmia. We intend to establish VIVO as an integral tool for cardiac electrophysiologists to reduce procedure time during ablation treatment of ventricular arrhythmias, patient complications and increasing procedural success. We further intend to establish LockeT as a standard for wound closure, shortening time to achieve hemostasis while improving patient comfort. Customers Our primary customers are hospitals providing cardiac electrophysiology lab procedures. We believe there are 2, 000 to 3, 000 EP labs in the U. S. and a similar number of labs outside of the U. S. performing approximately 600, 000 ablation procedures annually. During fiscal 2024, we had two individual customers that represented approximately 37 % and 15 % of our total revenues, respectively, and three customers (including the two just described) that in the aggregate represented approximately 62 % of our total revenues. Sales and Marketing During 2024 we hired a new Chief Commercial Officer, two regional directors, eight territory managers and four clinical support specialists, replacing our entire sales team. Our new salespeople average 10 years of electrophysiology sales experience. Our sales team sells both VIVO and LockeT. The sales team qualifies appropriate prospective customers, and with support from our direct clinical specialists they conduct product demonstrations, and support customer training and case usage. In Europe, our products are sold through distributors, supported by one full- time contracted sales consultant. In the future, we intend to market our products in the U. S. and certain international markets using a combination of a direct sales force and independent distributors. This may require us to make a significant investment building our U. S. commercial infrastructure and sales force and in recruiting and training our sales representatives and clinical specialists for U. S. commercialization of VIVO and LockeT. This is a lengthy process that requires recruiting appropriate sales representatives, establishing a commercial infrastructure in the United States, and training our sales representatives, and will require significant ongoing investment by us. Following initial training, our sales representatives typically require lead time in the field to grow their network of accounts, coordinate their sales efforts with each hospital' s capital budgeting and acquisition cycle and produce sales results. Successfully recruiting and training a sufficient number of productive sales representatives is required to achieve growth at the rate we desire. We previously entered into a joint marketing agreement with Stereotaxis, Inc. The parties agreed to terminate the agreement in December 2024. Outside the U. S., we will continue to foster additional key partner relationships with distributors who will market, sell and support our products. In addition, we believe there are opportunities to offer additional complementary products through our sales and marketing channels that would enhance the productivity of our sales force and provide additional scale to revenue, better covering fixed operating costs. Manufacturing and Availability of Raw Materials VIVO manufacturing, inventory and product fulfillment is housed in our approximate 2, 000 square feet facility in Fort Mill, South Carolina. This facility currently has one full- time employee who oversees manufacturing, quality objectives, and order fulfillment. The VIVO system includes VIVO software, loaded onto an off- the- shelf laptop, which we equip with a 3D camera. We purchase laptops and cameras that have been manufactured by third parties. Disposable VIVO Positioning Patches are also required for use of the system, and the manufacture of the patches is outsourced. In January 2025, we hired an in- house full- time software engineer for research and development activities related to VIVO. This includes updates to the existing VIVO version and development and product release of VIVO 3. LockeT manufacturing, inventory and product fulfillment has been subcontracted to the company that provided research and development of the product. Competition The medical device industry is highly competitive, subject to rapid change and is significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, manufacturing cost, and customer support. Our primary competitors in the cardiac electrophysiology space include known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x- ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense- Webster (J & J) and Boston Scientific Corp. LockeT' s direct competitors include Abbott' s Perclose device, Haemonetic' s VASCADE device and Inari Medical' s FlowStasis device. Research and Development The major focus of our research and development team is to leverage our existing technology platform for new applications and improvements to our existing applications, including multiple engineering efforts to improve our current products. Future research and development efforts will involve continued enhancements to and cost reductions of VIVO and LockeT, and commercialization opportunities for the acquired PeriKard technology. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Our research and development team works together with our commercial team to set development priorities based on communicated customer needs. The feedback received from our customers is reviewed and evaluated for incorporation into new products. With the hiring of an in- house full- time software engineer, we have begun the development of a generation 3 of VIVO. If successful, this version will have expanded indications to include ischemic heart disease and improve usability by the hospital staff. It would also contain

more automaticity, potentially reducing our need for clinical support. Resources Material to Our Business Patents and Proprietary Technology We have a number of patents covering our intellectual property, both in the U. S., as well in a number of international countries. We consider the U. S. to be the most important market for our products, and hence, the most important country for the filing of patents. Any foreign filings are merely replicates of the U. S. filings. For the U. S., our key patents include: ● VIVO – We have two U. S. patents granted on the original VIVO concept, which have been licensed from a third party. We consider the primary component to be the ideas around utilizing a 3D camera to identify the exact location of the body surface electrodes. These two patents expire in 2038. An additional two applications have been granted, which disclosed ideas around merging of the heart models to other heart images and expire in 2038 and 2040. An additional three applications were published, all filed in 2021, covering the idea of determining the thickness of the wall of the ventricle, covering the concept of the rendering of a heart model and likely outcomes of an EP procedure. An additional application was filed in September 2023 and is not yet published. ● LockeT – Suture Retention Device- We have four published U. S. patent applications. These cover the basic concept, methods of use and the design of the conceived device. PEACS, NV Software and Technology License Agreement On May 1, 2016, we entered into a certain Software and Technology License Agreement with PEACS, NV, a Netherlands company, or the License Agreement, for the exclusive worldwide license of the underlying technology to the VIVO product, including intellectual property rights and patent applications pertaining thereto. The license was for use of the technology for the field of use defined as " the localization of the origin of cardiac activation for the electrophysiology treatment and / or detection of cardiac arrhythmias. " The License Agreement called for us to pay for the prosecution and maintenance of patents to protect the technology. In May 2021, the License Agreement was modified to modify the field of use to specifically exclude the use of clinical applications for the implanting of atrial or ventricular pacemakers, including bi-ventricular pacemakers. The terms of the License Agreement are incorporated herein by reference to Exhibits 10. 32 and 10. 32. 1 hereto. LockeT Royalty Agreement In February 2022, we agreed to an assignment and royalty agreement, or the Royalty Agreement, for the LockeT device. Pursuant to the Royalty Agreement, we agreed to pay a royalty fee of 5 % on net sales up to $ 1 million. Thereafter, if a patent for the LockeT device is obtained from the U. S. Patent and Trademark Office, we will pay a royalty fee of 2 % of net sales up to a total of $ 10 million in royalties. In addition, at the time of the Merger, additional royalty rights with respect to LockeT device were granted to certain holders, or the Noteholders, of Old Catheter' s outstanding convertible promissory notes, including our Chief Executive Officer, David Jenkins, and certain of his affiliates, in exchange for forgiveness of the interest that had accrued under those notes but remained unpaid, pursuant to the terms of certain Debt Settlement Agreements. The Debt Settlement Agreements provided for the Noteholders to receive, in the aggregate, approximately 12 % of the net sales, if any, of the LockeT device, commencing upon the first commercial sale through December 31, 2035. Trademarks We own or have rights to trademarks that we use in connection with the operation of our business. We own or have rights to trademarks for Catheter Precision, LockeT and Ra Medical Systems and their logos, as well as other trademarks such as AMIGO. Trade Secrets We also have relied upon trade secrets, know- how and technological innovation, and may in the future rely upon licensing opportunities to develop and maintain our competitive position. We have protected our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information. Government Regulations Governmental authorities in the U. S. (at the federal, state, and local levels) and abroad extensively regulate, among other things, the research and development, testing, manufacture, quality control, clinical research, approval, labeling, packaging, storage, record- keeping, promotion, advertising, distribution, post- approval monitoring and reporting, marketing, and export and import of products such as those we market and are developing. See Item 1. A. Risk Factors — Risks Related to Government Regulation. United States Medical Device Regulation In the U. S., medical devices are subject to extensive regulation by the Food and Drug Administration (" FDA "), pursuant to the Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post- approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and / or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending pre- market approval (" PMA "), applications or premarket notification submissions (commonly referred to as " 510 (k) s), " issuance of warning letters or untitled letters, product recalls, import detentions, civil monetary penalties, and / or judicial sanctions, such as product seizures, injunctions, and criminal prosecution. The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices provide intermediate levels of risk. They are subject to general controls and must also comply with special controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device' s safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed. LockeT is a sterile, Class I product and was registered with the FDA in February of 2023. It does not require FDA marketing authorization. VIVO is an FDA- cleared Class II product. We are currently evaluating the regulatory path for any potential PeriKard products. Establishments that manufacture devices are required to register their establishments with the FDA and provide the FDA with a list of the devices that they handle at their facilities. The FDA conducts market surveillance and periodic visits, both announced and unannounced, to inspect or re- inspect equipment, facilities, laboratories and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a

Form 483, listing instances where the manufacturer has failed to comply with applicable regulations and / or procedures or, if observed violations are severe and urgent, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA (with assistance from the Justice Department in certain cases) make take enforcement action against the manufacturer or impose other sanctions or consequences, which may include: ● injunctions or consent decrees; ● civil monetary penalties; ● recall, detention or seizure of our products; ● operating restrictions, partial or total shutdown of production facilities; ● refusal of or delay in granting requests for 510 (k) clearance, de novo classification, or premarket approval of new products or modified products; ● withdrawing 510 (k) clearances, de novo classifications, or premarket approvals that are already granted; ● refusal to grant export approval or export certificates or devices; and ● criminal prosecution. Pre- Market Authorization and Notification While some Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U. S. only if the FDA has: (i) approved a PMA application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510 (k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the de novo process, generally applicable for novel Class I or II devices. Some devices that have been classified as Class III are regulated pursuant to the 510 (k) requirements because the FDA has not yet called for PMAs for these devices. 510 (k) Notification Product marketing in the U. S. for most Class II and limited Class I devices typically follows a 510 (k) pathway. To obtain 510 (k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510 (k) cleared device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of PMA applications, or a product previously granted de novo authorization. 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 it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device. There are three types of 510 (k) s: traditional; special, for certain device modifications; and abbreviated, for devices that conform to a recognized standard. The special and abbreviated 510 (k) s are intended to streamline review. The FDA intends to process special 510 (k) s within 30 days of receipt and abbreviated 510 (k) s within 90 days of receipt. Though the FDA has a goal to clear a traditional 510 (k) within 90 days of receipt, the clearance pathway for traditional 510 (k) s can take substantially longer. After a device receives 510 (k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510 (k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer' s decision not to seek a new 510 (k) clearance for the modified device, the agency may retroactively require the manufacturer to seek 510 (k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and / or recall the modified device until 510 (k) clearance or PMA is obtained. VIVO was cleared by the FDA via a traditional 510 (k) with supporting clinical data. This data was collected via a clinical study enrolling 51 subjects and took approximately 12 months to gather. In order to expand the indications for use of the current VIVO product with the FDA to include ischemic hearts, data collection via the Coventry study to support a new 510 (k) submission will be required. It is expected that future generations of VIVO will require similar data collection and 510 (k) submission to receive separate FDA clearance. Because the LockeT device is a Class I product, it did not require clinical data or a formal submission process. After completing validation testing and compiling a Device History File, LockeT was added to our listing of registered devices. The regulatory pathway for future LockeT devices will depend on the intended use and desired labeling claims and the requirements for clinical data. De Novo Classification Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513 (f) (1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate- risk devices classified in Class III by operation of law, Congress enacted section 513 (f) (2) of the FDCA. This provision allows the FDA to classify a low- to moderate- risk device not previously classified into Class I or II through the de novo classification pathway. The FDA evaluates the safety and effectiveness of devices submitted for review under the de novo classification pathway, and devices determined to be Class II through this pathway can serve as predicate devices for future 510 (k) applicants. The de novo classification pathway can require clinical data and is generally more burdensome than the 510 (k) pathway and less burdensome than the PMA pathway. Pre- Market Approval A product not eligible for 510 (k) clearance or de novo classification must follow the PMA pathway, which requires proof of the safety and effectiveness of the device to the FDA' s satisfaction. Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product' s marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA. The PMA process is generally more expensive, rigorous, lengthy, and uncertain than the 510 (k) premarket notification process and de novo classification process and requires proof of the safety and effectiveness of the device to the FDA' s satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer' s facilities for compliance with Quality System Regulations, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The FDA' s review of a PMA application typically takes one to three years but may last longer. The FDA will often convene an independent advisory panel to review the submission. If the FDA' s evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post- approval conditions that the FDA believes necessary to ensure

the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and / or placement of restrictions on the sale of the device until the conditions are satisfied. Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. Clinical Trials A clinical trial is almost always required to support a PMA application and de novo classification and is sometimes required for a premarket notification. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the U. S. be approved under an Investigational Device Exemption (" IDE "), which must become effective before clinical testing may commence. A nonsignificant risk device does not require FDA approval of an IDE. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30- day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA disapproves the IDE within this 30- day period, the clinical trial proposed in the IDE may not begin. In addition, even if the 30- day waiting period expires without objection by the FDA, the FDA can impose a clinical hold if safety issues arise. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA' s IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Pivotal clinical trials supporting premarket applications for devices are typically conducted at geographically diverse clinical trial sites and are designed to permit the FDA to evaluate the overall benefit- risk relationship of the device and to provide adequate information for the labeling of the device when considering whether a device satisfies the statutory standard for commercialization. Clinical trials, for significant and nonsignificant risk devices, must be approved by an institutional review board, or IRB — an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB' s requirements, or may impose other conditions or sanctions. Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing. Investigational devices may only be distributed for use in an investigation and must bear a label with the statement: " CAUTION- Investigational device. Limited by Federal law to investigational use. " Post- Market Requirements After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR requirements, labeling regulations, the medical device reporting 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 it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). Failure to properly identify reportable events or to file timely reports, as well as failure to address observations to FDA' s satisfaction, can subject us to warning letters, recalls, or other sanctions and penalties. Advertising, marketing and promotional activities for devices are also subject to FDA oversight and must comply with the statutory standards of the FDCA, and the FDA' s implementing regulations. The FDA' s oversight authority review of marketing and promotional activities encompasses, but is not limited to direct- to- consumer advertising, healthcare provider- directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA also regulates industry- sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against manufacturers that promote products for " off- label " uses (i. e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for " off- label " uses are fraudulent in violation of the Federal False Claims Act or other federal and state

statutes and that the submission of those claims was caused by off- label promotion. The failure to comply with prohibitions on " off- label " promotion can result in significant monetary penalties, revocation or suspension of a company' s business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U. S. government that imposes significant administrative obligations and costs, as has occurred in the past with respect to our legacy products that we no longer market. The Federal Trade Commission, or FTC, also oversees the advertising and promotion of our products (other than labeling) pursuant to its broad authority to police deceptive advertising for goods or services within the U. S. The FDA and FTC work together to regulate different aspects of activities by medical product manufacturers, consistent with the inter- agency Memorandum of Understanding. Under the Federal Trade Commission Act, or FTCA, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. In the context of performance claims for products such as our devices and services, compliance with the FTCA includes ensuring that there is scientific data to substantiate the claims being made, that the advertising is neither false nor misleading, and that any user testimonials or endorsements we or our agents disseminate related to the devices or services comply with disclosure and other regulatory requirements. Violations of the FDCA or FTCA relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, including state consumer protection laws. For a PMA or Class II 510 (k) or de novo devices, the FDA also may require post- marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA- approved device that could restrict the distribution or use of the product. In addition, quality control, manufacture, packaging, and labeling procedures must continue to conform to QSRs and other applicable regulatory requirements after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with QSRs. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements and patients are being subjected to serious risks, the agency can shut down our manufacturing operations, require recalls of our medical device products, refuse to approve new marketing applications, initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. European Economic Area (EEA) Regulation The EEA recognizes a single medical device approval (the CE Mark) which allows for distribution of an approved product throughout the EEA without additional general applications in each country. Individual EEA members, however, reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third parties called " Notified Bodies " award the CE Mark. These Notified Bodies are approved and subject to review by the " Competent Authorities " of their respective countries. Our Notified Bodies perform periodic on- site inspections to independently review our compliance with systems and regulatory requirements. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country' s application process. We have a CE Mark for the VIVO System. Beginning July 1, 2023, the United Kingdom requires its own medical device approval (UKCA). VIVO is currently registered with UK' s Medicines and Healthcare products Regulatory Agency to market the VIVO system in the UK. Since July 1, 2023, VIVO bears the UKCA symbol as required by the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (" MDR ") to continue UK distributions. MDR requirements now include on- going collection of clinical data to include in annual reports to ensure state- of- the- art technology and safety requirements are met. We are currently collecting data via a multi- center (and country) European Registry. This registry concluded enrollment in June 2023. The required 12- month follow- up and data collection was completed in late 2024. LockeT is currently undergoing MDR review and approval via the Notified Body. CE Mark is anticipated in the first half of 2025. Other Healthcare Laws Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, expose us to broadly applicable state, federal, and foreign fraud and abuse and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products. Such laws include, but are not limited to: ● the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U. S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U. S. federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act; ● U. S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. government. Persons and entities can be held liable under these laws if they are deemed to " cause

” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off- label; ● the U. S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation; ● in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information; ● the U. S. Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’ s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “ transfers of value ” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non- physician healthcare professionals (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, as well as information regarding ~~Ownership~~ **ownership** ~~We also have retained a total of 3 people as independent contractors.We are planning to increase our sales force in support of product launches but currently have no other plans to increase our staff.ITEM 1A.RISK FACTORS~~ Investing in our common stock involves a high degree of risk.You should carefully consider the risks and uncertainties described below,together with all of the other information in this Annual Report on Form 10- K,before making an investment decision.The risks and uncertainties described below may not be the only ones we face.If any of the risks actually occur,our business,financial condition,operating results,cash ~~flow~~ **flows** and prospects could be materially and adversely affected.In that event,the market price of our common stock could decline,and you could lose part or all of your investment. **Risk Factor Summary (This Summary is not intended to and does not describe all of the risk factors discussed below that may impact the Company.We urge investors to review the detailed descriptions of risk factors that follow.)** Risks Related to Our Financial Position and Need for Additional Capital Our operations to date have consumed substantial amounts of cash and our business, including the business of Old Catheter conducted prior to its being acquired by the Company, sustained negative cash flows from operations for the last several years. In addition, our auditors’ report on our financial statements included in this Form 10- K contains an explanatory paragraph about the substantial doubt to continue as a going concern. As of March ~~7~~ **14** , ~~2024~~ **2025** , we have approximately $ **787 thousand** ~~1. 86 million~~ in cash and cash equivalents, which, together with our anticipated cash from operations, is not adequate to meet our working capital needs through ~~May~~ **the remainder** of ~~2024~~ **2025** , and our business is currently not profitable. During ~~the first quarter of 2023~~ **2024** we raised approximately $ ~~9~~ **7** . ~~3~~ **2** million in **net** proceeds from securities transactions, but ~~Merger~~ **operating** costs and other negative cash flows have substantially depleted our cash. As a result, we will require **additional** future ~~additional~~ capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and / or products that are complementary to our own capabilities and / or products, in order to execute our strategic vision. However, there can be no assurances that we can complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. In addition, any additional equity financing will be dilutive to our current stockholders, and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition, and results of operations. See “ — We have entered into joint marketing agreements with respect to our products, and may enter into additional join marketing agreements, that will reduce our revenues from product sales, ” and “ — Royalty agreements with respect to LockeT, the surgical vessel closing pressure device, will reduce any future revenues from this product. ” Our business has a history of losses and will incur additional losses, and we may never achieve profitability. Our current business primarily derives revenues from the View into Ventricular Onset System or VIVO ™ System (“ VIVO ” or “ VIVO System ”) **and our LockeT product** . VIVO is FDA cleared **,** and CE marked, having received FDA 510 (k) clearance in June 2019. Old Catheter began a limited commercial launch of VIVO in the third quarter of 2021, and we began a full- scale launch in 2023 in conjunction with the expansion of a direct sales force in the U. S. Our current business strategies include a plan to expand uses for VIVO, which will require additional clearances **. LockeT, a suture retention device, is a sterile, Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to distributors. In May 2023, Catheter submitted LockeT for CE Mark approval. CE Mark approval is expected in the first half of 2025, at which time initial international shipments to distributors will begin** . While we do generate revenue, we are currently operating at a loss, and there is no guarantee that we will be able to grow revenues enough to offset our costs and ~~realize~~ **achieve** profitability. To date, we have not been profitable, and our accumulated deficit was approximately $ **292** ~~275. 7~~ million at December 31, ~~2023~~ **2024** . Historically, aside from Merger costs, our losses have resulted principally from costs incurred in research and development, and from general and administrative costs associated with our operations. During the ~~first quarter 2023~~ **2024** we raised approximately $ ~~9~~ **7** . ~~3~~ **2** million in **net** proceeds from securities transactions, but ~~Merger~~ **operating** costs and ~~other~~ negative cash flows have substantially depleted our cash. However, in order to continue the commercialization of our assets consistent

with our vision, we will need to conduct substantial additional research, development and clinical trials. Our business strategy also includes expanding uses for our products which will require us to seek additional regulatory clearances in the United States **and abroad** , and we also must continue to expand our patents in order to obtain meaningful patent protection for and establish freedom to commercialize our product candidates. We must also complete further clinical trials and seek regulatory approvals for any new product candidates we discover, license or acquire. We cannot be sure whether and when we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future. We may never achieve profitability. ~~25Our~~ -- **Our current cash flows are not sufficient to fund our current operations, and we believe that we will need to complete additional financings within the next three to six months. Our** management is responsible for establishing and maintaining adequate internal controls over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America (" U. S. GAAP "). Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our disclosure controls and to disclose any material changes to our internal controls identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. As described elsewhere in this Form 10- K and in our Quarterly Reports on Form 10- Q filed during ~~2023~~ **2024** , we have identified material weaknesses in our internal control over financial reporting related to (1) the lack of segregation of duties, (2) the lack of designed and operating review controls with respect to oversight of the financial reporting process, **and** (3) ~~errors with respect to the~~ review of work performed by service providers ~~,~~ **with regards to** (~~4~~ **i**) ~~errors in connection with accounting~~ **management' s provision of inputs** for **valuations to a third- party service provider and** ~~the royalty obligation acquired in the merger with Old Catheter,~~ (~~5~~ **ii**) **the Section 382** ~~use of an incorrect discount rate in calculating~~ - **calculation in** the ~~fair value of~~ **tax provision in that** the ~~royalty obligation and (6) timing~~ **Company' s provision did not reference the correct dates when determining ownership changes resulting in material changes in the amount** of ~~revenue recognition~~ **expiring net operating losses available to be utilized** . As a result of these material weaknesses, our management has concluded that our disclosure controls were not effective as of March 31, ~~2023~~ **2024** , June 30, ~~2023~~ **2024** , September 30, ~~2023~~ **2024 ,** and December 31, ~~2023~~ **2024** . For a discussion of management' s consideration of the material weaknesses described above, see below " Part II, Item 9A. Controls and Procedures: of this Annual Report on Form 10- K, and " Part I, Item 4. Controls and Procedures " included in our Quarterly Report on Form 10- Q for the quarter ended September 30, ~~2023~~ **2024** . As described below at " Part II, Item 9A. Controls and Procedures " of this Annual Report on Form 10- K and " Part I, Item 4. Controls and Procedures " included in our Quarterly Report on Form 10- Q for the quarter ended September 30, ~~2023~~ **2024** , we have concluded that our disclosure controls were not effective as of March 31, ~~2023~~ **2024** , June 30, ~~2023~~ **2024** , September 30, ~~2023~~ **2024 ,** and December 31, ~~2023~~ **2024** because material weaknesses existed in our internal control over financial reporting. We **have formulated and** are **implementing** ~~in the process of formulating~~ a plan to remediate the material weaknesses described therein; however, if we are unable to remediate our material weaknesses in a timely manner or we identify additional material weaknesses, we may be unable to provide required financial information in a timely or reliable manner and we may incorrectly report financial information. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In such a case, there could be a material adverse effect on our business. The existence of material weaknesses or significant deficiencies in internal control over financial reporting could adversely affect our reputation or investor perceptions of us, which could have a negative effect on the trading price of our stock. In addition, we may incur additional costs to remediate the material weaknesses in our internal control over financial reporting. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls or otherwise. There may be additional undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Further, to the extent we identify additional material weaknesses, we will not be able to fully assess whether corrective measures will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional errors that result in material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in additional business transactions, such as acquisitions, reorganizations or implementation of new information systems, any of which could negatively affect our internal control over financial reporting and result in material weaknesses. If we identify additional material weaknesses in our internal control over financial reporting or if we continue to be unable to assert that our internal control over financial reporting is effective, we may again be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. As a result of any internal control failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation or divert financial and management resources from our core business, and which would have a material adverse effect on our business, financial condition and results of operations. ~~26Compliance~~ -- **Compliance** with Section 404 of the Sarbanes- Oxley Act could have a material adverse impact on our business. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. As a " smaller reporting company " that is a non-

accelerated filer, we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be a non- accelerated filer. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance- related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 to us in a timely manner, or if we or our independent registered public accounting firm identifies additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. We will not be able to reach profitability unless we are able to achieve our product expansion and growth goals. Our goal to achieve profitability is dependent upon establishing VIVO as an integral tool used by cardiac electrophysiologists during ablation treatment of ventricular arrhythmias, as well as upon developing and marketing new products, such as LockeT, the wound closure device, and **our PeriKard products, and** the successful build out of our U. S. commercial infrastructure and sales force. During fiscal ~~2023~~ **2024** , over 70 % of our revenues were derived from four customers, two of whom represented over half of our revenues. In today' s healthcare environment, the process for new technologies to be adopted and penetrate market share has become more complex, with the need to win over multiple stakeholders within clinical, administrative and support teams in hospitals, and increasingly we must target the administrators in integrated delivery networks. To accomplish this, we will need to: ~~-~~ ● Develop initial users that demonstrate clinical and economic benefits and support studies which provide evidence of tangible benefits to prospective customers, such as procedural success, no or minimal patient complications and reduced procedure times. ~~-~~ ● Collaborate with clinical thought leaders to establish clinical techniques, evolve our product features and demonstrate enhanced capabilities to broaden the appeal of VIVO and LockeT. ~~-~~ ● Acquire data and expand our FDA clearance to market our products for additional procedure types. In Europe, VIVO is cleared for pre- procedural planning in all types of hearts and procedures, including ischemic hearts. In the U. S., we will need to seek clearance for ischemic hearts to broaden the indications for use of our products, which can expand clinical demand. Data from the Coventry study focused on reentrant ventricular tachycardia will be used to support a clinical submission with existing version of VIVO. ~~-~~ ● Enhance the design, user utility and clinical capability of VIVO and LockeT through further product development and collaboration with clinical users. ~~-~~ ● Seek to engage collaboration with larger market participants and their larger sales force coverage to integrate the prospecting, sale and support of our products in conjunction with other products used in electrophysiology procedures. ~~-~~ ● Opportunistically identify acquisitions to enhance our enterprise scale, sales synergy and fixed cost coverage. ~~-~~ ● Seek to obtain permanent CPT codes for reimbursement from Medicare to broaden the appeal of using VIVO in the physician' s clinic. The process takes five to seven years to complete. To date, we have met with reimbursement specialists and are working to determine the best strategy. ~~27In~~ ● **Develop new products, including potentially our PeriKard products. In** addition, our sales and marketing strategy for VIVO requires us to hire additional clinical support and sales representatives who are experienced in the EP field. **We** ~~In addition, we~~ must **also** make a significant investment building our U. S. commercial infrastructure and sales force, a lengthy process requiring ongoing investment and a certain amount of lead time to produce the growth rate we desire. If we are unable to accomplish one or more of the foregoing, we may be unable to achieve our product expansion and growth goals ~~,~~ and may be unable to achieve profitability. We may need to seek out additional collaborations in order to commercialize our products. We will continue to seek research collaborations, co- development and marketing agreements, and licensing deals for our products in development; however, there is no guarantee that we will be successful in our efforts. Any collaborator with whom we may enter into such collaboration agreements may not support fully our research and commercial interests since our programs may compete for time, attention and resources with such collaborator' s internal programs. Therefore, these future collaborators may not commit sufficient resources to our programs to move them forward effectively, or the programs may not advance as rapidly as they might if we had retained complete control of all research, development, regulatory and commercialization decisions. **Economic uncertainty or downturns, and related tariffs, particularly as they impact particular industries, could adversely affect our business and results of operations. In recent years, the U. S. and other significant markets have experienced inflationary pressures and cyclical downturns, and worldwide economic conditions remain uncertain. Economic uncertainty and associated macroeconomic conditions make it extremely difficult for our partners, suppliers, and us to accurately forecast and plan future business activities and could cause our customers to slow spending on our offerings and could limit the ability of hospitals to purchase sufficient quantities of our products. Inflationary pressures may lead to increases in the cost of our products, freight, overhead costs or wage rates and may adversely affect our operating results. Sustained inflationary pressures may have an adverse effect on our ability to produce and market our products cost effectively. A significant downturn in the domestic or global economy may cause our customers to pause, delay, or cancel spending on our products or seek to lower their costs by exploring alternative providers or our competitors. To the extent purchases of our products are perceived by customers and potential customers as discretionary, our revenue may be disproportionately affected by delays or reductions in general healthcare spending. Also, competitors may respond to challenging market conditions by lowering prices and attempting to lure away our customers. the current, volatile, political environment affecting tariffs and economic policies adopted by the U. S. and foreign governments can pose a significant risk to our business by increasing costs of raw materials, disrupting supply chains and making it harder to obtain supplies, and limiting product availability, which can lead to higher prices for our customers as well as reduced for the Company. We cannot predict the timing, strength, or duration of any economic disruption or any subsequent recovery generally, or in any particular industry. If the conditions in the general economy**

and the markets in which we operate worsen from present levels, our business, financial condition, and results of operations could be materially adversely affected. Artificial intelligence- based platforms may present new risks and challenges to our business. Artificial Intelligence, or AI, technologies may exacerbate existing risks, including risks associated with data privacy, cybersecurity, IP, healthcare fraud and abuse, drug development and manufacturing, and risks to patients or human subjects in clinical trials. AI also introduces new risks, due to the autonomous nature of the technology, which, in some cases, may be deployed to perform tasks, inform decisions, automate decisions, and make predictions, sometimes using unverified or false information. AI may amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups. Regulators are proposing, adopting, and implementing new AI laws and regulations. We may be required to change our business practices and policies as a result of such laws and regulations and may incur substantial compliance- related costs. Regulators are also using existing laws and regulations to take enforcement actions related to the deployment of AI in ways that result in non- compliance with current laws and regulations. If we fail to comply with AI laws and regulations, we may be subject to sanctions, fines, and reputational damage, orders to stop certain processing of personal data, orders to delete certain data or destroy AI algorithms derived from data collection, legal action on behalf of impacted individuals or other enforcement or other actions. If we or our vendors using AI technologies fail to take steps to protect our confidential data, trade secrets, IP and personal data, we may be subject to legal, regulatory, financial, and reputational risks. AI technologies present significant opportunities and risks to our business. Harnessing AI' s transformative potential may enable us to speed up the discovery and development of new products and new uses for existing products, optimize our manufacturing processes, and drive efficiencies. Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities and to capitalize on opportunities presented by AI may also place us at a competitive disadvantage. Failure to address AI risks will reduce our ability to deliver strategic objectives. Also, investments in AI may not realize the benefits that were anticipated. We have **previously** entered into joint marketing agreements with respect to our products ~~,~~ and may enter into additional joint marketing agreements ~~,~~ that will reduce our revenues from product sales. ~~Old Catheter~~ **We have previously** entered into ~~a Joint~~ **joint** ~~Marketing~~ **marketing** ~~Agreement with Stereotaxis, Inc. in January 2021, as subsequently amended in January 2022 and May 2022, pursuant to which Stereotaxis agrees to promote our VIVO System to customers who may benefit from the use of VIVO in robotic or non- robotic electrophysiology procedures. Pursuant to the agreement~~ **agreements** ~~, Stereotaxis can perform promotional activity at any hospital globally~~ that ~~has a Stereotaxis Robotic Magnetic Navigation System, referred to herein as a robotic hospital, and where VIVO has appropriate regulatory clearances. In addition, Stereotaxis will act as a spot distributor for us at mutually agreed upon hospitals where the VIVO System is included as a line item within a Stereotaxis quote. In exchange for its marketing, distribution and support activity, Stereotaxis receives a payment equal to 45 % of the revenue generated from VIVO at robotic hospitals. After the initial sale of VIVO products to customers by Stereotaxis, Catheter will be responsible for selling additional VIVO- related products to the customers but will continue to owe the 45 % payment to Stereotaxis with respect to any such sales. The agreement has a term that runs through December 31, 2025, provided however, that the agreement will automatically extend for successive two- year terms unless either party provides the other written notice of termination at least one year prior to the next- scheduled termination date. Stereotaxis will continue to be entitled to receive the 45 % payments described above for a period of six months following termination of the agreement. Although we believe that this agreement is in the best interest of our business and our stockholders, it will~~ materially ~~reduce~~ **reduced** the revenues that we ~~receive~~ **received** from VIVO products ~~that are sold by Stereotaxis~~ **, and although all such agreements have been terminated, we may enter into similar agreements in the future with respect to any or all of our products** , and any similar agreements entered into in the future may ~~have the same impact~~ **also materially reduce our per unit product revenues** . Royalty agreements with respect to LockeT, our surgical vessel closing pressure device, will reduce any future profits from this product. In February 2022, Old Catheter agreed to an assignment and royalty agreement for the Surgical Vessel Closing Pressure Device (" LockeT "). Pursuant to the agreement, Old Catheter agreed to pay a royalty fee of 5 % on net sales **of** up to $ 1 million. Thereafter, if a patent for the Surgical Vessel Closing Pressure Device is obtained from the U. S. Patent and Trademark Office, Old Catheter will pay a royalty fee of 2 % of net sales up to a total of $ 10 million in royalties. In addition, at the time of our merger with Old Catheter, additional royalty rights with respect to LockeT were granted to certain holders (the " Noteholders ") of Old Catheter' s outstanding convertible promissory notes in exchange for forgiveness of the interest that had accrued under those notes but remained unpaid, pursuant to the terms of certain Debt Settlement Agreements. The agreements provide for the Noteholders to receive, in the aggregate, approximately 12 % of the net sales, if any, of the Surgical Vessel Closing Pressure Device, commencing upon the first commercial sale through December 31, 2035. As a result, even if the Surgical Vessel Closing Pressure Device is successfully developed and marketed, our revenues from this device will be reduced by the amount of these royalties. ~~28We~~ **We** depend on our information technology systems for the efficient functioning of our business, as well as for accounting, financial reporting, 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, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud- based data management applications hosted by third- party service providers whose security and information technology systems are subject to similar risks. 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 our customers, or could disrupt our customers' ability **to** use our 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. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount, subject to deductibles, and we cannot be certain that such potential losses will not exceed our policy limits. 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. **The rate of technological innovation of our products might not keep pace with the rest of the market. The rate of innovation for the market in which our products compete is fast- paced and requires significant resources and innovation. If other products and technologies are developed that compete with, or may compete with, our products, it could be difficult for us to maintain our current competitive status. Likewise, the innovation and development cycle of competitors may impact our research and development efforts and ultimately, commercial adoption of viable research and development efforts. In addition, if we are not able to continue to commit sufficient resources to ensure that our products are compatible with other products within the electrophysiology lab, this could have a negative impact on our revenues.** From time to time we are involved in and 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 actions, 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 have previously been a party to securities class action and shareholder derivative litigation and other litigation. 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 our customers' confidence and reduce long- term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations. We must indemnify or advance reasonable legal expenses for officers and directors, including, in certain circumstances, former employees and directors, in their defense against legal proceedings, unless certain conditions apply. A prolonged uninsured expense and indemnification obligation could have a material adverse effect on our business, financial condition, and results of operations. We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business, or that may be of a strategic nature with a focus on a new direction. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution. **In addition** ~~29Our current Interim Chief Financial Officer~~ , **development of acquired products** ~~Margrit Thomassen, is currently only working for us on an~~ **and technologies may require significant investments of cash and management** ~~interim basis. As a result, we will need to hire a new, full-~~ time ~~Chief Financial Officer soon~~ **, which could materially adversely affect the development of our existing products and technology** . We do not maintain " key man " insurance policies on the lives of any of our employees, including our Executive Chairman and Chief Executive Officer, David A. Jenkins. Mr. Jenkins is critical to our current business development, and we would not be able to easily replace him. Our success also depends on our ability to retain our other current key employees and continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations. We face intense competition for executive- level talent from a variety of sources, including from current and potential competitors in the medical device and healthcare industries, and there is no guarantee that we can locate suitable replacements when they are needed **. Our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs** . Political, economic, and regulatory influences continue to change the healthcare industry in the United States. The ability of hospitals to pay fees for our products will partially depend on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from private health coverage insurers and other similar organizations. We may have difficulty gaining market acceptance for the products we sell if third- party payers do not provide adequate coverage and reimbursement to hospitals and / or other relevant healthcare providers. Major third- party payers of hospitals, such as private healthcare insurers, periodically revise their payment methodologies based, in part, upon changes in government sponsored healthcare programs. We cannot predict these periodic revisions with certainty, and such revisions may result in stricter standards for reimbursement of hospital charges for certain specified products, potentially adversely impacting our business, results of operations, and financial condition when we start receiving reimbursement from third party payers. The sales of our products and services will depend in part on the availability of reimbursement by third- party payers, such as government health administration authorities, private health insurers and other organizations. Third- party payers often challenge the price and cost- effectiveness of medical treatments and services. Governmental approval of health care products does not guarantee that these third- party payers will pay for the products. Even if third- party payers do accept our products and services, the amounts they pay may not be adequate to enable us to ~~realize~~ **make** a profit. Legislation and regulations affecting the pricing of therapies may change before our products and services are approved for marketing, and any such changes could further limit reimbursement, if any. The healthcare industry is highly

competitive. There are numerous approved products for treating the indications for which we have received clearance or approval and those that we may pursue in the future. Many of these cleared or approved products are well- established and are widely accepted by physicians, patients and third- party payors. Insurers and other third- party payors may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future. Our primary competitors in the cardiac electrophysiology, or EP, space include known medical devices such as pacemakers, electrocardiogram, or ECG ~~,~~ systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x- ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense- Webster (J & J) and Boston Scientific Corp. ~~30Many~~ -- **Many** of our competitors have substantially greater financial, manufacturing, commercial, and technical resources than we do. There has been consolidation in the industry, and we expect that to continue. Larger competitors may have substantially larger sales and marketing operations than we do. This may allow those competitors to spend more time with current and potential customers and to focus on a larger number of current and potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. In addition, we are often selling to customers who already utilize our competitors' products and who have established relationships with our competitors' sales representatives and familiarity with our competitors' products. Larger competitors may also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and non- U. S. regulatory clearances or approvals and marketing cleared or approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. This may render our technology or products obsolete or noncompetitive. Our competitors may also be better equipped than we are to respond to competitive pressures. If we are unable to compete successfully in our industry, it would have a material adverse effect on our business, financial condition, and results of operations. We have historically obtained certain components globally, some of which were uniquely customized, from limited sources. This subjected us to significant supply and pricing risks and exposed us to multiple potential sources of component shortages. Many components, including those that are available from multiple sources, are at times subject to industry- wide shortages and significant commodity pricing fluctuations that could materially adversely affect our financial condition and operating results. We may source alternative parts to mitigate the challenges caused by these shortages, but there is no guarantee we may be able to continually do so as we scale production to meet our growth targets. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products, as well as ~~impact~~ **impacting** our **production** capacity ~~production~~ . Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. If our supply of components for a new or existing product continues to be delayed or constrained for any reason, including if an outsourcing partner delayed shipments of completed products to us or additional time is required to obtain sufficient quantities from the original source, or if we have to identify and obtain sufficient quantities from an alternative source, then our financial condition and operating results could be materially adversely affected. In addition, the continued availability of these components at acceptable prices, or at all, can be affected for any number of reasons, including if suppliers decide to concentrate on the production of common components or components for other customers instead of components customized to meet our requirements. While we have entered into agreements for the supply of certain components, there can be no assurance that we will be able to extend or renew these agreements on similar terms, or at all. Some of our components are purchased off the shelf and therefore we have no contractual certainties regarding their availability or pricing. Component suppliers may suffer from poor financial conditions, which can lead to business failure for the supplier or consolidation within a particular industry, further limiting our ability to obtain sufficient quantities of components on commercially reasonable terms. While we believe that we will be able to secure components as needed, and where necessary locate additional or alternate sources or develop our own replacements for relevant components, there is no assurance that we will be able to do so quickly or at all. Additionally, we may be unable to obtain components on attractive terms and where applicable to achieve through negotiations with relevant suppliers cost reductions and / or avoid unfavorable changes to terms, source less expensive suppliers for certain parts and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results. ~~31Even~~ -- **Even** when any of our product candidates obtain regulatory approval, they may not gain market acceptance among hospitals, physicians, patients, and third- party payers. Physicians may decide not to use our products for a variety of reasons including: ~~-~~ ● timing of market introduction of competitive products; ~~-~~ ● demonstration of clinical safety and efficacy compared to other products; ~~-~~ ● cost- effectiveness; ~~-~~ ● limited or no coverage by third- party payers; ~~-~~ ● convenience and ease of administration; ~~-~~ ● prevalence and severity of adverse side effects; ~~-~~ ● restrictions in the label of the device; ~~-~~ ● other potential advantages of alternative treatment methods; and ~~-~~ ● ineffective marketing and distribution support of our products. If any of our product candidates are approved but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer. The recent coronavirus, or COVID- 19, outbreak adversely affected our financial condition and results of operations **,** and we cannot provide any certainty as to whether there will be future impacts from COVID- 19 or another pandemic. The COVID- 19 outbreak adversely affected our financial condition and results of operations. The impact of the outbreak of COVID- 19 on the businesses and the economy in the United States and the rest of the world was significant. The extent to which the COVID- 19 outbreak will continue to impact business and the economy is highly uncertain and cannot be predicted, and there can be no guarantee that a future pandemic will not have similar or worse impacts. Accordingly, we cannot predict the extent to which our financial condition and results of operation will be affected. In addition to selling our products in the U. S., we sell products outside of the U. S. We are subject to additional risks related to

operating in foreign countries, including: ~~-~~ ● differing regulatory requirements in foreign countries; ~~-~~ ● differing reimbursement regimes in foreign countries, including price controls and lower payment; ~~-~~ ● unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; ~~-~~ ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ~~-~~ ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ~~-~~ ● foreign taxes, including withholding of payroll taxes; ~~-~~ ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; ~~-~~ ● difficulties staffing and managing foreign operations; ● ~~32 -~~ workforce uncertainty in countries where labor unrest is more common than in the U. S.; ~~-~~ ● potential liability under the FCPA or comparable foreign regulations; ~~-~~ ● challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U. S.; ~~-~~ ● product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad; ~~-~~ ● the impact of the current situation relating to trade with China and tariffs and other trade barriers that may be implemented by governmental authorities **with respect to China and other countries** ; ~~-~~ ● the impact of public health epidemics on the global economy; and ~~-~~ ● business interruptions resulting from geo- political actions, including war and terrorism. These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition, and results of operations. The impact of the ongoing Russia- Ukraine and Israel- Gaza military conflicts, and other actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have affected, and may continue to affect, our business and results of operations, including our supply chain. On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region has occurred. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the U. S. and other countries and companies and organizations against officials, individuals, regions and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country' s potential response to such sanctions, tensions and military actions could have a material adverse effect on our operations. Any such material adverse effect from the conflict and enhanced sanctions activity may disrupt our supply chains and affect the delivery of our products and services or impair our ability to complete financial or banking transactions. We may suffer similar adverse effects from the Israel- Gaza conflict which has been ongoing since October 2023. We also cannot predict the impact of any heightened geopolitical instability or the results that may follow, including reductions in consumer confidence, heightened inflation, cyber disruptions or attacks, higher natural gas costs, higher manufacturing costs and higher supply chain costs. The impact of armed conflicts such as those described above could cause our results to differ materially from the outlook presented in this Annual Report. We may use independent clinical investigators and other third- party service providers to conduct and / or oversee the clinical trials of our product candidates. FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our product candidates or result in enforcement actions against us. ~~33We~~ **We** are exposed to potential product liability risks inherent in the design, manufacturing, and marketing of our products. These matters are subject to many uncertainties, and outcomes are not predictable. In addition, we may incur significant legal expenses regardless of whether we are found to be liable. While we maintain product liability insurance, there can be no assurance that such coverage is sufficient to cover all product liabilities that we may incur. We are not currently subject to any product liability proceedings, and we have no reserves for product liability disbursements. However, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage and delivery of our products. Should we incur product- related liabilities exceeding our insurance coverage, we would be required to use available cash or raise additional cash to cover such liabilities. **Our ability to use our net operating loss carryforwards may be limited.** As of December 31, ~~2023~~ **2024** , we had net operating loss carryforwards, or NOLs, available of approximately $ 147 million for federal income tax purposes and $ 111. 7 million for state income tax purposes. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or IRC, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership by 5 % stockholders over a three- year period, the corporation' s ability to use its pre- change NOLs and other pre- change tax attributes to offset its post- change income may be limited. We completed an IRC Section 382 analysis regarding the limitation of net operating losses through December 31, ~~2020~~ **2024 ,** and determined that ownership changes occurred in ~~May 2020. Management believes further ownership changes occurred~~ during ~~each of the years ended December 31,~~ 2023 ~~,~~ **and** ~~2022~~ **2024** ~~and 2021~~ . Accordingly, utilization of our NOLs is subject to an annual limitation for federal tax purposes under IRC Section 382. Due to the changes in control, we estimated that $ ~~51~~ **46** . ~~9~~ **2** million of the $ ~~147~~ **104. 3** million federal NOLs are effectively eliminated, according to IRC Section 382. In addition, $ ~~40~~ **61. 2 million of our $ 63** . 8 ~~million of our $ 111. 7~~ million in state NOLs were also eliminated. As a result of these eliminations, our **ability to utilize the** federal and state NOLs were reduced to $ ~~95~~ **58** . ~~1~~ **2** million and $ ~~70~~ **2** . ~~9~~ **6** million, respectively ~~, before taking into consideration the valuation allowance~~ . ~~We may have to make milestone payments under the Settlement Agreement we entered into with the DOJ. We have entered into a Settlement Agreement with the Department of Justice, or DOJ, and agreements with the participating states, resolving a DOJ civil investigation concerning certain Covered Conduct (as defined in the Settlement Agreement), and the~~

~~Office of Inspector General, or OIG, has agreed, in consideration of our full payment of amounts owed in the Settlement Agreement and our obligations under a Corporate Integrity Agreement, to release our permissive exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of specified covered conduct. The Corporate Integrity Agreement has a five- year term expiring in December 2025 and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization; however, the OIG has agreed that we are not subject to the terms of the Corporate Integrity Agreement for so long as we do not carry on the legacy Ra Medical business or use the related business assets. Pursuant to our Settlement Agreement with the DOJ, if during fiscal 2024 our revenues exceed $ 10 million, we have agreed to pay the United States and certain Medicaid participating states, $ 1. 25 million. Payment must be made within 90 days after the end of the fiscal year. 34Risks~~ -- **Risks** Related to Governmental Regulation and our Industry We are subject to pervasive and continuing regulation by the FDA and other regulatory agencies. Our medical device 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 applicable cGMPs under the Quality System Regulations, or QSR; ~~-~~ ● filing reports with the FDA ~~of~~ 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; ~~-~~ ● reporting recalls and 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, " Class II medical devices are also subject to " special controls, " including, in many cases, adherence to a particular guidance document and compliance with the performance standard. As a Class II, 510 (k)- cleared device, our VIVO product is subject to both general and special controls. Instead of obtaining 510 (k) clearance, most Class III devices are subject to premarket approval, or PMA. We do not believe any of our current products are Class III devices, but future products could be, which would subject them to the PMA process. Many medical devices are also regulated by the FDA as " electronic products. " In general, manufacturers and marketers of " electronic products " are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects / safety issues related to the products as well as complying with radiological performance standards. In addition, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting, or MDR, requirements, including the reporting of adverse events and malfunctions related to our products. We are required to file MDRs if our products 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 future sales. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which may have a material adverse effect on our business, financial condition, and results of operations. 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 marketing, business practices, and product quality management. For example, ~~as discussed above,~~ on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and related civil action, and in connection with the Settlement Agreement, we also have reached agreements that resolve previously disclosed related investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the agreements with the participating states, we were required to make an initial payment of $ 2. 5 million, of which we paid $ 2. 4 million in December 2020 and $ 0. 1 million in April 2021. We also were required to make a payment of $ 5. 0 million as a result of the January 2023 merger with Old Catheter in January 2023, which we made in February 2023. ~~We may be required to make additional payments in the future upon the achievement of revenue targets. 35Additionally~~ -- **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, the U. S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or 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. On December 28, 2020, we entered into the Settlement Agreement with the DOJ relating to claims under the civil False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices, which we are no longer marketing, for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute. Effective January 2022, we are also required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse- midwives. 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 for years after any resolution of these investigations and any resulting claims are resolved. Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510 (k) clearance, is authorized through the de novo classification process,

or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510 (k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510 (k) clearance must be supported by preclinical and clinical data. Our ability to enroll patients in clinical trials could be impacted by a resurgence of the COVID- 19 outbreak or another pandemic, as many patients would be likely to elect or would likely be asked to delay procedures at such a time. The PMA process typically is more costly, lengthy and stringent than the 510 (k) process. Unlike a 510 (k) review which determines " substantial equivalence, " a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U. S. and similar agencies in other countries. We may be required to obtain PMAs, PMA supplements or additional 510 (k) premarket clearances to market modifications to our existing products, and our current business strategy contemplates expanding uses of our products to include uses that will require additional clearances. The FDA requires device manufacturers to make and document a determination of whether a device modification requires approval or clearance; however, the FDA can review a manufacturer' s decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or premarket clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties. The FDA may not approve future PMA applications or supplements or clear our 510 (k) applications on a timely basis or at all. For example, the a new pandemic outbreak could affect the FDA' s ability to review applications or supplements. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations. International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non- U. S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non- U. S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations. ~~36Although --~~ **Although** we have obtained regulatory clearance for our VIVO and LockeT products in the U. S. and certain non- U. S. jurisdictions, our business plans include expanding uses for our products, which will require additional clearances; and even after clearance is obtained, our products will remain subject to extensive regulatory scrutiny. Although our VIVO and LockeT products have received regulatory clearance in the U. S. and certain non- U. S. jurisdictions, they are subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, effectiveness, and other post- market information, including both federal and state requirements in the U. S. and requirements of comparable non- U. S. regulatory authorities. In addition, our business plans include expanding uses for our products, which will require additional clearances. Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval or contain requirements for potentially costly post- marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to ~~assure~~ **ensure** compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post- clearance or post- approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. However, physicians can use their independent and professional judgment and use our products for off- label purposes, as FDA regulations do not restrict a physician' s choice of treatment with the practice of medicine. Prior to making certain changes to a cleared product, including certain changes to product labeling, the holder of a cleared 510 (k) application may be required to submit a new premarket application and obtain clearance or approval. If a regulatory agency discovers previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of our products, such regulatory ~~agency~~ **agencies** or enforcement authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. In addition to this type of penalty for failing to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: ~~-~~ ● subject us to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence; ~~-~~ ● issue warning or untitled letters that would result in adverse publicity or may require corrective advertising; ~~-~~ ● impose civil or criminal penalties; ~~-~~ ● suspend or withdraw regulatory clearances or approvals; ~~-~~ ● refuse to clear or approve pending applications or supplements to approved applications submitted by us; ~~-~~ ● impose restrictions on our operations, including closing our sub- assembly suppliers' facilities; ~~-~~ ● seize or

detain products; or -- ● require a product recall. In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. As disclosed previously, we settled a DOJ civil False Claims Act investigation concerning, among other things, whether we marketed and promoted our DABRA devices for unapproved uses that were not covered by federal healthcare programs. We are no longer marketing DABRA devices. ~~37Any --~~ **Any** government adverse finding, regulatory sanction or investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition, and results of operations. The FDA and similar foreign governmental authorities have the authority to order the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us 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. For example, prior to our acquisition of Old Catheter and switch in focus to developing and marketing its products, we conducted four recalls related to our previously marketed DABRA product. We no longer market DABRA, but any government- mandated recall or additional voluntary recall by us of VIVO, LockeT or another product we market in the future could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. These voluntary recalls and any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business. In addition, the FDA conducted an unannounced facility inspection in December 2019 in connection with our previously marketed DABRA product. The FDA issued ~~to~~ us a Form 483 that included observations ~~,~~ related to our previously marketed DABRA product, that schedules for the adjustment, cleaning, and other maintenance of equipment ~~have~~ **had** not been adequately established, a device master record index was not current, and document control procedures ~~have~~ **had** not been fully established. We responded to the FDA with the corrective measures we ~~are~~ **were** taking and to address the issues identified in the Form 483 and based on this information, the FDA issued to us an Establishment Inspection Report, or EIR, closing out the inspection. All actions were completed, and the final Form 483 report was sent to the FDA on September 25, 2020. We are no longer operating this facility, but the FDA could conduct inspections of our current facilities. Depending on the corrective action we take to address a product' s deficiencies or defects, the FDA may require, or we may voluntarily decide, that we will need to seek and obtain new approvals or clearances for a device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including adverse inspection findings, FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future. In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection related to our previously marketed DABRA product, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to our previously marketed DABRA product that we received rose to a level required to be reported to the FDA. At that time, in response, we informed the FDA that we had modified our complaint review procedures and we completed a retrospective evaluation and did not find any complaints which required a submission to the FDA. We have not requested, and the FDA has not issued, an EIR related to this inspection. We no longer market DABRA. ~~38The --~~ **The** failure by us to properly identify reportable events or to file timely reports with the FDA can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations. We and our suppliers are required to comply with the FDA' s QSR, which delineates, among other things, the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. We anticipate that we and certain of our third- party ~~component~~ suppliers will be subject to future inspections. If our facility or manufacturing processes or our suppliers' facilities or manufacturing processes are found to be in non- compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, the FDA could take legal or regulatory enforcement actions against us and / or our products, including but not limited to the cessation of sales or the initiation of a recall of distributed products, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and / or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third- party

regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA' s and other comparable non- U. S. regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post- approval regulatory requirements, or delay, suspend, or prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U. S. or abroad. The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and / or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management' s attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product. Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without new marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, are required to be supported by further clinical studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable. ~~39Under~~ -- **Under** the FDA medical device reporting regulations, or 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 against us. Any such adverse event involving our 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, will 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. There have been and continue to be proposals by the federal government, state governments, regulators and third- party payors to control or manage the increasing 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 on the market. 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 U. S., in March 2010, the Patient Protection and Affordable Care Act, or PPACA, was passed. The PPACA was intended to make significant changes to the way healthcare is financed by both federal and state governments and private insurers, with direct impacts to the medical device industry. Among other provisions, the PPACA imposed, with limited exceptions, a deductible excise tax of 2. 3 % on sales of medical devices by entities that manufacture or import certain medical devices offered for sale in the U. S. The Consolidated Appropriations Act, 2016 (Pub. L. 114- 113), signed into law in December 2015, included a two- year moratorium on the medical device excise tax. A second two- year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115- 120), extending the moratorium through December 31, 2019. On December 20, 2019, President Trump signed into law a permanent repeal of the medical device tax under the PPACA, but there is no guarantee that Congress or the President will not reverse course in the future. If such an excise tax on sales of any of our products in the U. S. is enacted, it could have a material adverse effect on our business, financial condition, and results of operations. In addition, the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value- based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs. Under the Trump Administration, there were ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so- called " individual mandate "). Such actions or similar actions could have a negative effect on the utilization of our products. On December 18, 2019, the U. S. Court of Appeals for the Fifth Circuit upheld a lower court' s determination in Texas v. Azar, 4: 18- cv- 00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. In June 2021, the U. S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA remains in effect in its current form. Further, legislative and regulatory changes under the PPACA remain possible ~~, although the federal administration under President Biden has signaled that it plans to build on the PPACA and expand the number of people who are eligible for health insurance under it~~ . It is unclear how future litigation and healthcare measures promulgated by the ~~Biden~~ **Trump** administration or future administrations will impact the implementation of the PPACA and our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-

~~intensive~~ **consuming** and expensive, resulting in a material adverse effect on our business. ~~40Other~~ -- **Other** healthcare reform legislative changes have also been proposed and adopted in the U. S. since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2 % per fiscal year. These reductions went into effect in April 2013, which, due to subsequent legislative amendments, will stay in effect through 2031, with the exception of a temporary suspension implemented under various COVID- 19 relief legislation from May 1, 2020 **,** through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of the sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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. As a result of reform of the U. S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for procedures using our products and cause our revenue to decline. Additionally, individual states in the U. S. have also become increasingly active in passing legislation and implementing 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, Medicare, 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, attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. 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. Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third- party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business. The ability of our customers to obtain reimbursement for procedures that are performed using our products from government and private third- party payors is critical to our success. The availability of coverage and reimbursement for procedures performed using our products affects which products customers purchase and the prices they are able to pay to us. Reimbursement can vary based on geographical location, type of provider / customer, and third- party payor and can significantly influence the acceptance of new products and services. Third- party payors may view some procedures performed using our products as experimental and may not provide coverage. Third- party payors may not cover and reimburse our customers for certain procedures performed using our products in whole or in part in the future, or payment rates may decline and not be adequate, or both. Further, coverage and reimbursement by third- party payors to our customers is also related to billing codes to describe procedures performed using our products. Hospitals and physicians use several billing codes to bill for such procedures. Obtaining Category I CPT codes for VIVO will be important to our future success. However, even if these codes are obtained, third- party payors may not recognize CPT codes available for use by our customers. Further, CPT codes may change over time, undermining our customer' s ability to continue to use those codes, and reimbursement may be interrupted. Furthermore, some payors may not accept these new or revised codes for payment. ~~41Reimbursement~~ -- **Reimbursement** rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, financial condition, and results of operations, and reimbursement may not be adequate for all customers. From time to time, typically on an annual basis, payment amounts are updated and revised by third- party payors. To be successful, our business model requires it to be possible for the cost of our products to generally be recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed. For that reason, even after we achieve CPT codes for our products, these annual updates, especially lower payments, could continue to directly impact the demand for our products. For example, in July 2013, the Centers for Medicare and Medicaid Services, or CMS, proposed reimbursement changes that would have decreased reimbursement for procedures in an outpatient- based facility, such as a catheterization lab. Although CMS chose not to implement those changes in 2013, we cannot assure you that CMS will not take similar actions in the future. After we develop new products or seek to market our products for new approved or cleared indications, there tends to be limited demand for the product unless government and private third- party payors provide adequate coverage and reimbursement to our customers. However, obtaining codes and reimbursement for new products requires an extended, multi- year effort. Even after reimbursement approval and coverage by government and private payors is obtained, providers submitting reimbursement claims for new products or existing products with new approved or cleared indications may face delay in payment if there is confusion by providers or payors regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products. Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U. S., there have been, and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the PPACA, some of which could significantly affect our business. It is uncertain what impact the current U. S. presidential administration or future administrations will have on healthcare spending. If enacted and implemented, any measures to restrict healthcare spending could result in decreased revenue from the sale of our products and decreased potential

returns from our research and development initiatives. Other legislative or administrative reforms to the U. S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations. We are regulated by federal Anti- Kickback Statutes. The Federal Anti- Kickback Statute is a provision of the Social Security Act of 1972 that prohibits as a felony offense the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (1) the referral of a patient for items or services for which payment may be made in whole or part under Medicare, Medicaid, or other federal healthcare programs, (2) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid, or other federal healthcare programs or (3) the purchase, lease, or order or arranging or recommending the purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Patient Protection and Affordable Care Act, or PPACA, amended section 1128B of the Social Security Act to make it clear that a person need not have actual knowledge of the statute, or specific intent to violate the statute, as a predicate for a violation. The OIG, which has the authority to impose administrative sanctions for violation of the statute, has adopted as its standard for review a judicial interpretation which concludes that the statute prohibits any arrangement where even one purpose of the remuneration is to induce or reward referrals. A violation of the Anti- Kickback Statute is a felony punishable by imprisonment, criminal fines of up to $ 25, 000, civil fines of up to $ 50, 000 per violation, and three times the amount of the unlawful remuneration. A violation also can result in exclusion from Medicare, Medicaid or other federal healthcare programs. In addition, pursuant to the changes to the PPACA, a claim that includes items or services resulting from a violation of the Anti- Kickback Statute is a false claim for purposes of the False Claims Act. We cannot assure that the applicable regulatory authorities will not determine that some of our arrangements with hospitals or physicians violate the federal Anti- Kickback Statute or other applicable laws. An adverse determination could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations. ~~42We~~ **We** are regulated by the federal Stark Law. The federal Stark Law, 42 U. S. C. 1395nn, also known as the physician self-referral law, generally prohibits a physician from referring Medicare and Medicaid patients to an entity (including hospitals) providing ‘ designated health services,’ if the physician or a member of the physician’ s immediate family has a ‘ financial relationship’ with the entity, unless a specific exception applies. Designated health services include, among other services, inpatient hospital services, outpatient prescription drug services, clinical laboratory services, certain imaging services (e. g., MRI, CT, ultrasound), and other services that our affiliated hospitals may order for their patients. The prohibition applies regardless of the reasons for the financial relationship and the referral. Like the Anti- Kickback Statute, the Stark Law contains statutory and regulatory exceptions intended to protect certain types of transactions and arrangements. Unlike safe harbors under the Anti- Kickback Statute with which compliance is voluntary, an arrangement must comply with every requirement of a Stark Law exception or the arrangement is in violation of the Stark Law. Because the Stark Law and implementing regulations continue to evolve and are detailed and complex, while we attempt to structure our relationships to meet an exception to the Stark Law, there can be no assurance that the arrangements entered into by us with affiliated hospitals will be found to be in compliance with the Stark Law, as it ultimately may be implemented or interpreted. The penalties for violating the Stark Law can include the denial of payment for services ordered in violation of the statute, mandatory refunds of any sums paid for such services, and civil penalties of up to $ 15, 000 for each violation, double damages, and possible exclusion from future participation in the governmental healthcare programs. A person who engages in a scheme to circumvent the Stark Law’ s prohibitions may be fined up to $ 100, 000 for each applicable arrangement or scheme. Some states have enacted statutes and regulations against self- referral arrangements similar to the federal Stark Law, but which may be applicable to the referral of patients regardless of their payer source and which may apply to different types of services. These state laws may contain statutory and regulatory exceptions that are different from those of the federal law and that may vary from state to state. An adverse determination under these state laws and / or the federal Stark Law could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations. We must comply with Health Information Privacy and Security Standards. HIPAA and regulations thereunder contain detailed requirements concerning the use and disclosure of individually identifiable patient health information by various healthcare providers, such as medical groups. HIPAA covered entities must implement certain administrative, physical, and technical security standards to protect the integrity, confidentiality and availability of certain electronic health information received, maintained, or transmitted. HIPAA also implemented standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including billing and claim collection activities. Violations of the HIPAA privacy and security rules may result in civil and criminal penalties, including a tiered system of civil money penalties that range from $ 100 to $ 50, 000 per violation, with a cap of $ 1. 5 million per year for identical violations. A HIPAA covered entity must also promptly notify affected individuals where a breach affects more than 500 individuals and report breaches affecting fewer than 500 individuals annually. State attorneys general may bring civil actions on behalf of state residents for violations of the HIPAA privacy and security rules, obtain damages on behalf of state residents, and enjoin further violations. Many states also have laws that protect the privacy and security of confidential, personal information, which may be similar to or even more stringent than HIPAA. Some of these state laws may impose fines and penalties on violators and may afford private rights of action to individuals who believe their personal information has been misused. We expect increased federal and state privacy and security enforcement efforts. ~~43If~~ **If** a breach of our measures protecting personal data covered by HIPAA, as amended by the HITECH Act, occurs, we may incur significant liabilities. HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health

information. The requirements and restrictions apply to " covered entities " (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA' s requirements and restrictions with respect to handling such protected health information and have executed business associate agreements with certain customers. It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government- imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state and may vary based on whether testing is performed in the U. S. or in the local country. Complying with these various 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. Further, compliance with data protection laws and regulations 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. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and / or criminal penalties, as well as private litigation and / or adverse publicity that could negatively affect our operating results and business. A cyber security incident could cause a violation of HIPAA and / or state consumer privacy laws, breach of customer and patient privacy, or other negative impacts. We rely extensively on our information technology (or IT) systems to manage scheduling and financial data, communicate with hospitals and their patients, vendors, and other third parties, and summarize and analyze operating results. In addition, we have made significant investments in technology, including the engagement of a third- party IT provider. A cyber- attack that bypasses our IT security systems could cause an IT security breach, a loss of protected health information, or other data subject to privacy laws, a loss of proprietary business information, or a material disruption of our IT business systems. This in turn could have a material adverse impact on our business and result of operations. In addition, our future results of operations, as well as our reputation, could be adversely impacted by theft, destruction, loss, or misappropriation of public health information, other confidential data, or proprietary business information. Computer malware, viruses, and hacking and phishing attacks by third parties have become more prevalent in our industry and may occur on our systems in the future. Because techniques used to obtain unauthorized access to or sabotage systems change frequently and generally are not recognized until successfully launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. As cyber- security threats develop and grow, it may be necessary to make significant further investments to protect data and infrastructure. If an actual or perceived breach of our security occurs, (i) we could suffer severe reputational damage adversely affecting customer or investor confidence, (ii) the market perception of the effectiveness of our security measures could be harmed, (iii) we could lose potential sales and existing customers, our ability to deliver our services or operate our business may be impaired, (iv) we may be subject to litigation or regulatory investigations or orders, and (v) we may incur significant liabilities. Our insurance coverage may not be adequate to cover the potentially significant losses that may result from security breaches. ~~44We~~ **We** must comply with environmental and Occupational Safety and Health Administration Regulations. We are subject to federal, state and local regulations governing the storage, use and disposal of waste materials and products. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations. Although we believe that our safety procedures for storing, handling and disposing of these materials and products comply with the standards prescribed by law and regulation, we cannot eliminate the risk of accidental contamination or injury from those hazardous materials. In the event of an accident, we could be held liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance coverage, which we may not be able to maintain on acceptable terms, or at all. We could incur significant costs and attention of our management could be diverted to comply with current or future environmental laws and regulations. Federal regulations promulgated by the Occupational Safety and Health Administration impose additional requirements on us, including those protecting employees from exposure to elements such as blood- borne pathogens. We cannot predict the frequency of compliance, monitoring, or enforcement actions to which we may be subject as those regulations are being implemented, which could adversely affect our operations. We must comply with a range of other Federal and State Healthcare Laws. We are also subject to other federal and state healthcare laws that could have a material adverse effect on our business, financial condition or results of operations. The Health Care Fraud Statute prohibits any person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, which can be either a government or private payer plan. Violation of this statute, even in the absence of actual knowledge of or specific intent to violate the statute, may be charged as a felony offense and may result in fines, imprisonment, or both. The Health Care False Statement Statute prohibits, in any matter involving a federal health care program, anyone from knowingly and willfully falsifying, concealing or covering up, by any trick, scheme or device, a material fact, or making any materially false, fictitious or fraudulent statement or representation, or making or using any materially false writing or document knowing that it contains a materially false or fraudulent statement. A violation of this statute may be charged as a felony offense

and may result in fines, imprisonment or both. Under the Civil Monetary Penalties Law of the Social Security Act, a person (including an organization) is prohibited from knowingly presenting or causing to be presented to any United States officer, employee, agent, or department, or any state agency, a claim for payment for medical or other items or services where the person knows or should know (a) the items or services were not provided as described in the coding of the claim, (b) the claim is a false or fraudulent claim, (c) the claim is for a service furnished by an unlicensed physician, (d) the claim is for medical or other items or service furnished by a person or an entity that is in a period of exclusion from the program, or (e) the items or services are medically unnecessary items or services. Violations of the law may result in penalties of up to $ 10, 000 per claim, treble damages, and exclusion from federal healthcare programs. In addition, the OIG may impose civil monetary penalties against any physician who knowingly accepts payment from a hospital (as well as against the hospital making the payment) as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid program beneficiaries. Further, except as permitted under the Civil Monetary Penalties Law, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary' s selection of a particular provider of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to $ 10, 000 for each wrongful act. In addition to the state laws previously described, we may also be subject to other state fraud and abuse statutes and regulations if we expand our operations nationally. Many states have adopted a form of anti- kickback law, self- referral prohibition, and false claims and insurance fraud prohibition. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Generally, state laws reach to all healthcare services and not just those covered under a governmental healthcare program. A determination of liability under any of these laws could result in fines and penalties and restrictions on our ability to operate in these states. We cannot assure you that our arrangements or business practices will not be subject to government scrutiny or be found to violate applicable fraud and abuse laws. ~~45Governmental~~ -- **Governmental** export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our products may be subject to U. S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products 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, we may be fined or other penalties could be imposed, including a 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 technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations. In addition to current and proposed economic sanctions on Russia, which may increase or continue for an indefinite period of time as a result of Russia' s invasion of Ukraine, the U. S. has imposed or proposed new or higher tariffs on certain products exported by a number of U. S. trading partners, including China, Europe, Canada, and Mexico. In response, many of those trading partners, including China, have imposed or proposed new or higher tariffs on American products. Continuing changes in government trade policies create a heightened risk of further increased tariffs that impose barriers to international trade. Tariffs on our customers' products may adversely affect our gross profit margins in the future due to the potential for increased pressure on our selling prices by customers seeking to offset the impact of tariffs on their own products. We believe that increases in tariffs on imported goods or the failure to resolve current international trade disputes could have a material adverse effect on our business and operating results. As with other medical device companies, our ability to maintain and solidify a proprietary position for our products will depend upon our success in obtaining effective patent claims that cover such products, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering VIVO or LockeT, as well as other technologies that are important to our business, which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to VIVO, LockeT or any new devices that we market could have a material adverse effect on our business, financial condition, and results of operations. Changes in either the patent laws or their interpretation in the U. S. 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 issued patents. Additionally, we cannot predict whether the patent applications we 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 or other third parties. ~~46The~~ -- **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 or in a timely manner. 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, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. 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~~ **whether** we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, if any patents are issued in the future, they may not provide us with any competitive advantages ~~,~~ or may be successfully challenged by third parties. Agreement terms that address non- competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing U. S. federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we now, or may in the future, conduct operations or ~~contract~~ **contracts** for services may afford little or no effective protection of our intellectual property. The failure to adequately protect our intellectual property and other proprietary rights could materially ~~harm~~ **damage** our business. The strength of patent rights involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own may fail to result in issued patents in the U. S. or foreign countries with claims that cover our products or services. Even if patents do successfully issue from the patent applications that we own, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our products and services, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products and services is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services. Patents have a limited lifespan. In the U. S., the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced. ~~47In~~ **In** addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know- how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our products and services that involve proprietary know- how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent products. We may not be able to protect our intellectual property and proprietary rights throughout the world. Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations. Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. Consequently, we may not be able to prevent third parties from utilizing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U. S. These products may compete with our products, and our patents 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, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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 at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, 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. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries 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 these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. **Third parties may assert that we are infringing their intellectual property rights, and any defense of such assertions may be unsuccessful and expensive, even if we are successful. Successfully commercializing our products depends in part on not infringing patents held by third parties. It is possible that one or more of our products, including those that we have developed in conjunction with third parties, infringe existing patents. We may also be liable for patent infringement by third parties whose products we use or combine with our own and for which we have no right to indemnification. In addition, because patent applications are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. Determining whether a product infringes a patent involves complex legal and factual issues and may not become clear until finally determined by a court in litigation. Our competitors may assert that our products infringe patents held by them. Moreover, as the number of competitors in our market grows, the possibility of a patent infringement claim against us increases. If we were unsuccessful in obtaining a license or redesigning our products, we could be subject to litigation. If we lose in this kind of litigation, a court could require us to pay substantial damages or prohibit us from using technologies essential to our products covered by third-party patents. An inability to use technologies essential to our products would have a material adverse effect on our financial condition, results of operations and cash flow and could undermine our ability to continue our current business operations. Expensive intellectual property litigation is frequent in the medical device industry and may cause to incur substantial expenses to defend. Infringement actions, validity challenges and other intellectual property claims and proceedings, whether with or without merit, can be expensive and time- consuming and would divert management' s attention from our business. We have incurred, and expect to continue to incur substantial costs in obtaining patents and may have to incur substantial costs defending our proprietary rights. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.** ~~48The~~ -- **The** price of our stock has been and may continue to be volatile, which could result in substantial losses for investors. Further, an active, liquid and orderly trading market for our common stock may not be sustained and we do not know what the market price of our common stock will be, and as a result it may be difficult for you to sell your shares of our common stock. Prior to our listing on the New York Stock Exchange in September 2018, there was no public market for shares of our common stock. Although our common stock is now listed on the NYSE American, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active trading market for our shares may not be sustained in the future. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this Annual Report, these factors include: ~~-~~● our failure to increase the sales of our products; ~~-~~● the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers and pricing of our products to support revenue projections; ~~-~~● unanticipated serious safety concerns related to the use of our products; ~~-~~● changes in our organization; ~~-~~● introduction of new products or services offered by us or our competitors; ~~-~~● announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; ~~-~~● our ability to effectively manage our future growth; ~~-~~● the size and growth of our target markets; ~~-~~● actual or anticipated variations in quarterly operating results; ~~-~~● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ~~-~~● significant lawsuits, including shareholder litigation, government actions or litigation related to intellectual property; ~~-~~● our cash position; ~~-~~● our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; ~~-~~● publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage, by securities analysts; ~~-~~● any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such products; ~~-~~● adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products; ~~-~~● changes in laws or regulations applicable to our products; ~~-~~● adverse developments concerning our suppliers or distributors; ~~-~~● our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices; ~~-~~● our inability to establish and maintain collaborations if needed; ~~-~~● changes in the market valuations of similar companies; ~~-~~● overall performance of the equity markets; ~~-~~● sales of large blocks of our common stock including sales by our executive officers and directors; ~~-~~● trading volume of our common stock; ● ~~49 -~~limited " public float " in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock; ~~-~~● additions or departures of key scientific or management personnel; ~~-~~● changes in accounting practices; ~~-~~● ineffectiveness of our internal controls; ~~-~~● general political and economic conditions; and ~~-~~● other events or factors, many of which are beyond our control. In addition, the stock

market in general, and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies **, including recent fluctuations following proposed and enacted tariffs by the US government** . Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. ~~The ownership of our common stock is highly concentrated, and may become more so in the near future, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the company stock price to decline. David A. Jenkins, our Executive Chairman of the Board, and his affiliates and family members, beneficially own or control, in the aggregate, approximately 16. 9 % of our outstanding shares of common stock. In addition, if the outstanding shares of our Series X convertible preferred stock, or Series X Preferred Stock, qualify to convert into common stock on or after July 9, 2024, which will occur if we satisfy the initial listing standards of the New York American or another securities exchange or are delisted from the NYSE American, it is possible that David A. Jenkins and affiliates and family members will beneficially own more than 50 % of our outstanding common stock. Accordingly, these persons have a substantial influence, and in the future may have de facto control, over the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit the other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise, and may adversely affect the liquidity of our common stock. In addition, it is possible that after July 9, 2024, we will satisfy the controlled company provisions of the NYSE American, in which case the combined company would not be required to satisfy all of the corporate governance requirements of the NYSE American, including without limitation, requirements that a majority of the Board be independent and that the combined company have independent compensation and nominating committees. See " — In the near future, we may be a " controlled company " within the meaning of NYSE American rules and, as a result, we may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements ". In the future, we may be a " controlled company " within the meaning of NYSE American rules and, as a result, we may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements. If the outstanding shares of our Series X Preferred Stock qualify to convert into common stock on or after July 9, 2024, which will occur if we satisfy the initial listing standards of the New York American or another securities exchange or are delisted from the NYSE American, it is possible that David A. Jenkins and affiliates will beneficially own more than 50 % of our outstanding common stock. In that case, the Company will be a " controlled company " as defined in Section 801 of the NYSE American Company Guide. Under the NYSE American rules, a company of which more than 50 % of the voting power is held by an individual, group or another company is a " controlled company " and may elect not to comply with certain NYSE American corporate governance requirements, including: · the requirement that a majority of the Company' s board of directors consists of independent directors ; · the requirement that the Company' s directors must be nominated by a Nominating Committee composed by a majority of independent directors ; and · the requirement that executive compensation must be determined or recommended to the Company' s board of directors for determination, by a Compensation Committee comprised of independent directors or by a majority of the independent directors on the Company' s board. 50Accordingly, if we qualify as a controlled company, we will likely elect to be treated as such and our stockholders will not be afforded the same protections generally as stockholders of other NYSE American- listed companies.** We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors. We are a smaller reporting company, as defined by SEC rules. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced financial statement requirements, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. Future sales and issuances of a substantial number of shares of our common stock or rights to purchase common stock by our stockholders in the public market could result in additional dilution of the percentage ownership of our stockholders and cause our stock price to fall. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of March ~~12~~ **17** , ~~2024~~ **2025** , we had ~~7~~ **9** , ~~573~~ **268** , ~~403~~ **632** outstanding shares of our common stock and outstanding options to purchase up to ~~614~~ **2** , ~~593~~ **222, 434** shares of our common stock **, as well as 2, 157, 000 shares subject to pre- funded warrants, and 15, 960, 613 shares subject to outstanding warrants that are currently out of the money** . At our special meeting of stockholders held on March 21, 2023, our stockholders approved the conversion of 1, 993. 581 shares of our Series X Preferred Stock into 1, 993, 581 shares of our common stock. The remaining 12, 656 ~~. 011~~ shares of Series X Preferred Stock may be convertible into ~~12~~ **1** , ~~656~~ **265** , ~~011~~ **601** shares of our common stock on or after July 9, 2024, in the event that we meet the initial listing standards of the NYSE American or another securities exchange or have been delisted from the NYSE American. **In July** ~~Also at the special meeting, our stockholders authorized the issuance of 497, 908 shares of our common stock and 7, 203 shares of our convertible Series A preferred stock, which are convertible into up to 4, 501, 060 shares of our common stock, as well as the issuance of warrants described below. Since the issuance of the Series A stock on March 21,~~ 2023 ~~, 3, 500 shares have been converted into 2, 187, 104 shares of our common stock. There are 3, 703 shares of our convertible Series A preferred stock currently outstanding, which are convertible into up to 2, 313, 956 shares of our common stock. In connection with our February 2022 equity offering,~~

~~July 2022 warrant repricing and 2020 equity offerings, we issued warrants to investors and our placement agents and, in connection with the sale of the Dermatology Business in 2021, we issued a warrant to the broker. In connection with our January 2023 warrant repricing, we issued a warrant to purchase up to 331, 608 shares of common stock at $ 4. 00 per share. Pursuant to a private placement in January 2023, as approved by the stockholders at our March 21, 2023 special meeting of stockholders, we also issued warrants to purchase up to 9, 998, 186 shares of common stock at a purchase price of $ 3. 00 per share. We had an aggregate of 11, 042, 137 warrants outstanding as of March 12, 2024. During the first quarter of 2020~~ , we adopted the ~~2020~~ **2023** ~~Inducement~~ Equity Incentive Plan, or the ~~2020~~ **2023** Plan ~~, for the purpose of attracting, retaining and incentivizing employees in furtherance of our success~~ . As of ~~December 31~~ **March 6** , ~~2023~~ **2025** , ~~540~~ **796, 615** shares were available for issuance **as new awards** under ~~the 2020 Plan. In July 2023, we adopted the 2023 Equity Incentive Plan, or~~ the 2023 Plan ~~. As of March 12~~ , ~~2024, 146, 545 shares were available for issuance under the 2023 Plan, and~~ options to purchase ~~410~~ **1, 681** , 000 shares were outstanding **, and 66, 667 shares of restricted stock awards had been authorized for future issuance** . The 2023 Equity Incentive Plan provides for quarterly increases in the number of shares authorized for issuance under the Plan based on a percentage of the increase in the number of shares outstanding during the quarter. We assumed options to purchase ~~753~~ **75** , ~~699~~ **367** shares in connection with the merger with Old Catheter, and as of March ~~12~~ **6** , ~~2024~~ **2025** , ~~204~~ **16** , ~~520~~ **427** of these options remained outstanding. **We** ~~In addition, in the first quarter of 2024, we~~ issued ~~employee and director stock~~ **to officers of the Company non- plan** options to purchase **525** ~~an aggregate of 410~~ , 000 shares **, which were outstanding as of March 6, 2025** . If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline. ~~51Further~~ -- **Further** , additional capital may be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our current management and may adversely affect the market price of our common stock. Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: ~~-~~ ● that our board of directors is divided into three classes serving staggered three- year terms, such that not all members of the board is elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors; ~~-~~ ● the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; ~~-~~ ● the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; ~~-~~ ● a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders; ~~-~~ ● a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; ~~-~~ ● the requirement for the affirmative vote of holders of at least 66 2 / 3 % of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our certificate of incorporation relating to the issuance of preferred stock and management of our business or our bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; ~~-~~ ● the ability of our board of directors, by majority vote, to amend our bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our bylaws to facilitate an unsolicited takeover attempt; and ~~-~~ ● advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. ~~52Our~~ -- **Our** certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U. S. are 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 certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or

our 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 certificate of incorporation further provides that the federal district courts of the U. S. are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions. 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 such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations. We are subject to the continued listing requirements of the NYSE American. If we are unable to comply with such requirements, our common stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our common stock and subject us to additional trading restrictions. Shares of our common stock are currently listed on the NYSE American. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity, minimum public float, and a minimum number of public stockholders. In addition to these objective standards, the NYSE American may delist the securities of any issuer if, in its opinion, the issuer' s financial condition and / or operating results appear unsatisfactory; if it appears that the extent of public distribution or the aggregate market value of the security has become so reduced as to make continued listing on the NYSE American inadvisable; if the issuer sells or disposes of principal operating assets or ceases to be an operating company; if an issuer fails to comply with the NYSE American' s listing requirements; if an issuer' s common stock sells at what the NYSE American considers a " low selling price " (generally trading below $ 0. 20 per share for an extended period of time); or if any other event occurs or any condition exists which makes continued listing on the NYSE American, in its opinion, inadvisable. On August 31, 2022, we received a deficiency letter from the NYSE American indicating that we were not in compliance with Section 1003 (f) (v) of the NYSE American Company Guide, because shares of our common stock have been selling for a low price per share for a substantial period time. We have since regained compliance with this Section, but there can be no guarantee that our stock price will not fall below the required levels again. We also received similar letters related to our late Form 10- Q filings during 2023, but we have since filed all late Forms and have remedied those deficiencies. ~~53If~~ **If** the NYSE American delists our shares of common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our common stock would qualify to be quoted on an over- the- counter market. If this were to occur, we could face significant material adverse consequences, including: ~~-~~● a limited availability of market quotations for our securities; ~~-~~● reduced liquidity for our securities; ~~-~~● a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; ~~-~~● a limited amount of news and analyst coverage; ~~-~~● a decreased ability to issue additional securities or obtain additional financing in the future. The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as " covered securities. " Because our shares of common stock are listed on the NYSE American, our shares of common stock qualify as covered securities under such statute. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If we were no longer listed on the NYSE American, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities. We have not paid dividends in the past and have no immediate plans to pay dividends. We plan to reinvest all of our earnings, to the extent we have earnings, in order to market our products and to cover operating costs and to otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.