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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____to_____

Commission file number 001-09341

iCAD, INC.

(Exact name of registrant as specified in its charter)

Delaware	**02-0377419**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
98 Spit Brook Road, Suite 100, Nashua, New Hampshire	**03062**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (603) 882-5200

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	**ICAD**	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12 (g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirement for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit). Yes ☒ No ☐.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing price for the registrant's Common Stock on June 30, 2023 was $38,675,432. Shares of voting stock held by each officer and director and by each person who, as of June 30, 2023, may be deemed to have beneficially owned more than 10% of the outstanding voting stock have been excluded. This determination of affiliate status for purposes of this calculation is not necessarily a conclusive determination of affiliate status for any other purpose.

As of March 22, 2024, the registrant had 26,540,030 shares of its common stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2024 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

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Special Note Regarding Forward Looking Statements

Certain information included in this Annual Report on Form 10-K and the documents incorporated by reference herein, that are not historical facts, contain "forward looking statements" within the meaning of the federal securities laws made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements involve a number of known and unknown risks, uncertainties and other factors that could cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievement expressed or implied by such forward looking statements. These risks and uncertainties include, but are not limited to, the ability to achieve business and strategic objectives, the risks of uncertainty of patent protection, the impact of supply and manufacturing constraints or difficulties, uncertainty of future sales levels, protection of patents and other proprietary rights, the impact of supply and manufacturing constraints or difficulties, product market acceptance, possible technological obsolescence of products, increased competition, litigation and/or government regulation, changes in Medicare reimbursement policies, risks relating to our existing and future debt obligations, competitive factors, the effects of a decline in the economy or markets served by the Company, cyber-attacks, acts of terrorism, acts of war, severe weather, a solar event, an electromagnetic event, a natural disaster, the age and condition of information technology assets, human error, or other factors could disrupt the Company's operations and cause the Company to incur unanticipated losses and expense, and other risks detailed in this report and in the Company's other filings with the United States Securities and Exchange Commission (the "SEC"). The words "believe", "demonstrate", "intend", "expect", "estimate", "anticipate", "likely", "seek", "would", "could", "may", "consider", "confident" and similar expressions identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context otherwise requires, the terms "iCAD", the "Company", "we", "our", "registrant", and "us" mean iCAD, Inc. and its consolidated subsidiaries.

PART I

Item 1. Business.

General

Introduction

iCAD, Inc. is a global leader in AI-powered cancer detection whose laser focus is to create a world where cancer can't hide. Cancer can grow and spread the longer it survives hidden and undetected. Remaining undetected, cancer poses one of the greatest threats to life. With iCAD's clinically validated, regulatory cleared industry-leading ProFound Breast Health Suite, cancer has no easy way to hide. The Company's ProFound Breast Health Suite enables medical providers and professionals to accurately and reliably identify where cancer may be hiding and because iCAD is able to find it earlier, it is more easily eliminated. The ProFound Breast Health Suite offers solutions for breast cancer detection, density assessment, one- or two-year breast cancer risk evaluation, and cardiovascular risk related to elevated levels of breast arterial calcifications.

Powered by the latest innovations in artificial intelligence ("AI"), and built on one the largest, most diverse US-based and global data sets, the ProFound Suite uniquely offers 360-degree solutions for cancer detection, density assessment, and personalized risk evaluation, all based on a 2D or 3D mammogram's collection of images. The ProFound Detection solution scores cases and suspicious lesions, helping radiologists identify and focus on areas of most concern and highest suspicion of cancer. The ProFound Density Assessment standardizes and simplifies breast density reporting, algorithmically examining a woman's breast anatomy from the mammogram image. The ProFound Risk solution provides a near-term probability for developing breast cancer in the next one or two years, making it more actionable and relevant than generalized lifetime risk scores. The ProFound Heart Health solution identifies the presence and quantity of breast arterial calcification which is proven to correlate with calcifications elsewhere in the body, raising concern for cardiovascular or heart health concerns.

The ProFound Breast Health Suite is cleared by the US Food & Drug Administration (the "FDA") and has received CE mark and Health Canada licensing. Used by thousands of providers serving millions of patients, ProFound is available in over 50 countries. iCAD estimates that ProFound has been used for more than 40 million mammograms worldwide in the last five years alone. With over 25 years of experience in AI cancer detection, iCAD has secured 45 patents, completed over 50 clinical studies, and trains its algorithms on one of the largest most diverse data sets, pulling data regularly from over 100 global locations. iCAD's deep experience and un-matched set of capabilities differentiates iCAD from its competition and positions it as an industry leader with an

AI solution that continually gets better as the Company continually refines its algorithm models using its extensive data set and research partners.

iCAD is increasing its leading position as the premiere breast AI solution by transitioning into a platform-based SaaS/DaaS (Software as a Service/Data as a Service) organization. This strategy will make our solutions more affordable and easier for leading medical providers to adopt. At the same time the company will benefit from a growing and more predictable revenue stream. iCAD is executing this strategy in three phases: Phase 1) Realigning our Base, Phase 2) Strengthening our Foundation and Phase 3) Investing in Growth Initiatives.

In 2023, the Company made good progress executing Phases 1 and 2, including:

- stabilized the business and reduced cash burn,
- continued the transition to a subscription-based annual recurring revenue model,
- expanded to fill key roles within the leadership team and recruitment of new board members; and,
- announced several new game-changing collaborations with esteemed partners.

The Company's next phase of transformation, Phase 3, will begin in 2024 and includes launching initiatives that strengthen and deepen business with existing accounts and growing through expanding its direct and indirect sales channels including expanding iCAD's geographic footprint.

On October 23, 2023, the Company sold its Xoft business line. Prior to completion of the sale, the Company had reported the results of two segments: Cancer Detection ("Detection") and Cancer Therapy ("Xoft" or "Therapy"). Upon completion of the Xoft sale, the Company is in a stronger financial position with a dedicated focus on a single operating segment.

The Company's headquarters are located in Nashua, New Hampshire. iCAD France LLC is a wholly owned subsidiary of iCAD, Inc., and is consolidated for reporting purposes.

AI in Mammography

When diagnosing breast cancer, early detection matters. Identified in stage 1, cancer is more likely to respond to treatment and can result in greater survival rates. In fact, according to the American Cancer Society, the relative 5-year survival rate from breast cancer is 99% when detected early.

However, the incidence of breast cancer is growing. According to the World Health Organization, breast cancer is the most common cancer worldwide, recently surpassing lung cancer, with 2.26 million new cases diagnosed worldwide in 2020. One in eight women will get breast cancer in her lifetime, and every 14 seconds, a woman is diagnosed with breast cancer world-wide. Compounding the situation, 59% of women in the US miss their recommended screening mammograms, and for those who regularly screen for breast cancer, 20-40% of cancers are missed in mammogram screenings with up to 50% missed in women with dense breast tissue. Traditional risk assessment models have relied on family history of the disease as a leading risk factor when in fact, and most surprising, 89% of women diagnosed with breast cancer have no direct family history of the disease and 90-95% are not related to inherited gene mutation (American Cancer Society).

Radiology Needs

As breast cancer detection is becoming increasingly complex, AI can help radiologists spot cancer faster, with greater accuracy and save more lives. With the continuing migration from 2D (FFDM) reading systems to 3D (DBT or "Tomo") systems, radiologists are spending twice the amount of time reading hundreds more images per 3D case compared to the four images captured with 2D (two images per breast). This geometric increase in the number of images to read leads to stress – 50% of radiologists are overworked – and burnout is reported to be 49% (Medscape Radiologist Lifestyle, Happiness & Burnout Report 2022). Simultaneously, false-positives and unnecessary recalls for suspected cancers have continued at similar rates while hard-to-detect interval cancers are being missed or diagnoses are delayed.

Patient Needs

The rise in workload for radiologists is felt by the patient too. Anxiously waiting weeks for results, or receiving unnecessary recalls and biopsies leads to undue stress and anxiety, not to mention distrust of the healthcare system. On average, only 10% of women recalled back from a routine screening mammogram for a diagnostic workup are ultimately found to have cancer, resulting in the patient being confused and frustrated with the process.

Additionally, a significant economic burden is placed upon patients and payors that extend throughout multiple years when a breast cancer diagnosis is at a later, more advanced stage. In addition to the associated clinical benefits, reducing the proportion of the population with later-stage cancer diagnoses, finding and treating breast cancer earlier may limit the need for more intensive and expensive treatments, which can increase patient's health-related quality of life, have a significant impact in managing healthcare costs among cancer patients, and reduce caregiver and societal burden. iCAD calculates if diagnoses were shifted one stage earlier for 20% of the 280,000 women in the US diagnosed with breast cancer each year, a savings of approximately $3.7 billion across 2-years of patient treatment and healthcare costs. iCAD's positively find or predict more cancers up to 2-3 years earlier by circling and scoring suspicious lesions for radiologists.

iCAD Addresses Both Provider and Patient Needs

Our AI-powered mammograms are setting a new standard of care in cancer detection, density assessment, and short-term risk evaluation. With iCAD's ProFound Breast Health Suite, radiologists' reading times may be cut in half with improved accuracy and specificity in finding suspicious cancerous lesions. Radiologists benefit from standard, objective, inclusive results measured by an algorithm built upon many millions of images. And, patients benefit from receiving timely personalized results, fact-based assessment of their breast density and short-term risk assessments that inform their screening plans.

As noted above, iCAD's mission is to create a world where cancer can't hide, because when cancer wins, we all lose. For the health of women everywhere, and the benefit of their communities, iCAD's AI-powered, image-based solutions help detect cancer faster, earlier and with greater accuracy as well as evaluate breast cancer and cardiovascular risk from a single mammogram.

The Market and Opportunity

The ProFound Breast Health Suite is cleared by the FDA and has received CE mark and Health Canada licensing. Used by thousands of providers serving millions of patients, ProFound is available in over 50 countries.

According to the December 2023 report, approximately 40.5 million annual mammograms are conducted in the US across 8,834 certified facilities, as measured by the FDA Mammography Quality Standards Act ("MQSA"). Yet, only 37% of facilities are using a CAD or advanced AI mammography solution, according to Research & Markets United States Mammography and Breast Imaging Market Outlook Report 2022-2025, leaving room for growth. Of the 3,268 facilities using AI, iCAD has an active customer base of 1,488, or approximately 46% of the AI market, and approximately 17% of the total US market. In the last five years alone, iCAD estimates reading more than 40 million mammograms worldwide.

Based on the number of DBT units relative to the total units left to be converted to DBT, and the associated large number of installation opportunities, the Company believes that its cancer detection, breast density assessment and risk assessment solutions for DBT may represent a significant growth opportunity in the United States. The Company believes that there is also a growth opportunity for 2D mammography and DBT AI solutions in international markets, both from the analog to digital conversion and as more countries adopt the practice of each exam being read by a single radiologist using AI, rather than the current practice of having two radiologists read each exam. Furthermore, additional western European countries have already implemented, or are planning to implement, mammography screening programs, which may increase the number of screening mammograms performed in those countries.

Since having released its first FDA cleared product in 2002, iCAD has remained committed to innovation in artificial intelligence by continuously improving and releasing the highest performing and most widely available solutions in breast care with FDA clearances, CE marks, and Health Canada licenses. Data is the key to training robust machine learning and AI. In this regard iCAD is well positioned to continually improve our models as we train our algorithms on one of the largest, most diverse data sets, pulling data regularly from over 100 global locations resulting in an AI solution that continually gets better as the Company continually refines its algorithm models using its extensive data set and research partners.

The latest versions of iCAD ProFound Breast Health Suite solutions are under review with the FDA, including version 4.0 of our ProFound Detection solution, built on the newest deep-learning neural network AI for breast cancer, density and risk. Per regulatory test data, iCAD has observed Detection v4.0 will deliver significant improvements in specificity, sensitivity, and the highest AUC (area under the curve) for Specificity and Sensitivity for breast cancer detection at 92.5%. Along with a new heart health solution measuring the level of calcification in breast arteries identifying cardiovascular concerns, and new cloud deployment options, iCAD's overall value and ease of implementation continue to improve.

Our Strategy

As noted elsewhere, iCAD is increasing its leading position as the premiere breast AI solution by transitioning into a platform-based SaaS/DaaS organization by implementing a three phased transformation: Phase 1) Realigning the Base, Phase 2) Strengthening the Foundation and Phase 3) Investing in Growth Initiatives.

Phase 1: Realigning the Base

Management actions taken in early 2023 allowed the Company to end the year in a strong cash position, with $21.7 million on-hand as of December 31, 2023. In addition, the Company made progress in its transition to a subscription-based recurring revenue business model. The Company hired several key members to the management team and also recruited new board members. Lastly, the Company announced several new collaborations with esteemed partners

Phase 2: Strengthening iCAD's Foundation

A new, strengthened leadership team accelerated the transformation further. First, was the transition of the corporate brand from one that was product focused to one that is patient centric, "Creating a World where Cancer Can't Hide," which was successfully introduced at the annual, global Radiological Society of North America meeting in November 2023.

Second, the Company secured a new and extended partnership with Google Health by signing a 20-year partnership to expand 2D AI solutions to encompass an application of AI as the independent, second reader. In addition, the Company completed an integration with GE Health's MyBreastAI suite by embedding iCAD solutions within GE mammography machines.

And third, the divestiture of Xoft provides iCAD more cash and focus to apply to the foundational Cancer Detection business segment.

Phase 3: Investing in Growth Initiatives

iCAD is actively focused on revenue growth and market expansion initiatives using a three-phased, overlapping approach. Phase one, expanding existing accounts; phase two, growing channels, both direct and indirect; and phase three entering new markets. The first phase, expanding existing accounts, will take advantage of iCAD's sizable install base, including reengaging customers who've lapsed on annual maintenance service agreements, are behind and upgrading to new versions, including the transition to cloud, winning back lost or deeply lapsed customers and accelerating deployment across large national accounts. Large enterprise customers like Solis, Radiology Partners, SimonMed, Ascension and Cleveland Clinic, who collectively serve about 15% of the US mammography screening market, offer great potential for iCAD as many are in the early stages of rolling out iCAD's solutions and continue to expand into more sites and markets each month. The focus of this phase is to accelerate deployment across national and regional accounts as well as re-engage 1,000 of iCAD's 4,000 customers who've lapsed on their maintenance agreements or who are operating on older software versions.

The second phase is growing channels, direct and indirect, in both the US and globally through direct sales and establishing new distribution partnerships.

Globally, more than 31,000 mammography systems serve approximately 250 million women in the age range recommended for annual mammograms. Expanding to the 63% of the market that is not using AI, plus additional wins in the segment using AI but not ProFound, results in significant opportunity for new business. iCAD has added sales leadership, sales representatives, and sales operations team members, and plans to add distribution partners to focus on new and expanded business given the large addressable market opportunity.

Phase three is focused on entering new markets with new solutions, most likely in fiscal year 2025. One example is the commercialization of the Heart Health solution, which was previously referred to as Breast Arterial Calcification. In the fourth quarter of 2022, iCAD announced a development and commercial collaboration agreement with Solis. This collaboration is focused on using mammography to define cardiovascular risk, a new application that could identify millions of women at risk for heart disease using data obtained from their mammogram. With heart disease being the number one killer among women in the US, this collaboration not only offers the potential to address a significant unmet need in patient care, but also to penetrate a sizable new market. This product is currently available for investigational use as we complete the FDA approval process.

ProFound Breast Health AI Suite

Backed by science, clinical evidence and proven patient outcomes, iCAD's ProFound Breast Health Suite of cancer detection, density assessment and risk evaluation solutions, provides an unmatched approach to accurately detecting more cancers earlier, providing certainty and peace of mind to providers and patients. The Company's mission is to see that these solutions be deployed universally as part of a standard of care for breast health in order to achieve its vision of a world where cancer can't hide.

ProFound Breast Cancer Detection

ProFound Detection exposes cancer's hiding place. It's clinically proven to improve breast cancer detection and radiologist performance.

The current version, ProFound Detection V3.0, is built with the latest in deep-learning, 3rd generation artificial intelligence, and delivers unparalleled accuracy and efficiency for 2D and 3D mammography screening with up to 2X enhanced clinical performance compared to other AI platforms as accessed in January of 2023 and compared to FDA 510K submissions K182373 (iCAD), K201019 (Hologic) and K193229 (ScreenPoint).

A key competitive differentiator is the fact that iCAD's algorithms are trained on over 6 million images including one of the largest 3D image datasets gathered from over 100 sites from around the globe. Competitively, iCAD's algorithm training data includes the highest amount of sourcing from the US, providing diverse data that is ethnically, racially, and age representative of the US population. The ProFound AI algorithm rapidly and accurately analyzes each individual image or slice to identify potentially malignant lesions. Analyzing for masses, distortion, calcifications, and asymmetry, it localizes, segments and classifies lesions giving them a score and a case score for the overall exam.

Offering clinical confidence, operational superiority, and proven patient outcomes, iCAD's ProFound Detection positively finds or predicts more cancers up to 2-3 years earlier by circling and scoring suspicious lesions for radiologists. With faster image processing vs. other AI solutions, radiologist cancer detection performance AUC rates improve by 6-7% compared to non-AI readers, reading times reduce by 53%, and reduced false positives improves patient satisfaction.

ProFound Detection is FDA cleared, CE marked, and Health Canada licensed. The next generation of ProFound Detection, V4.0, is under review with the FDA.

ProFound Breast Density Assessment

ProFound Density provides an objective and consistent breast density assessment, helping clinics align to the new FDA-MQSA notification requirement to patients, which take effect in September 2024.

Breast density is one of the strongest and most prevalent breast cancer risk factors. As breast density increases, the risk of developing and missing breast cancer increases. 50% of women over the age of 40 in the US have dense breasts, and, according to Susan G. Komen, women with very dense breasts are 4-5 times more likely to get breast cancer.

AI helps to remove the challenge of a subjective visual assessment by radiologists, as radiology-reviewed density metrics may swing wildly, between 6% to 85%, with clinicians even disagreeing with their own measurements from year to year. Inconsistency in density assessments can lead to additional unnecessary imaging, increase patient and facility costs, and patient anxiety.

Using mammographic images, iCAD's ProFound Density analyzes a woman's breast anatomy, measuring the adipose and fibroglandular tissue dispersion and texture, and categorizes her breast density within the appropriate BI-RADS® 5th edition density category. iCAD's ProFound Density solutions gives clinicians an integrated workflow for identifying and reporting breast density, allowing for personalized patient planning with supplemental screening and customized schedules when needed.

ProFound Density is FDA cleared, CE marked, and Health Canada licensed. The newest ProFound Density, V4.0, is under review by the FDA.

ProFound Breast Cancer Risk

iCAD's ProFound Risk is the first image-based, one-to-two-year risk assessment tool – based on reading a 2D or 3D mammogram. ProFound Risk uses a new model for predicting breast cancer during an annual mammogram screening that has been found to be 2.4X more accurate compared to traditional life-time models based on family and medical history. By evaluating several data points in a patient's scanned image, it calculates a more accurate short-term Risk Score for developing cancer in the near term one or two years. This capability for shorter-term insight for when cancer may appear opens the door for real change in standards of care. Rather than adjusting a patient's life-long screening plan based on lifetime models informed only from family history, genetic information and density scores, ProFound Risk can narrowly point to when that risk is present; making adjustments to a patient's screening plans when appropriate. Saving the health care system and patients time, costs, and worry.

As the field of mammography moves from age-based screening recommendations to more personalized risk-adaptive screening guidelines, iCAD is on the leading-edge of this exciting new realm that will enable clinicians to easily adapt to evolving screening practices and personalize patient care.

ProFound Risk is CE marked, Health Canada licensed, and available for investigational use only in the US; ProFound Risk is under review by the FDA.

ProFound Heart Health Risk

Breast cancer and heart disease are the two leading causes of death among women. Clinical results have found calcifications in arterial vessels within the breast are proven to correlate with calcifications elsewhere in the body, which raises concern for cardiovascular or heart health issues.

iCAD's ProFound Heart Health solution measures the presence and extent of breast arterial calcifications from the same mammogram used to identify breast cancer, breast density and breast cancer risk. From one mammogram, clinicians assess the patient's risk of heart disease and recommend further surveillance or review by other care teams.

Breast arterial calcification assessment is pending regulatory licensing and available for investigational use only. iCAD's Heart Health solution is under review by the FDA.

Expansion of Partnerships to Improve Access to Care, Streamline Workflow, and Foster Scientific Innovation

Recognized as a leader in breast AI-powered solutions, iCAD partners with industry leaders across platforms, technology, academic research, integration, and advocacy organizations to iterate and improve upon iCAD software and make solutions more accessible to customers. Interoperable with more than 50 PACS solutions worldwide, with 22 global distributors and growing, iCAD's market share is on the rise.

In 2023, iCAD continued its work with Duke University, Indiana University, University of Pennsylvania and Karolinska Institute on artificial intelligence advancements and clinical testing. Additionally, iCAD expanded its partnership with Google Health to enhance the Company's technology and expand access to millions of women and providers worldwide. iCAD's new 20-year research and development agreement includes co-development, testing, and integration of Google's AI technology with the ProFound Breast Health Suite for 2D mammography for worldwide commercialization to potentially ease radiologist workload and reduce healthcare disparities for women. The conventional double-read workflow used by most countries, where mammograms are assessed by two separate radiologists, has become increasingly challenging as there is a global radiologist workforce shortage. Leveraging AI as a viable alternative to current double reading by introducing iCAD as secondary independent reader can help radiology departments run more efficiently.

To make iCAD solutions more available to customers, iCAD expanded into new platform and channel partners, technology partners, and health system partners. In 2023, iCAD was the only breast cancer AI detection solution integrated into GE's new MyBreastAI Suite – an all-in-one platform made up of three workflow algorithms from iCAD's ProFound Breast Health Suite. GE has released MyBreast AI Suite first in the US and plans to release globally in 2024, simplifying the sales and implementation process for GE, and enabling AI use by customers across the globe. Additionally, iCAD developed several new partnerships and integrations with several AI distributors and marketplace aggregators to implement ProFound AI via cloud options, such as Ferrum, Change Healthcare, Blackford, and have several others currently under negotiation to further expand iCAD's footprint.

Looking forward, iCAD is dedicated to serving those in need by establishing free, equitable access to AI-read mammograms. To start, iCAD plans to bring ProFound Detection to Ghana and Guyana in partnership with RAD-AID, a nonprofit entity that works in over 30 countries to improve and optimize access to medical imaging and radiology in low-resource regions of the world. Together, iCAD and RAD-AID plan to improve diagnosis of breast cancer where breast cancer mortality rates are highest.

Flexibility in Software Licensing and Deployment Options

iCAD has historically offered its solution as perpetually licensed software, primarily pre-installed on and sold with an iCAD configured, off-the-shelf computer, capable of optimally running the software.

In 2022, iCAD began offering its full suite of breast AI solutions in a variety of more flexible options. First, iCAD uncoupled the purchase of iCAD software from the purchase of hardware, allowing customers to source their own computer hardware or use existing IT infrastructures. Second, iCAD launched several new software licensing models designed to leverage both capital and operating expense budgets for customers. In addition to offering perpetual licenses, the Company introduced a new SaaS subscription pricing model that allows customers to purchase a term-based subscription based on the number of imaging gantries or annual mammography exam volume.

To make iCAD's software more flexible, the Company's software has been developed to run as a self-contained software package, making it executable within a variety of infrastructure environments, including iCAD-configured computers or servers, virtualized environments, and integrations into partner cloud-based hosting environments. In 2024, iCAD plans to introduce more options including an iCAD cloud environment and additional hosting options through strategic partnerships.

How iCAD Markets and to Whom

Our aim is to create a world where cancer can't hide from AI-powered cancer detection and risk assessment solutions by reaching as many women as possible across the globe. In the last five years alone, iCAD estimates that more than 40 million mammograms were read worldwide, of which nearly 30% were tomosynthesis. That patient reach is buoyed by the Company's long-standing leadership position in breast cancer detection and the 1,500 facilities actively using iCAD solutions today. Nearly half of all US mammography sites reading with AI use iCAD's solutions.

In North America, iCAD sells its ProFound AI mammography solutions through a direct regional sales force which grew by 50% in 2023, and the Company's many channel partners including OEMs, Radiology Picture Archiving and Communication System (PACS) vendors, AI Platform vendors and distributors. The Company's OEM partners include GE Healthcare, focused on the manufacture and distribution of diagnostic imaging equipment, Fujifilm Medical Systems, a subsidiary of Fuji focused on the manufacture and distribution of X-rays and other imaging equipment, and Siemens Medical Systems. In Europe and the Middle East, the Company sells its AI mammography products through a direct sales force and 22 reseller relationships with regional distributors.

iCAD continues to build-out PACS partnerships with companies including Change Healthcare Inc. ("Change Healthcare"), a leading independent healthcare technology company focused on insights, innovation and accelerating the transformation of the US healthcare system, and Sectra AB ("Sectra"), an international medical imaging IT solutions and cybersecurity company.

Additionally, the Company has expanded on partnerships with additional AI Platform solution vendors. iCAD has AI Platform vendor distribution agreements with Ferrum Health, who partners with global leaders of AI applications to provide a robust catalog of AI applications on a single, secure platform serving clinical service lines across healthcare enterprises; and Blackford, a wholly owned subsidiary of Bayer AG – a platform built for integration with existing systems while simplifying integrations and the management of multiple disparate AI applications and algorithms.

In March 2022, iCAD became one of the first healthcare companies to validate its AI cancer detection solution with the NVIDIA software suite, enabling thousands of healthcare organizations worldwide to virtualize AI workloads within hospital data centers using VMware vSphere and industry-standard servers.

In October of 2022, iCAD and Solis Mammography (Solis) announced a collaboration to develop and commercialize AI to evaluate cardiovascular disease based on breast arterial calcifications. Multiple studies have shown a correlation between the amount of breast arterial calcifications, which are visibly detectable on mammograms, to cardiovascular risk. iCAD and Solis are working together to use AI to quantify the amount of breast arterial calcification in mammograms, correlated to the risk of disease, and define meaningful clinical pathways for high-risk women.

In November of 2022, iCAD announced a strategic development and commercialization agreement with Google Health to integrate Google's AI into iCAD's breast imaging portfolio, and then extended this to a 20-year agreement in 2023. iCAD intends to use Google's 2D AI in its commercial product offerings, especially outside the US, where 2D mammography is primarily used for screening. The Company expects to release its first product leveraging the Google AI technology in the next 1-2 years. Additionally, the Company announced plans to leverage the Google Health Cloud to launch its own cloud platform for the delivery of its breast AI offerings. The Company has already received its first order from Radiology Partners, allowing hundreds of thousands of women to be screened at Radiology Partners' owned outpatient imaging center sites with iCAD's ProFound Breast AI Suite.

These partnerships greatly expand visibility and access to the Company's Breast AI suite – including ProFound AI Detection, ProFound AI Risk and PowerLook Density Assessment - for more hospitals and imaging centers across North America.

Additionally, as part of its sales and marketing efforts, the Company engages in a variety of public relations and local outreach programs with numerous customers and continues to cultivate relationships with industry leaders in breast cancer solutions, including at trade shows where the future of medical image analysis solutions is discussed, and webinars where the Company collaborates with thought-leaders providing free research and education to radiology professionals.

The Competition

The Company operates in a highly competitive and rapidly changing market with specific detection, density, or risk competitive products available from nationally and internationally recognized companies. Many competitors have significantly greater financial, technical, and human resources than iCAD and are well-established in the healthcare market. In addition to the existing technologies or products that compete with the Company's products, some companies may develop technologies or products that may render the Company's products obsolete or noncompetitive. Moreover, competitors may achieve patent protection, regulatory approval, or product commercialization before iCAD does, which would limit the Company's ability to compete with them. iCAD believes that

efficacy, safety profile, feature differentiation, cost, and reimbursement are the primary competitive factors that will affect the success of the Company's products.

ProFound Breast AI Suite

The Company currently faces direct competition in its cancer detection and breast density assessment businesses from Hologic, Inc. (Marlborough, MA), Volpara Solutions Limited (Rochester, NY), ScreenPoint Medical (Nijmegen, Netherlands), Densitas Inc. (Halifax, Nova Scotia, Canada), Therapixel (Paris, France), and Lunit (Seoul, South Korea). The Company believes many factors, including breadth of innovative and clinically differentiated product offerings, ongoing development of clinical support, strong relationships with its strategic partners, and ability to provide the Company's solutions across several platforms and payment structures will provide it with a competitive advantage in breast AI.

Future offerings in breast cancer risk and heart health face competition as others are developing similar solutions, and in the case of heart health, CureMetrix received FDA clearance for cmAngio®, a similar solution for detecting breast arterial calcification.

Manufacturing and Professional Services

The Company manufactures and assembles its detection products. When a product sale is made to an end-customer by one of the Company's OEM partners, it is usually installed at the customer site by the OEM partner or the Company. When iCAD makes a product sale directly to the end-customer, the product is generally installed by iCAD personnel at the customer site.

iCAD's professional services staff provides comprehensive product support on a post-sale basis. Product support includes product demonstrations, product installations, applications training, and technical support. The Company's support center is a single point of contact for the end-customer, and provides remote diagnostics, troubleshooting, training, and service dispatch. Service repair efforts are generally performed at the customer site by third party service organizations or in the Company's repair depot by the Company's repair technicians.

Government Regulation

iCAD's operations, products and customers are subject to extensive government regulation by numerous government agencies. the Company's software, hardware systems and related accessories are regulated as medical devices in each of the jurisdictions where the Company operates, and iCAD's customers are subject to applicable provider quality standards.

Manufacturing and Sales

In the United States, numerous laws and regulations govern the processes by which iCAD's products are brought to market. These include the Federal Food, Drug, and Cosmetic Act ("FDCA") and its regulations, which govern, among other things, quality standards for product development, manufacturing, testing, labeling, storage, premarket clearance or approval, advertising and promotion, sales and distribution, and post-market surveillance of medical devices.

For devices in the United States, the FDA's premarket clearance or approval process controls the entry of products into the market, unless a device is exempt from premarket review. Whether a product requires clearance (510(k) premarket notification) or approval (premarket approval, "PMA") depends on the FDA's risk-based classification of the device. Some of the Company's products require submission of a premarket notification demonstrating that the device is at least as safe and effective, that is, "substantially equivalent", to a legally marketed device that is not required to be approved under a PMA. Once iCAD receives an order from the FDA declaring a device to be substantially equivalent, the iCAD product is "cleared" for commercial marketing in the United States. Other iCAD products require submission of a PMA, which requires non-clinical and clinical data supporting the safety and effectiveness of the device. Once the Company receives FDA approval of its PMA application based on the FDA's determination that the application contains sufficient, valid scientific evidence to assure that the device is safe and effective for its intended use(s), iCAD may market the device.

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After our products enter the market, iCAD and our products continue to be subject to FDA regulation. For example, the FDA Quality System Regulations ("QSR") require manufacturers to establish a quality system including extensive design, testing, control, documentation and other quality assurance procedures designed to ensure that their products consistently meet applicable FDA requirements and manufacturer specifications. iCAD's third-party manufacturers are also required to comply with applicable parts of the QSR. Manufacturers are subject to periodic inspections by the FDA to determine compliance with QSR. If at the conclusion of an inspection, FDA has made any observations that may constitute violations of applicable requirements, it may issue an FDA Form 483 ("483") requiring corrective action within a limited amount of time. If any observations are not addressed and/or corrective action taken, FDA may issue a warning letter and or take other enforcement action. The Company also is subject to FDA regulations covering labeling and adverse event reporting as well as the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Failure to comply fully with applicable regulations could lead to delayed marketing clearance or approval or enforcement action, including 483s, warning letters, product seizures, import/export refusal, civil or criminal penalties, injunctions, and criminal prosecution.

Similarly, medical device regulators in other jurisdictions require various levels of clearance, approval, certification, licensure and/or consent before regulated medical devices can be lawfully commercialized in those jurisdictions as well as ongoing compliance with manufacturing and other regulatory requirements. These approvals, the time required for regulatory review, and the continuing compliance requirements vary by jurisdiction. Obtaining and maintaining foreign regulatory approvals and maintaining compliance is an expensive and time-consuming process. Increasingly, medical device manufacturers are adopting globally harmonized quality standards as developed by the International Organization for Standardization, and risk management standards. Manufacturers of software as a medical device are further subject to specific security standards.

Additionally, the U.S. government regulates the transfer of information, commodities, technology and software considered to be strategically important to the United States in the interest of national security, economic and/or foreign policy concerns. A complicated network of federal agencies and inter-related regulations in the United States that govern exports, collectively referred to as "Export Controls." These regulate the shipment or transfer, by whatever means, of controlled items, software, technology, or services out of the United States. Exported medical products are also subject to the regulatory requirements of each country to which the medical product is exported.

Healthcare Laws

The Company is also subject to a variety of federal and state regulations in the United States and regulations in other jurisdictions that relate to iCAD's interactions with healthcare practitioners, government officials, purchasing decision makers, and other stakeholders across healthcare systems. These regulations, discussed in more detail below, include among others, the following:

- anti-kickback, false claims, and physician self-referral statutes;
- U.S. state laws and regulations regarding fee splitting and other relationships between healthcare providers and non-professional entities, such as companies that provide management and reimbursement support services;
- anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, the UK Anti-Bribery Act, the Canadian Corruption of Foreign Public Officials Act, and guidance promulgated by certain multi-national groups, such as the United Nations Convention Against Corruption and the Organization for Economic Cooperation and Development Convention on Combatting Bribery of Foreign Public Officials in International Business Transactions;
- laws regulating the privacy and security of health data, protected health information and personally identifiable information. These include the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, the General Data Protection Regulation ("GDPR") in the EU, and the Personal Information Protection and Electronic Documents Act in Canada;

- healthcare reform laws in the United States, such as the Affordable Care Act ("ACA") and the 21st Century Cures Act, which include new regulatory mandates and other measures designed to reduce the rate of medical inflation. These include, among other things, stringent new reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals; and

- rules and regulations promulgated by the U.S. Food and Drug Administration (the "FDA") which impact the Company's current and future products, including but not limited to ProFound AI.

These laws and regulations are extremely complex, open to interpretation, and, in some cases, still evolving. If iCAD's operations are found to violate any of the foreign, federal, state or local laws and regulations which govern its activities, iCAD may be subject to litigation, government enforcement actions, and applicable penalties, which could include civil and criminal penalties, damages, fines, exclusion from participation in certain payer programs or curtailment of the Company's operations. Compliance obligations under these various laws are often detailed and onerous, further contributing to the risk that the Company could be found to be out of compliance with particular requirements. The risk of being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

The FDA, CMS, the Department of Health and Human Services, Office of Inspector General ("HHS-OIG"), the Department of Justice, states' attorneys general and other governmental authorities actively enforce the laws and regulations discussed above. In the United States, medical device companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of medical devices, payments intended to influence the referral of federal or state healthcare business, and submission of false claims for government reimbursement. While iCAD makes every effort to comply with applicable laws, it cannot rule out the possibility that the government or other third parties could interpret these laws differently and challenge the Company's practices under one or more of these laws. The risk of liability under certain federal and state laws is increased by the right of individual plaintiffs, known as relators, to bring an action alleging violations of such laws and potentially be awarded a share of any damages or penalties ultimately awarded to the applicable government body. Violations of these laws may lead to civil and criminal penalties, damages, fines, exclusion from participation in certain payer programs or curtailment of the Company's operations.

iCAD is subject to numerous laws governing safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances, among others, both at the U.S. federal and state levels, and similar laws in other jurisdictions. iCAD may be required to incur significant costs to comply with these laws and regulations in the future, which may result in a material adverse effect upon the Company's business, financial condition and results of operations.

Federal, state, and foreign regulations regarding the manufacture and sale of medical devices and management services and software are subject to future change. iCAD cannot predict what impact, if any, such changes might have on the Company's business.

Anti-Kickback Laws

The federal Anti-Kickback Statute ("AKS") prohibits persons from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce:

- the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or

- purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by a government-sponsored healthcare program.

The AKS is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The statutory penalties for violating the AKS include imprisonment for up to ten years and fines of up to $100,000 per violation. In addition, through application of other laws, conduct that violates the AKS can also give rise to False Claims Act ("FCA") lawsuits and other penalties.

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Congress and the HHS-OIG have established a large number of statutory exceptions and regulatory safe harbors. An arrangement that fits squarely into an exception or safe harbor is immune from prosecution under the AKS. iCAD trains and educates employees and marketing representatives on the AKS and their obligations thereunder, and the Company endeavors to comply with the applicable safe harbors. However, the failure to comply with the exceptions and safe harbor requirements does not always impose liability under the AKS, as long as the arrangement does not implicate the principal policy objectives. Thus, some of iCAD's arrangements that may not be covered by a safe harbor, like many other common and non-abusive arrangements, nevertheless likely do not pose a material risk of program abuse or warrant the imposition of sanctions because they do not implicate any of the AKS's principal policy objectives. However, iCAD cannot offer assurances that, with respect to any arrangements that do not squarely meet an exception or safe harbor, the Company will not have to defend against alleged violations of the AKS. Allegations of violations of the AKS also may be brought under the federal Civil Monetary Penalty Law, which requires a lower burden of proof than other fraud and abuse laws, including the AKS.

Government officials have focused recent kickback enforcement efforts on, among other things, the sales and marketing activities of healthcare companies, including medical device manufacturers, and have brought cases against individuals or entities with personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. This trend is expected to continue. Settlements of these cases by healthcare companies have involved significant fines and/or penalties and in some instances criminal pleas or deferred prosecution agreements.

In addition to the federal AKS, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payment made by a government health care program but also with respect to other payers, including commercial insurance companies.

If iCAD is found to have violated the Anti-Kickback Statute or a similar state statute, it may be subject to civil and criminal penalties, including exclusion from the Medicare or Medicaid programs, or may be required to enter into settlement agreements with the government to avoid such sanctions. Typically, such settlement agreements require substantial payments to the government in exchange for the government to release its claims and may also require the Company to enter into a Corporate Integrity Agreement.

Physician Self-Referral Laws

iCAD is subject to federal and state laws and regulations that limit the circumstances under which physicians who have a financial relationship with entities that furnish certain specified healthcare services may refer to such entities for the provision of such services, including clinical laboratory services, radiology and other imaging services and certain other diagnostic services. These laws and regulations also prohibit such entities from billing for services provided in violation of the laws and regulations.

This federal ban on physician self-referrals, commonly known as the "Stark Law," prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member of the physician has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing for any good or service furnished pursuant to an unlawful referral. It further obligates any person collecting any amounts in connection with an unlawful referral to refund these amounts. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $170,000 for each such arrangement or scheme. The penalties for violating the Stark Law also include civil monetary penalties of up to $26,000 per service, and could result in denial of payment, disgorgements of reimbursement received under a non-compliant agreement, and possible exclusion from Medicare, Medicaid or other federal healthcare programs.

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In addition to the Stark Law, many states have their own self-referral laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states these self-referral laws apply not only to payment made by a government health care program but also payments made by other payers, including commercial insurance companies. In addition, some state laws require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider, even if the referral itself is not prohibited.

iCAD has financial relationships with physicians in the form of equipment leases and services arrangements. The Company's financial relationships with referring physicians and their immediate family members must comply with the Stark Law by meeting an applicable exception. Unlike the AKS, failure to meet an exception under the Stark Law results in a violation of the Stark Law, even if such violation is technical in nature. iCAD attempts to structure relevant relationships to meet a Stark Law exception, but the regulations implementing the exceptions are detailed and complex, and underwent significant changes in 2020, and therefore, the Company cannot provide assurance that every relationship complies fully with the Stark Law.

Violation of these laws and regulations may result in the prohibition of payment for services rendered, significant fines and penalties, and exclusion from Medicare, Medicaid and other federal and state healthcare programs, any of which could have a material adverse effect on iCAD's business, financial condition and results of operations. In addition, expansion of the Company's operations to new jurisdictions, new interpretations of laws in iCAD's existing jurisdictions, or new physician self-referral laws could require structural and organizational modifications of the Company's relationships with physicians to comply with those jurisdictions' laws. Such structural and organizational modifications could result in lower profitability and failure to achieve iCAD's growth objectives.

If iCAD fails to comply with federal and state physician self-referral laws and regulations as they are currently interpreted or may be interpreted in the future, or if other legislative restrictions are issued, the Company could incur a significant loss of revenue and be subject to significant monetary penalties, or exclusion from participation in federal healthcare programs which could have a material adverse effect on iCAD's business, financial condition and results of operations.

False Claims Laws

The federal FCA prohibits any person from knowingly presenting, or causing to be presented, a false claim or knowingly making, or causing to made, a false statement to obtain payment from the federal government. If iCAD violates the AKS or Stark Law, improperly bills for services, retains overpayments longer than 60 days after identification, or fails to act with reasonable diligence to investigate credible information regarding potential overpayments, the Company may be found to violate the federal FCA.

Those found in violation of the FCA can be subject to fines and penalties of three times the damages sustained by the government, plus mandatory civil penalties of $11,803 to $23,607 per false claim or statement. The qui tam or "whistleblower" provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically, causing greater numbers of healthcare companies, including medical device manufacturers, to defend false claim actions, pay damages and penalties or be excluded from Medicare, Medicaid or other federal or state healthcare programs.

In addition, various states have enacted false claim laws analogous to the FCA, and this legislative activity is expected to increase. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program.

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Increased Regulatory Scrutiny of Relationships with Healthcare Providers

Certain state governments and the federal government have enacted legislation, including the Physician Payments Sunshine Act provisions under the ACA, aimed at increasing transparency of iCAD's interactions with healthcare providers. As a result, the Company is required by law to disclose payments, gifts, and other transfers of value to certain healthcare providers in certain states and to the federal government. Any failure to comply with these legal and regulatory requirements could result in a range of fines, penalties, and/or sanctions, and could affect iCAD's business. The company has devoted and will continue to devote substantial time and financial resources to develop and implement enhanced structure, policies, systems and processes to comply with these enhanced legal and regulatory requirements, which may also impact iCAD's business.

Artificial Intelligence

Domestic and global rules and regulations regarding AI are in their infancy. However, given the recent interest in AI and machine learning from global stakeholders, new laws, guidance, rules and regulations may take any number of forms, now or in the years to come.

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 Artificial Intelligence Act ("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.

For more information, see "Item 1A. Risks Related to Regulation of the Company's Industry – The Company is subject to complex and evolving U.S. and foreign laws and regulations regarding AI, machine learning, and automated decision making."

U.S. Coverage and Reimbursement

In the United States, the federal and state governments establish guidelines and pay reimbursements to hospitals, freestanding clinics (independent diagnostic treatment facilities), and medical professionals for diagnostic examinations and therapeutic procedures under the federal Medicare program and the joint federal/state Medicaid program. CMS reviews and adjusts Medicare and Medicaid coverage policies and reimbursement levels periodically and considers various Medicare and other healthcare reform proposals that could significantly affect private and public reimbursement for healthcare services. State governments determine Medicaid reimbursement pursuant to state law and regulations. Many third-party payers use coverage decisions and payment amounts determined by CMS to set their coverage and reimbursement policies.

Because iCAD expects to receive payment for its products directly from iCAD's customers, the Company does not anticipate relying directly on payment for any of iCAD's products from third-party payers, such as Medicare, Medicaid, commercial health insurers and managed care companies. However, iCAD's business will be affected by coverage and payment policies adopted by federal and state governmental authorities for Medicare and Medicaid, as well as private payers, which often follow the coverage policies of these public programs. Such policies may affect which products customers purchase and the prices they are willing to pay for those products in a particular jurisdiction. For example, iCAD's business will be indirectly impacted by the ability of a hospital or medical facility to obtain coverage and third-party reimbursement for procedures performed using the Company's products. Third-party payers may deny coverage or pay an amount for the procedure that healthcare providers deem inadequate, which could cause such providers to use a lower-cost product from a competitor or perform a medical procedure without the Company's device.

Reimbursement decisions by individual third-party payers depend upon each third-party payer's evaluation of a number of factors, including some or all of the following:

- whether the product or service is a covered benefit under its health plan;
- whether the product or service is appropriate and medically necessary for the specific indication;
- cost effectiveness of the product or service;
- whether the product is being used in a manner consistent with its FDA-approved or cleared label (i.e., “on-label”); and
- a determination that the product or service is neither experimental nor investigational (e.g., that its use is supported by relevant evidence in the peer reviewed literature, its use is supported by medical professional society treatment guidelines).

The healthcare industry in the United States is increasingly focused on cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third-party payers. The ACA went into effect in 2012. While iCAD believes that elements of the program including the shift to value-based healthcare and increased focus on patient satisfaction will benefit the Company in the future, there could be negative consequences on patient access to new technologies. Other elements of this legislation, including comparative effectiveness research, payment system reforms (such as shared savings pilots) and other provisions, could meaningfully change the way healthcare is delivered and paid for in the United States, and may materially impact numerous aspects of the Company’s business, including the demand for and availability of iCAD’s products, the reimbursement available for iCAD’s products from governmental and third-party payers, and reduced medical procedure volumes.

iCAD is evaluating the effect that changes and proposed changes to the ACA and Biden Administration policies, and the adopted RO Model by the CMS, may have on the company’s business. iCAD cannot predict whether the ACA will be repealed, replaced, or modified or how such repeal, replacement or modification may be timed or structured. As a result, the Company cannot quantify or predict the effect of such repeal, replacement, or modification might have on iCAD’s business and results of operations. However, any changes that lower reimbursement for the Company’s products or reduce medical procedure volumes could adversely affect iCAD’s business and results of operations.

Reimbursement in Other Jurisdictions

Typically, coverage and payment for healthcare products and services in other jurisdictions is determined through a public tender process that takes into consideration the results of a cost-effectiveness or value analysis conducted by a federal government-level technology assessment group, and through reference to coverage and payment policies established for the same or similar product/service in comparable jurisdictions.

Market acceptance of iCAD’s medical products in both the United States and other countries is dependent upon the purchasing and procurement practices of the Company’s customers, patient demand for the Company’s products and procedures, and the reimbursement policies of patients’ medical expenses set by government healthcare programs, private insurers or other healthcare payers.

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Intellectual Property

The Company primarily relies on a combination of patents, trade secrets and copyright law, third-party and employee confidentiality agreements, and other protective measures to protect its intellectual property rights pertaining to its products and technologies.

The Company has certain patents to its ongoing programs that expire between 2024 and 2040. These patents help the Company maintain a proprietary position in its markets. The Company does not believe that the patents expiring in 2024 are material to its business. Additionally, the Company has a number of patent applications pending domestically, some of which have been also filed internationally, and the Company plans to file additional domestic and foreign patent applications when it believes such protection will benefit the Company. These patents and patent applications relate to current and future uses of iCAD's cancer detection technologies and products, including cancer detection solutions for tomosynthesis, CAD for CT colonography and lung and CAD for MRI breast and prostate. The Company has also secured a non-exclusive patent license from the National Institute of Health which relates broadly to CAD in colonography.

Sources and Availability of Materials

The 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 by a sole manufacturer or a limited number of manufacturers or assembled by it from supplies it obtains from a limited number of suppliers. Critical components required to manufacture these products, whether by outside manufacturers or directly, 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.

Engineering and Product Development

iCAD's products have been developed by its own research and development staff or were developed by the companies iCAD acquired. Research and development expenses are primarily attributable to personnel, consulting, subcontract, licensing and data collection expenses relating to the Company's new product development and clinical testing. iCAD believes its products are competitive and that none of the current versions of the Company's products are approaching obsolescence. iCAD has invested and expects to continue to invest in new research and development and enhancements of the Company's current products to maintain iCAD's competitive position. For the years ended December 31, 2023 and 2022, we incurred $5.2 million and $5.5 million, of research and development expense, respectively.

Human Capital Resources

As of December 31, 2023, the Company had 69 employees, 67 of whom are full time employees, with 24 involved in sales and marketing, 16 in research and development, 12 in service, manufacturing, quality assurance, technical support and operations functions, and 15 in administrative functions. None of the Company's employees are represented by a labor organization. The Company considers its relations with employees to be good.

The Company's human capital resource objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and future employees, advisors and consultants. In addition to competitive base salaries, the other competitive benefits that we provide to employees include incentive plans and paid vacation. The principal purposes of these employee benefits are to attract, retain, reward and motivate our personnel and to provide long-term incentives that align the interests of employees with the interests of our stockholders.

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Foreign Regulations

International sales of the Company's products are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. Obtaining and maintaining foreign regulatory approvals is an expensive and time-consuming process. We cannot be certain that we will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which we plan to market our products. If we fail to receive and maintain such approvals, our ability to generate revenue may be significantly diminished.

Available Information

The Company files annual, quarterly and current reports, proxy or stockholder information statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements, and certain other information that we may file electronically with the SEC (http://www.sec.gov). We also make available for download free of charge through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") as soon as reasonably practicable after we have filed it electronically with, or furnished it to, the SEC. We maintain our corporate website at http://www.icadmed.com. Our website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

Item 1A. Risk Factors.

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 is a summary of certain important factors that have affected, and/or in the future could affect, the Company's operations and 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 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 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.
- 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 result in reputational harm and liability.
- 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.

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- 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 shifting to a software as a service (SaaS) model is uncertain.

The Company's success in growing revenue and market share from subscription-based offerings will depend, to a large extent, on the willingness of 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 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 at the rate we expect, meaning adoption occurs more slowly or more quickly than forecasted, either of which would harm the Company's business. The Company's business model continues to evolve and it may not be able to compete effectively, generate significant revenues or maintain profitability for our subscription-based offerings. The Company has and will continue to incur expenses associated with the infrastructures and marketing of subscription offerings in advance of its ability to recognize the revenues associated with these offerings. Demand for subscription, cloud-based services may unfavorably impact demand for certain other products and services. With a continued shift away from the sale of perpetual software licenses to providing access to software through subscription agreements the Company may, in the near term, experience a deferral of revenues and to a lesser extent cash received from customers.

The Company has incurred significant losses from inception through 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 $4.9 million in 2023 and has an accumulated deficit of approximately $272 million at December 31, 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 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, 2023, the Company had cash and cash equivalents and investments in money market funds totaling $21.7 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.

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Risks 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 newly introduced enhancements to the Company's existing products 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;
- other technological developments; and
- inherent risks related to AI, machine learning, and related fields.

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Often, 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. 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.

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Management cannot guarantee that providers and physicians will be able to obtain adequate reimbursement for the Company's products or services.

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 result in reputational harm and liability.

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. 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 full field digital mammography systems, digital computer aided detection products and tomosynthesis as well as advanced image analysis and workflow solutions. 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 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 2023, the Company's OEM partners accounted for 32% of its total revenue, with one major partner, GE Healthcare, accounting for 22% of the Company's revenue. In addition, in 2023, one direct customer, accounted for 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.

Revenue from the Company's new subscription license model may be difficult to predict.

The Company is devoting resources to the transition to a new software license model to complement its traditional perpetual licensing models. This model allows the Company to license its software through subscription licenses, generally for a three-year term, and that potentially may not be renewed. 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, 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 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.

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The 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 markets for many of the Company's products are subject to changing technology.

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.

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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.

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Instability 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 2023, approximately 13% of the Company's revenue was derived from customers outside of the U.S., primarily within 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.

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A 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;

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- political or civil unrest or instability, terrorism or epidemic or pandemics (including any risks related to or resulting from future variants of COVID-19) and other similar outbreaks or events;
- 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 future prospects depend on its ability to retain current key employees and attract additional qualified personnel.

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, 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 13% of the Company's revenue for 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.

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.

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Risks Related to Intellectual Property

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 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 2024 and 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.

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Many 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.

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As 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 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 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.

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Strategic transactions, 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 businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. Any of these transactions could be material to our 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 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 the effect that any such transactions might have on our operating results.

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.

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.

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The 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.

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.

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 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.

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Provisions 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, 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 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.

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.

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.

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.

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General 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, 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.

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Changes 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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Risk management and strategy

The Company recognizes the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of data.

Managing Material Risks & Integrated Overall Risk Management

The Company has strategically integrated cybersecurity risk management into our broader risk management framework to promote a company-wide culture of cybersecurity risk management. This integration ensures that cybersecurity considerations are an integral part of our decision-making processes at every level. Our management team works closely with our IT department to continuously evaluate and address cybersecurity risks in alignment with our business objectives and operational needs.

Engage Third-parties on Risk Management

Recognizing the complexity and evolving nature of cybersecurity threats, we engage with a range of external experts, including cybersecurity consultants, to evaluate and test our risk management systems. These partnerships enable us to leverage specialized knowledge and insights, and ensure our cybersecurity strategies and processes remain at the forefront of industry best practices. Our collaborations with these third-parties include threat assessments and security enhancement consultations.

Oversee Third-party Risk

Because we are aware of the risks associated with third-party service providers, we implement stringent processes to oversee and manage these risks. We conduct thorough security assessments of all third-party providers before engagement and maintain ongoing monitoring to ensure compliance with our cybersecurity standards. The monitoring includes ongoing assessments by our security analysts. This approach is designed to mitigate risks related to data breaches or other security incidents originating from third-parties.

Risks from Cybersecurity Threats

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing.

Governance

The Board is acutely aware of the critical nature of managing risks associated with cybersecurity threats. The Board has established robust oversight mechanisms to ensure effective governance in managing risks associated with cybersecurity threats because we recognize the significance of these threats to our operational integrity and stakeholder confidence.

Board of Directors Oversight

The Audit Committee of the Board (the "Audit Committee") is central to the Board's oversight of cybersecurity risks and bears the primary responsibility for this domain. The Audit Committee is composed of board members with diverse expertise including, risk

management, technology, and finance, equipping them to oversee cybersecurity risks effectively.

Management's Role Managing Risk

The Chief Product Officer (the "CPrO"), the Chief Technology Officer (the "CTO"), the Chief Operations Officer (the "COO"), and the Chief People Officer (the "CPO") form the Risk Management team (the "RMT"). The RMT and the Chief Executive Officer ("CEO") play a pivotal role in informing the Audit Committee on cybersecurity risks. They provide comprehensive briefings to the Audit Committee on a regular basis, with a minimum frequency of once per year. These briefings encompass a broad range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events; and
- Compliance with regulatory requirements and industry standards.

In addition to our scheduled meetings, the Audit Committee, RMT, and CEO maintain an ongoing dialogue regarding emerging or potential cybersecurity risks. Together, they receive updates on any significant developments in the cybersecurity domain, ensuring the Board's oversight is proactive and responsive. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major initiatives. This involvement ensures that cybersecurity considerations are integrated into the broader strategic objectives of the Company. The Audit Committee conducts an annual review of the company's cybersecurity posture and the effectiveness of its risk management strategies. This review helps in identifying areas for improvement and ensuring the alignment of cybersecurity efforts with the overall risk management framework.

Risk Management Personnel

Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with the RMT. With deep experience in technology, operations, security, compliance and risk management, the RMT brings a wealth of expertise in enterprise cybersecurity and are instrumental in developing and executing our cybersecurity strategies. The RMT oversees our governance programs, tests our compliance with standards, remediates known risks, and leads our employee training program.

Monitor Cybersecurity Incidents

The RMT is continually informed about the latest developments in cybersecurity, including potential threats and innovative risk management techniques. This ongoing knowledge acquisition is crucial for the effective prevention, detection, mitigation, and remediation of cybersecurity incidents. The RMT implements and oversees processes for the regular monitoring of our information systems. This includes the deployment of advanced security measures and regular system audits to identify potential vulnerabilities. In the event of a cybersecurity incident, the RMT is equipped with a well-defined incident response plan. This plan includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents.

Reporting to Board of Directors

The RMT regularly informs the CFO and CEO of all aspects related to cybersecurity risks and incidents. This ensures that the highest levels of management are kept abreast of the cybersecurity posture and potential risks facing the Company Furthermore, significant cybersecurity matters, and strategic risk management decisions are escalated to the Board, ensuring that they have comprehensive oversight and can provide guidance on critical cybersecurity issues.

See "Item 1A. General 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." for more information.

Item 2. Properties.

The Company's executive offices are leased pursuant to a lease originally entered into in December 2006. The lease covers approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire. In November of 2022, the lease was extended through May 31, 2026 with monthly base rent payments of $16,983. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the facility.

The Company also leases warehouse space in Nashua, New Hampshire. In January 2024, in anticipation of the March 2024 end date of the lease for the Company's then-current warehouse facility, the Company entered into a 36-month lease for a new warehouse facility, also located in Nashua, New Hampshire. The new facility is approximately 3,000 square feet, with annual rent payments totaling approximately $46,000 for the entire term.

In addition to the foregoing leases relating to its principal properties, the Company also has a lease for office space in Lyon, France.

If the Company is required to seek additional or replacement facilities, it believes there are adequate facilities available at commercially reasonable rates.

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Item 3. Legal Proceedings.

From time to time, we may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business. Although the results of litigation and claims are inherently unpredictable and uncertain, we are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market for our Common Stock

The Company's common stock is traded on the NASDAQ Capital Market under the symbol "ICAD".

Holders of Common Stock

As of March 22, 2024, there were 80 holders of record of the Company's common stock. We believe that there are a substantially greater number of beneficial owners of our common stock.

Dividends

The Company has not paid any cash dividends on its common stock to date, and the Company does not expect to pay cash dividends in the foreseeable future. Future dividend policy will depend on the Company's earnings, capital requirements, financial condition, and other factors considered relevant by the Company's Board of Directors.

Securities Authorized for Issuance Under Equity Compensation Plans

Information with respect to the Company's equity compensation plans in effect at December 31, 2023 will be included in the definitive Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for the Company's 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement") and is incorporated herein by reference.

Issuer's Purchases of Equity Securities

For the majority of restricted stock units granted to employees under the applicable stock incentive plan, the number of shares issued on the date that the restricted stock units vest is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate tax authorities on behalf of our employees. The Company did not have any repurchases of securities in the year ended December 31, 2023.

Recent Sales of Unregistered Securities

None.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the Company's consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K.

Results of Operations

Overview

iCAD, Inc. is a global leader in AI-powered cancer detection on a mission to create a world where cancer can't hide. Cancer wins when it hides. Remaining undetected, cancer poses one of the greatest threats to life. The Company's ProFound Breast Health Suite enables medical providers and professionals to accurately and reliably identify where cancer may be hiding and when it might make its move. The ProFound Breast Health Suite offers solutions for breast cancer detection, density assessment, one or two years breast cancer risk evaluation, and cardiovascular risk related to elevated levels of breast arterial calcifications. Prior to the third quarter of 2023, the Company had two reporting segments: Detection and Therapy. The Company completed the sale of its Xoft (Therapy) business line on October 23, 2023. Accordingly, the Company has only one reporting segment, Detection. The applicable assets and liabilities of the Xoft business have been classified as held for sale in the Consolidated Balance Sheet as of December 31, 2022, and

the results of its operations for all periods presented are reflected as discontinued operations in the Consolidated Statements of Income. Unless otherwise indicated, all disclosures and amounts relate to the Company's continuing operations.

Powered by the latest innovations in artificial intelligence (AI), and built on one of the largest, most diverse US-based and global data sets, the ProFound Suite uniquely offers 360-degree solutions for cancer detection, density assessment, and personalized risk evaluation, all based on a 2D or 3D mammogram's collection of images. The ProFound Detection solution scores cases and suspicious lesions, helping radiologists identify and focus on areas of most concern and highest suspicion of cancer. The ProFound Density Assessment standardizes and simplifies breast density reporting, algorithmically examining a woman's breast anatomy from the mammogram image. The ProFound Risk solution provides a near-term probability for developing breast cancer in the next one or two years, making it more actionable and relevant than generalized lifetime risk scores. The ProFound Heart Health solution identifies the presence and quantity of breast arterial calcification which is proven to correlate with calcifications elsewhere in the body, raising concern for cardiovascular or heart health concerns.

The ProFound Breast Health Suite is cleared by the US Food & Drug Administration (FDA) and has received CE mark and Health Canada licensing. Used by thousands of providers serving millions of patients, ProFound is available in over 50 countries. iCAD estimates that ProFound has been used for more than 40 million mammograms worldwide in the last five years.

The Company's headquarters are located in Nashua, New Hampshire. In addition, the Company has a separate manufacturing and warehousing facility, also located in Nashua, New Hampshire. Lastly, the Company has office space in Lyon, France.

Discussion of Operating Results:

Year Ended December 31, 2023 compared to Year Ended December 31, 2022

Revenue. Revenue for the year ended December 31, 2023 was $17.3 million compared with revenue of $19.8 million for the year ended December 31, 2022, a decrease of $2.5 million, or 12.5%.

The table below presents the components of revenue for 2023 and 2022 (in thousands):

	For the year ended December 31,			
	2023	2022	$ Change	% Change
Detection revenue				
Product revenue	$ 9,930	$ 12,620	$ (2,690)	(21.3)%
Services revenue	7,388	7,182	206	2.9%
Total	$ 17,318	$ 19,802	$ (2,484)	(12.5)%

Product revenue decreased by $2.7 million and Services revenue increased by $0.2 million. The decrease is due primarily to reduced demand, a reduction in sales force which began in late 2022, our shift to a subscription model and continued weakness in recovery to pre-pandemic levels prior to Covid-19. During 2023, we have seen an increased customer demand for subscription licenses, which currently remains a small portion of our total license revenue. We believe this trend could accelerate, and we have begun to shift our marketing efforts to better promote a subscription model.

Cost of revenue and gross profit for 2023 and 2022 were as follows (in thousands):

	For the year ended December 31,			
	2023	2022	Change	% Change
Products	$ 1,387	$ 1,658	$ (271)	(16.3)%
Services	1,060	1,217	(157)	(12.9)%
Amortization and depreciation	86	108	(22)	(20.4)%
Total cost of revenue	2,533	2,983	(450)	(15.1)%
Gross profit	$ 14,785	$ 16,819	$ (2,034)	(12.1)%
Gross profit %	85.4%	84.9%		

Cost of Revenue. Total cost of revenue decreased by $0.5 million, or 15.1%, from $3.0 million for the year ended December 31, 2022 to $2.5 million for the year ended December 31, 2023. Cost of revenue for Products decreased $0.3, or 16.3%, from $1.7 million for the year ended December 31, 2022 to $1.4 million for the year ended December 31, 2023. Cost of revenue for Services decreased $0.2 million, or 12.9%, from $1.2 million for the year ended December 31, 2022 to $1.1 million for the year ended December 31, 2023. The total decrease in Cost of revenue is consistent with the decrease in total Revenue.

Gross Profit. Gross profit was $14.8 million for the year ended December 31, 2023 compared to $16.8 million for the year ended December 31, 2022, a decrease of $2.0 million, or 12.1%. Gross profit as a percentage of revenue increased to 85.4% in the year ended December 31, 2023 from 84.9% in the year ended December 31, 2022. The increase was due primarily to the mix of products sold across the periods.

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Operating Expenses:

Operating expenses for 2023 and 2022 were as follows (in thousands**):**

	For the year ended December 31,			
	2023	**2022**	**Change**	**% Change**
Operating expenses:				
Engineering and product development	$ 5,161	$ 5,493	$ (332)	(6.0)%
Marketing and sales	7,740	10,790	(3,050)	(28.3)%
General and administrative	9,324	10,517	(1,193)	(11.3)%
Amortization and depreciation	249	217	32	14.7%
Total operating expenses	$ 22,474	$ 27,017	$ (4,543)	(16.8)%

Operating expenses were $22.5 million for the year ended December 31, 2023, compared to $27.0 million for the year ended December 31, 2022, a decrease of $4.5 million or 16.8%. The decrease is due primarily to several cost savings initiatives that occurred in Q4 of 2022 and Q1 of 2023.

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2023 decreased by $0.3 million, or 6.0%, from $5.5 million in 2022 to $5.2 million in 2023. The decrease was due primarily to timing as certain projects in 2023 met the criteria for capitalization.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2023 decreased by $3.1 million, or 28.3%, from $10.8 million in 2022 to $7.7 million in 2023. The decrease was due primarily to headcount reductions and additional cost savings initiatives that occurred in late 2022 and early 2023 as well as lower commission expense in 2023.

General and Administrative. General and administrative expenses for the year ended December 31, 2023 decreased by $1.2 million, or 11.3%, from $10.5 million in 2022 to $9.4 million in 2023. The decrease was due primarily to higher personnel costs as the Company utilized higher cost third-parties in place of permanent roles throughout 2022.

Amortization and Depreciation. Amortization and depreciation expenses for the year ended December 31, 2023 increased by less than $0.1 million, or 14.7%, from $0.22 million in 2022 to $0.25 million in 2023. The increase is due primarily to the deployment of a new enterprise resource planning ("ERP") system in early 2023.

Other Income, Tax and Expense (in thousands):

	For the year ended December 31,			
	2023	**2022**	**Change**	**Change %**
Interest expense	$ (16)	$ (10)	$ (6)	60.0%
Interest income	729	213	516	242.3%
Other	(14)	(39)	25	(100.0)%
Total other income	$ 699	$ 164	$ 535	326.2%
Income tax expense	$ (20)	$ 116	$ (136)	(117.2)%
Income (loss) from discontinued operations, net of tax	$ 2,163	$ (3,738)	$ 5,901	(157.9)%

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Interest Expense. The Company recorded less than $0.01 million of interest expense in each of the years ended December 31, 2023 and December 31, 2022.

Interest income. Interest income of $0.7 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively, reflects income earned from the Company's money market accounts. The increase year over year results from higher market interest rates over the period.

Tax expense. The Company recorded tax expense of less than $0.01 million and a tax benefit of $0.1 million for the year ended December 31, 2023 and 2022, respectively. The amount of tax expense or benefit varies based on geographic mix of earnings and losses.

Income (loss) from discontinued operations: This reflects the net income of our former Xoft (Therapy) business, which was sold in October 2023. Upon the closing of the sale, the Company recorded a gain of approximately $2.6 million, which offset the operational losses incurred since the beginning of the year ended December 31, 2023 through the date of the sale in October 2023. See Note 2, for more information.

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Liquidity and Capital Resources

The Company believes that its cash and cash equivalents balance of $21.7 million as of December 31, 2023 and projected cash balances are sufficient to sustain operations through at least the next 12 months following the filing of this Form 10-K. The Company's cash balance increased by approximately $0.4 million year-over-year due primarily to the sale of the Company's former Xoft (Therapy) business line in October 2023. In addition, the Company launched an At-the-Market ("ATM") equity program with Craig-Hallum Capital Group LLC to sell shares of the Company's common stock. See Note 2 and Note 13 respectively, for more information. Lastly, the Company took actions in early 2023 to cut costs and conserve cash. The Company's ability to generate cash adequate to meet its future capital requirements will depend primarily on operating cash flow. If sales or cash collections are reduced from current expectations, or if expenses and cash requirements are increased, the Company may require additional financing, although there are no guarantees that the Company will be able to obtain the financing if necessary. The Company will continue to closely monitor its liquidity and the capital and credit markets.

The Company had net working capital of $24.3 million at December 31, 2023. The ratio of current assets to current liabilities at December 31, 2023 and 2022 was 4.40 and 2.28, respectively.

Net cash used for operating activities for the year ended December 31, 2023 was $5.0 million, compared to $12.8 million for 2022. This improvement of approximately 61% year over year is due primarily to cost savings initiatives commenced during the first quarter of 2023.

Net cash provided by investing activities for the year ended December 31, 2023 was $3.3 million compared to cash used of approximately $0.5 million for the year ended December 31, 2022. The sales of the former Xoft (Therapy) business in October 2023 provided $4.5 million of cash, net of transaction expenses, in 2023 which was partially offset by cash used for investments, primarily a new ERP system.

Net cash provided by financing activities for the year ended December 31, 2023 was $2.0 million and consisted primarily of cash proceeds related to the ATM sales of common stock. Net cash provided by financing activities for the year ended December 31, 2022 was $0.4 million related primarily to cash received for employee equity plan activities.

The CARES Act allowed employers to defer the deposit and payment of employers share of Social Security payroll taxes that would otherwise have been owed from the date of enactment of the legislation. The legislation requires that the deferred taxes be paid over the two-year period, with half the amount required to be paid by December 31, 2021, and the other half by December 31, 2022. During 2022, the Company remitted $0.1 million which represented the second half of the amount due. As of December 31, 2022, the Company has repaid all amounts previously deferred.

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Lease Obligations:

Operating Leases:

See Item 2 of this Annual Report on Form 10-K.

Settlement Obligations:

As a result of the acquisition of Xoft, the Company recorded a royalty obligation pursuant to a settlement agreement entered into between Xoft and Hologic, in August 2007. Xoft received a nonexclusive, irrevocable, perpetual, worldwide license, including the right to sublicense certain Hologic patents, and a non-compete covenant as well as an agreement not to seek further damages with respect to the alleged patent violations. In return, the Company had a remaining obligation to pay a minimum annual royalty payment of $250,000 payable through 2016. In addition to the minimum annual royalty payments, the litigation settlement agreement with Hologic also provided for payment of royalties based upon a specified percentage of future net sales on any products that practice the licensed rights. The estimated fair value of the patent license and non-compete covenant is $100,000 and was amortized over the estimated useful life of approximately four years. As of December 31, 2023, the remaining liability for minimum royalty obligations totaling $0.4 million is recorded within accrued expenses and accounts payable.

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Critical Accounting Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the U.S. requires management to make judgments, assumptions and estimates that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company considers an accounting estimate to be critical to the financial statements if the estimate is complex in nature, requires judgment, and if different estimates were used, the results could have a material impact on the consolidated financial statements. On an ongoing basis, the Company evaluates its estimates and the application of its policies. The Company bases its estimates on historical experience, current conditions and on various other assumptions that are believed to be reasonable under the circumstances. The Company believes the following critical accounting estimates are the most significant to understanding the consolidated financial statements.

Revenue Recognition

The Company recognizes revenue under the provisions of ASU 2014-09, *Revenue from Contracts with Customers* ("ASC 606"). The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASC 606 explains that to achieve the core principle, an entity should take the following actions:

Step 1: Identify the contract with the customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price.

Step 5: Recognize revenue when or as the entity satisfies a performance obligation.

The Company's contracts with customers may include promises to transfer multiple products and services to a customer. Identifying distinct performance obligations that should be accounted for separately versus together may require significant judgment. For arrangements with multiple performance obligations, the Company allocates revenue to each performance obligation based on its relative standalone selling price. Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company generally determines standalone selling prices based on the prices charged to customers and uses a range of amounts to estimate standalone selling prices when the Company sells each of the products and services separately and need to determine whether there is a discount that needs to be allocated based on the relative standalone selling prices of the various products and services. The Company typically has more than one range of standalone selling prices for individual products and services due to the stratification of those products and services by customers and circumstances. In these instances, the Company may use information such as the type of customer and geographic region to determine the range of standalone selling prices.

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Allowance for Expected Credit Losses

The allowance for expected credit losses represents management's estimate for potential uncollectible accounts receivable. This estimate is developed from management's ongoing credit evaluation of Company customers and a detailed review of its outstanding accounts receivable balances.

Inventory

Inventory consists of finished products, work-in-process, and raw materials. The Company values its inventory at the lower of cost or net realizable value. Cost includes materials, labor, and manufacturing overhead and is determined using the first-in, first-out (FIFO) method. On a quarterly basis, management reviews inventory quantities on hand and analyzes the provision for excess and obsolete inventory based primarily on product expiration dating and estimated sales forecast, which is based on sales history and anticipated future demand.

Goodwill

Goodwill represents the amount of consideration paid in connection with business acquisitions in excess of the fair value of assets acquired and liabilities assumed. The Company performs an annual impairment test each year on October 1 using both qualitative and quantitative methods and assumptions. The quantitative test utilizes a combination of both the market and income approach. The most significant estimates in the income approach relate to management's assumptions to calculate a present value of estimated future cash flows.

Stock Based Compensation

The Company uses the Black-Scholes option pricing model to value stock options which requires extensive use of accounting judgment and financial estimates, including estimates of the expected term participants will retain their vested stock options before exercising them, the estimated volatility of its common stock price over the expected term, and the number of options that will be forfeited prior to the completion of their vesting requirements.

Other Commitments

Other Commitments include non-cancelable purchase orders with key suppliers executed in the normal course of business.

Effect of New Accounting Pronouncements

See note 3 in the Notes to Consolidated Financial Statements in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We do not believe we are subject to material foreign currency exchange rate fluctuations, as most of our sales and expenses are domestic and therefore are denominated in the U.S. dollar. For international sales, the majority of those customers pay in the U.S. dollar. We do not hold derivative securities and have not entered into contracts embedded with derivative instruments, such as foreign currency and interest rate swaps, options, forwards, futures, collars, and warrants, either to hedge existing risks or for speculative purposes.

Item 8. Financial Statements and Supplementary Data.

See Financial Statements attached hereto.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

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Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures.

The Company, under the supervision and with the participation of its management, including its principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures as of the end of the period covered by this Annual Report on Form10-K. Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of December 31, 2023.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. The Company conducts periodic evaluations to enhance, where necessary its procedures and controls.

(b) Management's Annual Report on Internal Control Over Financial Reporting.

The Company, under the supervision and with the participation of its management, including its principal executive officer and principal financial officer, is responsible for the preparation and integrity of the Company's Consolidated Financial Statements, establishing and maintaining adequate internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) for the Company and all related information appearing in this Annual Report on Form 10-K.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on its assessment, our Chief Executive Officer and our Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2023.

(c) Changes in Internal Control Over Financial Reporting.

The Company's principal executive officer and principal financial officer conducted an evaluation of the Company's internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) to determine whether any changes in internal control over financial reporting occurred during the fourth quarter of the year ended December 31, 2023, that have materially affected, or which are reasonably likely to materially affect internal control over financial reporting. Based on that evaluation there has been no such change during such period.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 of Form 10-K will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 of Form 10-K will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 of Form 10-K will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 of Form 10-K will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 of Form 10-K will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

a) The following documents are filed as part of this Annual Report on Form 10-K:

i. Financial Statements - See Index on page F-1

ii. Financial Statement Schedule - See Index on page F-1. All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are not applicable and, therefore, have been omitted.

iii. Exhibits - the following documents are filed as exhibits to this Annual Report on Form 10-K:

1.1	At-The-Market Issuance Sales Agreement between iCAD, Inc. and Craig-Hallum Capital Group LLC dated August 11, 2023 (incorporated by reference to Exhibit 1.1 to the Quarterly Report on Form 10-Q filed with the SEC on August 11, 2023).
2.1**	Asset Purchase Agreement dated October 22, 2023 by and among iCAD, Inc. Xoft Solutions, LLC, Xoft, Inc., Elekta Inc. and Nucletron Operations B.V. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on October 23, 2023).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed with the SEC on August 6, 2015).
3.2	Amended and Restated By-laws (incorporated by reference to Exhibit 3(b) to the Current Report on Form 10-K filed with the SEC on March 17, 2008.
3.3	Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on July 21, 2021).
4.1*	Description of Registrant's Securities.
10.1†	2016 Stock Incentive Plan as Amended as of July 2021 (incorporated by reference to Appendix B to the definitive proxy statement on Form DEF14A filed with the SEC on June 7, 2021).
10.2†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 of Quarterly Report on Form 10-Q filed with the SEC on November 15, 2014).
10.3	Lease Agreement, dated December 6, 2006, between the Company and Gregory D. Stoyle and John J. Flatley, Trustees of the 1993 Flatley Family Trust, of Nashua, NH (incorporated by reference to Exhibit 10(mm) to the Annual Report on Form 10-K filed with the SEC on March 22, 2007).
10.4†	Employment Agreement, dated May 26, 2020, between the Company and Stacey Stevens (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on May 29, 2020).
10.5†	Employment Agreement, dated May 26, 2020, between the Company and Jonathan Go (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on May 29, 2020).
10.6	First Amendment to Lease, dated September 19, 2016, between the Company and The Irvine Company (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 21, 2016).
10.7†	2012 Stock Incentive Plan (incorporated by reference to Appendix B to the definitive proxy statement on Form DEF14A filed with the SEC on April 9, 2012).

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10.8†	Amendment No. 1 to the 2012 Stock Incentive Plan (incorporated by reference to Appendix A to the definitive proxy statement on Form DEF14A filed with the SEC on April 2, 2014).
10.9	2019 Employee Stock Purchase Plan (incorporated by reference to Appendix A to the definitive proxy statement on Form DEF14A filed with the SEC on November 8, 2019).
10.10**	Loan and Security Agreement, dated as of March 30, 2020, by and between Western Alliance Bank, iCAD, Inc., Xoft, Inc. and Xoft Solutions LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 31, 2020).
10.11**	First Amendment to Loan and Security Agreement, dated June 16, 2020, between iCAD, Inc., Xoft, Inc., Xoft Solutions LLC and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on August 7, 2020).
10.12†	Employment agreement dated August 4, 2021, by and between iCAD, Inc. and Charles Carter (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on August 6, 2021).
10.13	Lease between The Irvine Company LLC and iCAD, Inc. dated June 29, 2012, together with First Amendment to Lease dated September 19, 2016, Second Amendment to Lease dated August 12, 2019, and Third Amendment to Lease dated May 19, 2022 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on August 15, 2022).
10.14	Lease between John J. Flatley Company and iCAD, Inc., dated December 6, 2006, together with First Amendment to Lease dated December 21, 2011, Second Amendment to Lease dated August 8, 2016, Third Amendment to Lease dated December 16, 2019, and Fourth Amendment to Lease dated November 22, 2022 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on November 28, 2022).
10.15	Consulting Agreement dated January 18, 2023, by and between iCAD, Inc. and Daniel Shea (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 24, 2023).
10.16†	Employment agreement dated March 10, 2023, by and between iCAD, Inc. and Dana Brown (incorporated by reference to Exhibit 10.P to the Current Report on Form 10-K filed with the SEC on March 31, 2023.
10.17†	Separation agreement dated March 10, 2023, by and between iCAD, Inc. and Stacey Stevens (incorporated by reference to Exhibit 10.Q to the Current Report on Form 10-K filed with the SEC on March 31, 2023.
10.18†	Employment Agreement between iCAD, Inc. and Eric Lonnqvist, dated April 13, 2023 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K file with the SEC on April 17, 2023).
10.19*	Lease between Anita R. Jacques Revocable Trust, dated January 6, 2024 and iCAD, Inc.
19.1*	iCAD, Inc. Insider Trading Policy
21.1*	List of Subsidiaries
23.1*	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	iCAD, Inc. Clawback Policy
101*	The following materials formatted in Inline XBRL (eXtensible Business Reporting Language); (i) Consolidated Balance Sheets as of December 31, 2023 and December 31, 2022, (ii) Consolidated Statements of Operations for the years ended

December 31, 2023 and 2022, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2023 and 2022, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022, and (v) Notes to Consolidated Financial Statements.

104 Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

† Denotes a management compensation plan or arrangement.

* Filed herewith.

** The Registrant has omitted certain schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K and shall furnish supplementally to the SEC copies any of the omitted schedules and exhibits upon request by the SEC.

Item 16. Form 10-K Summary.

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly sed this report to be signed on its behalf by the undersigned, thereunto duly authorized.

iCAD, INC.

Date: March 29, 2024

By: /s/ Dana Brown
Dana Brown
Chief Executive Officer, President and Director

The undersigned officers and directors of iCAD, Inc., hereby severally constitute and appoint Dana Brown and Eric Lonnqvist, nd each of them individually, with full power of substitution and resubstitution, as their true and lawful attorneys and agents, to do any nd all acts and things in their name and behalf in their capacities as directors and officers and to execute any and all instruments for them and in their names in the capacities indicated elow, which said attorneys and agents, may deem necessary or advisable to enable said corporation to comply with the Securities Exchange Act of 1934, as amended, and any rules, regulations and requirements of the Securities and Exchange Commission, in connection with this Annual Report on Form 10-K, including pecifically but without limitation, power and authority to sign for them or any of them in their names in the capacities indicated below, ny and all amendments hereto, and they do hereby ratify and confirm all that said attorneys and agents, or either of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the ollowing persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dana Brown Dana Brown	Chief Executive Officer, President, and Director (Principal Executive Officer)	March 29, 2024
/s/ Eric Lonnqvist Eric Lonnqvist	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2024
/s/ Hedvig Hricak Hedvig Hricak, MD, Ph.D.	Director	March 29, 2024
/s/ Michael John Doyle Michael John Doyle	Director	March 29, 2024
/s/ Rakesh Patel Rakesh Patel, MD	Director	March 29, 2024
/s/ Andy Sassine Andy Sassine	Director	March 29, 2024
/s/ Susan Wood Susan Wood, Ph.D.	Director	March 29, 2024

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
iCAD, Inc.
Nashua, New Hampshire

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of iCAD, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition - Identification of distinct performance obligations in certain revenue contracts

As described in Note 3 to the consolidated financial statements, certain of the Company's revenue contracts with customers may include promises to transfer multiple products and services to a customer. To the extent a contract includes multiple promised products or services, the Company must apply judgment to determine whether the products or services meet the criteria to be distinct. For these revenue contracts, the Company accounts for the individual products and services separately if they are distinct.

We identified the determination of distinct performance obligations within certain revenue contracts as a critical audit matter. The determination of whether multiple products and services within a contract were distinct performance obligations that should be accounted for separately required management to exercise judgment and included a high degree of subjectivity. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Evaluating management's accounting policies and practices, including the reasonableness of management's judgments related to the identification of each distinct performance obligation.

- Testing certain revenue contracts together with their underlying documents to evaluate management's identification of each distinct performance obligation.

/s/ BDO USA, P.C.
We have served as the Company's auditor since 1989.
Boston, Massachusetts
March 29, 2024

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iCAD, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
	(in thousands except shares and per share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 21,670	$ 21,313
Trade accounts receivable, net of allowance for credit losses of $277 in 2023 and $100 in 2022	6,392	5,769
Inventory, net	917	2,054
Prepaid expenses and other current assets	699	1,571
Current assets held for sale	—	7,534
Total current assets	29,678	38,241
Property and equipment:		
Internal-use software	1,172	—
Equipment	1,482	1,421
Leasehold improvements	110	110
Furniture and fixtures and other	104	23
Property and equipment	2,868	1,554
Less accumulated depreciation and amortization	1,045	850
Property and equipment, net	1,823	704
Other assets:		
Operating lease assets	461	670
Other assets	849	19
Intangible assets, net of accumulated amortization of $8,488 in 2023 and $8,372 in 2022	148	264
Goodwill	8,362	8,362
Deferred tax assets	97	116
Noncurrent assets held for sale	—	3,329
Total assets	$ 41,418	$ 51,705
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 712	$ 1,446
Accrued and other expenses	2,448	2,541
Lease payable, current	188	217
Deferred revenue, current	3,400	3,653
Current liabilities held for sale	—	5,595
Total current liabilities	6,748	13,452
Lease payable, long-term	273	455
Deferred revenue, long-term	974	393
Deferred tax	6	6
Noncurrent liabilities held for sale	—	2,497
Total liabilities	8,001	16,803
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $ .01 par value: authorized 1,000,000 shares; none issued.	—	—
Common stock, $ .01 par value: authorized 60,000,000 shares; issued 26,540,030 in 2023 and 25,446,407 in 2022. Outstanding 26,354,199 in 2023 and 25,260,576 in 2022	265	254
Additional paid-in capital	306,250	302,899
Accumulated deficit	(271,683)	(266,836)
Treasury stock at cost, 185,831 shares in 2023 and 2022	(1,415)	(1,415)
Total stockholders' equity	33,417	34,902

Total liabilities and stockholders' equity	$ 41,418	$ 51,705

See accompanying notes to consolidated financial statements.

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iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

	For the Years Ended December 31,	
	2023	2022
	(in thousands except per share data)	
Revenue:		
Products	$ 9,930	$ 12,620
Services	7,388	7,182
Total revenue	17,318	19,802
Cost of Revenue:		
Products	1,387	1,658
Services	1,060	1,217
Amortization and depreciation	86	108
Total cost of revenue	2,533	2,983
Gross profit	14,785	16,819
Operating expenses:		
Engineering and product development	5,161	5,493
Marketing and sales	7,740	10,790
General and administrative	9,324	10,517
Amortization and depreciation	249	217
Total operating expenses	22,474	27,017
Loss from operations	(7,689)	(10,198)
Other income (expense)		
Interest expense	(16)	(10)
Interest income	729	213
Other	(14)	(39)
Other income, net	699	164
Loss before income tax expense	(6,990)	(10,034)
Benefit (provision) for income taxes	(20)	116
Loss from continuing operations	(7,010)	(9,918)
Income (loss) from discontinued operations	2,163	(3,738)
Net loss and comprehensive loss	$ (4,847)	$ (13,656)
Net loss per share:		
Loss from continuing operations, basic and diluted	$ (0.27)	$ (0.39)
Loss from discontinued operations, basic and diluted	0.08	(0.15)
Net loss per share, basic and diluted	$ (0.19)	$ (0.54)
Weighted average number of shares used in computing net loss per share:		
Basic	25,613	25,202
Diluted	25,613	25,202

See accompanying notes to consolidated financial statements.

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iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity
(in thousands except shares)

	Common Stock		Additional Paid-in	Accumulated	Treasury	Stockholders'
	Number of Shares Issued	Par Value	Capital	Deficit	Stock	Equity
Balance at December 31, 2021	25,326,086	$ 253	$ 300,859	$ (253,180)	$ (1,415)	$ 46,517
Issuance of common stock relative to vesting of restricted stock, net of 150 shares forfeited for tax obligations	725	—	—	—	—	—
Issuance of common stock pursuant to stock option plans	73,500	1	206	—	—	207
Issuance of common stock pursuant to employee stock purchase plan	46,096	—	148	—	—	148
Stock-based compensation	—	—	1,686	—	—	1,686
Net loss	—	—	—	(13,656)	—	(13,656)
Balance at December 31, 2022	25,446,407	$ 254	$ 302,899	$ (266,836)	$ (1,415)	$ 34,902
Issuance of common stock, net of issuance costs of $338	1,057,814	11	1,955	—	—	1,966
Issuance of common stock pursuant to stock option plans	35,809	—	80	—	—	80
Stock-based compensation	—	—	1,316	—	—	1,316
Net loss	—	—	—	(4,847)	—	(4,847)
Balance at December 31, 2023	26,540,030	$ 265	$ 306,250	$ (271,683)	$ (1,415)	$ 33,417

See accompanying notes to consolidated financial statements.

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iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2023	**2022**
	(in thousands)	
Cash flow from operating activities:		
Net loss	(4,847)	$ (13,656)
Adjustments to reconcile net loss to net cash used for operating activities:		
Gain on sale of business	(2,592)	—
Amortization	170	211
Depreciation	239	310
Non-cash lease expense	462	708
Bad debt provision	177	732
Stock-based compensation expense	1,316	1,686
Deferred tax	20	(116)
Other, net	(1)	9
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	419	(739)
Inventory	1,489	(1,218)
Prepaid and other assets	840	1,152
Accounts payable	(811)	(806)
Accrued and other expenses	(1,554)	(961)
Lease liabilities	(484)	(767)
Deferred revenue	193	665
Total adjustments	(117)	866
Net cash provided by (used for) operating activities	(4,964)	(12,790)
Cash flow used for investing activities:		
Proceeds from sale of business, net of transaction costs	4,539	—
Additions to patents, technology and other	—	(10)
Additions to property and equipment	(922)	(524)
Capitalization of internal-use software development costs	(342)	—
Net cash provided by (used for) investing activities	3,275	(534)
Cash flow from financing activities:		
Issuance of common stock for cash, net	1,966	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	—	148
Issuance of common stock pursuant to stock option plans	80	207
Net cash provided by financing activities	2,046	355
Increase (decrease) in cash and cash equivalents	357	(12,969)
Cash and cash equivalents, beginning of year	21,313	34,282
Cash and cash equivalents, end of year	$ 21,670	$ 21,313
Supplemental disclosure of cash flow information:		
Interest paid	$ 16	$ 9
Taxes paid	$ —	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 3,011

See accompanying notes to consolidated financial statements.

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iCAD, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 1 – Organization and Business

Unless otherwise noted, all amounts presented in these Notes to the Consolidated Financial Statements are in thousands of dollars. iCAD, Inc. and subsidiaries (the "Company" or "iCAD") is a global medical technology company providing innovative cancer detection solutions.

As discussed in Note 2, the Company completed the sale of its Xoft business line in October 2023. Accordingly, the Company now operates in one segment: Cancer Detection ("Detection"). The Detection segment solutions include advanced artificial intelligence and image analysis workflow solutions that enable healthcare professionals to better serve patients by identifying pathologies and pinpointing the most prevalent cancers earlier, a comprehensive range of high-performance, upgradeable computer-aided detection systems and workflow solutions for digital breast tomosynthesis, full-field digital mammography, magnetic resonance imaging and computed tomography. The Company's commercial products are cleared with the United States Food and Drug Administration and various global regulatory agencies. The Company sells its products throughout the world through its direct sales organization as well as through various OEM partners, distributors, technology platform partners, and resellers. See Note 15 of these consolidated financial statements for segment, major customer and geographical information.

The Company maintains its headquarters and a separate manufacturing facility in Nashua, New Hampshire and an office in Lyon, France.

Note 2 – Discontinued Operations

On October 22, 2023, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement"), by and among (i) the Company, Xoft Solutions, LLC, a Delaware limited liability company, and Xoft, Inc., a Delaware corporation, each a wholly owned subsidiary of the Company (collectively with the Company, the "Sellers" and each, a "Seller"), and (ii) Elekta Inc., a Georgia corporation, and Nucletron Operations B.V., a company organized under the laws of the Netherlands (together, "Buyers" and each a "Buyer"), pursuant to which the Company agreed to transfer to the Buyers substantially all of the assets and liabilities primarily related to the Company's Xoft business lines (the "Business"), including with respect to employees, contracts, intellectual property and inventory, for total cash consideration of approximately $5.76 million dollars from the Buyers to the Company, and the assumption by Buyers of all liabilities relating to the Business (the "Transaction"). This payment is guaranteed by Elekta AB, a company organized under the laws of Sweden, the ultimate parent company of the Buyers. In accordance with the Purchase Agreement, the Company received a cash payment of approximately $5 million in November 2023 with the remaining $0.7 million held in escrow for a period of 15 months following October 22, 2023. The escrow balance is reflected in the caption Other assets in the long-term section of the Company's Consolidated Balance Sheet as of December 31, 2023.

The closing of the Transaction occurred simultaneously with the execution of the Purchase Agreement.

In connection with the Transaction, the parties entered into a transition services agreement pursuant to which the Company will provide certain migration and transition services to facilitate an orderly transition of the operation of the Business to the Buyers during the 5-month period following consummation of the Transaction, extendable at the option of the parties.

The Purchase Agreement contains certain representations, warranties, covenants and indemnification provisions, including for breaches of covenants and for losses resulting from the Company's liabilities specifically excluded from the Transaction.

The Business, which had previously been presented as a separate reporting segment, meets the criteria for being reported as a discontinued operation and has been segregated from continuing operations. The following table summarizes the results from discontinued operations (in thousands):

	For the period ended October 22, 2023	For the year ended December 31, 2022

Revenue	$ 4,804	$ 8,142
Total cost of sales	2,580	5,152
Gross profit	$ 2,224	$ 2,990
Total operating expenses	2,653	6,728
Pre-tax loss from operations of discontinued business	(429)	(3,738)
Provision for income taxes	—	—
Loss from operations of discontinued business	$ (429)	$ (3,738)
Gain on sale of discontinued operations	2,592	—
Provision for income taxes on gain on sale	—	—
Income (loss) from discontinued operations, net of tax	$ 2,163	$ (3,738)

The following table summarizes the assets and liabilities held for sale in the Company's Consolidated Balance Sheets (in thousands):

	December 31, 2022
Assets	
Accounts receivable, net of allowance for credit losses	$ 3,129
Inventories, net	3,335
Prepaid expenses and other current assets	1,070
Total current assets held for sale	$ 7,534
Net property and equipment	$ 370
Operating lease assets	2,691
Other assets	268
Total noncurrent assets held for sale	$ 3,329
Liabilities	
Accounts payable	$ 527
Accrued and other expenses	2,140
Lease payable - current portion	365
Deferred revenue - current portion	2,563
Total current liabilities held for sale	$ 5,595
Lease payable, net of current	2,348
Deferred revenue, net of current	149
Noncurrent liabilities held for sale	$ 2,497

Total operating expenses presented in the table above exclude amounts that had previously been allocated to the Business for certain shared marketing expenses. The previously allocated amounts were less than $0.1 million and $0.6 million for the years ended December 31, 2023 and 2022, respectively. The previously allocated expenses are included in the Marketing and sales line for all periods presented in the Condensed Consolidated Statements of Operations.

The Business is included in the Company's Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022. The Business generated less than $0.1 million of cash during the year ended December 31, 2023, primarily for operating activities. Estimated cash used by the Business during the year ended December 31, 2022 was approximately $3.6 million, primarily for operating activities.

Note 3 – Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses during the reporting period and disclosure of contingent assets and liabilities at the date of the financial statements. Actual results could differ from those estimates. It is reasonably possible that changes may occur in the near term that would affect management’s estimates with respect to assets and liabilities.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, iCAD France, LLC. As described in Note 2, the Company completed the sale of the Xoft business line in October 2023. Accordingly, the applicable assets and liabilities of the Xoft business have been classified as held for sales in the Consolidated Balance Sheet for periods prior to the date of sale, and the results of its operations for all periods presented are reflected as discontinued operations in the Consolidated Statements of Operations. Unless otherwise indicated, all disclosures and amounts in the Notes to the Consolidated Financial Statements relate to the Company's continuing operations. All material inter-company transactions and balances have been eliminated in consolidation.

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Risk and Uncertainty

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, the United States and most countries of the world imposed some level of unprecedented restrictions such as travel bans and business closures which caused substantial reductions in economic activity. As a provider of devices and services to the health care industry, the Company believes its operations have been materially affected in all periods presented. While the worst of the disruptions appear to have subsided as of December 31, 2023, the Company continues to be impacted by slowness in the overall economic recovery. The Company's expected results for future periods could reflect a continuing negative impact from the COVID-19 pandemic for similar or additional reasons.

In late February 2022, Russian military forces launched significant military action against Ukraine. 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 has continued through December 31, 2023 and beyond. 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; may be subject to government export controls, economic sanctions, embargoes, or trade restrictions; and experience currency, inflation, and interest rate uncertainties. While the impact to the Company has been limited to date, it is not possible to predict the potential outcome should the conflict expand and/or additional sanctions be imposed. For the fiscal year ended 2023, approximately 10% of the Company's total revenue was derived from customers located in Europe.

Cash and cash equivalents

The Company defines cash and cash equivalents as all bank accounts, money market funds, deposits and other money market instruments with original maturities of 90 days or less and which are unrestricted as to timing or method of withdrawal. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits of $250,000 per depositor. The money market investment account as described in Note 5 is not exposed to the federally insured limit as it is not a deposit account. As of December 31, 2023, the Company held cash at financial institutions in excess of the federally insured limit. Historically, the Company has not experienced any losses related to these balances.

Financial instruments

Financial instruments consist of cash and cash equivalents, trade accounts receivable, contract assets, accounts payable, accrued and other expenses and notes payable. Due to their short-term nature and market rates of interest, the carrying amounts of the financial instruments approximated fair value as of December 31, 2023 and 2022.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable are customer obligations due under normal trade terms. Credit limits are initially established through a process of reviewing the financial history and stability of each customer and the Company performs continuing credit evaluations of its customers' financial condition and generally does not require collateral. Included in accounts receivable at December 31, 2023 are unbilled receivables of approximately $0.9 million which are scheduled to be invoiced primarily in 2024. Unbilled receivables of approximately $0.2 million were included in accounts receivable as of December 31, 2022. The unbilled receivables result primarily from the Company's sale of term licenses, which often provide for annual billing over a term of one to three years, where revenue is recognized upon delivery of a license with non-cancellable terms.

As described in Note 4, the Company adopted new accounting guidance effective January 1, 2023 that impacted its approach to calculating expected losses on its Accounts receivable balances. The Company maintains an allowance for expected credit losses associated with its Accounts receivable balance. The Company uses an expected credit loss model that uses historical loss rates of its accounts receivable for the previous twelve months as well as expectations about the future where the Company has been able to develop forecasts to support its estimates. Using the outputs of the model, the Company's policy is to maintain allowances for potential losses. An amount is written off against the allowance for credit losses after all attempts to collect the receivable have failed. Based on the information available, the Company believes the allowance for credit losses as of December 31, 2023 and 2022 is adequate.

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Inventory

The Company uses the first-in, first-out method to track inventory, which is valued at the lower of cost or net realizable value. The Company regularly reviews inventory quantities on hand and records an inventory reserve for excess and/or obsolete inventory primarily based upon the estimated usage of its inventory, as well as other factors.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which is generally three to five years, except for leasehold improvements, which are depreciated over the shorter of the term of the lease, or useful life of the asset.

Goodwill

In accordance with FASB Accounting Standards Codification ("ASC") Topic 350-20, *"Intangibles—Goodwill and Other*" ("ASC 350-20"), the Company tests goodwill for impairment on an annual basis and between annual tests if events or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount.

Factors the Company considers important, which could trigger an impairment of Goodwill, include the following:

- significant and sustained underperformance relative to historical or projected future operating results;
- significant changes in the manner or use of the Company's assets in the strategy for the Company's overall business;
- significant negative industry or economic trends;
- significant and sustained decline in the Company's stock price; and
- a decline in the Company's market capitalization below net book value.

Upon the sale of its former Xoft business, the Company has one reporting unit: Detection.

The Company performs an annual impairment assessment as of October 1 of each year by comparing the fair value of its reporting unit to its carrying value as of this date. The Company records an impairment charge if such an assessment were to indicate that the fair value of its reporting unit was less than the carrying value. When the Company evaluates potential impairments outside of its annual measurement date, judgment is required in determining whether an event has occurred that may impair the value of goodwill or intangible assets. For 2023, the fair value of the reporting unit was based on the Company's market capitalization as of October 1, 2023, which was in excess of the carrying value of the reporting unit. Accordingly, the Company concluded that no impairment charges were required. For years prior to 2023, the Company used the following approach in assessing fair value of its reporting unit.

Fair value of the reporting unit is based on a weighting of the income approach and the market approach. For purposes of the income approach, fair value is determined based on the present value of estimated future cash flows, discounted at an appropriate risk adjusted rate. The Company uses internal forecasts to estimate future cash flows and includes estimates of long-term future growth rates based on our most recent views of the long-term forecast for each segment. Accordingly, actual results can differ from those assumed in our forecasts. Discount rates are derived from a capital asset pricing model and by analyzing published rates for industries relevant to our reporting units to estimate the cost of equity financing. The Company uses discount rates that are commensurate with the risks and uncertainty inherent in the respective businesses and in our internally developed forecasts.

In the market approach, the Company uses a valuation technique in which values are derived based on market prices of publicly traded companies with similar operating characteristics and industries. A market approach allows for comparison to actual market transactions and multiples. It can be somewhat limited in its application because the population of potential comparable publicly-traded companies can be limited due to differing characteristics of the comparative business and ours, as well as the fact that market data may not be available for divisions within larger conglomerates or non-public subsidiaries that could otherwise qualify as comparable, and the specific circumstances surrounding a market transaction (e.g., synergies between the parties, terms and conditions of the transaction, etc.) may be different or irrelevant with respect to our business.

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The Company corroborates the total fair values of the reporting unit using a market capitalization approach since it now operates with only one reporting unit. The blend of the income approach and market approach is more closely aligned to the Company's business profile, including markets served and products available. In addition, required rates of return, along with uncertainties inherent in the forecast of future cash flows, are reflected in the selection of the discount rate. Equally important, under the blended approach, reasonably likely scenarios and associated sensitivities can be developed for alternative future states that may not be reflected in an observable market price. The Company assesses each valuation methodology based upon the relevance and availability of the data at the time the valuation is performed and weights the methodologies appropriately.

Long Lived Assets

In accordance with FASB ASC Topic 360, “Property, Plant and Equipment” (“ASC 360”), the Company assesses long-lived assets for impairment if events and circumstances indicate it is more likely than not that the fair value of the asset group is less than the carrying value of the asset group.

ASC 360-10-35 uses “events and circumstances” criteria to determine when, if at all, an asset (or asset group) is evaluated for recoverability. Thus, there is no set interval or frequency for recoverability evaluation. In accordance with ASC 360-10-35-21 the following factors are examples of events or changes in circumstances that indicate the carrying amount of an asset (asset group) may not be recoverable and thus is to be evaluated for recoverability.

- A significant decrease in the market price of a long-lived asset (asset group);
- A significant adverse change in the extent or manner in which a long-lived asset (asset group) is being used or in its physical condition;
- A significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset (asset group), including an adverse action or assessment by a regulator;
- An accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset (asset group);
- A current period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset (asset group);
- significant and sustained decline in the Company’s stock price.

In accordance with ASC 360-10-35-17, if the carrying amount of an asset or asset group (in use or under development) is evaluated and found not to be fully recoverable (the carrying amount exceeds the estimated gross, undiscounted cash flows from use and disposition), then an impairment loss must be recognized. The impairment loss is measured as the excess of the carrying amount over the assets (or asset group’s) fair value.

The Company did not record any impairment charges on its long-lived assets for the years ended December 31, 2023 or December 31, 2022.

Intangible assets subject to amortization consist primarily of patents, technology intangibles, trade names, customer relationships and distribution agreements purchased in the Company's previous acquisitions. These assets are amortized on a straight-line basis or the pattern of economic benefit over their estimated useful lives of 5 to 10 years.

Leases

In accordance with FASB ASC Topic 842, "Leases" ("ASC 842"), the Company determines if an arrangement contains a lease at inception. A lease is an operating or financing contract, or part of a contract, that conveys the right to control the use of an identified tangible asset for a period of time in exchange for consideration.

At lease inception, the Company recognizes a lease liability equal to the present value of the remaining lease payments, and a right of use asset equal to the lease liability, subject to certain adjustments, such as for lease incentives. In determining the present value of the lease payments, the Company uses its incremental borrowing rate, determined by estimating the Company's applicable, fully collateralized borrowing rate, with adjustment as appropriate for lease term. The lease term at the lease commencement date is determined based on the non-cancellable period for which the Company has the right to use the underlying asset, together with any periods covered by an extension option if the Company is reasonably certain to exercise that option.

Right-of-use assets and obligations for leases with an initial term of 12 months or less are considered short term and are a) not recognized in the consolidated balance sheet and b) recognized as an expense on a straight-line basis over the lease term. The Company does not sublease any of its leased assets to third parties and the Company's lease agreements do not contain any residual value guarantees or restrictive covenants. The Company has lessor agreements that contain lease and non-lease components, but the Company is accounting for the complete agreement under FASB ASC Topic 606, "Revenue from Contracts with Customers", ("ASC 606"), after determining that the non-lease component is the predominant component of these agreements.

ASC 842 includes a number of reassessment and re-measurement requirements for lessees based on certain triggering events or conditions. There were no impairment indicators identified during the year ended December 31, 2023 that would require impairment testing of the Company's right-of-use assets.

Certain of the Company's leases include variable lease costs to reimburse the lessor for real estate tax and insurance expenses, and certain non-lease components that transfer a distinct service to the Company, such as common area maintenance services. The Company has elected to separate the accounting for lease components and non-lease components for real estate and equipment leases.

Stock-Based Compensation

The Company maintains stock-based incentive plans, under which it provides stock incentives to employees, directors and contractors. The Company grants to employees, directors and contractors, options to purchase common stock at an exercise price equal to the market value of the stock at the date of grant. The Company may grant restricted stock to employees and directors. The underlying shares of the restricted stock grant are not issued until the shares vest, and compensation expense is based on the stock price of the shares at the time of grant. The Company follows ASC 718, *"Compensation – Stock Compensation*", ("ASC 718"), for all stock-based compensation. The Company has granted performance based restricted stock based on achievement of certain revenue targets. Compensation cost for performance based restricted stock requires significant judgment regarding probability of the performance objectives and compensation cost is re-measured at every reporting period. As a result, compensation cost could vary significantly during the performance measurement period.

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The Company uses the Black-Scholes option pricing model to value stock options which requires extensive use of accounting judgment and financial estimates, including estimates of the expected term participants will retain their vested stock options before exercising them, the estimated volatility of its common stock price over the expected term, and the number of options that will be forfeited prior to the completion of their vesting requirements. The Company estimates forfeitures based on historical experience with pre-vested forfeitures. To the extent actual forfeitures differ from the estimate, the difference is recorded to compensation expense in the period of the forfeiture. Fair value of restricted stock is determined based on the stock price of the underlying option on the date of the grant. Application of alternative assumptions could produce significantly different estimates of the fair value of stock-based compensation and consequently, the related amounts recognized in the Consolidated Statements of Operations.

Revenue Recognition

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised products or services and the amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products or services and excludes any sales incentives or taxes collected from customers which are subsequently remitted to government authorities. The Company's revenue contracts with customers may include promises to transfer multiple products and services to a customer.

The Company applies the following five steps to guide revenue recognition:

1) **Identify the contract(s) with a customer**—A contract with a customer exists when (i) the Company enters into an enforceable contract with a customer that defines each party's rights regarding the products or services to be transferred and identifies the payment terms related to those products or services, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for products or services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company's contracts are typically in the form of a purchase order. For certain large customers, the Company may also enter into master service agreements that define general terms but are not customer commitments to purchase until coupled with a purchase order. The Company applies judgment in determining the customer's ability and intention to pay, which is based on a variety of factors including the customer's historical payment experience or published credit and financial information pertaining to the customer.

2) **Identify the performance obligations in the contract**—Performance obligations promised in a contract are identified based on the products or services that will be transferred. A product or service is distinct if both a) the customer can benefit from the product or service either on its own or together with other resources that are readily available from third parties or from the Company, and b) is separately identifiable from other promises in the contract. To the extent a contract includes multiple promised products or services, the Company must apply judgment to determine whether the products or services meet the criteria to be distinct. If these criteria are not met the promised products or services are accounted for as a combined performance obligation. While the Company does not typically sell options to purchase products or services at a predetermined price, doing so would represent a material right and require analysis to determine if the material right is a distinct performance obligation.

3) **Determine the transaction price**—The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring products or services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur.

4) **Allocate the transaction price to the performance obligations in the contract**—If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative Stand-alone Sales Price ("SSP") basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct product or service that forms part of a performance obligation. The Company determines SSP based on the price at which the performance obligation is sold separately. If the SSP is not observable through past transactions, the Company estimates the SSP taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

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5) **Recognize revenue when (or as) the Company satisfies a performance obligation**—The Company satisfies performance obligations either over time or at a point in time as discussed in further detail below. Revenue is recognized at the time the related performance obligation is satisfied by transferring a promised product or service to a customer.

The Company recognizes revenue from its contracts with customers primarily from the sale of products and from the sale of services. Revenue is recognized when control of the promised goods or services is transferred to a customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. For iCAD's typical product revenue, control typically transfers upon shipment as title and risk of loss have passed to the customer. Services and supplies are considered to be transferred as the services are performed or over the term of the service or supply agreement. The Company enters into contracts that can include various combinations of products and services, which are generally capable of being distinct and accounted for as separate performance obligations. Perpetual software licenses are accounted for as a single performance obligation and revenue is recognized at the point in time when ownership is transferred to the customer. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Company from a customer, are excluded from revenue. Shipping and handling costs associated with outbound freight after control of a product has transferred to a customer are accounted for as fulfillment costs and are included in cost of revenue. The Company continues to provide for estimated warranty costs on original product warranties at the time of sale.

Goods and Services Classifications

Products. Product revenue consists of sales of cancer detection perpetual or term licenses. The Company transfers control and recognizes a sale when the product is shipped from the manufacturing or warehousing facility to the customer.

Service Contracts. The Company sells service contracts in which the Company provides professional services including product installations, maintenance, training and service repairs. The service contracts range from 12 months to 48 months. The Company typically receives payment at the inception of the contract and recognizes revenue on a straight-line basis over the term of the agreement.

Professional Services. Revenue from fixed fee service contracts is recognized on a straight-line basis over the term of the agreement. Revenue from professional service contracts entered into with customers on a time and materials basis is recognized over the term of the agreement in proportion to the costs incurred in satisfying the obligations under the contract.

Other. Other revenue consists primarily of miscellaneous products and services. The Company transfers control and recognizes a sale when the installation services are performed or when the Company ships the product from the Company's manufacturing or warehouse facility to the customer.

For all of contracts, payment terms are generally net 30 from the time of invoicing and consideration is fixed in nature. If the Company were to offer extended payment terms, it would assess whether a significant financing component existed.

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Significant Judgments

The Company's contracts with customers may include promises to transfer multiple products and services to a customer and identifying distinct performance obligations that should be accounted for separately versus together may require significant judgment. For arrangements with multiple performance obligations, the Company allocates revenue to each performance obligation based on its relative standalone selling price. Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company generally determines standalone selling prices based on the prices charged to customers and uses a range of amounts to estimate standalone selling prices when the Company sells each of the products and services separately and needs to determine whether there is a discount that needs to be allocated based on the relative standalone selling prices of the various products and services. The Company typically has more than one range of standalone selling prices for individual products and services due to the stratification of those products and services by customers and circumstances. In these instances, the Company may use information such as the type of customer and geographic region in determining the range of standalone selling prices.

The Company may provide credits or incentives to customers, which are accounted for as variable consideration when estimating the transaction price of the contract and amounts of revenue to recognize. The amount of variable consideration to include in the transaction price is estimated at contract inception using either the estimated value method or the most likely amount method based on the nature of the variable consideration. These estimates are updated at the end of each reporting period as additional information becomes available and revenue is recognized only to the extent that it is probable that a significant reversal of any amounts of variable consideration included in the transaction price will not occur. The Company provides for estimated warranty costs on original product warranties at the time of sale.

Assets Recognized from the Costs to Obtain a Contract with a Customer

The Company recognizes incremental costs of obtaining a contract with a customer as an asset if the Company expects the benefit of those costs to be longer than one year and as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less.

Right to Invoice

Where applicable, the Company recognizes revenue from a contract with a customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date and the amount to which the Company has a right to invoice.

Sales and Other Similar Taxes

The Company excludes sales taxes and similar taxes from the measurement of the transaction price.

Significant Financing Component

The Company does not adjust the promised amount of consideration for the effects of a significant financing component if the Company expects, at contract inception, that the period between when the entity transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.

Promised Goods or Services that are Immaterial in the Context of a Contract

The Company assesses materiality of promised goods or services as performance obligations in the context of a contract and the Company does not aggregate and assess immaterial items at the entity level. When determining whether a good or service is immaterial in the context of a contract, the assessment will be made based on the application of ASC 606 at the contract level.

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The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed.

Cost of Revenue

Cost of revenue consists of the costs of products purchased for resale, cost relating to service including costs of service contracts to maintain equipment after the warranty period, inbound freight and duty, manufacturing, warehousing, material movement, inspection, scrap, rework, depreciation and in-house product warranty repairs, amortization of acquired technology and any applicable medical device tax.

Warranty Costs

The Company provides for the estimated cost of standard product warranty against defects in material and workmanship based on historical warranty trends, including the cost of product returns during the warranty period. Warranty costs have not historically been material to the Company's consolidated financial statements.

Engineering and Product Development Costs and Capitalized Internal-Use Software Costs

Engineering and product development costs relate to research and development efforts including Company sponsored clinical trials are expensed as incurred. Capitalized costs include payroll and payroll-related costs for employees and external consulting fees in the Company's development directly associated with the Company's internal-use software projects. Capitalization begins when the planning stage is complete and the Company commits resources to the software project and capitalization continues during the application development stage. Capitalization ends when the software has been tested and is ready for its intended use. Costs incurred during the planning, training and post-implementation stages of the software development life-cycle are expensed as incurred. When placed into service, the Company amortizes completed internal-use software to cost of revenue over its estimated useful life.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising expense for the years ended December 31, 2023 and 2022 was approximately $0.2 million and $0.4 million, respectively.

Income Taxes

The Company follows the liability method under ASC Topic 740 "*Income Taxes*", ("ASC 740"). The primary objectives of accounting for taxes under ASC 740 are to (a) recognize the amount of tax payable for the current year and (b) recognize the amount of deferred tax liability or asset for the future tax consequences of events that have been reflected in the Company's financial statements or tax returns. As of December 31, 2023 and December 31, 2022, the Company has provided a valuation allowance for its U.S. federal and state net operating loss carryforwards due to the uncertainty of the Company's ability to generate sufficient taxable income in future years to obtain the benefit from the utilization of the net operating loss carryforwards. As of December 31, 2023 and 2022, the Company has not provided a valuation allowance for its foreign net operating loss carryforward. Any subsequent changes in the valuation allowance will be recorded through operations in the provision (benefit) for income taxes. See note 13 of these consolidated financial statements for detailed information.

Note 4 – Recently Issued Accounting Standards

Recently adopted accounting pronouncements

In June 2016, the Financial Accounting Standards Board (the "FASB") issued ASU 2016-13, "Financial Instruments—Credit Losses (Topic 326)" ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaced the then-existing incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. These changes will result in earlier recognition of credit losses. In November 2019, the FASB elected to defer the adoption date of ASU 2016-13 for public business entities that meet the definition of a smaller reporting company to fiscal years beginning after December 15, 2022. Early adoption of the guidance in ASU 2016-13 was permitted. The Company adopted ASU 2016-13 effective January 1, 2023. Adoption caused the Company to modify its approach to estimating its allowance for potentially uncollectable accounts receivable. Specifically, the Company began applying an expected credit loss model

that uses historical loss rates of its accounts receivable for the previous twelve months as well as expectations about the future where the Company has been able to develop forecasts to support its estimates. Adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements.

Recently issued accounting pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07). ASU 2023-07 is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses, including for single reportable segment entities. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. We are evaluating the disclosure requirements related to the new standard.

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures (ASU 2023-09). ASU 2023-09 requires more detailed income tax disclosures. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We are evaluating the disclosure requirements related to the new standard.

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Note 5 – Fair Value Measurements

The Company follows the provisions of FASB ASC Topic 820, "*Fair Value Measurement and Disclosures*" ("ASC 820"), which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The Company applies the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, which are the following:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value

The assigned level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Money market funds included in cash and cash equivalents in the accompanying balance sheet are considered a Level 1 measurement as they are valued at quoted market prices in active markets.

The following table sets forth the Company's assets which are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

Fair Value Measurements (in thousands) as of December 31, 2023

	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$ 15,475	$ —	$ —	$ 15,475
Total Assets	$ 15,475	$ —	$ —	$ 15,475

Fair Value Measurements (in thousands) as of December 31, 2022

	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$ 15,067	$ —	$ —	$ 15,067
Total Assets	$ 15,067	$ —	$ —	$ 15,067

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There were no Level 3 instruments measured at fair value at December 31, 2023 or December 31, 2022.

Items Measured at Fair Value on a Nonrecurring Basis

Certain assets, including long-lived assets and goodwill, are measured at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be impaired. There were no items measured at fair value on a nonrecurring basis as of or during the years ended December 31, 2023 and 2022.

Note 6 – Revenue

Disaggregation of Revenue

The following tables presents the Company's revenues disaggregated by major product or service line, timing of revenue recognition and sales channel, reconciled to its reportable segments (in thousands).

	Years ended December 31, Reportable Segments Detection	
	2023	**2022**
Major Product/Service Lines		
Products	$ 9,930	$ 12,620
Services	7,388	7,182
	$ 17,318	$ 19,802
Timing of Revenue Recognition		
Goods transferred at a point in time	$ 8,015	$ 12,545
Services transferred over time	9,303	7,257
	$ 17,318	$ 19,802
Sales Channels		
Direct sales force	$ 11,634	$ 12,468
OEM partners	5,684	7,334
	$ 17,318	$ 19,802

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Contract Balances

Contract liabilities are a component of deferred revenue, current contract assets are a component of prepaid and other assets and non-current contract assets are a component of other assets. The following table provides information about receivables, current and non-current contract assets, and contract liabilities from contracts with customers (in thousands).

	Balance at December 31, 2023	Balance at December 31, 2022	Balance at December 31, 2021
Receivables, which are included in 'Trade accounts receivable'	$ 6,392	$ 5,769	$ 4,263
Current contract assets, which are included in "Prepaid and other assets"	$ —	$ 748	$ 1,895
Non-current contract assets, which are included in "other assets"	$ 157	$ 15	$ 844
Contract liabilities, which are included in "Deferred revenue"	$ 4,374	$ 4,046	$ 3,621

The Company records a receivable when revenue is recognized prior to receipt of cash payments and the Company has the unconditional right to such consideration, or deferred revenue when cash payments are received or due in advance of performance. For multi-year agreements, the Company generally invoices customers annually at the beginning of each annual service period.

The Company records net contract assets or contract liabilities on a contract-by-contract basis. The Company records a contract asset for unbilled revenue when the Company's performance exceeds amounts billed or billable. The Company classifies the net contract asset as either current or non-current based on the expected timing of the Company's right to bill under the terms of the contract. The current contract asset balance primarily relates to the net unbilled revenue balances with two significant customers, which the Company expects to be able to bill for within one year. The non-current contract asset balance consists of net unbilled revenue balances with two customers which the Company expects to be able to bill for in more than one year.

Contract liabilities, or deferred revenue from contracts with customers, is primarily composed of fees related to long-term service arrangements, which are generally billed in advance. Deferred revenue also includes payments for installation and training that has not yet been completed and other offerings for which the Company has been paid in advance and earns the revenue when it transfers control of the product or service.

Changes in deferred revenue from contracts with customers were as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Balance at beginning of period	$ 4,046	$ 3,621
Deferral of revenue	7,669	8,546
Recognition of deferred revenue	(7,341)	(8,121)
Balance at end of period	$ 4,374	$ 4,046

The Company expects to recognize estimated revenues related to performance obligations that are unsatisfied (or partially satisfied) in the amounts of approximately $3.4 million over the next 12 months. The remainder of the balances is expected to be recognized over the next two to three years.

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Assets Recognized from the Costs to Obtain a Contract with a Customer

The Company recognizes an asset for the incremental costs of obtaining a contract with a customer if it expects the benefit of those costs to be longer than one year. As of and for the years ending December 31, 2023 and 2022, there were no such assets.

Note 7 – Net Loss per Common Share

The Company follows FASB ASC 260-10, *"Earnings per Share"*, which requires the presentation of both basic and diluted earnings per share on the face of the statements of operations. The Company's basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period and, if there are dilutive securities, diluted income per share is computed by including common stock equivalents which includes shares issuable upon the exercise of stock options, net of shares assumed to have been purchased with the proceeds, using the treasury stock method.

A summary of the Company's calculation of net loss per share is as follows (in thousands, except per share amounts):

	2023	2022
Loss from continuing operations	$ (7,010)	$ (9,918)
Income (loss) from discontinued operations	2,163	(3,738)
Net loss	$ (4,847)	$ (13,656)
Basic shares used in the calculation of earnings per share	25,613	25,202
Effect of dilutive securities:		
Stock options	—	—
Restricted stock	—	—
Diluted shares used in the calculation of earnings per share	25,613	25,202
Net loss per share (Basic and Diluted):		
Loss from continuing operations	$ (0.27)	$ (0.39)
Income (loss) from discontinued operations	0.08	(0.15)
Net loss per share (Basic and Diluted)	$ (0.19)	$ (0.54)

The following table summarizes the number of shares of common stock options that were not included in the calculation of diluted net loss per share because such shares are antidilutive:

	Year Ended December 31,	
	2023	2022
Common stock options	2,897,663	2,610,659

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Note 8 – Accounts Receivable Reserves

The rollforward of the Company's allowance for credit losses related to its accounts receivable for the years ended December 31 is as follows (in thousands):

	2023	2022
Balance at beginning of period	$ 100	$ 97
Additions charged to costs and expenses	177	77
Reductions	—	(74)
Balance at end of period	$ 277	$ 100

Note 9 – Inventories

Inventory balances at December 31, 2023 and 2022 were as follows (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 583	$ 1,427
Work in process	55	184
Finished Goods	324	488
Inventory Gross	962	2,099
Inventory Reserve	(45)	(45)
Inventory Net	$ 917	$ 2,054

Note 10 – Goodwill and Intangible assets

At December 31, 2023 and 2022, all of the Company's goodwill of $8,362,000 is allocated to its single reporting unit: Detection. There were no additions, impairments or other changes to the Company's goodwill balance for either of the years ended December 31, 2023 or 2022.

Amortization expense related to intangible assets was approximately $116,000 and $128,000 for the years ended December 31, 2023 and 2022, respectively. Within Patents and licenses in the table below are amounts for pending patents which are not amortized until the issuance of the patent by the patent office (in thousands).

	2023	2022	Weighted average useful life (in years)
Gross Carrying Amount			
Patents and licenses	$ 626	$ 626	5
Technology	7,477	7,477	10
Customer relationships	272	272	7
Tradename	261	261	10
Total amortizable intangible assets	8,636	8,636	
Accumulated Amortization			
Patents and licenses	$ 540	$ 537	
Technology	7,471	7,387	
Customer relationships	217	189	
Tradename	260	259	
Total accumulated amortization	8,488	8,372	
Total amortizable intangible assets, net	$ 148	$ 264	

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Estimated remaining amortization of the Company's intangible assets is as follows (in thousands):

For the years ended December 31:	Estimated amortization expense
2024	30
2025	29
2026	1
2027	1
2028 and thereafter	87
	$ 148

Included within the line item "2028 and thereafter" above are amounts associated with pending patents which are not amortized until the issuance of the patent by the patent office.

Note 11 – Accrued and Other expenses

Accrued and other expenses consist of the following at December 31 (in thousands):

	2023	2022
Accrued salary and related expenses	$ 952	$ 725
Accrued accounts payable	1,036	1,307
Accrued professional fees	227	400
Accrued royalties and related	213	56
Other accrued expenses	20	53
	$ 2,448	$ 2,541

Note 12 – Leases

The Company has leases for office space, office equipment, and a warehouse. The leases expire at various dates through 2027. In November 2022, the Company extended the term of its Nashua, NH office lease, resulting in an increase of approximately $0.6 million to its right of use asset and related liability. In January 2024, in anticipation of the March 2024 end date of its leased warehouse in Nashua, NH, the Company entered into a 36 month lease for a new warehouse beginning February 1, 2024 through 2027. The new warehouse space, also in Nashua, NH, is for approximately 3,000 square feet with annual rent payments totaling approximately $46,000 for the duration of the lease. The tables below are presented in thousands, unless otherwise noted.

		Year Ended December 31,	
Lease Cost	**Classification**	**2023**	**2022**
Operating lease cost - Right of Use	Operating expenses	$ 247	$ 209
Operating lease cost - Variable Costs	Operating expenses	51	66
Total		$ 298	$ 275

	Year Ended December 31,	
	2023	**2022**
Cash paid for operating cash flows from operating leases	$ 257	$ 242

	As of December 31,	
	2023	**2022**
Weighted-average remaining lease term of operating leases (in years)	1.92	2.52
Weighted-average discount rate for operating leases	6.79%	6.79%

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Maturities of the Company's lease liabilities as of December 31, 2023 were as follows (in thousands):

Year Ended December 31:	Total
2024	219
2025	204
2026	85
Total lease payments	508
Less: effects of discounting	(47)
Total lease liabilities	461
Less: current portion of lease liabilities	(188)
Long-term lease liabilities	$ 273

Note 13 – Stockholders' Equity

(a) Financing Activity

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.

(b) Stock Options

The Company's 2016 Stock Incentive Plan (the "2016 Plan") provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. Awards may be granted singly, in combination, or in tandem. All awards granted under the 2016 Plan are required to be granted at not less than 100% of the fair market value of the related award on the respective grant date. Awards under the 2016 Plan may be granted to employees, directors and advisors to the Company and its subsidiaries.

At the Company's 2021 annual meeting, the 2016 Plan was amended to increase the number of shares of common stock available thereunder from 2,600,000 to 4,700,000. At December 31, 2023, there were 882,176 shares available for issuance under the 2016 Plan.

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	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Outstanding, December 31, 2022	2,610,992	$ 7.54	3.76
Granted	1,467,574	$ 1.81	
Exercised	(35,809)	$ 2.24	
Forfeited	(1,145,094)	$ 5.35	
Outstanding, December 31, 2023	2,897,663	$ 5.57	5.45
Exercisable at December 31, 2022	1,906,189	$ 7.59	
Exercisable at December 31, 2023	1,593,935	$ 8.08	

The Company's stock-based compensation expense, including options and restricted stock by category is as follows (amounts in thousands):

	Year Ended December 31,	
	2023	**2022**
Cost of revenue	$ 2	$ 3
Engineering and product development	222	220
Marketing and sales	308	518
General and administrative expense	784	945
	$ **1,316**	$ **1,686**

As of December 31, 2023, there was approximately $1.3 million of total unrecognized compensation costs related to unvested options. That cost is expected to be recognized over a weighted average period of 1.8 years.

During the first quarter of the year ended December 31, 2023, the Company recorded incremental stock-based compensation of approximately $0.23 million as a result of modifications of certain stock option awards. The modifications related to extending the contractual life of certain stock options by five years for four grantees whose awards were scheduled to expire during 2023. In addition, the amount of time to exercise vested stock options upon termination for one grantee was extended from 60 days to 24 months.

Options granted under the stock incentive plans were valued utilizing the Black-Scholes model using the following assumptions and had the following fair values:

	Year Ended December 31,	
	2023	**2022**
Average risk-free interest rate	4.36%	2.29%
Expected dividend yield	None	None
Expected life (in years)	2.9	3.5
Expected volatility	72.69 - 134.37%	66.30 - 72.04%
Weighted average fair value	$ 0.98	$ 2.33

The Company's 2023 and 2022 average expected volatility and average expected life is based on the Company's historical information. The risk-free rate is based on the rate of U.S. Treasury zero-coupon issues with a term most closely approximating the expected life of option grants. The Company has paid no dividends on its common stock in the past and does not anticipate paying any dividends in the future.

Intrinsic values of options (in thousands) and the closing market price used to determine the intrinsic values are as follows:

Intrinsic value of stock options

	Year Ended December 31,	
	2023	2022
Outstanding	$ 252	$ —
Exercisable	$ 30	$ —
Exercised	$ 2	$ —
Company's stock price at December 31	$ 1.77	$ 1.83

As of December 31, 2022, the exercise price of all outstanding stock options was higher than the Company's closing stock price. Accordingly, the intrinsic value is zero in the table above.

(c) Employee Stock Purchase Program:

In December 2019, the Company's Board of Directors adopted, and the stockholders approved the 2019 Employee Stock Purchase Plan ("ESPP"), effective January 1, 2020. The ESPP provides for the issuance of up 950,000 shares of common stock, subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. The ESPP may be terminated or amended by the Board of Directors at any time. Certain amendments to the ESPP require stockholder approval.

Substantially all of the Company's employees whose customary employment is for more than 20 hours a week are eligible to participate in the ESPP. Any employee who owns 5% or more of the voting power or value of the Company's shares of common stock is ineligible to participate in the ESPP.

Any eligible employee can enroll in the Plan as of the beginning of a respective quarterly accumulation period. Employees who participate in the ESPP may purchase shares by authorizing payroll deductions of up to 15% of their base compensation during an accumulation period. Unless the participating employee withdraws from participation, accumulated payroll deductions are used to purchase shares of common stock on the last business day of the accumulation period (the "Purchase Date") at a price equal to 85% of the lower of the fair market value on (i) the Purchase Date or (ii) the first day of such accumulation period. Under applicable tax rules, no employee may purchase more than $25,000 worth of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The Company issued zero and 46,096 shares of common stock under the ESPP for the years ended December 31, 2023 and 2022, respectively. There are 836,824 shares of Company common stock reserved for issuance under the ESPP as of December 31, 2023. In October 2022, the Company suspended the ESPP such that the accumulation period from October 1, 2022 through December 31, 2022 and beyond will not occur.

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Note 14 – Income Taxes

Income Taxes

The components of income tax expense for the years ended December 31 are as follows (in thousands):

	2023	2022
Current provision:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	$ —	$ —
Deferred provision:		
Federal	$ 1	$ —
State	—	—
Foreign	19	(116)
	$ 20	$ (116)
Total	$ 20	$ (116)

A summary of the differences between the Company's effective income tax rate and the Federal statutory income tax rate for the years ended December 31 is as follows:

	2023	2022
Federal statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	3.7%	2.5%
Net state impact of deferred rate change	0.2%	(1.0)%
Stock compensation expense	(4.2)%	(0.7)%
Other permanent differences	(0.6)%	(0.4)%
Change in valuation allowance	0.6%	(13.7)%
Tax credits	0.5%	2.0%
Accrual to tax return	0.2%	0.0%
Foreign Rate Differential	0.0%	0.0%
True Ups - NOL Expiration/162(m) limits	(21.8)%	(8.9)%
Other	0.3%	0.0%
Effective income tax	(0.1)%	0.8%

Deferred tax assets and liabilities are recognized for the expected future tax consequences of net operating loss carryforwards, tax credit carryforwards and temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the available evidence, it is more likely than not that the deferred tax assets will not be realized.

Deferred income taxes reflect the impact of "temporary differences" between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. The Company has fully reserved the U.S. net deferred tax assets, as it is more likely than not that the deferred tax assets will not be utilized. The Company has not reserved the foreign net deferred tax assets, as it is more likely than not that the deferred tax assets will be utilized. Deferred tax assets (liabilities) are composed of the following at December 31, 2023 and 2022 (in thousands):

	2023	2022
Inventory (Section 263A)	$ 97	$ 311
Inventory reserves	15	61
Bad debt reserves	68	215
Other accruals	242	813
Deferred revenue	549	129
Accumulated depreciation/amortization	—	17
Stock options	1,127	1,108
Developed technology	205	976
Tax credits	4,480	4,427
NOL carryforward	38,263	38,234
Lease Liability	113	792
Section 174 R&D	2,425	1,749
Deferred tax assets	47,584	48,832
Valuation allowance	(47,364)	(47,930)
Right of Use Asset	(113)	(786)
Accumulated depreciation/amortization	(10)	—
Goodwill tax amortization	(7)	(6)
Net deferred tax asset (liability)	$ 90	$ 110

The decrease in the net deferred tax assets and corresponding valuation allowance during the year ended December 31, 2023 is primarily attributable to the expiration of certain net operating loss and credit carryforwards.

As of December 31, 2023, the Company has federal net operating loss carryforwards totaling approximately $158.4 million. Federal net operating loss carryforwards totaling $109.8 million will expire at various dates from 2024 and 2037. The remaining $48.6 million of the federal net operating losses generated since December 31, 2017 can be carried forward indefinitely. As of December 31, 2023, the Company has provided a valuation allowance for its federal and state net operating loss carryforwards due to the uncertainty of the Company's ability to generate sufficient taxable income in future years to obtain the benefit from the utilization of the net operating loss carryforwards. As of December 31, 2023, the Company has foreign net operating loss carryforwards totaling approximately $0.4 million. As of December 31, 2022, the Company has not provided a valuation allowance for its foreign net operating loss carryforward. In the event of a deemed change in control, an annual limitation imposed on the utilization of the net operating losses may result in the expiration of all or a portion of the net operating loss carryforwards.

The Company currently has approximately $4.6 million in net operating losses that are subject to limitations related to its former Xoft business line. Approximately $656,000 can be used annually through 2029. The Company has available tax credit carryforwards (adjusted to reflect provisions of the Tax Reform Act of 1986) to offset future income tax liabilities totaling approximately $4.5 million. The credits expire in various years through 2042. The Company has additional tax credits of $1.4 million related to Xoft which have been fully reserved for and as a result no deferred tax asset has been recorded. These credits expire in various years through 2030.

ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

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As of December 31, 2023 and 2022, the Company had no unrecognized tax benefits and no adjustments to liabilities or operations were required under ASC 740-10. The Company's practice is to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was zero for the years ended December 31, 2023 and 2022. The Company files United States federal and various state income tax returns. The Company also files tax returns in France. Generally, the Company's three preceding tax years remain subject to examination by federal and state taxing authorities. The Company is not under examination by any other federal or state jurisdiction for any tax year.

The Company does not anticipate that it is reasonably possible that unrecognized tax benefits as of December 31, 2023 will significantly change within the next 12 months.

Note 15 – Segment Reporting

(a) Segment Reporting

The Company manages and operates as one business: Detection, which consists of the Company's advanced image analysis and workflow products. The business operations are managed by a single executive leadership team, which is led by the chief executive officer, who the Company has concluded is the Chief Operating Decision Maker ("CODM"). The Company does not operate separate lines of business with respect to any of its products nor does it prepare discrete financial information with respect to any of its products. The Company does not track its assets by operating segment and the CODM does not use asset information to allocate resources or make operating decisions. Accordingly, the Company views its business as one reportable operating segment with operations in the US and outside of the US.

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(b) Geographic Information

The Company's sales are made to customers and distributors of mammography medical equipment. Outside of the US, revenues to a single country did not exceed 10% of total revenue in any year. Total revenues outside the US were approximately $2.3 million or 13% of total revenue in 2023 and $3.3 million or 17% of total revenue in 2022

As of December 31, 2023 and 2022, the Company had outstanding receivables of $0.8 million and $1.5 million, respectively, from distributors and customers of its products who are located outside of the U.S.

	Percent of Export sales	
Region	**2023**	**2022**
Europe	10%	11%
All other	3%	6%
Total	13%	17%
Total Export Revenue	$ 2,333	$ 3,312

Significant export sales in Europe are as follows:

	Percent of Export sales	
Region	**2023**	**2022**
France	64%	52%
Belgium	13%	10%
Italy	6%	12%
Germany	4%	8%
Switzerland	4%	9%
All other	9%	9%

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(c) Major Customers

The Company had one major OEM customer, GE Healthcare, with revenues of approximately $3.8 million in 2023 and $4.4 million in 2022, or 22% of total revenues in each period. Cancer detection products are also sold through OEM partners other than GE Healthcare. For the year ended December 31, 2023, no OEM partner other than GE Healthcare represented more than 5% of total revenue. OEM partners in total composed approximately 32% of total revenue for the year ended December 31, 2023 and 29% of total revenue for the year ended December 31, 2022 . The Company also had one major direct customer with revenues of approximately $1.4 million, or 8% of total revenue for year ended December 31, 2023 and $0.8 million, or 4% of total revenue for the year ended December 31, 2022.

OEM partners represented $1.6 million or 28% of outstanding receivables as of December 31, 2023, with GE Healthcare accounting for $1.2 million or 74% of this amount. The largest direct customer represents $1.5 million or 27% of outstanding receivables as of December 31, 2023. These customers in total represented $3.2 million or 55% of outstanding receivables as of December 31, 2023.

Note 16 – Commitments and Contingencies

(a) Purchase Commitments

The Company has non-cancelable purchase orders with key suppliers executed in the normal course of business that total approximately $0.7 million.

(b) Employment Agreements

The Company has entered into employment agreements with certain executives and key employees. The employment agreements provide for minimum severance payments, performance-based annual bonus compensation, and accelerated vesting of equity awards upon certain provisions, as defined in their respective agreements, in the event that their employment is terminated without cause and/or upon change in control.

(c) Royalty Obligations

In connection with prior litigation, the Company received a nonexclusive, irrevocable, perpetual, worldwide license, including the right to sublicense certain Hologic patents, and a non-compete covenant as well as an agreement not to seek further damages with respect to the alleged patent violations. In return, the Company had a remaining obligation to pay a minimum annual royalty payment of $250,000 payable through 2016. In addition to the minimum annual royalty payments, the litigation settlement agreement with Hologic also provides for payment of royalties if such royalties exceed the minimum payment based upon a specified percentage of future net sales on any products that practice the licensed rights. The estimated fair value of the patent license and non-compete covenant is $100,000 and was amortized over the useful life of approximately four years. In addition, a liability has been recorded within accrued expenses and accounts payable for future payment and for minimum royalty obligations totaling $0.4 million.

(d) Legal Matters

In addition to the foregoing, the Company may be a party to various legal proceedings and claims arising out of the ordinary course of its business. Although the final results of all such matters and claims cannot be predicted with certainty, the Company currently believes that there are no current proceedings or claims pending against it the ultimate resolution of which would have a material adverse effect on its financial condition or results of operations, other than as set forth above. However, should the Company fail to prevail in any legal matter or should several legal matters be resolved against the Company in the same reporting period, such matters could have a material adverse effect on the Company's operating results and cash flows for that particular period. The Company may be party to certain actions that have been filed against the Company which are being vigorously defended. The Company has determined that potential losses in these matters are neither probable or reasonably possible at this time. In all cases, at each reporting period, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, "Contingencies." Legal costs are expensed as incurred.

Note 17 – Employee Benefit Plan

The Company has a 401(k) retirement plan (the "401(k) Plan") for the benefit of eligible employees, as defined. Each participant may elect to contribute up to 90% of his or her compensation to the 401(k) Plan each year, subject to certain Internal Revenue Service limitations. The Company makes a safe harbor matching contribution of 100% of every dollar contributed, not to exceed 3% of participants' eligible wages. The Company contributed approximately $0.4 million and $0.6 million during the years ended December 31, 2023 and 2022, respectively.

Note 18 – **Subsequent Events**

As more fully described in Note 12, in January 2024, in anticipation of the March 2024 end date of its leased warehouse in Nashua, NH, the Company entered into a 36 month lease for a new warehouse beginning February 1, 2024 through 2027. The Company has evaluated all other events and transactions subsequent to the balance sheet date to the date of filing and is not aware of any events or transactions that occurred subsequent to the balance sheet date that would require recognition or disclosure in the consolidated financial statements.