Risk Factors Comparison 2024-04-01 to 2023-03-28 Form: 10-K

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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 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 ~~•~~ · We ~~may~~ **will** be required to raise additional funds to finance our operations and ~~remain~~ **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 ~~and~~ **,** will incur additional losses, and ~~we~~ 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 marketing agreements, that will reduce our revenues from product sales. ~~•~~ · Royalty agreements with respect to ~~our~~ **LockeT, the** surgical vessel closing pressure device **,** ~~in development~~ 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. ~~· • Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud. •~~ 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 carryforwards 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 ~~• Our medical device operations~~** are subject to pervasive and continuing **regulation by the** FDA **and other** regulatory ~~requirements~~ **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. ~~Risks~~ **24Risks** Related to Ownership of Our Common Stock **Including Volatility** ~~• The price of our stock has been and may continue to be volatile, which could result in substantial losses for investors. Further, an~~ **and** ~~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. • The ownership of our common stock is highly~~ **Highly** ~~concentrated~~ **Concentrated Ownership** ~~, 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.~~ Risks Related to Our Financial Position and Need for Additional Capital **Our** ~~We are no longer pursuing Ra Med' s historical lines of business and have instead determined to move forward with Catheter' s products following our acquisition of Catheter. Catheter' s~~ operations to date have consumed substantial amounts of cash and **our business, including the business of Old** Catheter ~~has~~ **conducted prior to its being acquired by the Company,** sustained negative cash flows from ~~Catheter' s~~ operations for the last several years. ~~The Catheter~~ **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, 2024, we have approximately $ 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 of 2024, and our** business ~~may~~ **is currently not profitable. During the first quarter of 2023 we raised approximately $ 9. 3 million in proceeds from securities transactions, but Merger costs and other negative cash flows have substantially depleted our cash. As a result, we will** require 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** ~~Catheter' s~~ 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 ~~our~~ **LockeT, the** surgical vessel closing pressure device **,** ~~in development~~ will reduce any future revenues from this product. " Our ~~only~~ **business has a history of losses and will incur additional losses, and we may never achieve profitability. Our** current business **primarily** ~~is conducted through Catheter, our wholly owned subsidiary, which currently~~ derives revenues from the View into Ventricular Onset System or VIVO ™ System (" VIVO " or " VIVO System "). ~~In the past, Catheter generated revenue from the sales of the Amigo ® Remote Catheter System (" Amigo "), the business line of which Catheter discontinued in 2017.~~ 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** ~~currently~~ -- **current** ~~in the research and development phase~~ **business strategies include a plan to expand uses** for ~~a generation 2 product~~ **VIVO, which will require additional clearances** . While ~~Catheter does~~ **we do** generate revenue, ~~Catheter is still~~ **we are currently** operating at a loss, and there is no guarantee that ~~Catheter~~ **we** will be able to grow ~~the~~ revenues enough to offset **our** ~~Catheter' s~~ costs ~~to~~ **and** realize profitability. To date, ~~Catheter has~~ **we have** not been profitable, and **our** ~~Catheter' s~~ accumulated deficit was approximately $ ~~116~~ **275** . **7** ~~9 million and $ 110. 5~~ million at December 31, ~~2022~~ **2023** ~~and December 31, 2021, respectively~~ . ~~Catheter' s~~ **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** ~~Catheter' s~~ operations. ~~In~~ **During the first quarter 2023 we raised approximately $ 9. 3 million in proceeds from securities transactions, but Merger costs and other negative cash flows have substantially depleted our cash. However, in** order to **continue the** ~~commercialize~~ **commercialization of our** ~~Catheter' s~~ assets **consistent with our vision** , we will need to conduct substantial additional research, development and clinical trials. ~~Catheter~~ **Our business strategy also includes expanding uses for our products which** will ~~also need~~ **require us** to ~~receive necessary~~ **seek additional** regulatory clearances in the United States **,** and **we also must continue to expand our patents in order to** obtain meaningful patent protection for and establish freedom to commercialize **our** ~~Catheter' s~~ product candidates. We must also complete further clinical trials and seek regulatory approvals for any new product candidates ~~Catheter~~ **we** ~~discovers~~ **discover** , ~~licenses~~ **license** or ~~acquires~~ **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 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, 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, (3) errors with respect to the review of work performed by service providers, (4) errors in connection with accounting for the royalty obligation acquired in the merger with Old Catheter, (5) use of an incorrect discount rate in calculating the fair value of the royalty obligation and (6) timing of revenue recognition. As a result of these material weaknesses, our management has concluded that our disclosure controls were not effective as of March 31, 2023, June 30, 2023, September 30, 2023 and December 31, 2023. 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. 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, we have concluded that our disclosure controls were not effective as of March 31, 2023, June 30, 2023, September 30, 2023 and December 31, 2023 because material weaknesses existed in our internal control over financial reporting. We are 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 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 ~~our~~ **LockeT, the** wound closure ~~product that is under development~~ **device, and the successful build out of our U. S. commercial infrastructure and sales force. During fiscal 2023, 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~~ **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 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. In addition, we must 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** ~~Catheter' s~~ products. We will continue to seek research collaborations, co- development and marketing agreements, and licensing deals for **our** ~~Catheter' s~~ 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 ~~program~~ **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 ~~program~~ **programs** to move ~~it~~ **them** forward effectively, or the ~~program~~ **programs** may not advance as rapidly as ~~it~~ **they** might if we had retained complete control of all research, development, regulatory and commercialization decisions. **We have 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 entered into a Joint 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, 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, ~~2023~~ **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 ~~material~~ **materially** reduce the revenues that we receive from VIVO products that are sold by Stereotaxis, and any similar agreements entered into in the future may have the same impact. **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 ~~, which is under development~~ **(" LockeT ")** . Pursuant to the agreement, **Old** Catheter agreed to pay a royalty fee of 5 % on net sales 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** ~~the Surgical Vessel Closing Pressure Device~~ 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. ~~We~~ **28We** 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 ~~would~~ **could** ~~impact our business operations would~~ 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 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. 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 ~~action~~ **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 ~~as set forth in Legal Proceedings~~ . 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 ~~focused on the combined company and the business that we may acquire~~ . 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. ~~Our~~ **29Our** current **Interim** Chief Financial Officer, ~~Brian Conn~~ **Margrit Thomassen** , is currently only working for us on **an** ~~a part- time~~ interim basis. As a result, we will need to hire a new, full- time Chief Financial Officer soon ~~. In addition, as has been previously disclosed, Will McGuire, our Chief Executive Officer, has been diagnosed with a serious illness not caused by COVID- 19 and has been undergoing treatment for his illness. Discussions are ongoing with Mr. McGuire, but we anticipate that we may also need to seek a replacement Chief Executive Officer in the near future~~ . We do not maintain " key man " insurance policies on the lives of ~~these individuals or the lives of~~ any of our ~~other~~ 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 ~~. 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 an " emerging growth company, " 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 an " emerging growth company " unless at that time we are still a " smaller reporting company. " 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 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies 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. As previously disclosed, in 2019, we identified material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the aggregation of control deficiencies in our control environment, in particular an inappropriate " tone at the top " set by certain members of senior management, a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization. The material weaknesses discussed were remediated as of December 31, 2019. We incurred significant costs to remediate those weaknesses, primarily personnel costs, external consulting and legal fees, system implementation costs, and related indirect costs including the use of facilities and technology. However, completion of remediation does not provide assurance that our controls will operate properly or that our financial statements will be free from error, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. 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, we have acquired Catheter, and 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, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may 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. We face additional challenges to maintain adequate internal controls as we integrate our operations and businesses following our merger with Catheter. 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~~ . 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 ~~conditions~~ **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 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. ~~Many~~ **30Many** 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** ~~Because we~~ have historically obtained certain components globally, some of which ~~are~~ **were** uniquely customized, from limited sources **. This** ~~, we are subject~~ **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 our 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 ~~many~~ **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** ~~most of our~~ components, there is no assurance that we will be able to do so quickly or at all. Additionally, we may be **unable** ~~unsuccessful in our continuous efforts~~ to **obtain components on attractive terms and where applicable to achieve through** ~~negotiate~~ **negotiations** with ~~existing~~ **relevant** suppliers ~~to obtain~~ 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. ~~Even~~ **31Even** 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 ~~recommend~~ **use** our ~~treatments~~ **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 ~~drug~~ **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 ~~, we are uncertain of the full effect the pandemic will have on us for the longer term since the scope and duration of the pandemic is unknown, and evolving factors such as the level and timing of the distribution of efficacious vaccines across the world and the extent of any resurgences of the virus or emergence of new variants of the virus, such as the Delta variant and the Omicron variant, will impact the stability of economic recovery and growth. We may experience long- term disruptions to our operations resulting from changes in government policy or guidance; quarantines of employees, customers and suppliers in areas affected by the pandemic; and closures of businesses or manufacturing facilities critical to its business. A variety of risks associated with marketing our products internationally could materially adversely affect our business. 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; ~~•~~ · the impact of public health epidemics on the global economy ~~, such as the new coronavirus currently impacting the U. S., Europe, China and elsewhere~~ ; 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** ~~action in Ukraine~~ , and ~~the~~ **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 ~~is possible~~ **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 ~~Russia' s invasion of Ukraine~~ **armed conflicts such as those described above** could cause our results to differ materially from the outlook presented in this Annual Report ~~. 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 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 may be adversely affected by product liability claims, unfavorable court decisions or legal settlements. 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, ~~2022~~ **2023** , we had net operating loss carryforwards, or NOLs, **available** of approximately $ **147** ~~54. 5~~ million for federal income tax purposes and $ ~~47~~ **111** . ~~8~~ **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 and determined that ownership changes occurred in May 2020. Management believes further ownership changes occurred during each of the years ended December 31 **, 2023** , 2022 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 ~~all of our~~ $ ~~54~~ **51** . ~~5~~ **9 million of the $ 147** million federal NOLs are effectively eliminated, according to IRC Section 382. In addition, $ 40. 8 million of our $ ~~47~~ **111** . ~~8~~ **7** million in state NOLs were also eliminated. As a result of these eliminations, our federal and state NOLs were reduced to ~~zero and~~ $ ~~6~~ **95. 1 million and $ 70** . 9 million, respectively, before taking into consideration the valuation allowance ~~terms of~~ **.We may have to make milestone payments under** the **Settlement** ~~Corporate Integrity~~ Agreement ~~for so long as~~ we **entered into with** ~~do not carry on~~ the **DOJ** ~~legacy Ra Medical business or use the related business assets~~ .Pursuant to our Settlement Agreement with the DOJ,if during fiscal **2023 or** 2024 our revenues exceed $ 10 million,we have agreed to pay the United States and certain Medicaid participating states,$ 1. **0 million for 2023,and $ 1.** 25 **million for 2024,for each corresponding fiscal year where our revenue exceeds $ 10** million.Payment must be made within 90 days after the end of the fiscal year. **Product clearances** ~~34Risks Related to Governmental Regulation~~ and **approvals can often be denied** ~~our~~ **or significantly delayed** ~~Industry We are subject to pervasive and continuing regulation by the FDA and other regulatory agencies.Our medical device operations are~~ .

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 . We have entered into a Settlement..... business assets post our merger with Catheter . 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 ~~the~~ 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. ~~Additionally~~ **35Additionally** , 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 ~~had~~ **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 . We may have to make milestone..... can often be denied or significantly delayed . 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 ~~COVID- 19~~ **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. ~~Although~~ **36Although** we have obtained regulatory clearance for our VIVO **and LockeT** ~~product~~ **products** in the U. S. and certain non- U. S. jurisdictions, ~~it~~ **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** ~~product~~ **products** ~~has~~ **have** received regulatory clearance in the U. S. and certain non- U. S. jurisdictions, **they are** ~~it will be~~ 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 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 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. ~~Any~~ **37Any** 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 ~~recent~~ 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 not been adequately established, a device master record index was not current, and document control procedures have not been fully established. We responded to the FDA with the corrective measures we are taking and to address the ~~issued~~ **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 ~~are~~ **were** ~~complete~~ **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 ~~the~~ **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 ~~have~~ **did** not ~~found~~ **find** any complaints which ~~require~~ **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. ~~The~~ **38The** 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 ~~. 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~~ . 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, ~~may have~~ **are required** to be supported by further clinical studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable. ~~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. Under~~ **39Under** 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 ~~. Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets~~ . There have been and continue to be proposals by the federal government, state governments, regulators and third- party payors to control or manage the 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 ~~will remain~~ **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 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 and expensive, resulting in a material adverse effect on our business. ~~Other~~ **40Other** 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~~ **third** - party payors may not ~~continue to~~ recognize ~~the~~ CPT codes available for use by our customers. ~~The~~ **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. ~~Reimbursement~~ **41Reimbursement** 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. ~~Because~~ **To be successful, our business model requires it to be possible for** the cost of our products **to** generally ~~is~~ **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, ~~we may find~~ **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~~ **obtaining** codes and reimbursement for new products ~~may require~~ **requires** an extended, multi- year effort. Even ~~with~~ **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 ~~of~~ **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. ~~We~~ **42We** 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. ~~If~~ **43If** a breach of our measures protecting personal data covered by HIPAA, **as amended by** the HITECH Act, ~~or the CCPA~~ occurs, we may incur significant liabilities. HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, ~~impose~~ **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. ~~In addition, California has enacted the CCPA which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt- out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt- in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non- compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply.~~ 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. ~~We 44~~**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~~ 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~~ **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. ~~Governmental~~ **45Governmental** 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. ~~The~~ **46The** 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 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 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 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. ~~In~~ **47In** 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 ~~practicing~~ **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. **48The 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. 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 ~~24~~ **16** . ~~6~~ **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. ~~Accordingly~~ **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 ~~an emerging growth company and~~ a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to ~~emerging growth companies and~~ smaller reporting companies will make our common stock less attractive to investors. We are ~~an emerging growth~~ **a smaller reporting** company, as defined **by SEC rules** ~~in the JOBS Act~~ . For as long as we continue to be ~~an emerging growth~~ **a smaller reporting** company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not ~~emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, or IPO, which would mean that we would lose our emerging growth company status at the beginning of 2024, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of the prior June 30th, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a "~~ smaller reporting ~~company~~ **companies , including reduced financial statement** ~~" which may allow us to take advantage of many of the same exemptions from disclosure~~ requirements **,** ~~including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act~~ 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. ~~Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U. S. generally accepted accounting principles, or GAAP, or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.~~ 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 ~~20~~ **12** , ~~2023~~ **2024** , we had ~~2~~ **7** , ~~492~~ **573** , ~~558~~ **403** outstanding shares of our common stock and outstanding options to purchase up to ~~990~~ **614, 593** shares of our common stock. At our special meeting of stockholders held on March 21, 2023, our stockholders approved the conversion of 1, 993. ~~627~~ **581** shares of our Series X Preferred Stock into 1, 993, ~~627~~ **581** shares of our common stock. The remaining 12, ~~655~~ **656** . ~~965~~ **011** shares of Series X Preferred Stock may be convertible into 12, ~~655~~ **656** , ~~965~~ **011** 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. 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, ~~148~~ **042** , ~~855~~ **137** warrants outstanding as of March ~~23~~ **12** , ~~2023~~ **2024** . ~~We have an effective shelf registration statement and had an ATM offering thereunder until January 18, 2022 and a second effective ATM offering thereunder from September 2, 2022 through October 7, 2022. During the year ended December 31, 2022, we sold 1, 071, 240 shares of common stock under the second ATM offering. No shares were sold under the first ATM offering during 2022. In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 8, 552 shares of our common stock were available for issuance to our employees, directors and consultants as of December 31, 2022. The 2018 Employee Stock Purchase Plan, or ESPP, was paused after the end of the contribution period in May 2022. No shares were available for sale under the ESPP as of December 31, 2022. Both the 2018 Plan and the ESPP include an " evergreen " provision that provides for an annual increase in the number of shares available for future grant or sale each year, as applicable, as determined by our board of directors~~ . During the first quarter of 2020, we adopted the 2020 Inducement Equity Incentive Plan, or the 2020 Plan, for the purpose of attracting, retaining and incentivizing employees in furtherance of our success. As of December 31, ~~2022~~ **2023** , ~~181~~ **540** shares were available for issuance 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, 000 shares were outstanding. 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, ~~694~~ **699** shares in connection with the merger with **Old** Catheter **, and as of March 12, 2024, 204, 520 of these options remained outstanding. In addition, in the first quarter of 2024, we issued employee and director stock options to purchase an aggregate of 410, 000 shares** . 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. ~~Further~~ **51Further** ~~, SEC regulations limit the amount of funds we can raise during any 12- month period pursuant to our shelf registration statement on Form S- 3. We are currently subject to General Instruction I. B. 6 to Form S- 3, or the Baby Shelf Rule, and the amount of funds we can raise through primary public offerings of securities in any 12- month period using our registration statement on Form S- 3 is limited to one- third of the aggregate market value of the voting and non- voting common equity held by non- affiliates. We are currently limited by the Baby Shelf Rule as of the filing of this Annual Report, until such time as our public float exceeds $ 75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by SEC staff. 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 ~~now~~ 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. ~~Our~~ **52Our** 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. ~~is~~ **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 ~~and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder~~. 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. ~~If~~ **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** 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.