Risk Factors Comparison 2024-03-28 to 2023-03-16 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~~ **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. **· 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 adversely impact our 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. · We 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 the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business. · 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. 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 ~~experience upon~~ **operations will be harmed. · 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. 17Risks 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 ~~evaluate~~ **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 ~~our~~ or ~~prospects~~ 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, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~81~~ **91** . 9 million. Our independent registered public accounting firm, in its report on our financial statements for the year ended December 31, ~~2022~~ **2023** , has raised substantial doubt about our ability to continue as a going concern. ~~We~~ **To remain viable, we** will require additional capital in the near term to ~~continue as a going concern to~~ proceed with the commercialization of our planned TAEUS applications and to meet our growth ~~and profitability~~ targets. **Our near- term capital needs include supporting the** ~~We have expended and expect to continue to expend significant resources on~~ hiring of personnel, payroll and benefits, continued scientific and potential product research and development, ~~potential product testing and pre-~~ clinical ~~and clinical investigations~~ **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** ~~and promotion~~ , capital expenditures, working capital, **responses to business opportunities,** and general and administrative expenses. We **are actively exploring additional sources** ~~also expect to incur costs and expenses related to consulting, laboratory development, and the hiring~~ of ~~scientists~~ **liquidity** and **may seek to raise such capital through, among** other ~~operational personnel~~ **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** . ~~We~~ **However, general market conditions or the market price of our common stock** may not ~~be able to secure financing~~ **support these capital raising transactions** on **terms** favorable ~~terms~~ **to us** , or at all ~~,~~ **. If we are unable** to ~~meet~~ **obtain adequate financing** ~~our~~ **or** ~~future~~ **financings on terms satisfactory to us when we require it, we will be forced to undertake** capital ~~needs and~~ **preservation measures that may include delaying** ~~our~~ **or reducing** ~~failure to obtain financing when needed could force us to delay, reduce or eliminate~~ 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** . ~~We will need~~ **Factors that could limit our ability** to raise additional capital **after this offering include, among** ~~in order to finance the full commercialization of our NAFLD TAEUS application and to complete the development of any~~ other ~~TAEUS application through public~~ **matters: 18 · the expectation that we will continue to incur losses and generate negative cash flows from operations; ·** ~~or~~ **our substantially limited liquidity** ~~private equity offerings, debt financings, corporate collaboration~~ and ~~licensing arrangements~~ **capital resources to meet** ~~or~~ **our obligations as they become due; ·** ~~other~~ -- **the** ~~financing alternatives~~ **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** . ~~18To~~ **To** date, we have financed our operations ~~primarily~~ through the net proceeds from offerings of common and preferred stock **, warrants** and convertible notes ~~. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. Therefore, we will require additional capital in order to: (i) continue to conduct research and development activities; (ii) continue to conduct clinical studies; (iii) fund the costs of seeking regulatory approval of TAEUS applications; (iv) expand our sales and marketing infrastructure; (v) acquire complementary business technology or products; and (vi) respond to business opportunities, challenges, increased regulatory obligations or unforeseen circumstances~~ . 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 ~~trials~~ **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; · ~~selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;~~ · 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. ~~We may raise funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we raise additional funds through issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our Company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. See " Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in dilution of the percentage ownership of our stockholders and could cause the price of our securities to fall. " below. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third~~

parties, we may have to relinquish valuable rights to our technologies, future revenue streams or products or to grant licenses on terms that may not be favorable to us and our collaborators and strategic partners may not perform as expected. 19General market conditions or the market price of our common stock may not support capital raising transactions such as a public or private offering of our common stock or other securities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, results of operation and financial condition, including the possibility that a lack of funds could cause our business to fail and liquidate with little or no return to investors. Our efforts may never result in the successful development of commercial applications based on our TAEUS technology. Our TAEUS technology is still in development. We have received regulatory clearance for the commercial sale of our NAFLD application in the European Union but otherwise do not have any applications for our TAEUS technology approved for sale. Applications for our TAEUS technology, even if approved for sale, may never become commercially viable or generate significant revenue. Our ability to generate significant revenues and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive all required regulatory approvals for our TAEUS applications and find customers who will purchase our future products or strategic partners that will incorporate our technology into their products. Even if we develop commercially viable applications for our TAEUS technology, which may include licensing, we may never recover our research and development expenses and we may never be able to produce material revenues or operate on a profitable basis. Our research and development efforts remain subject to all of the risks associated with the development of new products based on emerging technologies, including, without limitation, unanticipated technical or other problems, the inability to develop a product that may be sold at an acceptable price point and the possible insufficiency of funds needed in order to complete development of these products. Technical problems may result in delays and cause us to incur additional expenses that would increase our losses. If we cannot complete, or if we experience significant delays in developing applications based on, our TAEUS technology, particularly after incurring significant expenditures, our business may fail. Our success is substantially dependent on the success of applications for our TAEUS platform. Our ability to generate meaningful revenues in the future will depend on the successful development and commercialization of our TAEUS platform applications. The commercial success of our TAEUS platform applications and our ability to generate revenues will depend on many factors, including the following: · our successful development of applications for our TAEUS technology, such as those we intend to pursue for the diagnosis of NAFLD and the monitoring of thermal ablation surgery, and the acceptance in the marketplace by physicians and patients of such applications; · the successful design and manufacturing of a device or devices which enable the use of our TAEUS technology by physicians on their patients; · receipt of necessary regulatory approvals; · sufficient coverage or reimbursement by third- party payors; · our ability to successfully market our products; · our ability to demonstrate that our TAEUS applications have advantages over competing products and procedures; · the amount and nature of competition from competing or alternative imaging products; and · our ability to establish and maintain commercial manufacturing, distribution and sales force capabilities. 20Our TAEUS platform applications may not achieve adequate market acceptance by the 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: **19** · 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 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 . In addition to the foregoing effects, as a result of future COVID- 19 outbreaks or other pandemics we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including: · interruption of key clinical trial activities and attendance at industry events due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures; · delays or difficulties in enrolling patients in clinical trials of our TAEUS FLIP device; · interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact approval timelines; · absenteeism or loss of employees at the Company, or at our collaborator companies, due to health reasons or government restrictions or otherwise, that are needed to develop, validate, manufacture and perform other necessary functions for our operations; · supply chain disruptions making it difficult for our collaborator companies to order and receive materials needed

~~for the manufacture of our TAEUS product; · government responses including orders that make it difficult for us, our supplier and our potential customers to remain open for business, and other seen and unforeseen actions taken by government agencies; · equipment failures, loss of utilities and other disruptions that could impact our operations or render them inoperable; and · effects of a local or global recession or depression that could depress economic conditions for a prolonged period and limit access to capital by the Company. Even if not rising to the level of a global pandemic, the outbreak of illness locally at the location of our offices or clinical trials could have a material adverse impact on our operations and financial condition and results. 21We 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~~ . 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 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 ~~animal and~~ human studies of ~~any of~~ our TAEUS ~~applications~~ **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 ~~animal studies or human clinical~~ 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 payers and on our partners' ability to successfully manufacture and commercialize a device for such application. ~~Our~~ **20Our** 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 ~~NAFLD~~ 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 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. ~~22Any~~ -- **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 ~~. If we license technologies or applications, we may not be able to realize the intended benefit of such transactions~~ . 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 ~~may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon the development of an application, repeat or conduct new clinical trials, or require a new formulation of an application for clinical testing; · collaborators~~ could independently develop, or develop with third parties, products that compete directly or indirectly with our applications and technologies ~~; · a collaborator with marketing and distribution rights to one or more applications may not commit sufficient resources to their marketing and distribution~~ ; · 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. ~~As~~ **21As** 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 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. ~~23We~~ **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. **22In** ~~Competition in the medical imaging market is intense~~

~~and we may be unable to successfully compete. 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. 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 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.** ~~24Changes~~ -- **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, 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; ~~· there is economic pressure to contain healthcare costs in markets throughout the world;~~ and · there are proposed and existing laws and regulations in international and domestic markets regulating pricing and profitability of companies in the healthcare industry. 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 ~~, including COVID- 19~~ ; · 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 ~~. We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business~~ . Our success largely depends upon the continued services of our executive management team and key employees. The 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 for these individuals on terms that would not be unduly expensive or burdensome to us. 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. ~~25Our~~ -- **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~~ **these** laws ~~and~~ **, as well as** regulations ~~may~~ **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 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. ~~Such claims may cause financial loss, damage our reputation by raising questions about our products' safety and efficacy, adversely affect regulatory approvals and interfere with our efforts to market our products.~~ 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. ~~We may also face adverse publicity resulting from product field actions or regulatory proceedings brought against us. Claims could also be asserted under state consumer protection acts.~~ 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. ~~26Our~~ -- **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. ~~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.~~ Much of our value arises **from** ~~out of~~ 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** ~~As of December 31~~ , **any** ~~2022, we maintained a patent portfolio consisting of thirty- three (33)~~ patents issued ~~in the United States and twenty- three (23) 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 ~~in foreign jurisdictions~~ **. Should such challenges be successful** , **competitors might be able** ~~five (5) patent applications pending in the United States and thirty- one (31) patent applications pending in foreign jurisdictions relating~~ to **market products and use manufacturing processes that are substantially similar to** ~~our~~ **ours . Consequently, we may be unable to prevent our proprietary** technology ~~. These patents and patent applications mostly cover certain innovations relating to fat imaging, fat quantitation, and temperature monitoring in the liver and other tissues. Each of our utility patents generally~~

~~has a term of 20 years~~ from **being exploited abroad, which could affect our ability to expand to international markets** ~~its respective priority (earliest filing) date. Design patents have a term of 14 years from a respective filing date. Among our~~ - **or require costly efforts** ~~issued utility patents in the United States, the first patent is set~~ to ~~expire in 2033~~ **protect our technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our TAEUS platform,** ~~and~~ **brand and business. See** the ~~last patent is set to expire in 2041~~ **section of this Annual Report titled " Intellectual Property " under " Item 1. Business " for further information on our 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. ~~Policing~~ **25Policing** ~~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. 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. ~~27If~~ **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. ~~Additionally~~ **26Additionally** , 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. ~~Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively. In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. 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. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our TAEUS platform, brand and business. 28Risks Related to Government Regulation~~ 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 ~~. 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~~ . 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 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 ~~and~~ to obtain CE mark certification in order to **continue or commence** ~~market~~ **marketing** medical devices. The CE mark is applied following approval 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. ~~29We~~ **27We** 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. ~~International sales of medical devices manufactured in the United States that are not approved by the FDA for use in the United States, or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the United States due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first. Before a new medical device or a new intended use for an existing product can be marketed in the United States, a company must first submit and receive either 510 (k) clearance or premarketing approval, or PMA, from the FDA, unless an exemption applies.~~ Our NAFLD TAEUS device ~~will be~~ **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** ~~a de novo review is more likely to require~~ 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 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 TAEUS device may require approval by means of a PMA. 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. ~~Furthermore, even~~ **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. ~~30The~~ -- **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 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. ~~If~~ **28If** any of these events were to occur, our business and financial condition would be harmed **. We 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 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. ~~If~~ **29If** 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, 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. ~~31Healthcare reform measures could hinder or prevent our planned products' commercial success.~~ 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 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 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 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~~ ● **out** ability to generate revenues and achieve or maintain profitability; and ~~·~~ ● the availability of capital ~~. If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected~~ . 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; ~~32~~ · 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 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 part 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~~ **31Our** ~~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~~ 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; ~~33~~ · 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 ~~and warrants~~. 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. Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future~~. From January 1, ~~2022~~ **2023** through December 31, ~~2022~~ **2023**, intra- day trading prices of shares of our common stock ~~, on a Reverse Stock Split- adjusted basis (as discussed below in Item 7 under " Nasdaq Capital Market Listing and Reverse Stock Split "),~~ on the Nasdaq Capital Market fluctuated from a low of $ ~~3~~ **0**. ~~16~~ **87** to a high of $ ~~15~~ **5**. ~~80~~ **39**, and may continue to fluctuate significantly 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. ~~34We~~ **32Our stock is subject to minimum requirements to remain listed on the Nasdaq Capital Market, including a minimum bid price requirement, and** may be ~~subject to securities litigation~~ **delisted if it does not maintain compliance with those requirements. On January 5**, ~~which is expensive~~ **2022, 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 Company held a special meeting of the stockholders in November 2022 for the purpose of approving a reverse stock split. Following stockholder approval, the Company filed a Certificate of Amendment to the Company' s Fourth Amended** and **Restated Certificate of Incorporation with the Secretary of State of Delaware to effect a 1- for- 20 reverse stock split of the shares of the Company' s Common Stock, effective as of December 9, 2022 (the " Reverse Stock Split "). As a result of the 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** ~~could~~ **would** ~~divert management attention~~ **respond to such a reverse stock split**. In 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, ~~2022~~ **2023** to December 31, ~~2022~~ **2023** was approximately ~~51~~ **66**, ~~768~~ **369** 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** ~~We do not currently have and may never obtain research coverage by~~ securities ~~and~~ **or** industry ~~analysts. If no or few analysts commence research coverage of us, or one or more of the~~ analysts who cover us ~~issues an~~ **or may cover us in the future change their recommendation regarding our common stock** ~~adverse~~ **adversely** ~~opinion~~ **, or provide more favorable relative recommendations** about our ~~company~~ **competitors**, the price of our ~~securities~~ **common stock** would likely decline. If ~~one~~ **any securities** or **industry** ~~more of these analysts~~ **analyst who covers us or may cover us in the future were to** ~~ceases~~ **cease** ~~research~~ coverage of us or ~~fails~~ **fail** to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price ~~of our securities~~ 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. ~~Until~~ **33Until** 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. ~~Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.~~ 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. ~~35These~~ -- **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 ~~immediate~~ plans to pay dividends. 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. ~~Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.~~ 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** · 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. ~~36In~~ **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** ~~General Risk Factors Our business is affected by macroeconomic~~ ----- **economic** conditions **or political developments** ~~. Various macroeconomic factors~~ could adversely affect our business **,** ~~and the results of our operations and~~ financial condition ~~, including changes~~ **or results of operations. Our results of operations could be adversely affected by general conditions** in ~~inflation, interest rates~~ **the national or global economy** and ~~foreign currency exchange rates~~ **financial markets. For example, governmental statements, actions or policies, political unrest** and ~~overall~~ **global financial crises can cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged** economic ~~conditions and uncertainties~~ **downturn, political unrest or additional global financial crises** , including those resulting from the ~~current~~ **COVID- 19 pandemic** and ~~future conditions in~~ the **ongoing Russia- Ukraine war** ~~global financial markets. For instance~~ , **Israel- Hamas war** ~~we experienced inflationary pressures in 2022~~ and ~~expect such pressures to continue~~ **the conflict between China and Taiwan, could result** in ~~2023. Cost inflation~~ **a variety of risks to our business** , including ~~increases in raw material prices~~ **weakened demand for our products** , ~~labor rates~~ **if approved** , ~~and transportation costs may impact our~~ **or our** ~~profitability. Our~~ ability to **raise additional** ~~recover these cost increases through price increases is significantly limited by the process by which we are reimbursed for our products and services by government and private payers. The volatility of the~~ capital ~~markets~~ **when needed on acceptable terms, if at all. A weak or declining economy** could also **strain** ~~affect the value of~~ our **suppliers, possibly resulting** ~~investments and our ability to liquidate our investments~~ in **supply disruption** ~~order to fund our operations~~ . **Any of the foregoing** ~~Increasing interest rates and reduced access to capital markets~~ could **harm** ~~also adversely affect the ability of~~ our ~~suppliers, distributors, licensors, collaborators, contract manufacturers and other commercial partners to remain effective~~ business ~~partners or to remain in business. The loss of a critical business partner, or a failure to perform by a critical business partner, could have a disruptive effect on 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 ~~affect~~ **impact** our **business** ~~results of operations. Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail~~ . 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. ~~The ongoing military action by Russia in Ukraine could have negative impact on the global economy, which could materially adversely affect our business, operations, operating results and financial condition. In February 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the United States and other countries and companies and organizations against officials, individuals, regions, and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country' s potential response to such sanctions, tensions, and military actions could adversely affect the global economy and financial markets and thus could affect our business, operations, operating results and financial condition as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms. The extent and duration of the military action, sanctions and resulting market disruptions, including supply chain disruptions, are impossible to predict, but could be substantial. Any such disruptions caused by Russian military action or resulting sanctions may magnify the impact of other risks described in this Annual Report on Form 10- K.~~ 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 ~~. Our business could be negatively impacted by corporate social responsibility and sustainability matters~~ . 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**