

Risk Factors Comparison 2025-03-31 to 2024-03-28 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all other information contained in this Annual Report, including our financial statements and the related notes, before investing in our securities. The risks and uncertainties described below are not the only ones we face but include the most significant factors currently known by us that make investing in our securities speculative or risky. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, also may become important factors that affect us. If any of the following risks materialize, our business, financial condition and results of operations could be materially harmed. In that case, the trading price of our securities could decline, and you may lose some or all of your investment. RISK FACTOR SUMMARY Below is a bulleted summary of our principal risk factors, however this list does not fully represent all of our known risk factors. We encourage you to carefully review the full risk factors contained in this Annual Report in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- Risks Related to our Business**
 - We have a history of operating losses, we may never achieve or maintain profitability, and we will need to raise significant additional capital if we are going to continue as a going concern.
 - We may not be able to successfully execute our business model.** Our efforts may never result in the successful development of commercial applications based on our TAEUS technology, on which our success is substantially dependent.
 - Our TAEUS platform applications may not achieve adequate market acceptance by the physicians, patients, third-party payors and others in the medical community.**
 - The outbreak of pandemics, such as COVID-19, could result in product misuse and potential adverse impact our treatment outcomes, which could harm the Company's reputation, result in product liability litigation, distract management and result in additional costs, all of which could harm the Company's business, including our pre-sales activities, clinical trials and ability to obtain regulatory approvals.**
 - We may not remain commercially viable if there is an inadequate level of reimbursement by governmental programs and other third-party payors for our planned products or associated procedures.
 - We have limited resources and depend on third parties to design and manufacture, and seek regulatory approval of, our TAEUS applications.
 - We will need to develop marketing and distribution capabilities both internally and through our relationships with third parties in order to sell any of our TAEUS products receiving regulatory approval.
 - Competition in the medical imaging market is intense and we may be unable to successfully compete.
 - The medical device market is characterized by rapid innovation. To compete effectively, the Company may need to develop and / or acquire new products, seek regulatory clearance, market them successfully, and identify new markets for the Company's technology.**
 - We intend to market our TAEUS liver device in the EU and are subject to the risks of doing business outside of the United States.
 - We depend on our senior management team and their loss patients. The transition in certain of one of our more key employees leadership positions will be critical to our success, and inability our business could be negatively impacted if we do not successfully manage these transitions.**
 - If we are unable to attract and retain highly skilled employees could harm our business, we may not be able to successfully manage our business and achieve our objectives.**
 - Misdiagnosis, warranty and other claims, as well as product field actions and regulatory proceedings, initiated against us could increase our costs, delay or reduce our sales and damage our reputation.
 - The outbreak of pandemics, such as COVID-19, could adversely impact our business, including our pre-sales activities, clinical trials and ability to obtain regulatory approvals.**
- Risks Related to Intellectual Property and Other Legal Matters**
 - If we are unable to protect our intellectual property, which entails significant expense and resources, then our financial condition, results of operations and the value of our technology and products could be adversely affected.
 - Policing unauthorized use of our proprietary rights can be difficult, expensive and time-consuming, and we might be unable to determine the extent of this unauthorized use.
 - Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.
 - Risks Related to Government Regulation**
 - If we fail to obtain and maintain necessary regulatory clearances or approvals for our TAEUS applications, or if clearances or approvals for future applications and indications are delayed or not issued, our commercial operations will be harmed.
 - Disruptions at the FDA, including due to a reduction in the FDA's workforce and / or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies, which could negatively impact our business.**
 - Healthcare reform measures could hinder or prevent our planned products' commercial success.
 - If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.
- Risks Related to Owning Our Securities**
 - Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in volatility in the price of our securities.
 - Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future for reasons unrelated to our operating performance or prospects, and as a result, investors in our common stock could incur substantial losses.
 - We may be subject to securities litigation, which is expensive and could divert management attention.
 - If we are unable to implement and maintain effective internal control over financial reporting, including by remediating current material weaknesses in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities may decrease.
 - Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.
 - Future sales and issuances of our common stock or rights to purchase common

stock, including pursuant to our at- the- market offering program or equity incentive plan, could result in dilution of the percentage ownership of our stockholders and could cause the price of our securities to fall. · Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable. General Risk Factors · Our business is affected by macroeconomic conditions. · Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail. · The ongoing military action in Ukraine and the Middle East could have negative impact on the global economy, which could materially adversely affect our business, operations, operating results and financial condition. · Our business could be negatively impacted by corporate social responsibility and sustainability matters. Risks Related to Our Business We have a history of operating losses and will need to raise significant additional capital to continue our business and operations. If we are unable to raise capital or secure financing on favorable terms, or at all, to meet our capital and operating needs, we will be forced to delay or reduce our product development program and commercialization efforts, which would have a material adverse effect on our business. We are experiencing financial and operating challenges. We have only generated limited revenues to date and have a history of losses from operations. As of December 31, 2023-2024, we had an accumulated deficit of \$ 91-103. 9-4 million. Our independent registered public accounting firm, in its report on our financial statements for the year ended December 31, 2023-2024, has raised substantial doubt about our ability to continue as a going concern. To remain viable, we will require additional capital in the near term to proceed with the commercialization of our planned TAEUS applications and to meet our growth targets. Our near- term capital needs include supporting the hiring of personnel, payroll and benefits, continued scientific and potential product research and development, clinical studies to support our FDA de novo submission, expenses associated with the development of relationships with strategic partners, intellectual property development and prosecution, funding the costs of seeking regulatory approval of TAEUS applications, expanding our sales and marketing infrastructure, capital expenditures, working capital, responses to business opportunities, and general and administrative expenses. We are actively exploring additional sources of liquidity and may seek to raise such capital through, among other means, public or private equity offerings (including sales of our common stock under our at- the- market equity offering program), debt financings, corporate collaborations and / or licensing arrangements. However, general market conditions or the market price of our common stock may not support these capital raising transactions on terms favorable to us, or at all. If we are unable to obtain adequate financing or financings on terms satisfactory to us when we require it, we will be forced to undertake capital preservation measures that may include delaying or reducing our product development programs and commercialization efforts, materially curtailing or eliminating our operations, selling or disposing of our rights or assets, pursuing a sale or other strategic transactions, or undergoing restructuring or insolvency proceedings. Factors that could limit our ability to raise additional capital after this offering include, among other matters: ~~18~~ · the expectation that we will continue to incur losses and generate negative cash flows from operations; · our substantially limited liquidity and capital resources to meet our obligations as they become due; · the potential that our common stock will be delisted by Nasdaq in the event we fail to maintain compliance with the minimum bid price requirement; and · risks and uncertainties that are described in more detail in the Risk Factors and Management’ s Discussion and Analysis of Financial Condition and Results of Operations sections in this Annual Report on Form 10- K. ~~To 19~~To date, we have financed our operations through the net proceeds from offerings of common and preferred stock, warrants and convertible notes. Our future funding requirements will depend on many factors, including, but not limited to: · the costs, timing and outcomes of regulatory reviews associated with our future products, including TAEUS applications; · the progress, timing, costs and outcomes of our clinical studies, including the ability to timely enroll patients in such clinical trials; · the costs and expenses of expanding our sales and marketing infrastructure; · the costs and timing of developing variations of our TAEUS applications and, if necessary, obtaining regulatory clearance of such variations; · the degree of success we experience in commercializing our products, particularly our TAEUS applications; · the extent to which our TAEUS applications are adopted by hospitals for use by primary care physicians, hepatologists, radiologists and oncologists for diagnosis of fatty liver disease and the thermal ablation of lesions; · the number and types of future products we develop and commercialize; · the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property- related claims; · the extent and scope of our general and administrative expenses; · the outcome, timing and cost of regulatory approvals, including the potential that the FDA or comparable regulatory authorities may require that we perform more studies than those that we currently expect; · the amount of sales and other revenues from technologies and products that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third- party reimbursement; · the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish; · cash requirements of any future acquisitions and / or the development of other products; · the costs of operating as a public company; · the cost and timing of completion of commercial- scale, outsourced manufacturing activities; and · the time and cost necessary to respond to technological and market developments. **In August 2024, we announced a new management team and laid out strategic steps to become a more actionable and predictable company as we work towards bringing the Company’ s TAEUS technology to market. We are a company with limited operating history and we may not have the necessary resources, expertise and experience to successfully execute our business model on a global scale, such as obtaining the necessary approvals or clearances from the regulatory agencies of our target markets. Our ability to execute our model is dependent on a number of factors, including the ability of our senior management team to execute our model, our ability to incentivize, train and support international distribution partners in different geographic regions, our ability to begin or maintain our pace of product development, manufacturing and commercialization, our ability to meet the changing needs of the medical imaging market, and the ability of our employees to perform at a high- level. If we are unable to execute our model, or if our model does not drive the growth that we anticipate, or if our market opportunity is not as large as we have estimated, it could adversely affect our business and our prospects.** 20Our TAEUS platform applications may not achieve adequate market acceptance by physicians, patients, third- party payors and others in the medical community. Our TAEUS applications that receive regulatory approval

may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If our TAEUS applications do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from sales. The degree of market acceptance of products based on our TAEUS platform will depend on a number of factors, including: · potential or perceived advantages or disadvantages compared to alternative products; · pricing relative to competitive products and availability of third- party coverage or reimbursement; · the timing of bringing our product to market as compared to possible other new entrants to the market; · our ability to effectively raise market awareness and explain product benefits and whether we have resources sufficient to do so; · relative convenience, dependability and ease of administration; and · willingness of the target patient population to try new products and of physicians to utilize such products. Our revenues will be adversely affected if, due to these or other factors, the products we are able to commercialize do not gain significant market acceptance.

Public health crises, such as COVID-19 or other similar pandemics in the future, can it could result in product misuse and potential adverse impact on our treatment outcomes, which could harm the Company's reputation, result in product liability litigation, distract management and result in additional costs, all of which could harm the Company's business. If the Company's products are used by non- licensed or untrained practitioners, it could result in product misuse and adverse treatment outcomes, which could harm the Company's reputation and the Company's business. The Company's products may be purchased or operated by physicians with varying levels of training, and in many states, by non- physicians including [nurse practitioners and] technicians. Outside the U. S., many jurisdictions do not require specific qualifications or training pre- sales activities, clinical trials and ability to obtain regulatory approvals. Public health crises such as pandemics or similar outbreaks could adversely impact our or business operators of its products. For instance, The Company will not be able to supervise the COVID-19 pandemic impacted procedures performed with the Company's applications, nor does the Company require that direct medical supervision occur clinical trial activities that is determined by delaying patient enrollment state law. The Company and visits due to the prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions, and the inability to access sites-- its distributors intend to offer but do not require product training to the purchasers for-- or initiation and monitoring operators of the Company's products. In addition, the COVID-19 pandemic had physicians may result in product misuse an- and effect on- adverse treatment outcomes, which could harm the Company's reputation and its business, at the FDA and, in other health authorities by causing them-- the event to reallocate resources to addressing the these actions pandemic, which resulted-- result in delays of reviews product liability litigation, distract management and subject approvals of submissions such as that for our NAFLD TAEUS application. The level and nature of the disruption caused by COVID-19 and any other-- the Company pandemic is unpredictable, may be cyclical and long- lasting and vary from location to location- liability, including legal expenses. Medical-21 Medical imaging products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third- party payors, including governmental programs (e. g., Medicare and Medicaid in the United States), private insurance plans and managed care programs, for the services provided to their patients. Third- party payors and governments may approve or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement decisions by payors for these services are based on a wide range of methodologies that may reflect the services' assessed resource costs, clinical outcomes and economic value. These reimbursement methodologies and decisions confer different, and sometimes conflicting, levels of financial risk and incentives to healthcare providers and patients, and these methodologies and decisions are subject to frequent refinements. Third- party payors are also increasingly adjusting reimbursement rates, often downwards, indirectly challenging the prices charged for medical products and services. There can be no assurance that our products will be covered by third- party payors, that adequate reimbursement will be available or, even if payment is available, that third- party payors' coverage policies will not adversely affect our ability to sell our products profitably. We have limited data regarding the efficacy of our TAEUS platform applications. If any of our applications that receive regulatory approval do not perform in accordance with our expectations, we are unlikely to successfully commercialize our applications. Although we have completed a number of studies with respect to our TAEUS liver device, we have limited data regarding the efficacy of other TAEUS platform applications. Since our success depends in large part on the medical and third- party payor community's acceptance of our TAEUS applications, even if we receive regulatory approval for our applications, we believe that we will need to obtain additional clinical data from users of our applications to persuade medical professions- professionals to use our applications. We may also be required to conduct post-approval clinical testing to obtain such additional data. Clinical testing is expensive, can take a significant amount of time to complete and can have uncertain outcomes. Negative results of these clinical studies could have a material, adverse impact on our business. We cannot be certain that results from limited human studies of our TAEUS liver device will be indicative of future studies or that any of our TAEUS applications will be successfully commercialized. To successfully commercialize any application based on our TAEUS platform technology, we expect it will be necessary to conduct various pre- clinical and human studies to demonstrate that the product is safe and effective for human use. For instance, we have conducted a number of human studies with respect to our TAEUS liver device. These studies have initially demonstrated a meaningful correlation between the measurement of liver fat by our TAEUS FLIP product and by MRI- PDFF. However, there can be no assurance that results from these studies are indicative of results that would be achieved in future studies of this or any future TAEUS applications, which may be required in order for our applications incorporating our technology to obtain or maintain regulatory approval. Even if clinical trials or other studies demonstrate the safety and effectiveness of any applications of our technology and the necessary regulatory approvals are obtained, the commercial success of any of such application will depend upon their acceptance by patients, the medical community, and third- party payors and on our partners' ability to successfully manufacture and

commercialize a device for such application. ~~20Our~~ **Our** limited commercial experience makes it difficult to evaluate our business, predict our future results or forecast our financial performance and growth. We discontinued our initial pre-clinical Nexus 128 product in 2019 and our TAEUS liver device has obtained CE mark approval but has not yet been fully commercialized. This limited commercial experience makes it difficult to evaluate our business, predict our future results or forecast our financial performance and growth. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer. **We 22We** have formed, and may in the future form or seek, strategic alliances and collaborations or enter into licensing arrangements, and we may not realize the benefits of such alliances, collaborations or licensing arrangements. ~~In April 2016, we entered into a Collaborative Research Agreement with GE Healthcare, under which GE Healthcare has agreed to support our efforts to commercialize our TAEUS technology for use in an NAFLD application by, among other things, providing equipment and technical advice, and facilitating introductions to GE Healthcare clinical ultrasound customers. This agreement does not commit GE Healthcare to a long-term relationship and it may disengage with us at any time. This agreement has a term lasting until December 16, 2024 and is subject to termination by either party upon not less than 60 days' notice. See the section of this Annual Report titled "TAEUS System for Early Assessment and Monitoring of Nonalcoholic Fatty Liver Disease, or NAFLD" under "Item 1. Business" for further description of this agreement.~~ We intend in the future to form or seek additional strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our technologies and applications. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, restrict our ability to collaborate with other third parties or otherwise disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Further, strategic alliances and collaborations are subject to numerous risks, which may include the following: · collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration; · collaborators may not pursue development and commercialization of our technologies and applications or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities; · collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our applications and technologies; · collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; · disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our technologies and applications, or that result in costly litigation or arbitration that diverts management attention and resources; · collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable applications or technologies; and · collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property. ~~21As~~ **As** a result, if we enter into collaboration agreements and strategic partnerships or license our applications or technologies, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our applications could delay the development and commercialization of our technologies and applications in certain geographies or for certain applications, which would harm our business prospects, financial condition and results of operations. **We 23We** have limited resources and depend on third parties to design and manufacture, and seek regulatory approval of, our TAEUS applications. If any third party fails to successfully design, manufacture or obtain regulatory approval of TAEUS applications, our business will be materially harmed. We do not currently have, nor do we plan to acquire, the infrastructure or capability to design or manufacture our TAEUS applications. To support our design and manufacturing efforts, we have contracted StarFish Product Engineering, Inc., a medical device contract manufacturing company, rather than design or manufacture our TAEUS applications ourselves. We have limited control over the efforts and resources that these and any other third-party OEMs will devote to developing and manufacturing our TAEUS applications and their capabilities to serve our needs, including quality control, quality assurance and qualified personnel. In addition, for any future applications of our TAEUS technology we currently expect to depend on OEMs to acquire CE marks for the device or devices that they develop and manufacture which are necessary to permit marketing of those devices in the European Union followed by corresponding FDA approval. An OEM may not be able to successfully design and manufacture the products it develops based on our TAEUS technology, may not devote sufficient time and resources to support these efforts or may fail in gaining the required regulatory approvals of our TAEUS applications. The failure by an OEM to perform in accordance with our expectations would substantially harm the value of our TAEUS technology, brand and business. We will need to develop marketing and distribution capabilities both internally and through our relationships with third parties in order to sell any of our TAEUS products receiving regulatory approval. If we experience problems in developing these capabilities, our ability to sell our products could be limited. We have limited experience selling our products and will need to develop marketing, sales and distribution capabilities in order to sell our TAEUS applications that receive the necessary regulatory approval. We have limited experience managing a sales force and customer support operations and may be unable to attract, retain and manage the collaborative manufacturing and distribution arrangements or the specialized workforce necessary to successfully commercialize our products. In addition, our

sales and marketing organization must effectively explain the uses and benefits of our products as compared to alternatives in order to promote market acceptance and demand for our products. Although we have begun to hire a small internal sales and marketing team to engage and support channel partners and clinical customers, further developing these functions will be time-consuming and expensive and our efforts may not be successful. We intend to partner with others to assist us with some or all of these functions. However, we may be unable to find appropriate third parties with which to enter into these arrangements and any such third parties may not perform as expected. Furthermore, third-party distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our TAEUS applications and grow or maintain product sales. If these distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products. In addition, disagreements with our distributors or non-performance by these third parties could lead to costly and time-consuming litigation or arbitration and disrupt distribution channels for a period of time and require us to re-establish a distribution channel. If we are unable to manage the growth of our business, our future revenues and operating results may be harmed. Because of our small size, growth in accordance with our business plan, if achieved, will place a significant strain on our financial, technical, operational and management resources. As we expand our activities, there will be additional demands on these resources. The failure to continually upgrade our technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties, including issues relating to our research and development activities and retention of experienced scientists, managers and technicians, could have a material adverse effect on our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to implement these actions in a timely manner, our results may be adversely affected.

22**In** general, competition in the medical imaging market is very significant and characterized by extensive research and development and rapid technological change. Competitors in this market include very large companies with significantly greater resources than we have. To successfully compete in this market, we will need to develop TAEUS applications that offer significant advantages over alternative imaging products and procedures for such applications. **24****While** we believe the technology behind our TAEUS platform is unique in the industry, developments by other medical imaging companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive. Alternative medical imaging devices may be more accepted or cost-effective than our products. Competition from these companies for employees with experience in the medical imaging industry could result in higher turnover of our employees. If we are unable to respond to these competitive pressures, we could experience delayed or reduced market acceptance of our products, higher expenses and lower revenue. If we are unable to compete effectively with current or new entrants to these markets, we will be unable to generate sufficient revenue to maintain our business. Our competitors include producers of CT and MRI systems that include multi-national corporations such as Royal Philips, Siemens AG and Fujifilm Corporation, many of whom also manufacture and sell ultrasound equipment. In the **NAFLD MASLD** diagnosis market we will compete with makers of surgical biopsy tools, such as Cook Medical and Sterylab S. r. l. In the thermal ablation market, we will compete with manufacturers of surgical temperature probes, such as Medtronic plc and St. Jude Medical, Inc. These competitors and other potential competitors have substantially greater financial, technical and other resources, such as larger R & D staff, more robust manufacturing capabilities and more experienced marketing and manufacturing organizations. These competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than TAEUS applications that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than us. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against those of our competitors.

The medical device industry is subject to continuous technological development and product innovation. If the Company does not continue to innovate and develop new products and applications, the Company's competitive position may deteriorate as other companies successfully design and commercialize new products and applications or enhancements to the Company's current products. To successfully expand the Company's product offerings, the Company may need to, among other things:

- **develop or otherwise acquire new products that either add to or significantly improve the Company's current product offerings;**
- **obtain regulatory clearance for these new products;**
- **convince the Company's existing and prospective customers that the Company's product offerings are an attractive revenue-generating addition to their practice;**
- **sell the Company's product offerings to a broad customer base;**
- **identify new markets and alternative applications for the Company's technology;**
- **protect the Company's existing and future products with defensible intellectual property; and**
- **satisfy and maintain all regulatory requirements for commercialization.**

Changes in the healthcare industry could result in a reduction in the size of the market for our products or may require us to decrease the selling price for our products, either of which could have a negative impact on our financial performance. Trends toward managed care, healthcare cost containment, and other changes in government and private sector initiatives in Europe, **and** the United States **and** China are placing increased emphasis on lowering the cost of medical services, which could adversely affect the demand for or the prices of our products. For example:

- major third-party payors of hospital and non-hospital based healthcare services could revise their payment methodologies and impose stricter standards for reimbursement of imaging procedures charges and / or a lower or more bundled reimbursement;
- there has been a consolidation among healthcare facilities and purchasers of medical devices who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices; and
- there are proposed and existing laws and regulations in international and domestic markets regulating pricing and profitability of companies in the healthcare industry.

25**These** trends could lead to pressure to reduce prices for our products and could cause a decrease in the demand for our products in any given market that could adversely affect our revenue and profitability, which could harm our business. We intend to market our approved TAEUS applications globally, and currently market our TAEUS liver probe in the EU, and are therefore subject to the risks of doing

business outside of the United States. Because we intend to market our approved TAEUS applications globally, and currently market our TAEUS liver probe in the EU, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: · changes in a specific country's or region's political and cultural climate or economic condition; · local outbreaks of sickness or disease; · war or terrorist attack, including cyberterrorism; · unexpected changes in laws and regulatory requirements in local jurisdictions; · difficulty of effective enforcement of contractual provisions in local jurisdictions; · inadequate intellectual property protection in certain countries; ~~23-~~ trade- protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges; · effects of applicable local tax structures and potentially adverse tax consequences; and · significant adverse changes in currency exchange rates. ~~Our success largely depends upon the continued services of our executive management team and key employees. The~~ **There is** loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Our executive management team has significant experience and knowledge of medical devices and ultrasound systems, and the loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend significant time and money in the pursuit of replacements, which may result in a delay in the implementation of our business plan and plan of operations. We can give no assurance that we could find satisfactory replacements, **if approved, the Company's TAEUS applications will be widely adopted by customers or their patients. Market acceptance of our TAEUS applications will be affected by a variety of factors, including but not limited to usability, performance, reliability and customer preference. It is possible that demand for this device will** these individuals on terms that would not be unduly expensive as strong as anticipated. The Company may be unable to establish and manage a sufficient or effective sales force in a timely or cost-effective manner, and any sales force the Company does establish may not be capable of generating demand ~~or for~~ **burdensome our TAEUS applications, therefore hindering the Company's ability to us generate revenues and achieve or sustain profitability. The Company can offer no assurance that the sales model for our TAEUS applications will be well-received by customers or lead to sustainable demand. 26**In August 2024, the Company and Francois Michelin mutually agreed on Mr. Michelin's resignation as the Company's Chief Executive Officer and as a member of the Board of Directors, and Irina Pestrikova resigned as the Company's Senior Director of Finance and Principal Financial Officer. **The departure and transition of key leadership personnel can take significant knowledge and experience from our company. While this loss of knowledge and experience can be mitigated through a successful transition, there can be no assurance that we will be successful in such efforts. If we do not successfully manage senior leadership transitions, it could be viewed negatively by our prospective customers, employees, or investors and could have an adverse impact on our business and strategic direction.** To execute our growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices. In addition, we will need to identify and hire sales executives and competition for commercial and marketing talent is significant. We may experience difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the FD & C Act and similar laws of other countries, or the rules and regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we establish; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. For any products for which we obtain regulatory approval and begin commercializing in Europe, ~~China~~ or the United States, respectively, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. Our sales team in the European Union marketing our TAEUS liver probe are subject to these laws, as well as regulations that restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Misdiagnosis, warranty and other claims, as well as product field actions and regulatory proceedings, initiated against us could increase our costs, delay or reduce our sales and damage our reputation, adversely affecting our financial condition. ~~Our~~ **27**Our business exposes us to the risk of malpractice, warranty or product liability claims inherent in the sale and support of medical device products, including those based on claims that the use or failure of one of our products resulted in a misdiagnosis or harm to a patient. Although to date we have not been involved in any medical malpractice or product liability litigation, we may incur

significant liability if such litigation were to occur. If we cannot successfully defend ourselves against product liability or related claims, we may incur substantial liabilities or be required to limit the distribution of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ~~24~~ · decreased demand for our products; · injury to our reputation and negative media attention; · initiation of investigations by regulators and adverse impacts to our ability to obtain regulatory approvals; · costs to defend the related litigation; · a diversion of management's time and our resources; · substantial monetary awards to trial participants or patients; · product recalls, withdrawals or labeling, marketing or promotional restrictions; · loss of revenue; · exhaustion of any available insurance and our capital resources; · the inability to commercialize a product at all or for particular applications; and · a decline in the price of our securities. Although we currently maintain liability insurance in amounts that we believe are commercially reasonable, any liability we incur may exceed our insurance coverage. Our insurance policies may also have various exclusions, and we may be subject to a claim for which we have no coverage. Liability insurance is expensive and may cease to be available on acceptable terms, if at all. A malpractice, warranty, product liability or other claim or product field action not covered by our insurance or exceeding our coverage could significantly impair our financial condition. In addition, a product field action or a liability claim against us could significantly harm our reputation and make it more difficult to obtain the funding and commercial relationships necessary to maintain our business. Our internal computer systems, or those used by third-party manufacturers or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our future manufacturers and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs and our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products could be delayed.

28 Public health crises, such as COVID- 19 or other similar pandemics in the future, can adversely impact our business, including our pre- sales activities, clinical trials and ability to obtain regulatory approvals. Public health crises such as pandemics or similar outbreaks could adversely impact our business. For instance, the COVID- 19 pandemic impacted our clinical trial activities by delaying patient enrollment and visits due to the prioritization of hospital resources toward the COVID- 19 outbreak, travel restrictions, and the inability to access sites for initiation and monitoring. In addition, the COVID- 19 pandemic had an effect on the business at the FDA and other health authorities by causing them to reallocate resources to addressing the pandemic, which resulted in delays of reviews and approvals of submissions such as that for our NAFLD TAEUS application. The level and nature of the disruption caused by COVID- 19 and any other pandemic is unpredictable, may be cyclical and long- lasting and vary from location to location.

Much of our value arises from our proprietary technology and intellectual property for the design, manufacture and use of medical imaging systems, including development of our TAEUS applications. We rely on patent, copyright, trade secret and trademark laws to protect our proprietary technology and limit the ability of others to compete with us using the same or similar technology. Third parties may infringe or misappropriate our intellectual property, which could harm our business. Additionally, any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours.

Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our TAEUS platform, brand and business. See the section of this Annual Report titled " Intellectual Property " under " Item 1. Business " for further information on our

~~Intellectual~~ **Intellectual Property** portfolio. Expenses related to a patent portfolio include periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and / or applications due in several stages over the lifetime of patents and / or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which a failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. ~~25 Policing~~ **Policing** unauthorized use of our intellectual property is difficult, costly and time- intensive. We may fail to stop or prevent misappropriation of our technology, particularly in countries where the laws may not protect our proprietary rights to the same extent as do the laws of the United States. Proceedings to enforce our patent and other intellectual property rights in non- U. S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. If we cannot prevent other companies from using our proprietary technology or if our patents are found invalid or otherwise unenforceable, we may be unable to compete effectively against other manufacturers of ultrasound systems, which could decrease our market share. In addition, the breach of a patent licensing agreement by us may result in termination of a patent license. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate.

~~If~~ **29 If** we are unable to protect the confidentiality of our proprietary information and know- how, the value of our technology and products could be adversely affected. In addition to our patent activities, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know- how. Any involuntary disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological

achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff was previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their former employee's therapeutic development activities for us. We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our TAEUS applications. The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U. S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Other medical imaging market participants, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and / or export our products or to use product names. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third-party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret. Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our TAEUS applications to avoid infringement. Similarly, interference or derivation proceedings provoked by third parties or brought by the U. S. Patent and Trademark Office ("USPTO") may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our TAEUS applications or using product names, which would have a significant adverse impact on our business. 26

Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products or from using product names that are the same or similar to our product names, and our business may be harmed as a result. 30

Failure to comply with laws and regulations could harm our business. Our business is or in the future may be subject to regulation by various federal, state, local and foreign governmental agencies, including agencies responsible for monitoring and enforcing employment and labor laws, workplace safety, environmental laws, consumer protection laws, anti-bribery laws, import / export controls, securities laws and tax laws and regulations. In certain jurisdictions, these regulatory requirements may be more stringent than those in the United States. Noncompliance with applicable regulations or requirements could subject us to investigations, sanctions, mandatory recalls, enforcement actions, adverse publicity, disgorgement of profits, fines, damages, civil and criminal penalties or injunctions and administrative actions. If any governmental sanctions, fines or penalties are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, operating results and financial condition could be harmed. In addition, responding to any action will likely result in a significant diversion of management's attention and our resources and substantial costs. Enforcement actions and sanctions could further harm our business, operating results and financial condition. The **ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel. Such changes and other disruptions at the FDA may increase the time to meet with the FDA and receive FDA feedback, review and / or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, the Trump Administration recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal**

government. It is unclear how these executive actions or other potential actions by the Trump Administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. These budgetary pressures may reduce the FDA's ability to perform its responsibilities. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our De Novo submission or take other actions critical to the development or marketing of our TAEUS applications, if approved, which could have a material adverse effect on our business. 31

The medical devices that we manufacture and market will be subject to regulation by numerous worldwide regulatory bodies, including the EMA, FDA and other comparable regulatory agencies. Additionally, third parties designing, manufacturing or conducting human studies of our devices will be subject to local regulations, such as those of Health Canada. These agencies and regulations require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, based on the risk level of the device. Governmental regulations specific to medical devices are wide-ranging and govern, among other things: · product design, development and manufacture; · laboratory, pre-clinical and clinical testing, labeling, packaging storage and distribution; · premarketing clearance or approval; · record keeping; · product marketing, promotion and advertising, sales and distribution; and · post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals. The European Union has revised its regulatory system for medical devices by implementing regulation (EU) 2017 / 745 on medical devices (“ Medical Device Regulation ” or “ MDR ”) and regulation (EU) 2017 / 746 on in vitro diagnostic medical devices. The MDR became effective on May 26, 2021 (the “ Date of Application ” or “ DoA ”). The changes to the regulatory system implemented by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, refined classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well as a refined responsibility of economic operators. We are currently in a transitional period, where our existing certified products will be required to continue to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive) and with the Medical Device Regulation to obtain CE mark certification in order to continue or commence marketing medical devices. The CE mark is applied following **approval certification** from a Notified Body or declaration of conformity. It is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives or the MDR, as the case may be. CE mark approvals issued prior to May 26, 2021 will, subject to certain conditions (including, among others, continued compliance with the MDR, no significant changes to design or intended purpose, a quality management system, and engagement with a notified body to obtain conformity assessment), remain valid until December 31, 2028. In March 2020, we received CE mark approval for our TAEUS FLIP (Fatty Liver Imaging Probe) System. The CE marking indicates that TAEUS complies with all applicable regulations in the EU, and other CE mark geographies, including the 27 EU member states. We believe that future TAEUS applications will qualify for sale in the European Union as Class IIa medical devices. The MDR requires a clinical evaluation for all medical devices and clinical trials for selected medical devices to be (re-) certified under the rules of the MDR. Depending on the classification of our applications, future CE mark certifications or recertification of our applications may require additional clinical evaluations or trials, as the case may be. 27 **We** are also required to comply with the regulations of each other country where we commercialize products, such as the requirement that we obtain approval from the FDA and the China Food and Drug Administration before we can launch new products in the United States and China, respectively. Our **NAFLD-MASLD** TAEUS device is being reviewed under a “ de novo ” process for a risk-based classification determination whether the device is of low to moderate risk and that it can be appropriately regulated as a Class II device and thereby eligible for 510 (k) clearance. While the 510 (k) pathway for product marketing typically requires only non-clinical testing proof of substantial equivalence to a lawfully marketed predicate device for a given indication, the FDA has requested clinical studies to support a reclassification to a lower risk class via the de novo process. Even with the clinical data we expect to provide with the de novo submission for our **NAFLD-MASLD** TAEUS device, the FDA may decide to reject the request to classify the device into Class II. If that happens, the device will be regulated as a Class III device and we will be required to fulfill more rigorous PMA requirements. Thus, although at this time we do not anticipate that we will be required to do so, it is possible that our **NAFLD-MASLD** TAEUS device may require approval by means of a PMA. **We** 32 **We** may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Even if we obtain regulatory approval for our TAEUS device, our product will remain subject to regulatory oversight. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Therefore, even if we believe we have successfully developed our TAEUS technology, we may not be permitted to market TAEUS applications in the United States if we do not obtain FDA regulatory clearance to market such applications. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth. In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations that require us to report to certain regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission

of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. The FDA and the Federal Trade Commission (the "FTC") also regulate the advertising and promotion of our planned products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions: · adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties; · repair, replacement, refunds, recall or seizure of our products; · operating restrictions, partial suspension or total shutdown of production; · refusing our **De Novo submissions**, requests for 510 (k) clearance or premarket approval of new products, new intended uses or modifications to existing products; · withdrawing 510 (k) clearance or premarket approvals that have already been granted; and · criminal prosecution. **29f If** any of these events were to occur, our business and financial condition would be harmed. **We-33We** have experienced and may in the future experience delays and other difficulties in enrolling a sufficient number of patients in our clinical trials which could delay or prevent the receipt of necessary regulatory approvals. We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials. We may face challenges in enrolling patients to participate in our clinical trials. Patients suffering from diseases within target indications may enroll in competing clinical trials, which could negatively affect our ability to complete enrollment of our trials. Additionally, enrollment may be delayed by unforeseen circumstances, as occurred with the COVID- 19 pandemic. Enrollment challenges in clinical trials often result in increased development costs for a product candidate, significant delays and potentially the abandonment of the clinical trial. We may have other delays in completing our clinical trials and we may not complete them at all. Since we lack significant experience in completing clinical trials and bringing a medical device through commercialization, we have hired outside consultants with such experience. Clinical trials for our TAEUS device may be delayed or terminated as a result of many factors, including the following: · patients failing to complete clinical trials due to dissatisfaction with the procedure, side effects, or other reasons; · failure by regulators to authorize us to commence a clinical trial; · suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety, the failure of study sites and / or investigators in our clinical research program to comply with GCP requirements, or our failure, or the failure of our contract manufacturers, to comply with current cGMP requirements; · delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers; · treatment candidates demonstrating a lack of efficacy during clinical trials; · inability to continue to fund clinical trials or to find a partner to fund the clinical trials. Any delay or failure to complete clinical trials could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, our TAEUS device. Our TAEUS applications may require recertification or new regulatory clearances or premarket approvals and we may be required to recall or cease marketing our TAEUS applications until such recertification or clearances are obtained. Most countries outside of the United States require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries. In the United States, material modifications to the intended use or technological characteristics of our TAEUS applications will require new 510 (k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer' s decision. Any modification to an FDA- cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510 (k) clearance or possibly a premarket approval. **We-34We** may not be able to obtain recertification or additional 510 (k) clearances or premarket approvals for our applications or for modifications to, or additional indications for, our TAEUS technology in a timely fashion, or at all. Delays in obtaining required future governmental approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If foreign regulatory authorities or the FDA require additional approvals, we may be required to recall and to stop selling or marketing our TAEUS applications, which could harm our operating results and require us to redesign our applications. In these circumstances, we may be subject to significant enforcement actions. **29f If** any OEMs fail to comply with the FDA' s Quality System Regulations or other regulatory bodies' equivalent regulations, manufacturing operations could be delayed or shut down and the development of our TAEUS platform could suffer. The manufacturing processes of OEMs are required to comply with the FDA' s Quality System Regulations and other regulatory bodies' equivalent regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our TAEUS applications. They may also be subject to similar state requirements and licenses and engage in extensive recordkeeping and reporting and make available their manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If any OEM fails such an inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse inspection could result in, among other things, a shut- down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our products, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, these OEMs may be engaged with other companies

to supply and / or manufacture materials or products for such companies, which would expose our OEMs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a third- party manufacturers' facility. If the FDA or a foreign regulatory agency does not approve these facilities for the manufacture of our products, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would impede or delay our ability to develop, obtain regulatory approval for or market our products, if approved. Additionally, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our results of operations to suffer. Our TAEUS applications may in the future be subject to product recalls that could harm our reputation. Governmental authorities in Europe, ~~and~~ the United States ~~and China~~ have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government- mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our TAEUS applications would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would negatively affect the price of our securities. There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. In the EU, the Medical Devices Directive is being replaced with the more expansive ~~MDR Medical Devices Regulation~~, which may increase the costs of obtaining and maintaining required regulatory approvals for our products. We cannot predict what other healthcare initiatives, if any, will be implemented by EU member countries, or the effect any future legislation or regulation will have on us. In the United States, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the " Affordable Care Act "), was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. ~~It~~ ~~35~~It remains unclear whether changes will be made to the Affordable Care Act, or whether it will be repealed or materially modified. For example, the Tax Cuts and Jobs Act of 2017 modified certain aspects of the Affordable Care Act and the ~~Biden~~ ~~Trump~~ Administration and U. S. Congress may take further action regarding the Affordable Care Act. Therefore, we cannot assure you that the Affordable Care Act, as currently enacted or as may be further amended or discontinued in the future, will not harm our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm: ~~•~~ our ability to set a price that we believe is fair for our products; ~~•~~ our ability to generate revenues and achieve or maintain profitability; and ~~•~~ the availability of capital. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. Other jurisdictions such as the European Union have similar laws. The regulations that will affect how we operate include: ~~30~~ the federal healthcare program Anti- Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs; · the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government; · federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; · the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the U. S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; · the Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and · state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers. ~~The~~ ~~36~~The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti- Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws

and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal and similar foreign healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability. Our research and development and manufacturing operations may involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. In addition, our research and development and manufacturing operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Risks Related to Owning Our Securities, Our Financial Results and Our Need for Financing

Our operating results will be affected by numerous factors such as:

- variations in the level of expenses related to our proposed products;
- status of our product development efforts;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;
- intellectual property prosecution and any infringement lawsuits to which we may become a party;
- regulatory developments affecting our products or those of our competitors, including the timing and success of obtaining various regulatory approvals for our products' testing, production and marketing;
- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, which have not yet been approved for marketing;
- market acceptance of our TAEUS applications;
- the availability of reimbursement for our TAEUS applications;
- our ability to attract new customers and grow our business with existing customers;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, industry and market conditions;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- litigation or other claims against us;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

Any or all of these factors could adversely affect our cash position requiring us to raise additional capital which may be on unfavorable terms and result in substantial dilution. Additionally, the risks surrounding our business, as well as the limited market for our common stock, have resulted, and will likely continue to result, in volatility in the price of our common stock. Our stock **is subject to minimum requirements to remain listed** price has fluctuated in the past, has recently been volatile and may be volatile in the future. From January 1, 2023 through December 31, 2023, intra-day trading prices of shares of our common stock on the Nasdaq Capital Market **fluctuated from a low of \$ 0. remain listed on the Nasdaq Capital Market**, including a minimum bid price **requirement and stockholders' equity** requirement, and may be delisted if it does not maintain compliance with those requirements. On **January 5 - May 3, 2022 - 2024**, the Company received a notification letter from the Listing Qualifications Department of Nasdaq notifying the Company that, because the closing bid price for the Company's common stock listed on Nasdaq was below \$ 1. 00 for 30 consecutive trading days, the Company no longer met the minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550 (a) (2), requiring a minimum bid price of \$ 1. 00 per share (the "Minimum Bid Price Requirement"). **The Effective August 16, 2024, the Company effected** held a special meeting of the stockholders in November 2022 for the purpose of approving a reverse stock split **at**. Following stockholder approval, the Company filed a Certificate **ratio** of **one** Amendment to the Company's Fourth Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware to effect a 1- for- **fifty 20** reverse stock split of the shares of the Company's Common Stock, effective as of December 9, 2022 (the " **August Reverse Stock Split** "). **The August Reverse Stock Split did not have the intended effect of regaining compliance with the Nasdaq Minimum Bid Price Rule and shares of the Company's common stock opened for trading on a post- split basis on the Nasdaq Capital Market on August 20, 2024 at a bid price of \$ 0. 99. 38**The Company held a special meeting of the stockholders on **October 28, 2024 for the purpose of approving a subsequent reverse stock split. Following stockholder approval, the Company filed a Certificate of Amendment to the Company's Certificate of Incorporation with the Secretary of State of Delaware to effect a 1- for- 35 reverse stock split of the shares of the Company's common stock, effective as of November 7, 2024 (the " November Reverse Stock Split ")**. As a result of the **November** Reverse Stock Split, the Company regained compliance with the Nasdaq Minimum Bid Price Requirement. If we fall below the Minimum Bid Price Requirement again, we cannot be certain that our stockholders will approve a reverse stock split or, if approved, how the market would respond to such a reverse stock split. **While Nasdaq rules do not impose a specific limit on the number of times a listed company may effect a reverse stock split to maintain or regain compliance with the Minimum Bid Price Requirement, Nasdaq has stated that a series of reverse stock splits may undermine investor confidence in securities listed on Nasdaq.** In future **fluctuated from a low of \$ 0.87 to a high of \$ 5.39, and may continue to** also be materially and

adversely affected if our common stock or warrants are not listed on a national securities exchange. Our stock price has fluctuated— **fluctuate significantly** in the past, has recently been volatile and may be volatile in the future. The stock market in general and the market for healthcare companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. Additionally, securities of certain companies have experienced significant and extreme volatility in stock price due to a sudden increase in demand for stock resulting in aggregate short positions in the stock exceeding the number of shares available for purchase, forcing investors with short exposure to pay a premium to repurchase shares for delivery to share lenders. This is known as a “short squeeze.” These short squeezes have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share declines steadily as interest in those stocks abates. While we have no reason to believe our shares would be the target of a short squeeze, there can be no assurance that they will not be in the future, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value. **32 Our stock is subject to minimum requirements to remain listed on the Nasdaq Capital Market** the past, companies that have experienced volatility in the market price of their securities have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business. There is a limited market for our common stock. Although our common stock is traded on the Nasdaq Capital Market, the volume of trading has historically been limited. Our average daily trading volume of our shares from January 1, ~~2023~~ **2024** to December 31, ~~2023~~ **2024 (on an adjusted basis taking into account the August Reverse Split and November Reverse Split)** was approximately ~~66-98~~ **369-294** shares. Thinly traded stock can be more volatile than stock trading in a more active public market. While we have made efforts to increase trading in our stock, we cannot predict the extent to which an active public market for our common stock will develop or be sustained. Therefore, a holder of our common stock who wishes to sell his or her shares may not be able to do so immediately or at an acceptable price. If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our securities and trading volume could decline. The trading market for our securities is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the securities or industry analysts who cover us or may cover us in the future change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any securities or industry analyst who covers us or may cover us in the future were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price or trading volume of our common stock to decline. If we are unable to implement and maintain effective internal control over financial reporting, including by remediating current material weaknesses in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our securities may decrease and we may become subject to litigation or enforcement actions. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes- Oxley Act of 2002 (the “Sarbanes- Oxley Act”) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. Currently, we have material weaknesses in our internal control over financial reporting and, as a result, we may not detect errors on a timely basis and our financial statements may be materially misstated. Specifically, we have insufficient personnel resources within the accounting function to segregate the duties over financial transaction processing and reporting. We intend to improve our internal control over financial reporting; however, the process is time- consuming, costly and complicated. We are constrained in the improvements we are able to make due to our limited resources. Until our internal controls are improved our ability to maintain effective internal controls over financial reporting will be limited. ~~33 Until~~ **Until** such time as we are no longer a smaller reporting company, our auditors will not be required to attest as to our internal control over financial reporting. If we continue to identify 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 required, if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third- party litigation as well as investigations by the stock exchange on which our securities are listed, the Securities and Exchange Commission (the “SEC”) or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies. ~~We~~ **40 We** are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. We have not paid dividends in the past and have no plans to pay dividends **for the foreseeable future**. We plan to reinvest all of our earnings, to the extent we have earnings, in order to further develop our technology and potential products and to cover

operating costs. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we will, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. We incur significant costs as a result of being a public company that reports to the SEC and our management is required to devote substantial time to meet compliance obligations. As a public company listed in the United States, we incur significant legal, accounting and other expenses relating to our compliance obligations. We are subject to reporting requirements of the Exchange Act and the Sarbanes- Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. In addition, there are significant corporate governance and executive compensation- related provisions in the Dodd- Frank Act Wall Street Reform and Protection Act that contribute to our legal and financial compliance costs, make some activities more difficult, time- consuming or costly and also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Furthermore, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan and our at- the- market equity offering program, could result in dilution of the percentage ownership of our stockholders and could cause the price of our securities to fall. We expect that significant capital will be needed in the future to continue our planned operations. To the extent we raise capital by issuing common stock, convertible securities or other equity securities, our stockholders may experience substantial dilution, and new investors could gain rights superior to our existing stockholders. Certain provisions of our Fourth Amended and Restated Certificate of Incorporation, as amended (our “ Certificate of Incorporation ”) and Amended and Restated Bylaws (our “ Bylaws ”) and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Certificate of Incorporation and Bylaws: · authorize our board of directors to issue preferred stock without stockholder approval and to designate the rights, preferences and privileges of each class; if issued, such preferred stock would increase the number of outstanding shares of our capital stock and could include terms that may deter an acquisition of us; · limit who may call stockholder meetings; ~~34-41~~ · do not provide for cumulative voting rights; · provide that all vacancies in our board of directors may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; · provide that stockholders must comply with advance notice procedures with respect to stockholder proposals and the nomination of candidates for director; · provide that stockholders may only amend our Certificate of Incorporation upon a supermajority vote of stockholders; and · provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims. In addition, section 203 of the Delaware General Corporation Law limits our ability to engage in any business combination with a person who beneficially owns 15 % or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following any such person’ s share acquisition. These provisions may have the effect of entrenching our management team and may deprive stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock. Unfavorable national or global economic conditions or political developments could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the national or global economy and financial markets. For example, governmental statements, actions or policies, political unrest and global financial crises can cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, political unrest or additional global financial crises, including those resulting from the COVID- 19 pandemic and the ongoing Russia- Ukraine war, Israel- Hamas war and the conflict between China and Taiwan, could result in a variety of risks to our business, including weakened demand for our products, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate, further political developments and financial market conditions could adversely impact our business. We regularly maintain cash balances at third- party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. Any failure of a depository institution to return these deposits on demand, or if a depository institution is subject to other adverse conditions in the financial or credit markets, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. ~~Our 42~~Our business and operations are subject to risks related to climate change. The effects of global climate change present risks to our business. Natural disasters, extreme weather and other conditions caused by or related to climate change could adversely impact our supply chain, the courier delivery services we use, the availability and cost of raw materials and components, energy supply, transportation, or other inputs necessary for the operation of our business. Climate change and natural disasters could also result in physical damage to our facilities as well as those of our suppliers, health care providers and other business partners, which could cause disruption in our business and operations. Our facilities and our laboratory equipment would be costly to replace and could require substantial lead time to repair or replace. Although we believe we possess adequate insurance for the disruption of our business from causalities, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. There has been an increased focus from investors, customers, employees and other stakeholders concerning corporate social responsibility and sustainability matters, including addressing climate change and diversity in company management, which may result in increases in our costs to operate our business or restrict certain aspects of our activities. The standards by which corporate social responsibility and

sustainability efforts and related matters are measured are developing and evolving, and certain areas are subject to assumptions that could change over time and the extent and severity of climate change impacts are unknown. In addition, we could be criticized for the scope of such initiatives or goals or a lack of diversity on our board of directors or among our executive officers, or perceived as not acting responsibly in connection with these matters. Any such matters could have a material adverse impact on our future results of operations, financial position and cash flows. 35