Risk Factors Comparison 2024-03-29 to 2023-03-31 Form: 10-K

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The Company operates in a changing environment that involves numerous known and unknown risks and uncertainties that could materially adversely affect its operations. The following ~~highlights some~~ **is a summary** of ~~the~~ **certain important** factors that have affected, and / or in the future could affect, the Company' s operations **and** ~~. The following is a summary of certain important factors~~ that may make an investment in iCAD speculative or risky. You should carefully consider the fuller risk factor disclosure set forth in this Annual Report **on Form 10- K** , in addition to the other information herein, including the section of this report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and the Company' s financial statements and related notes. • The Company has incurred significant losses from inception through ~~2022~~ **2023** and there can be no assurance that we will be able to achieve and sustain future profitability. • The Company' s quarterly and annual operating and financial results and gross margins are likely to fluctuate significantly in future periods. • The Company **has been informed** ~~continues to be impacted~~ by ~~slowness in~~ the **FDA that** ~~overall economic recover related to the COVID- 19 pandemic. A continuation or~~ **our** ~~worsening of~~ **ProFound AI ® Risk product is appropriate for classification through** the ~~pandemic will~~ **De Novo pathway and** have ~~a material adverse impact on iCAD~~ **paused U. S. sales of the product until we obtain FDA regulatory clearance. • The Company** ' s **use of AI, machine learning, and automated decision making, including through the ProFound Breast Health Suite, gives rise to legal,** business, **and operational risks. Legal, regulatory, social and ethical issues relating to the use of AI and machine learning technologies in our offerings and business may** ~~results~~ **result** ~~of operations~~ **in reputational harm** and **liability** ~~financial condition and on the market price of iCAD' s common stock~~ . • The markets for the Company' s products and treatments and newly introduced enhancements to iCAD' s existing products and treatments may not develop as expected, the Company may continue to face barriers to broad market acceptance. • Sales and market acceptance of Company products is dependent upon the coverage and reimbursement decisions made by third- party payers, including carve- out radiology benefits managers. The failure of third- party payers to provide appropriate levels of coverage and reimbursement, and / or meeting prior authorization and other requirements for approval to use Company products and treatments facilitated by the Company' s products could harm the Company' s business and prospects. • A limited number of customers account for a significant portion of the Company' s total revenue. The loss of a principal customer could seriously hurt the Company' s business. ~~24~~ **16** • The markets for many of the Company' s products are subject to changing technology **. • The Company is subject to complex and evolving U. S. and foreign laws and regulations regarding privacy, data protection, and other matters. The Company may be subject to criminal or civil sanctions if it fails to comply with privacy and security regulations regarding the use and disclosure of sensitive personally identifiable information** . • Revenue from the Company' s new subscription license model may be difficult to predict. • The Company distributes its products in highly competitive markets and the Company' s sales may suffer as a result. • The Company relies on intellectual property and proprietary rights to maintain its competitive position and may not be able to protect these rights. • The Company' s future prospects depend on its ability to retain current key employees and attract additional qualified personnel. • The market price of the Company' s common stock has been, and may continue to be volatile, which could reduce the market price of the Company' s common stock. • Future issuances of shares of the Company' s common stock may cause significant dilution of equity interests of existing holders of common stock and decrease the market price of shares of the Company' s common stock. Risks Related to Financial Position, Operating Results and Need for Additional Capital The **rate at which the** Company **is** ~~' s shift~~ **shifting** to a ~~subscription~~ **software as a** service **(SaaS)** model is uncertain ~~, and there has not been broad market acceptance of the Company' s new products~~ . The Company **' s** ~~has further had difficulties migrating their applications to a cloud- based model. Our~~ success in growing revenue and market share from ~~our~~ subscription- based offerings will depend, to a large extent, on the willingness of ~~our~~ **the Company' s** customers and the markets we serve to accept this model for commercializing applications that they view as critical to the success of their businesses. Many companies have invested substantial effort and financial resources to integrate traditional enterprise software and IT staffing into their businesses and may be reluctant or unwilling to switch to a recurring fee model for our software applications or to migrate these applications to cloud- based services **. Conversely, the rate of adoption of this model may occur faster than the Company forecasted resulting in a short term impact to revenue due to recognizing subscription- based licenses ratably as well as an impact to cash as cash is also collected ratably vs all up front with perpetual models** . Other factors that may affect market acceptance of our products and cloud- based applications include: • the security capabilities, reliability and availability of cloud- based services; • customer concerns with entrusting a third party to store and manage their data, especially confidential or sensitive data; • our ability to ~~minimize~~ **invest** the time and resources required to offer our software under this model; • our ability to maintain high levels of customer satisfaction, including with respect to maintaining uptime and system availability standards consistent with market expectations; • our ability to implement upgrades and other changes to our software without disrupting our service; • the level of customization or configuration we offer; and • the price, performance and availability of competing products and services. The market for these services may not develop ~~further~~ **at the rate we expect** , ~~or may develop~~ **meaning adoption occurs** more slowly **or more quickly** than **forecasted** ~~we expect~~ , either of which would harm ~~our~~ **the Company' s** business. ~~Our~~ **The Company' s** business model continues to evolve and ~~we~~ **it** may not be able to compete effectively, generate significant revenues or maintain profitability for our subscription- based offerings. ~~We have~~ **The Company has** and will continue to incur expenses associated with the infrastructures and marketing of ~~our~~ subscription offerings in advance of ~~our~~ **its** ability to recognize the revenues associated with these offerings. Demand for ~~our~~ subscription, cloud- based services may

unfavorably impact demand for certain ~~of our~~ other products and services. With a continued shift away from the sale of perpetual software licenses to providing access to ~~our~~ software through subscription agreements ~~we~~ **the Company** may, in the near term, experience a deferral of revenues and to a lesser extent cash received from ~~our~~ customers. The Company has incurred significant losses from inception through ~~2022~~ **2023** and there can be no assurance that it will be able to achieve and sustain future profitability. The Company has incurred significant losses since inception. The Company incurred a net loss of approximately $ ~~14~~ **4. 9** million in ~~2022~~ **2023** and has an accumulated deficit of approximately $ ~~267~~ **272** million at December 31, ~~2022~~ **2023** . The Company may not be able to achieve profitability. Substantially all of our operating losses have resulted from costs incurred in connection with research and development efforts, including clinical studies, and from general and administrative costs associated with our operations ~~. We expect our operating expenses to significantly increase as we continue to invest in research and development efforts~~ . We also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur substantial and increasing operating losses for the foreseeable future. The Company' s quarterly and annual operating and financial results and its gross margins are likely to fluctuate significantly in future periods. The Company' s quarterly and annual operating and financial results are difficult to predict and may fluctuate significantly from period to period. The Company' s revenue and results of operations may fluctuate as a result of a variety of factors that are outside of the Company' s control including, but not limited to, general economic conditions, the timing of orders from the Company' s OEM partners, its OEM partners' ability to manufacture and ship their digital mammography systems, its timely receipt by the FDA for the clearance or approval to market Company products, its ability to timely engage other OEM partners for the sale of Company products, the timing of product enhancements and new product introductions by Company or its competitors, the pricing of Company products, changes in customers' budgets, changes to the economic strength of the Company' s customers, economic changes in the markets served by the Company' s customers, competitive conditions and the possible deferral of revenue under the Company' s revenue recognition policies. The Company may need to raise additional capital to fund its products, including manufacturing, sales and marketing activities, expand its investments in research and development, and commercialize new products and services. As of December 31, ~~2022~~ **2023** , the Company had cash and cash equivalents and investments in money market funds totaling $ 21. ~~3~~ **7** million. The Company expects its cash and cash equivalents and investments in money market funds will be able to fund its operations for at least the next twelve months. However, this does not reflect the possibility that the Company may not be able to access a portion of our existing cash and cash equivalents and investments in marketable securities due to market conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, the Company' s ability to access its cash and cash equivalents and investments in money market funds may be threatened and could have a material adverse effect on its business and financial condition. The Company may require additional capital to develop and commercialize its products and to develop new products. In addition, the Company' s operating plans may change as a result of many factors that may currently be unknown, and the Company may need to seek additional funds sooner than planned. The Company cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable, if at all. The terms of any future financing may adversely affect the holdings or the rights of the Company' s stockholders and the issuance of additional securities, whether equity or debt, by the Company, or the possibility of such issuance, may cause the market price of the Company' s common stock to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and the Company may be required to agree to certain restrictive covenants, such as limitations on its ability to incur additional debt, limitations on its ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact its ability to conduct business. The Company could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or products or otherwise agree to terms that are unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, raising additional capital through the issuance of equity or debt securities would cause dilution to holders of the Company' s equity securities and / or increased fixed payment obligations, and may affect the rights of then- existing holders of its equity securities. Furthermore, these securities may have rights senior to those of its common stock and could contain covenants that would restrict its operations and potentially impair its competitiveness, such as limitations on its ability to incur additional debt, limitations on its ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact its ability to conduct our business. Any of these events could significantly harm the Company' s business, financial condition and prospects. Even if the Company believes that it has sufficient funds for our current or future operating plans, the Company may seek additional capital if market conditions are favorable or if it has specific strategic considerations. ~~25Risks~~ **17Risks** Related to the Company and its Business **We have been informed by the FDA that our ProFound AI ® Risk product is appropriate for classification through the De Novo pathway and have paused U. S. sales of the product until we obtain FDA regulatory clearance. We have been informed by the FDA through a 513 (g) request for classification that, ProFound AI ® Risk may be suitable for classification under section 513 (f) (2) of the FDCA Act, also referred to as De Novo classification. Under the FDA Clinical Decision Support (CDS) Software Draft Guidance in effect in 2019 when the product was released, we believed that ProFound AI ® Risk met the definition of a clinical decision support software and at that time, based on the FDA' s then guidance, the FDA did not intend to enforce compliance with the applicable requirements of the FD & C Act, including, but not limited to, premarket clearance and premarket approval requirements. In September of 2022, the FDA issued their final CDS guidance which had several changes from the 2019 Draft Guidance that impacted iCAD' s original decision. In May of 2023 iCAD sent the FDA a request for pre- submission meeting and in November of 2023 iCAD sent the FDA a 513 (g) Request for Information submission regarding the requirements applicable to the product under the FDCA in order to determine the applicable**

regulatory pathway. In February of 2024, the Company received a response from the FDA indicating that ProFound AI Risk may be suitable for classification through the De Novo pathway. We have begun preparing our De Novo submission and expect to file the submission with the FDA later this year. While there have been no adverse safety issues reported in the U. S. by our customers which have deployed ProFound AI Risk, we have paused sales of ProFound AI ® Risk in the U. S. and will inform customers of our need to provide the FDA with additional information under their revised guidance. However, we do not currently intend to recall any licenses previously sold and granted as there is no risk of patient injury. Sales of ProFound AI ® Risk have not been significant to our aggregate sales and we have only made sales to a limited number of customers. Note that ProFound AI ® Risk is, however, approved for use in countries outside of the U. S. including Canada and the European Union, and we have received no reports of safety issues from any users. We are presently determining the optimal regulatory strategy designed to satisfy applicable FDA requirements. The changes in FDA guidance applicable to ProFound AI ® Risk do not affect sales of our other products which include our primary product ProFound AI ® Detection as well as ProFound AI ® Density. We may not be able to complete all activities necessary to comply with FDA De Novo Request (21 CFR 860. 220 [DB4] [JG5]) under the FD & C Act on a timely basis or without expending significant resources. We are unable to control the timing of FDA action and we may be required to provide additional information within certain timeframes. We also may be required to gather and prepare additional clinical data that are relevant to support reasonable assurance of the safety and effectiveness of the device or non- clinical data including bench performance testing. If the FDA determines that we have not satisfied its requirements, any failure of ours to address such requirements or provide requested documentation could disrupt our business operations related to the ProFound AI ® Risk product and the timing of our commercialization efforts and could have a material adverse effect on our financial condition and operating results. In addition, the FDA could take action against us for the period of time from the change in FDA guidance applicable to ProFound AI ® Risk to the present time, in connection with our decision not to recall the licenses previously sold and granted and could require us to recall the product in the future. We may also be at risk from claims made by our customers who have commenced sales of ProFound AI ® Risk to their customers. The markets for the Company' s products and ~~treatments and~~ newly introduced enhancements to the Company' s existing products ~~and treatments~~ may not develop as expected, the Company continues to face barriers to broad market acceptance. The successful commercialization of the Company' s newly developed products and treatments and newly introduced enhancements to the Company' s existing products and treatments are subject to numerous risks, both known and unknown, including: • market acceptance of the Company' s products; • uncertainty of the development of a market for such product or treatment; • trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than the Company' s products, technologies, treatments or therapies; • recommendation and support for the use of the Company' s products or treatments by influential customers, such as hospitals, radiological practices, breast surgeons and radiation oncologists and treatment centers and U. S. and international medical professional societies; • the availability and extent of data demonstrating the clinical efficacy of the Company' s products or treatments; • competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; ~~and~~ • other technological developments **; and • inherent risks related to AI, machine learning, and related fields** . ~~26Often~~ **18Often** , the development of a significant market for a product or treatment will depend upon the establishment of appropriate reimbursement for use of the product or treatment. Moreover, even if addressed, such reimbursement levels frequently are not established until after a product or treatment is developed and commercially introduced, which can delay the successful commercialization of a product or treatment. If the Company is unable to successfully commercialize and create a significant market for the Company' s newly developed products and treatments and newly introduced enhancements to the Company' s existing products and treatments, the Company' s business and prospects could be harmed. The Company may be exposed to significant product liability for which the Company may not have sufficient insurance coverage or be able to procure sufficient insurance coverage. The Company' s product and general liability insurance coverage may be inadequate with respect to potential claims and adequate insurance coverage may not be available in sufficient amounts or at a reasonable cost in the future. If available at all, product liability insurance for the medical device industry generally is expensive. Future product liability claims could be costly to defend and / or costly to resolve and could harm the Company' s reputation and business. Sales and market acceptance of the Company' s products is dependent upon the coverage and reimbursement decisions made by third- party payers, including carve- out radiology benefits managers. The failure of third- party payers to provide appropriate levels of coverage and reimbursement, and / or meeting prior authorization and other requirements for approval to use the Company' s products and treatments facilitated by the Company' s products could harm the Company' s business and prospects. Sales and market acceptance of the Company' s medical products and the treatments facilitated by Company products in the United States and other countries is dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. Market acceptance of the Company' s products and treatments has and will continue to depend upon the Company' s customers' ability to obtain coverage for, and appropriate reimbursement from third- party payers for, these products and treatments. In the United States, The Centers for Medicare and Medicaid Services (" CMS ") establishes coverage and reimbursement policies for healthcare providers treating Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for the Company' s products and treatments. In the absence of a national coverage determination, coverage policies for Medicare patients may vary by regional Medicare Administrative Contractors. Reimbursement rates for treatments vary based on the geographic price index, the site of service, and other factors. Coverage and reimbursement policies and rates applicable to patients with private insurance are dependent upon individual private payer decisions which may not follow the policies and rates established by CMS. The use of Company products and treatments outside the United States is similarly affected by coverage and reimbursement policies adopted by foreign

governments and, to a lesser extent, private insurance carriers. ~~On September 29, 2020, CMS finalized a rule regarding its new RO Model, designed, according to CMS, to improve the quality of care for cancer patients receiving radiotherapy and reduce Medicare expenditures through bundled payments. In the final notice, CMS did not include IORT treatments (including CPT codes 77424, 77425, and 77469) within the new alternative payment model for radiation oncology. As a result, whether or not a particular physician practice or hospital is subject to the new radiation oncology payment model, IORT services covered by Medicare will continue to be subject to the existing payment systems for physician services and hospital outpatient services. On December 10, 2021, the Protecting Medicare and American Farmers from Sequestration Cuts Act delayed the RO Model implementation until no earlier than January 1, 2023, when it became effective.~~ Management cannot provide assurance that government or private third- party payers will continue to reimburse the Company' s products or services, nor can management provide assurance that the payment rates will be adequate. If providers and physicians are unable to obtain adequate reimbursement for the Company' s products or services, this could have a material adverse effect on the Company' s business and operations. In addition, in the event that the current methodology for calculating payment for these products or services changes, this could have a material adverse effect on the Company' s business and business operations. ~~27Management~~ **19Management** cannot guarantee that providers and physicians will be able to obtain adequate reimbursement for the Company' s products or services **. The rapid evolution of AI and machine learning will require the application of resources to develop, test, and maintain the Company' s offerings, including but not limited to the ProFound Breast Health Suite, to help ensure that AI and machine learning are implemented responsibly in order to minimize unintended or harmful consequences. Uncertainty around new and emerging AI applications may require additional investment in the development of proprietary datasets, machine learning models, and systems to test for accuracy, bias, and other variables, which are often complex, may be costly, and could impact the Company' s profit margin as we expand the use of AI technologies in our offerings. There are significant risks involved in developing, maintaining, and deploying these technologies and there can be no assurance that the usage of such technologies will always enhance the Company' s products or services or be beneficial to our business, including our efficiency or profitability. In particular, AI or automated decision making technologies may be incorrectly designed or implemented; may be trained or reliant on incomplete, inadequate, inaccurate, biased, or otherwise poor quality data or on data to which the developer does not have sufficient rights; and / or may be adversely impacted by unforeseen defects, technical challenges, cyber security threats, or material performance issues. The Company' s ability to continue to develop or use such technologies may be dependent on access to technology offered by vendors and specific third- party software and infrastructure, such as processing hardware or third- party AI models, and the Company cannot control the quality of vendor offerings or the availability or pricing of such third- party software and infrastructure, especially in a highly competitive environment. The Company faces competition from other companies in its industry who use similar machine learning technologies to us. Failure to offer or deploy new AI technologies as effectively as the Company' s competitors could adversely affect our business. In addition, market acceptance and consumer perceptions of AI and machine learning technologies are uncertain. AI technologies, including generative AI, may create content or information that appears correct but is factually inaccurate or flawed. This may expose the Company to brand or reputational harm, competitive harm, consumer complaints, legal liability, and other adverse consequences, any of which could materially adversely affect the Company' s business, results of operations, and financial condition. The use of AI technologies presents emerging ethical and social issues, and if the Company enables or offers solutions that draw scrutiny or controversy due to their perceived or actual impact on the Company' s customers or on society as a whole, it may experience brand or reputational harm, competitive harm, consumer complaints, legal liability, and other adverse consequences, any of which could materially adversely affect the Company' s business, results of operations, and financial condition** . The Company' s business is dependent upon future market growth of full field digital mammography systems, digital computer aided detection products, and tomosynthesis as well as advanced image analysis ~~and workflow solutions for use with MRI and CT and the market growth of electronic brachytherapy~~ . This growth may not occur or may occur too slowly to benefit us. The Company' s future business is substantially dependent on the continued growth in ~~the market for electronic brachytherapy,~~ full field digital mammography systems, digital computer aided detection products and tomosynthesis as well as advanced image analysis and workflow solutions ~~for use with MRI and CT~~ . The market for these products may not continue to develop or may develop at a slower rate than the Company anticipates due to a variety of factors, including, general economic conditions, delays in hospital spending for capital equipment, the significant costs associated with the procurement of full field digital mammography systems and CAD products ~~and MRI and CT systems~~ and the reliance on third party insurance reimbursement. If the market for the products and technologies upon which the Company' s products are dependent does not grow or grows too slowly, this could have a material adverse effect on the Company' s business. A limited number of customers **and distribution partners** account for a significant portion of the Company' s total revenue. The loss of a principal customer could seriously hurt the Company' s business. A limited number of major customers have in the past and may continue in the future to account for a significant portion of the Company' s revenue. The Company' s principal sales distribution channel for its digital products is through its OEM partners. In ~~2022~~ **2023** , the Company' s OEM partners accounted for ~~26~~ **32** % of its total revenue, with one major ~~customer~~ **partner** , GE Healthcare, accounting for ~~16~~ **22** % of the Company' s revenue. In addition, in ~~2022~~ **2023** , **one** ~~four customers, consisting of both OEM and~~ direct ~~customers~~ **customer** , accounted for ~~29~~ **8** % of the Company' s total revenue **. Other than GE Healthcare, no individual customer or partner accounted for greater than 10 % of the Company' s total revenue for the year ended December 31, 2023** . The loss of the Company' s relationships with principal customers or a decline in sales to principal customers could materially adversely affect its business and operating results. The Company is devoting resources to the ~~development of~~ **transition to** a new software license model to complement its traditional perpetual licensing models. This model allows the Company to license ~~Detection~~ **its** software through subscription licenses **, generally for**

a three- year term, and that **potentially** may **not** be **renewed** ~~canceled at any time~~. The Company has limited operating history with subscription licensing models and may not be able to accurately predict initial subscription enrollment or future renewal or cancellation rates. Subscription renewal rates may decline or fluctuate as a result of a number of factors, including but not limited to customer satisfaction or dissatisfaction with Company products, the price of Company products, the prices of similar competitive products, or customer budget sensitivity. If any of the Company' s assumptions about revenue from the subscription licensing model are incorrect, the Company' s actual results may vary materially from those anticipated, estimated, or projected. If goodwill and / or other intangible assets that the Company has recorded in connection with its acquisitions become impaired, the Company could have to take significant charges against earnings. Under current accounting, management must assess, at least annually and potentially more frequently, whether the value of the Company' s goodwill of $ 8. 4 million at December 31, ~~2022~~ **2023** and its other intangible assets have been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect the Company' s reported results of operations in future periods. The Company' s effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued. As a global company, the Company is subject to ~~taxation~~ **a variety of taxes** in numerous countries, states and other jurisdictions. In preparing the Company' s financial statements, the Company records the amount of tax payable in each of the countries, states and other jurisdictions in which the Company operates. The Company' s future effective tax rate, however, may be lower or higher than prior years due to numerous factors, including a change in the Company' s geographic earnings mix, changes in the measurement of the Company' s deferred taxes, and recently enacted and future tax law changes in jurisdictions in which the Company operates. The Company is also subject to ongoing tax audits in various jurisdictions, and tax authorities may disagree with certain positions the Company has taken and assess additional taxes. Any of these factors could cause the Company to experience an effective tax rate significantly different from previous periods or the Company' s current expectations, which could adversely affect the Company' s business, results of operations and cash flows. ~~28The~~ **20The** Company' s ability to use its net operating loss carryovers and certain other tax attributes may be limited. Under the Internal Revenue Code of 1986, as amended (the " Code "), a corporation is generally allowed a deduction for net operating losses (" NOLs ") carried over from a prior taxable year. Under that provision, the Company can carryforward its NOLs to offset future taxable income, if any, until such NOLs are fully utilized or expire. The same is true of other unused tax attributes, such as tax credits. Under the Tax Cut and Jobs Act of 2017 (the " Tax Act "), federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the federal Tax Act. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percent change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. The Company may experience ownership changes in the future as a result of subsequent shifts in the Company' s stock ownership, some of which may be outside of the Company' s control. If an ownership change occurs and the Company' s ability to use its net operating loss carryforwards or other tax attributes is materially limited, it would harm the Company' s future operating results by effectively increasing the Company' s future tax obligations. The Company' s business depends on its ability to adapt to evolving technologies and industry standards and introduce new technology solutions and services accordingly. If the Company cannot adapt to changing technologies, its technology solutions and services may become obsolete, and its business may suffer. Because the healthcare information technology market is constantly evolving, the Company' s existing technology may become obsolete and fail to meet the requirements of current and potential customers. The Company' s success will depend, in part, on its ability to continue to enhance its existing technology solutions and services, develop new technology that addresses the increasingly sophisticated and varied needs of its customers, and respond to technological advances and emerging industry standards and practices on a timely and cost- effective basis. The development of the Company' s proprietary technology entails significant technical and business risks. The Company may not be successful in developing, using, marketing, selling, or maintaining new technologies effectively or adapting its proprietary technology to evolving customer requirements or emerging industry standards, and, as a result, the Company' s business and reputation could suffer. The Company may not be able to introduce new technology solutions on schedule, or at all, or such solutions may not achieve market acceptance. Moreover, competitors may develop competitive products that could adversely affect the Company' s results of operations. The Company' s failure to introduce new products or to introduce these products on schedule could have an adverse effect on its business, financial condition and results of operations. ~~The~~ **21The** ~~Company depends upon a limited number of suppliers and manufacturers for its products, and certain components in its products may be available from a sole or limited number of suppliers. The Company' s products are generally either manufactured and assembled for it by a sole manufacturer, by a limited number of manufacturers or assembled by the Company from supplies it obtains from a limited number of suppliers. Critical components required to manufacture the Company' s products, whether by outside manufacturers or directly by the Company, may be available from a sole or limited number of component suppliers. The Company generally does not have long- term arrangements with any of its manufacturers or suppliers. The loss of a sole or key manufacturer or supplier could materially impair the Company' s ability to deliver products to its customers in a timely manner and would adversely affect the Company' s sales and operating results. The Company' s business would be harmed if any of its manufacturers or suppliers could not meet its quality and performance specifications and quantity and delivery requirements. 29Additionally, the Company' s suppliers and manufacturers are, and will continue to be, subject to extensive government regulation in connection with the manufacture of any medical devices. The Company' s suppliers and manufacturers must ensure that they are compliant with applicable quality systems and other regulatory requirements, as mandated by the FDA and other regulatory authorities. If the Company' s materials suppliers or manufacturers face manufacturing or quality control problems this may lead to delays in product production or shipment or the Company' s~~

~~supplier or manufacturer no longer being able to continue operations. The Company' s business would be harmed if any of its manufacturers or suppliers could not meet its quality and performance specifications and quantity and delivery requirements.~~ ~~The~~ Company distributes its products in highly competitive markets and its sales may suffer as a result. The Company operates in highly competitive and rapidly changing markets that contain competitive products available from nationally and internationally recognized companies. Many of these competitors have significantly greater financial, technical and human resources than the Company and are well established. In addition, some companies have developed or may develop technologies or products that could compete with the products the Company manufactures and distributes or that would render the Company' s products obsolete or noncompetitive. **New business models, products and diagnostic tools are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as artificial intelligence and machine learning, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.** The Company' s competitors may achieve patent protection, regulatory approval, or product commercialization that would limit the Company' s ability to compete with them. These and other competitive pressures could have a material adverse effect the Company' s business. Disruptions in service or damage to the Company' s third- party providers' data centers could adversely affect the Company' s business. The Company relies on third parties who provide access to data centers. The Company' s information technologies and systems are vulnerable to damage or interruption from various causes, including (i) acts of God and other natural disasters, war and acts of terrorism and (ii) power losses, computer systems failures, internet and telecommunications or data network failures, operator error, losses of and corruption of data and similar events. The Company conducts business continuity planning and works with its third- party providers to protect against fires, floods, other natural disasters and general business interruptions to mitigate the adverse effects of a disruption, relocation or change in operating environment at the data centers the Company utilizes. In addition, the occurrence of any of these events could result in interruptions, delays or cessations in service to the Company' s customers. Any of these events could impair or prohibit the Company' s ability to provide its services, reduce the attractiveness of its services to current or potential customers and adversely impact its financial condition and results of operations. In addition, despite the implementation of security measures, the Company' s infrastructure, data centers, or systems that it interfaces with, including the Internet and related systems, may be vulnerable to physical break- ins, hackers, improper employee or contractor access, computer viruses, programming errors, denial- of- service attacks or other attacks by third- parties seeking to disrupt operations or misappropriate information or similar physical or electronic breaches of security. Any of these can cause system failure, including network, software or hardware failure, which can result in service disruptions. As a result, the Company may be required to expend significant capital and other resources to protect against security breaches and hackers or to alleviate problems caused by such breaches. ~~30Instability~~ **22Instability** in geographies where the Company has operations and personnel or where the Company derives revenue could have a material adverse effect on the Company' s business, customers, operations and financial results. Economic, civil, military and political uncertainty may arise or increase in regions where the Company operates or derives revenue. Further, countries from which the Company derives revenue may experience military action and / or civil and political unrest. For the fiscal year ended ~~2022~~ **2023** , approximately **13** ~~6. 0~~ % of the Company' s revenue was derived from customers **outside** ~~located in Europe, and approximately 24. 0 %~~ of the **U. S., primarily within** ~~Company' s export revenue was derived from customers located in~~ Europe. In late February 2022, Russian military forces launched significant military action against Ukraine. Sustained conflict and disruption in the region is likely. **In early October 2023, an armed conflict between Hamas-led Palestinian militant groups and Israeli military forces broke out with a Hamas attack on southern Israel, to which Israeli military forces retaliated. Sustained conflict and disruption in these regions is likely.** The aggregate impact to Eastern Europe and Europe as a whole **, and throughout the Middle East** , as well as actions taken by other countries, including new and stricter sanctions by the United States, Canada, the United Kingdom, the European Union, and other countries and organizations against officials, individuals, regions, and industries in Russia, Belarus and Ukraine, and each country' s potential response to such sanctions, tensions and military actions, is not knowable at this time, and could have a material adverse effect on the Company, its business and operations. Any such material adverse effect from the conflict and enhanced sanctions activity may disrupt the Company' s sales to customers in the region. Prolonged unfavorable economic conditions or uncertainty may have an adverse effect on the Company' s sales and profitability **.** If the Company' s products fail to perform properly due to errors or similar problems, the Company' s business could suffer. Despite testing, complex software may contain defects or errors. Addressing software errors may delay development of the Company' s solutions, and if discovered after deployment, may require the expenditure of substantial time and resources to correct. Errors in the Company' s software could result in: • harm to the Company' s reputation; • lost sales; • delays in commercial releases; • product liability claims; • delays in or loss of market acceptance of the Company' s solutions; • license terminations or renegotiations; • unexpected expenses and diversion of resources to remedy errors; and • privacy and security vulnerabilities. Furthermore, the Company' s customers might use its software together with products from other companies or those that they have developed internally. As a result, when problems occur, it might be difficult to identify the source of the problem. Even when the Company' s software does not cause these problems, the existence of these errors might cause the Company to incur significant costs, divert the attention of its technical personnel from the Company' s solution development efforts or impact its reputation

and cause significant customer relations problems. Unfavorable results of legal proceedings could materially adversely affect the Company' s financial results **.** From time to time, the Company is a party to or otherwise involved in legal proceedings, claims and government inspections or investigations and other legal matters, both inside and outside the United States, arising in the ordinary course of business or otherwise. Legal proceedings are often lengthy, taking place over a period of years with interim motions or judgments subject to multiple levels of review (such as appeals or rehearings) before the outcome is final. Litigation is subject to significant uncertainty and may be expensive, time- consuming, and disruptive to operations. For these and other reasons, the Company may choose to settle legal proceedings and claims, regardless of their actual merit. ~~31A~~ **23A** legal proceeding finally resolved against the Company, could result in significant compensatory damages, and in certain circumstances, punitive or trebled damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief. If the Company' s existing insurance does not cover the amount or types of damages awarded, or if other resolutions or actions taken as a result of the legal proceeding were to restrain the Company' s ability to market one or more of the Company' s material products or services, the Company' s consolidated financial position, results of operations or cash flows could be materially adversely affected. In addition, legal proceedings, and any adverse resolution thereof, can result in adverse publicity and damage to the Company' s reputation, which could adversely impact the Company' s business. If the Company is subject to claims that its employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, the Company could incur substantial expenses. The Company employ individuals who were previously employed at other medical device and technology companies. The Company may be subject to claims that the Company or its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of employees' former employers or other third parties. The Company may also be subject to claims that former employers or other parties have an ownership interest in patents or intellectual property. Litigation may be necessary to defend against these claims. The Company may not be successful in defending these claims, and if the Company is successful, litigation could result in substantial cost and be a distraction to its management and other employees. Healthcare industry consolidation could impose pressure on the Company' s prices, reduce potential customer base and reduce demands for the Company' s systems. Many hospitals and imaging centers have consolidated to create larger healthcare enterprises with greater market and purchasing power. When hospitals and imaging centers combine, they often consolidate infrastructure, and consolidation of the Company' s customers could result in fewer overall customers. If this consolidation trend continues, it could reduce the size of the Company' s potential customer base, reduce demand for the Company' s systems, give the resulting enterprises greater bargaining or purchasing power, and may lead to erosion of the prices for the Company' s systems or decreased margins for its systems, all of which would adversely affect the Company' s ability to generate revenue. Clinical trials are very expensive, lengthy, and difficult to design and implement and have uncertain outcomes, and, as a result, the Company may suffer delays or suspensions in current or future trials which would have a material adverse effect on the Company' s ability to obtain regulatory approvals timely or at all, and if the Company fails to receive such approvals, on its ability to generate revenues. Clinical trials involve a time- consuming and expensive process with an uncertain outcome, and the results of earlier trials are not necessarily predictive of future results. Human clinical trials are difficult to design and implement and very expensive, due in part to being subject to rigorous regulatory requirements. Additionally, the Company may encounter problems at any stage of the trials that cause it to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including: • non- approval of an investigational device exemption (IDE), which is required by the FDA for the study in humans of a significant risk device that is not approved for the indication being studied; • failure to reach an agreement with contract research organizations or clinical trial sites; • failure of third- party contract research organizations to properly implement or monitor the clinical trial protocols; • failure of IRBs to approve the Company' s clinical trial protocols or suspension or termination of the Company' s clinical trial by the IRB, DSMB, or the FDA; ~~32~~ **24** • **political or civil unrest or instability** ~~slower than expected rates of patient recruitment and enrollment~~ , ~~which may be further negatively impacted by the~~ **terrorism or epidemic or pandemics (including any risks related to or resulting from future variants of** COVID- 19 **) and** ~~global pandemic; • inability to retain patients in clinical trials, which may be further negatively impacted by the~~ **other similar outbreaks or events** ~~COVID- 19 lobal pandemic~~ ; • lack of effectiveness during clinical trials; • unforeseen safety issues; • inability or unwillingness of medical clinical investigators and institutional review boards to follow the Company' s clinical trial protocols; • failure of clinical investigators or sites to maintain necessary licenses or permits or comply with good clinical practices, or GCP, or other regulatory requirements; and • lack of sufficient funding to finance the clinical trials. In addition, the Company or regulatory authorities may suspend the Company' s clinical trials at any time if it appears that the Company is exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in the Company' s regulatory submissions or the conduct of these trials. Any suspension of clinical trials will delay possible regulatory approval, increase costs, and adversely impact the Company' s ability to develop products and generate revenue. The Company' s success depends in large part on the continued service of its executive officers and other key employees. The Company may not be able to retain the services of its executive officers and other key employees. The loss of executive officers or other key personnel could have a material adverse effect on the Company. During the year ended December 31, ~~2022~~ **2023** , the Company underwent changes in management, including changes to the Company' s Chief Executive Officer, Chief Financial Officer and Chair of the Board. In addition, in order to support its continued growth, the Company will be required to effectively recruit, develop and retain additional qualified personnel. If the Company is unable to attract and retain additional necessary personnel, it could delay or hinder its plans for growth. Competition for such personnel is intense, and there can be no assurance that the Company will be able to successfully attract, assimilate or retain sufficiently qualified personnel. The failure to retain and attract necessary personnel could have a material adverse effect on the Company' s business, financial condition and results of operations. The Company' s international operations expose it to various risks, any number of which could harm the Company' s business. The Company' s revenue from sales outside of the United States represented approximately ~~25~~ **13** % of the Company' s revenue for

~~2022~~ **2023** . The Company is subject to the risks inherent in conducting business across national boundaries, any one of which could adversely impact its business. In addition to currency fluctuations, these risks include, among other things: economic downturns; changes in or interpretations of local law, governmental policy or regulation; changes in healthcare practice patterns; restrictions on the transfer of funds into or out of the country; varying tax systems; and government protectionism. One or more of the foregoing factors could impair the Company' s current or future operations and, as a result, harm the Company' s overall business. The requirements of being a publicly traded company may strain the Company' s resources and divert management' s attention. As a publicly traded company, the Company has incurred, and will continue to incur, significant legal, accounting and other expenses that the Company did not incur as a private company. In addition, the Sarbanes- Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act ") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas such as " say on pay " and proxy access. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which the Company operates its business in ways the Company cannot currently anticipate. The Company' s management and other personnel devote, and will continue to devote, a substantial amount of time to these compliance initiatives. Failure to comply with these requirements could subject the Company to enforcement actions by the SEC, divert management' s attention, damage our reputation, and adversely affect the Company' s business, results of operations, or financial condition ~~. In particular, if the Company' s independent registered public accounting firm is not able to render the required unqualified attestation, it could result in a loss of investor confidence in the accuracy, reliability, and completeness of our financial reports~~ . The Company may be unable to comply with the applicable continued listing requirements of Nasdaq. The Company' s common stock is currently listed on Nasdaq. In order to maintain this listing, the Company must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our common stock of $ 1. 00 per share. There can be no assurance that the Company we will be able to comply with the applicable listing standards. For example, if the Company were to fail to meet the minimum bid price requirement for 30 consecutive business days, the Company could become subject to delisting. **25Risks** ~~The Company expects the novel coronavirus (COVID- 19) pandemic, including the emergence of new variants, to have a significant effect on the Company' s results of operations. In addition, the pandemic has resulted in significant financial market volatility, and its impact on the global economy appears to be significant. A continuation or worsening of the pandemic will have a material adverse impact on the Company' s business, results of operations and financial condition and on the market price of the Company' s common stock. As a provider of devices and services to the health care industry, the Company' s operations have been materially affected, and may continue to be impacted, by the COVID- 19 pandemic. Beginning with the first quarter of 2020 through the year- ended December 31, 2022, the COVID- 19 pandemic has presented a number of challenges and risks for the Company' s business, including, but not limited to, decreased product demand due to reduced numbers of in- person meetings with potential clients; pandemic- related public health impacts, including significant shifts in workforce availability and priorities, on customer, supplier, and iCAD' s business process; supply chain interruptions; disruptions to the Company' s clinical trials; challenges operating in a virtual work environment; impacts resulting from travel limitations and mobility restrictions; and other challenges presented by disruptions to the Company' s normal operations in response to the pandemic, as well as uncertainties regarding the duration and severity of the pandemic on the global economy and the Company' s operations, and the unpredictable and periodic emergence of new variants of the COVID- 19 virus. Although the Company does not provide guidance to investors relating to the Company' s results of operations, the Company' s quarterly results for the quarter ending March 31, 2023, and possibly future quarters, could reflect a continued negative impact from the COVID- 19 pandemic for similar or additional reasons. The Company' s exposure to trade accounts receivable losses may increase if its customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID- 19 pandemic, or other customer- specific factors. The Company has historically not experienced significant trade account receivable losses, but it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade account receivables as hospitals' cash flows are impacted by their response to the COVID- 19 pandemic. 33Risks~~ Related to Intellectual Property The Company relies heavily on proprietary technology that it protects primarily through licensing arrangements, patents, trade secrets, proprietary know- how and non- disclosure agreements. There can be no assurance that any pending or future patent applications will be granted or that any current or future patents, regardless of whether the Company is an owner or a licensee of the patent, will not be challenged, rendered unenforceable, invalidated, or circumvented or that the rights will provide a competitive advantage to the Company. There can also be no assurance that the Company' s trade secrets or non- disclosure agreements will provide meaningful protection of Company proprietary information. Further, the Company cannot assure that others will not independently develop similar technologies or duplicate any technology developed by the Company or that its technology will not infringe upon patents or other rights owned by others. Unauthorized third parties may infringe the Company' s intellectual property rights or copy or reverse engineer portions of the Company' s technology. In addition, because patent applications in the United States are not generally publicly disclosed until eighteen months after the application is filed, applications may have been filed by third parties that relate to the Company' s technology. Moreover, there is a risk that foreign intellectual property laws will not protect the Company' s intellectual property rights to the same extent as intellectual property laws in the United States. The rights provided by a patent are finite in time. The Company has certain patents that expire between ~~2023~~ **2024** and ~~2029~~ **2040** . In the absence of significant patent protection, the Company may be vulnerable to competitors who attempt to copy the Company' s products, processes or technology. In addition, in the future, the Company may be required to assert infringement claims against third

parties, and there can be no assurance that one or more parties will not assert infringement claims against the Company. Any resulting litigation or proceeding could result in significant expense to the Company and divert the efforts of its management personnel, whether or not such litigation or proceeding is determined in the Company' s favor. In addition, if any of the Company' s intellectual property and proprietary rights are deemed to violate the proprietary rights of others, the Company may be prevented from using those intellectual property or proprietary rights, which could prevent it from being able to sell its products. Litigation could also result in a judgment or monetary damages being levied against the Company. If the Company fails to obtain licenses to necessary intellectual property or does not comply with its obligations in license agreements, the Company could lose important rights. The Company may need to obtain licenses from owners of intellectual property to advance its research and products or allow commercialization of its products, and the Company has done so from time to time. If the Company does not obtain any of these licenses at a reasonable cost and on reasonable terms, the Company would be unable to further develop and commercialize one or more of its products, which could harm the Company' s business. Risks Related to Regulation of the Company' s Industry The healthcare industry is highly regulated, and government authorities may determine that the Company has failed to comply with applicable laws, rules or regulations. Additionally, the Company may incur substantial costs defending its interpretations of U. S. federal and state government regulations, and if the Company loses, the government could force the Company to restructure its operations and subject it to fines, monetary penalties and possibly exclude the Company from participation in U. S. government- sponsored health care programs such as Medicare and Medicaid. Both in the United States and in other jurisdictions, the healthcare industry is subject to extensive and complex federal, state and local laws, rules and regulations, compliance with which imposes substantial costs on the Company. Such laws and regulations include those that are directed at payment for services and the conduct of operations, preventing fraud and abuse, and prohibiting general business corporations, such as the Company' s, from engaging in practices that may influence professional decision- making, such as splitting fees with physicians. In addition, the Company believes that its business will continue to be subject to increasing regulation as legislatures and governmental agencies periodically consider proposals to revise or create new requirements, particularly in response to and following the COVID- 19 pandemic, the scope and effect of which the Company cannot predict. Such proposals, if implemented, could impact the Company' s operations, the use of its services, and its ability to market new services, and could create unexpected liabilities for the Company. ~~34Many~~ **26Many** healthcare laws are complex, and their application to specific services and relationships may not be clear. The laws often have related rules and regulations that are subject to interpretation and may not provide definitive guidance as to their application to the Company' s operations, including its arrangements with physicians and professional corporations. Further, healthcare laws differ from jurisdiction to jurisdiction and it is difficult to ensure the Company' s business complies with evolving laws in all jurisdictions. Consequently, the Company' s operations, including its arrangements with healthcare providers, are subject to audits, inquiries and investigations from government agencies from time to time. The Company believes it is in substantial compliance with these laws, rules and regulations based upon what the Company believes are reasonable and defensible interpretations of these laws, rules and regulations. However, U. S. federal and state laws are broadly worded and may be interpreted or applied by prosecutorial, regulatory or judicial authorities in ways that the Company cannot predict. Accordingly, the Company may in the future become the subject of regulatory or other investigations or proceedings, and its interpretations of applicable laws, rules and regulations may be challenged. Any challenge to the Company' s operations or arrangements with third parties that the Company has structured based upon its interpretation of these laws, rules and regulations could potentially disrupt business operations and lead to substantial defense costs and a diversion of management' s time and attention, even if the Company successfully defends its interpretation. In addition, if the government successfully challenges the Company' s interpretation of the applicability of these laws, rules and regulations as they relate to its operations and arrangements, such successful challenge may have a material adverse effect on the Company' s business, financial condition, results of operations, cash flows, and the trading price of the Company' s common stock. In the event regulatory action were to limit or prohibit the Company from carrying on its business as it presently conducts it or from expanding its operations into certain jurisdictions, the Company may need to make structural, operational and organizational modifications to the Company or to its contractual arrangements with physicians and professional corporations. The Company' s operating costs could increase significantly as a result. The Company could also lose contracts, or its revenues could decrease under existing contracts. Any restructuring would also negatively impact the Company' s operations because its management' s time and attention would be diverted from running its business in the ordinary course. Compliance with the many laws and regulations governing the healthcare industry could restrict the Company' s sales and marketing practices, and other relationships with healthcare professionals. Once the Company' s products are sold, the Company must comply with various U. S. federal and state healthcare fraud and abuse laws, rules and regulations pertaining false claims, kickbacks and physician self- referral. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers' compensation programs and TRICARE. Compliance with these laws could restrict the Company' s sales and marketing practices, and any challenge to the Company' s practices could disrupt its operations and lead to substantial defense costs and a diversion of management' s time and attention, even if the Company successfully defends its practices. If the Company is unable to successfully defend its practices, in addition to incurring significant expense in defending itself, the Company could be subject to a significant settlement, monetary penalties, and costs related to implementation of changes to its practices, which could have a material adverse effect on its business. Healthcare reform legislation in the United States may adversely affect the Company' s business and / or results of operations. The Company is unable to predict what legislation or regulation relating to the health care industry or third- party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on the Company' s business. Any cost containment measures or other health care system reforms that are adopted could have a material and adverse effect on the Company' s ability to commercialize its existing and future products successfully. The Company cannot predict

whether any existing or enacted legislation will be repealed, replaced, or modified or how such repeal, replacement or modification may be timed or structured. ~~35As~~ **27As** a result, the Company cannot quantify or predict the effect of such repeal, replacement, or modification might have on its business and results of operations. However, any changes that lower reimbursement for the Company' s products or reduce medical procedure volumes could adversely affect its business and results of operations. The Company' s products and manufacturing facilities are subject to extensive regulation with potentially significant costs for compliance. In the United States, the Company' s CAD systems ~~and Xoft Systems~~ are medical devices subject to extensive regulation by the FDA under the FDCA. The FDA' s regulation of the Company' s products includes its manufacturing operations, product labeling, adverse event reporting, and the FDA' s general prohibition against promoting products for unapproved or " off- label " uses. The Company' s failure to fully comply with applicable regulations could result in the issuance of warning letters, non- approvals, suspensions of existing approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution. Moreover, unanticipated changes in existing regulatory requirements or adoption of new requirements could increase the Company' s operating and compliance burdens and adversely affect its business, financial condition and results of operations. Sales of the Company' s products in certain countries outside of the United States are also subject to extensive regulatory approvals. Obtaining and maintaining foreign regulatory approvals is an expensive and time- consuming process. The Company cannot be certain that it will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which the Company plans to market its CAD products ~~and Xoft Systems~~, and if the Company fails to receive such approvals, its ability to generate revenue may be significantly diminished. The Company may not be able to obtain regulatory approval for any of the other products that we may consider developing. The Company has received the required premarket approvals from FDA or the equivalent foreign authority in the relevant jurisdictions in which its currently offers its products. Before the Company is able to commercialize any new product or promote a new indicated use of an existing product, it must obtain the required regulatory approvals. The process for satisfying these regulatory requirements is lengthy and costly and will require the Company to comply with complex standards for research and development, clinical trials, testing, manufacturing, quality control, labeling, and promotion of products. Additionally, even if the Company receives regulatory approval for a new product or indicated use in one jurisdiction, its products may be subject to separate regulatory approval in each country or jurisdiction in which the Company plans to market its products. The Company cannot be certain that it will be able to obtain the necessary regulatory approvals timely or at all in any country or jurisdiction. Successfully obtaining regulatory approval in one jurisdiction does not guarantee approval in another; however, a delay or failure to obtain regulatory approval in one jurisdiction may negatively affect the regulatory process in another. If the Company is unable to obtain regulatory approval for other products or indicated uses, its ability to generate sufficient revenue to continue its business may be significantly impacted. The Company' s products may be recalled even after it has received FDA or other governmental approval or clearance. If the safety or efficacy of any of the Company' s products is called into question, the Company may initiate or the FDA and similar governmental authorities in other countries may press the Company to implement or even require a product recall, even if the Company' s product received approval or clearance by the FDA or a similar governmental body. Such a recall would divert the focus of the Company' s management and its financial resources and could materially and adversely affect the Company' s reputation with customers and its financial condition and results of operations. **28Strategic transactions** ~~36The Company is subject to complex and evolving U. S. and foreign laws and regulations regarding privacy~~, ~~data protection~~ **acquisitions or joint ventures could disrupt our business , cause dilution to our stockholders** and **otherwise harm our business and results of operations, and the Company may not receive the intended benefits of any such activities. We may engage in strategic transactions, acquire** other ~~matters~~ **businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses** . ~~The Company may~~ **Any of these transactions could** be ~~subject~~ **material** to ~~criminal or~~ **our** ~~civil~~ **financial condition and operating results and expose us to many risks, including: • disruption in our relationships with customers, distributors, manufacturers or suppliers as a result of such a transaction; • unanticipated liabilities related to acquired companies; • difficulties integrating acquired personnel, technologies and operations into our existing business; • diversion of management' s time and focus away from operating our business to acquisition integration challenges; • increases in our expenses and reductions in our cash available for operations and other uses; and • possible write- offs or impairment charges relating to acquired businesses. In addition, the anticipated benefit of any transaction may not materialize. For example, in October 2023, the Company transferred substantially all of the assets and liabilities primarily related to the Company' s Xoft business lines for total consideration of approximately $ 5. 76 million dollars, in part, to allow the Company to capitalize and focus on the Company' s Profound AI and related products and proposed products. Future** ~~sanctions~~ **transactions , including acquisitions or dispositions, could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures, acquisitions, or other transactions,** if **any, or** ~~it fails to comply with privacy and security regulations regarding~~ the ~~use and disclosure of sensitive personally identifiable information~~ **effect that any such transactions might have on our operating results** . Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability and integrity of personally identifiable information, including HIPAA. In the provision of services to the Company' s customers, the Company and its third- party vendors may collect, use, maintain and transmit patient health information in ways that are subject to many of these laws and regulations. The Company is also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U. S. laws, including in particular the laws of Europe. The Company' s customers are covered entities, and the Company is a business associate of its customers under HIPAA as a result of the Company' s contractual obligations to perform certain functions on behalf of and provide certain services to those customers. In the ordinary course of business, the Company

collects and stores sensitive data, including personally identifiable information received from its customers. The secure processing, maintenance and transmission of this information is critical to the Company' s operations. Despite its security measures and business controls, the Company' s information technology and infrastructure may be vulnerable to attacks by hackers, breached due to employee error, malfeasance or other disruptions or subject to the inadvertent or intentional unauthorized release of information. Any such occurrence could compromise the Company' s networks and the information stored thereon could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information by the Company or its subcontractors could (i) result in legal claims or proceedings, liability under laws that protect the privacy of personal information and regulatory penalties, (ii) disrupt the Company' s operations and the services it provides to its customers and (iii) damage the Company' s reputation, any of which could adversely affect the Company' s profitability, revenue and competitive position. Federal and state consumer laws are being applied increasingly by the Federal Trade Commission and state attorneys general to regulate the collection, use and disclosure of personal or patient health information, through web sites or otherwise, and to regulate the presentation of web site content. Numerous other federal and state laws protect the confidentiality, privacy, availability, integrity and security of personally identifiable information. These laws in many cases are more restrictive than, and not preempted by, HIPAA and may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for the Company and its customers and potentially exposing the Company to additional expense, adverse publicity and liability. The Company may not remain in compliance with the diverse privacy requirements in each of the jurisdictions in which it does business. HIPAA and federal and state laws and regulations may require users of personally identifiable information to implement specified security measures. Evolving laws and regulations in this area could require the Company to incur significant additional costs to re- design its products in a timely manner to reflect these legal requirements, which could have an adverse impact on its results of operations. New personally identifiable information standards, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which the Company must handle healthcare related data, and the cost of complying with standards could be significant. If the Company does not properly comply with existing or new laws and regulations related to patient health information, it could be subject to criminal or civil sanctions. **29The Company is subject to complex and evolving U. S. and foreign laws and regulations regarding AI, machine learning, and automated decision making. The Company' s business increasingly relies on machine learning, AI, and automated decision making. However, in recent years the use of personal data to train, or otherwise in connection with machine learning, AI and automated decision making, has come under increased regulatory scrutiny, and governments and regulators in the United States, European Union, and other places have announced the need for greater regulation regarding the use of machine learning and AI generally. New laws, guidance, and decisions in this area may limit the Company' s ability to use machine learning and AI, or require the Company to make changes to its platform or operations that may decrease our operational efficiency, result in an increase to operating costs and / or hinder our ability to improve our services. For example, certain global privacy laws regulate the use of automated decision making and may require that the existence of automated decision making be disclosed to the data subject with a meaningful explanation of the logic used in such decision making in certain circumstances, and that safeguards must be implemented to safeguard individual rights, including the right to obtain human intervention and to contest any decision. Other global privacy laws allow individuals the right to opt out of certain automated processing of personal data and create other requirements that impact automated decision- making. At the federal level, the president of the United States recently issued an Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, which charges multiple agencies, including The National Institute of Standards and Technology, with producing guidelines in connection with the development and use of AI. In the European Union, there is now political agreement on the EU AI Act, which establishes a comprehensive, risk- based governance framework for AI in the EU market. The EU AI Act is expected to enter into force in 2024, and the majority of the substantive requirements will apply two years later (beginning 2026). The EU AI Act will apply to companies that develop, use and / or provide AI in the European Union and includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security, accuracy, general purpose AI and foundation models, and proposes fines for breach of up to 7 % of worldwide annual turnover (revenue). Additionally, in September of 2022, the European Commission proposed two Directives seeking to establish a harmonized civil liability regime for AI in the European Union, in order to facilitate civil claims in respect of harm caused by AI and to include AI- enabled products within the scope of the European Union' s existing strict liability regime. Once fully applicable, the EU AI Act will have a material impact on the way AI is regulated in the European Union, and together with developing guidance and / or decisions in this area, may affect our use of AI and our ability to provide, improve, or commercialize our services, and could require additional compliance measures and changes to our operations and processes. Moreover, the intellectual property ownership and license rights, including copyright, surrounding AI technologies has not been fully addressed by courts or laws or regulations, and the use or adoption of AI technologies into our offerings may result in exposure to claims of copyright infringement or other intellectual property misappropriation. As the legal and regulatory framework for AI and automated decision making evolves, we may not always be able to anticipate how to respond to these laws or regulations, and compliance may adversely impact our operations and involve significant expenditure and resources. Any failure by us to comply may result in significant liability, potential increases in civil claims against us, negative publicity, an erosion of trust, and / or increased regulation and could materially adversely affect our business, results of operations, and financial condition.** ~~37Data~~ -- **Data** protection laws in the United States, Europe and around the world may restrict the Company' s activities and increase the Company' s costs. Various statutes and rules in the United States, Europe and around the world regulate privacy and data protection which may affect the Company' s collection, use, storage, and transfer of information both abroad and in the United States. New laws and regulations are being

enacted, so that this area remains in a state of flux. Monitoring and complying with these laws requires substantial financial resources. Failure to comply with these laws may result in, among other things, civil and criminal liability, negative publicity, restrictions on further use of data, and / or liability under contractual warranties. In addition, changes in these laws (including newly released interpretations of these laws by courts and regulatory bodies) may limit the Company' s data access, use and disclosure, and may require increased expenditures by us. The European Union' s General Data Protection Regulation (" GDPR ") requires the Company to meet new and more stringent requirements regarding the handling of personal data about EU residents. Failure to meet the GDPR requirements could result in penalties of up to 4 % of worldwide revenue. ~~Risk~~ **Risks** Related to the Company' s Common Stock A substantial number of shares of the Company' s common stock are eligible for future sale, and the sale of shares of common stock into the market, or the perception that such sales may occur, may depress the Company' s stock price. Sales of substantial additional shares of the Company' s common stock in the public market, or the perception that these sales may occur, may significantly lower the market price of the Company' s common stock. The Company is unable to estimate the amount, timing or nature of future sales of shares of its common stock. The Company has previously issued a substantial number of shares of common stock, which are eligible for resale under Rule 144 of the Securities Act of 1933, as amended (the " Securities Act "), and may become freely tradable. The Company has also registered shares that are issuable upon the exercise of options and warrants. If holders of options, or warrants choose to exercise or convert their securities and sell shares of common stock issued upon ~~the~~ such exercise or conversion in the public market or if holders of currently restricted common stock choose to sell such shares of common stock in the public market under Rule 144 or otherwise, or attempt to publicly sell such shares all at once or in a short time period, the prevailing market price for the Company' s common stock may decline. ~~38Provisions~~ **30Provisions** in the Company' s Certificate of Incorporation and in Delaware law could make it more difficult for a third party to acquire the Company, discourage a takeover and adversely affect existing stockholders. The Company' s Certificate of Incorporation authorizes the Board of Directors **(the" Board")** to issue up to 1, 000, 000 shares of preferred stock. The preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by the Company' s Board ~~of Directors~~ , without further action by stockholders, and may include, among other things, voting rights (including the right to vote as a series on particular matters), preferences as to dividends and liquidation, conversion and redemption rights, and sinking fund provisions. Although there are currently no shares of preferred stock outstanding, future holders of preferred stock may have rights superior to the Company' s common stock and such rights could also be used to restrict the Company' s ability to merge with or sell its assets to a third party. The Company is also subject to the provisions of Section 203 of the Delaware General Corporation Law, which could prevent the Company from engaging in a " business combination " with a 15 % or greater stockholder for a period of three years from the date such person acquired that status unless appropriate board or stockholder approvals are obtained. These provisions could deter unsolicited takeovers or delay or prevent changes in the Company' s control or management, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market price. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests. The publicly traded shares of the Company' s common stock have experienced, and may experience in the future, significant price and volume fluctuations. This market volatility could reduce the market price of the Company' s common stock without regard to its operating performance. In addition, the trading price of the Company' s common stock could change significantly in response to actual or anticipated variations in its quarterly operating results, announcements by the Company or its competitors, factors affecting the medical imaging industry generally, changes in national or regional economic conditions, changes in securities analysts' estimates for the Company or its competitors' or industry' s future performance or general market conditions, making it more difficult for shares of the Company' s common stock to be sold at a favorable price or at all. The market price of the Company' s common stock could also be reduced by general market price declines or market volatility in the future or future declines or volatility in the prices of stocks for companies in the Company' s industry. **The Company has previously issued options that are exercisable or convertible into a significant number of shares of its common stock. Should existing holders of options exercise their options for shares of the Company' s common stock, it may cause significant dilution of equity interests of existing holders of the Company' s common stock and reduce the market price of shares of the Company' s common stock. On August 11, 2023, the Company entered into an at- the- market issuance sales agreement (the " Sales Agreement ") with Craig- Hallum Capital Group LLC whereby the Company, at its discretion, may issue and sell up to $ 25 million of shares of the Company' s common stock, from time to time, by any method deemed to be an " at- the- market " offering, as defined in Rule 415 of the Securities Act, or any method specified in the Sales Agreement. During the year ended December 31, 2023, the Company sold 1, 057, 814 shares of its common stock at a weighted average price of $ 2. 18 per share resulting in cash proceeds of $ 2. 0 million, net of issuance costs, pursuant to the Sales Agreement. Subsequent to December 31, 2023, the Company has not sold additional shares of its common stock. To the extent we raise additional capital by issuing equity securities (including but not limited to securities issued in connection with the Sales Agreement), our shareholders may experience substantial dilution.** ~~39General~~ **31General** Risk Factors Security breaches and other disruptions could compromise the Company' s information and expose the Company to liability, which would cause its business and reputation to suffer and could subject it to substantial liabilities. If the Company' s security measures are breached or fail and unauthorized access is obtained to a customer' s data, the Company' s service may be perceived as insecure, the attractiveness of its services to current or potential customers may be reduced, and the Company may incur significant liabilities. The Company' s services involve the storage and transmission of customers' proprietary information and patient information, including health, financial, payment and other personal or confidential information. The Company relies on proprietary and commercially available systems, software, tools and monitoring, as well as other processes, to provide security for processing, transmission and storage of such information. Because of the sensitivity of this information and due to requirements under applicable laws and regulations, the effectiveness of such security efforts is very important. However, there can be no assurance

that the Company will not be subject to cybersecurity incidents that bypass its security measures, impact the integrity, availability or privacy of personally identifiable information or other data subject to privacy laws or disrupt the Company' s information systems, devices or business, including its ability to deliver services to its customers. As a result, cybersecurity, physical security and the continued development and enhancement of the Company' s controls, processes and practices designed to protect its enterprise, information systems and data from attack, damage or unauthorized access remain a priority. As cyber threats continue to evolve, the Company may be required to expend significant additional resources to continue to modify or enhance its protective measures or to investigate and remediate any cybersecurity vulnerabilities. The occurrence of any of these events could result in (i) harm to customers; (ii) business interruptions and delays; (iii) the loss, misappropriation, corruption or unauthorized access of data; (iv) litigation, including potential class action litigation, and potential liability under privacy, security and consumer protection laws or other applicable laws; (v) reputational damage; and (vi) federal and state governmental inquiries, any of which could have a material, adverse effect on the Company' s financial position and results of operations and harm its business reputation. **See " Item IC. Cybersecurity " for more information.** Changes in interpretation or application of Accounting Principles Generally Accepted in the United States of America (" GAAP ") may adversely affect the Company' s operating results. Management prepares the Company' s consolidated financial statements to conform to GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board (" FASB "), American Institute of Certified Public Accountants, the SEC and various other regulatory or accounting bodies. A change in interpretations of, or management' s application of, these principles can have a significant effect on the Company' s reported results and may even affect the Company' s reporting of transactions completed before a change is announced. In addition, when the Company is required to adopt new accounting standards, the Company' s methods of accounting for certain items may change, which could cause the Company' s results of operations to fluctuate from period to period and make it more difficult to compare the Company' s financial results to prior periods. As the Company' s operations evolve over time, the Company may introduce new products or new technologies that require it to apply different accounting principles, including ones regarding revenue recognition, than the Company has applied in past periods. The application of different types of accounting principles and related potential changes may make it more difficult to compare the Company' s financial results from quarter to quarter, and the trading price of the Company' s common stock could suffer or become more volatile as a result. The Company cannot be certain of the future effectiveness of its internal controls over financial reporting or the impact of the same on its operations or the market price for the Company' s common stock. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002 (" Section 404 "), the Company is required to include in its Annual Report on Form 10- K its assessment of the effectiveness of the Company' s internal controls over financial reporting. The Company has dedicated a significant amount of time and resources to ensure compliance with this legislation for the year ended December 31, ~~2022~~ **2023** and will continue to do so for future fiscal periods. Although the Company believes that it currently has adequate internal control procedures in place, it cannot be certain that its internal controls over financial reporting will continue to be effective. If the Company cannot adequately maintain the effectiveness of its internal controls over financial reporting, it might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect the Company' s financial results and the market price of its common stock. ~~40Changes~~ **32Changes** in credit markets or to the Company' s credit rating could impact its ability to obtain financing for business operations or result in increased borrowing costs and interest expense. The Company' s credit ratings reflect each credit rating agency' s opinion of its financial strength, operating performance and ability to meet its debt obligations at the time such opinion is issued. The Company utilizes the short- and long- term debt markets to obtain capital from time to time. Adverse changes in the Company' s credit ratings may result in increased borrowing costs for future long- term debt or short- term borrowing facilities and may limit financing options, including access to the unsecured borrowing market. Such changes may also breach restrictive covenants under current or future debt facilities or instruments, which could reduce the Company' s operating flexibility. Macroeconomic conditions, such as continued or increased volatility or disruption in the credit markets, may adversely affect the Company' s ability to refinance existing debt or obtain additional financing for working capital, capital expenditures or fund new acquisitions ~~. The Company has previously issued options that are exercisable or convertible into a significant number of shares of its common stock. Should existing holders of options exercise their options for shares of the Company' s common stock, it may cause significant dilution of equity interests of existing holders of the Company' s common stock and reduce the market price of shares of the Company' s common stock.~~ Item 1B. Unresolved Staff Comments.