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, 2021

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. ☐

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, 2021 was $400,889,699. Shares of voting stock held by each officer and director and by each person who, as of June 30, 2021, 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 21, 2022, the registrant had 25,172,491 shares of its common stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2022 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 continued impact of the COVID-19 pandemic, 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, 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

iCAD, Inc. is a global medical technology company providing innovative cancer detection and therapy solutions. The Company reports in two operating segments: Cancer Detection ("Detection") and Cancer Therapy ("Therapy"). Originally incorporated in Delaware in 1984 as Howtek, Inc., the Company changed its name in 2002 to iCAD, Inc. The Company's headquarters are located in Nashua, New Hampshire. Xoft, Inc., Xoft Solutions LLC and iCAD France LLC are wholly owned subsidiaries of iCAD, Inc. and are consolidated for reporting purposes.

iCAD continues to evolve from a business focused on image analysis for the early detection of cancers to a broader participant in the cancer therapy market. The Company's strategy is to provide patients and clinicians with a broad portfolio of innovative clinical and workflow solutions and technologies that address the two primary stages of the cancer care cycle, namely detection and treatment. The Company believes that its products can enhance early cancer detection and earlier targeted intervention, which could result in better health outcomes, overall savings to the healthcare system, and increased market demand and adoption of iCAD's solutions.

Cancer Detection Segment

Background and Overview

According to the World Cancer Research Fund, breast cancer is the most common cancer in women worldwide, and the second most common cancer overall, with more than two million new cases diagnosed worldwide in 2020. Approximately 39 million mammography procedures were performed in the United States in 2021.

Although mammography is the most effective method for early detection of breast cancer, studies have shown that an estimated 20% or more of all breast cancers go undetected in the screening stage. The American Cancer Society estimates that, overall, screening mammograms do not find approximately one in five breast cancers. Observational errors are responsible for more than half of cancers missed, but products which utilize artificial intelligence ("AI") and computer-aided detection ("CAD") have been proven to reduce the risk of observational errors in mammography. These cancer detection solutions can improve interpretation workflow by using sophisticated deep learning AI algorithms designed to rapidly and accurately analyze image data and mark suspicious areas in the image that may warrant more attention or highlight the possibility that the area may contain a subtle, but significant abnormality. While breast cancer has been the primary focus of iCAD's detection technology, the underlying technology has potential applications to aid in the diagnosis of many additional types of cancer.

In the United States, digital breast tomosynthesis ("DBT") is rapidly replacing full-field digital mammography ("FFDM") in breast cancer screening due to DBT's clinical value in cancer detection. According to the United States Food and Drug Administration (the "FDA"), as of February 1, 2022, the United States alone had approximately 8,745 Mammography Quality Standards Act ("MQSA") certified facilities which provide mammography screening. These facilities operate approximately 23,873 MQSA accredited FFDM and/or DBT units with many of these units capable of both FFDM and DBT mammography. While many of these centers still use 2D FFDM systems, either alone or in combination with DBT systems, the Company believes approximately 11,000 of the mammography units in the United States are DBT capable based on January 2022 MQSA data. DBT greatly increases image data relative to FFDM, which creates significant workflow challenges for radiologists who face the additional workload and time required to accurately read all of the image data contained in DBT cases. Further, as incidence rates of cancer continue to rise, it is becoming increasingly important to find cancer sooner, optimize radiology workflow and reduce unnecessary recalls resulting from false positives. iCAD's technology addresses these challenges with a variety of AI, CAD, and breast density and short-term risk assessment solutions for use with mammography, DBT, and Computed Tomography ("CT") imaging, to enhance both detection and diagnosis stages of the cancer care cycle.

The Company launched Profound AI, a DBT cancer detection and workflow solution built on deep learning AI in the European Union (the "EU") and Canada in 2016 and, after receiving FDA premarket approval in the United States in 2017. Most recently, ProFound AI 3.0 received FDA 510(k) clearance in March 2021 for commercial use in the United States for reading DBT exams generated using compatible DBT systems. This latest version of ProFound AI offers clinical and workflow improvements over the prior version.

The Company's 2D FFDM breast density solution received FDA 510(k) clearance in December 2013. In December 2018, the Company also developed a breast density assessment product for tomosynthesis that assesses breast density using 2D synthetic images that are generated from 3D tomosynthesis datasets.

In July 2020, the Company received a CE mark in the European Economic Area (the "EEA") for ProFound AI Risk, the world's first image-based 2-year risk assessment model that assesses short-term breast cancer risk based primarily on information found in a 2D mammogram. In September 2020, ProFound AI Risk for 2D was introduced in the U.S. market as a decision support tool for radiologists. In September 2021, ProFound AI Risk for DBT was launched as a clinical decision support tool that provides an accurate short-term breast cancer risk estimation that is truly personalized for each woman, based only on a 2D or 3D mammogram.

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 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 alternative practice of having two radiologists read each

case. Furthermore, additional western European countries have already implemented, or are planning to implement, mammography screening programs, which may increase the number of mammograms performed in those countries.

Breast Health Solutions Suite

The Company's breast health solutions suite includes cancer detection solutions, automated breast density assessment, and breast cancer risk assessment, all for both 2D and 3D mammography. These solutions are designed to improve clinicians' performance and enhance breast cancer screening.

PowerLook

PowerLook is the Company's back-end architecture platform, which hosts AI algorithm solutions and manages the communications between (i) imaging acquisition systems ("Gantries"), and (ii) image storage and review systems such as Picture Archive and Communication Systems ("PACS") and (iii) breast imaging viewing and interpretation systems. Workflow efficiency is critical in digital imaging environments and PowerLook was designed to streamline these processes. PowerLook includes a powerful and flexible DICOM (Digital Image and Communications in Medicine) compliant connectivity solution, which is designed to enable universal compatibility with leading PACS and review workstations. iCAD has worked with its industry partners to ensure optimal integration into the graphical user interface of their PACS and review workstations. The algorithms supported on the Powerlook platform have also been optimized for, and tested with, each supported digital imaging acquisition manufacturer based upon the characteristics of their unique components.

PowerLook v10.2, the latest version of the platform, consists of a hybrid-server environment, where algorithm processing still occurs on-premise (within the hospital) but license activation and usage tracking is executed via the cloud. This enables iCAD to implement various pricing and payment models, including various subscription-based models. This platform can be compartmentalized to integrate into other infrastructure, such as direct integration into imaging system infrastructure or the eventual potential offering of a cloud-hosted Software-as a-Service (SaaS) model.

SecondLook

SecondLook is a machine learning-based cancer detection algorithm that analyzes 2D FFDM images to identify and mark suspicious masses and calcifications. This technology provides radiologists with a "second look" that helps detect potentially actionable cancers earlier than screening mammography alone. SecondLook uses a sophisticated, patented machine learning algorithm designed to identify the masses and calcifications that are most likely to be malignant. The algorithm was trained using data from 2D mammography studies, enabling the product to distinguish between characteristics of cancerous and normal tissue. This differentiation results in earlier detection of hard-to-find cancers, improved workflow for radiologists, and higher quality patient care. SecondLook first received FDA premarket approval in 2002 and is currently available in the United States, Canada, and select countries in Europe and Asia.

Automated Density Assessment, 2D and 3D

The Company's Automated Density Assessment solution provides an automated, consistent and standardized breast density assessment based on the American College of Radiology's BI-RADS 5th Edition density categorization system, which is particularly important in the United States as at least 38 states and the District of Columbia require some level of breast density notification to patients as part of their screening mammogram. In July 2021, the Company introduced the latest version of the Company's automated density solution, which was the first-to-market deep learning breast density assessment algorithm based on 2D synthetic images generated by DBT gantries from multiple vendors, including Hologic Medical Technology (Hologic) and Siemens. In addition, the product continues to support breast density assessment based on 2D images from leading FFDM manufactures.

ProFound AI, 2D and 3D

DBT was introduced in the United States in 2010 and has been demonstrated to have multiple advantages over 2D mammography, including improved tissue visualization and detection that results in lower recall rates for patients. Clinical studies indicate that DBT improves the ability to distinguish malignant from benign tumors and can better detect malignant lesions hidden by overlapping tissues, each of which can reduce the number of unnecessary biopsies and false positive recall rates. Initial studies have indicated that physicians using DBT have the ability to detect 41% more invasive cancers than those using 2D mammography, and also can reduce false-positive reads by up to 15%.

While DBT has been shown to have clinical benefits for screening mammography, it can also significantly increase radiologist interpretation time compared to 2D mammography. AI-based solutions can significantly improve the efficiency and efficacy of reading breast tomosynthesis cases by identifying and highlighting suspicious breast masses and calcifications.

ProFound AI for DBT is iCAD's deep-learning algorithm specifically designed to detect malignant soft-tissue densities and calcifications in DBT exams by analyzing each DBT image, or slice. In early 2018, the Company completed a large multi-reader, multi-case crossover design clinical reader study, which showed that ProFound AI can increase radiologist clinical performance by improving radiologist sensitivity by an average of 8%, improving radiologist specificity by an average of 6.9% and reduce recall rates in non-cancer cases by an average of 7.2%. The reader study also showed that the product can reduce DBT reading times by an average of 52.7%. Results from this reader study were published in the peer-reviewed journal, *Radiology: Artificial Intelligence*, in July 2019.

In 2018, the Company received regulatory clearances in the EU, Canada, and the U.S. for its multi-vendor, DBT AI cancer detection and workflow solution, Powerlook Tomo Detection 2.0, which was subsequently rebranded ProFound AI for DBT. In 2019, the Company launched ProFound AI for 2D, a similar AI cancer detection and workflow solution for 2D mammography. Profound AI for 2D is CE approved and primarily targets the European market, where 2D mammography remains the predominant procedure for breast cancer screening. On March 12, 2021, Version 3.0 of ProFound AI for DBT cleared FDA510(k) review for use in commercial reading of DBT exams from compatible DBT systems. ProFound AI for DBT Version 3.0 included algorithm changes that improved both sensitivity and specificity in reading DBT exams versus prior versions and included the Profound AI for 2D algorithm as a feature within ProFound AI for DBT. In May 2021, the Profound AI for 2D algorithm received EU approval for use with Fuji and Hologic Clarity HD DBT systems. In the fall of 2021, ProFound AI 3.0 for DBT added support for images acquired with Hologic's Clarity HD DBT system as well as adding support for highlighting suspicious findings in GE, Hologic, and Siemens systems' synthetic 2D images and in Hologic's 3D Quorum slab images.

iCAD plans to continue its focus on (i) advancing the performance of its ProFound AI for DBT solution through algorithm improvements and additional training on larger datasets, and (ii) building clinical support for and adoption of its products and solutions. iCAD has presented ProFound AI for DBT data from numerous studies at various prominent industry meetings and trade shows. Information about past presentations and future announcements can be found in press releases on the company's website at www.icadmed.com/press-releases. The Company has Original Equipment Manufacturer ("OEM") relationships with General Electric Company ("GE"), Siemens AG ("Siemens"), and FUJIFILM Corporation ("Fuji") and expects to use ProFound AI to expand its OEM partnerships with other mammography systems, PACS providers, and cloud-hosted AI platform providers.

ProFound AI™ Risk, 2D and 3D

ProFound AI Risk is the first and only commercially available clinical decision support tool that provides an accurate and personalized estimate of short-term breast cancer risk, based solely on a screening mammogram.

The Company worked with leading researchers at the Karolinska Institute in Stockholm, Sweden, one of the world's foremost medical research universities, to develop and clinically validate ProFound AI Risk. Unlike existing risk models that focus on family history and clinical lifestyle factors to estimate longer term risk, ProFound AI Risk focuses on a short-term risk interval. The estimation of risk of cancer occurrence within the next one to two years provides potentially different information on which to base further action relative to an elevated life-time risk of breast cancer. iCAD believes short-term risk models such as ProFound AI Risk will enable risk-based screening approaches rather than the age/ -based approach of annual screening. The COVID-19 pandemic has highlighted the benefit of risk-based screening as several medical societies recommended that women of average risk postpone their routine annual mammograms until the threat of COVID-19 had passed. As mammography screening begins to evolve from what has traditionally been an age-based annual screening paradigm to a short-term risk-based paradigm in the years ahead, iCAD is on the leading edge of this shift.

ProFound AI Risk for 2D FFDM received a CE Mark in EEA in July 2020 and in September 2020, iCAD announced the publication of data in the peer-reviewed journal, *Radiology*, indicating that ProFound AI Risk more accurately identifies the prospect of near-term development of breast-cancer than traditional risk models.

The October 2021 launch of the latest version of ProFound AI Risk was a significant achievement for iCAD, as this leading-edge technology is the first commercially available clinical decision support tool that provides an accurate short-term breast cancer risk estimation truly personalized for each woman. The latest version of ProFound AI Risk offers the flexibility to work with 2D and 3D mammography images with high accuracy, showing over 10% improvement in AUC, a commonly used statistical measure of clinical accuracy, when compared to the Gail and Tyrer-Cuzick conventional lifetime risk models. The latest version of ProFound AI is designed for global application, able to (i) provide a one, two or three-year risk estimation, (ii) factor in ethnic and racial backgrounds in the assessment of the score, and (iii) factor in country specific screening guidelines and incident and mortality rates.

Expansion of Software Licensing Model Options for the Breast Health Solutions Suite

iCAD has historically offered solely perpetually-licensed software, primarily pre-installed on and sold with an iCAD configured, third-party manufactured server, capable of optimally running the software. As a result, customers using this model can only classify iCAD software and hardware as a capital purchase for accounting purposes by making a single up-front payment.

Beginning in 2022, iCAD will offer the full suite of software in a variety of more flexible and customer accessible options. First, iCAD will uncouple the purchase of iCAD software from the purchase of hardware. Second iCAD will evaluate a range of software licensing models designed to accommodate both capital and operating purchasing for customers. To make iCAD 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 servers, alternatively sourced specification-compliant servers, virtualized environments, integrations into channel partner infrastructure and cloud-based hosting servers. iCAD will continue to sell iCAD configured servers to customers who prefer a single-vendor, turnkey solution with guaranteed compatibility and support. The Company is actively evaluating software licensing models.

iCAD will continue to offer existing perpetual-license model for the Company's software to as many customers who prefer a one-time purchase which effectively provides ownership of the license. For those customers who need or prefer an operating expense model or minimal capital investment, iCAD is evaluating subscription models for the same on-premises software products. If customers or channel partners have specification compliant infrastructure, iCAD may be able to license the Company's software under either model.

Once a subscription model is offered, it will, by definition, result in reduced short-term revenue attributable to each customer electing a subscription license in lieu of a perpetual license. For example, when a perpetual license on a representative product is sold, revenue in the quarter of such sale could range from approximately $25,000 to $35,000 per license/per gantry depending on numerous factors. That same installation under a

subscription model could result in monthly revenue of approximately $800 to $1,200 for an expected minimum of three years or more, depending on cancellation terms and the duration of a customer's subscription.

iCAD is committed to providing solutions that will enable as many customers to purchase or utilize the Company's products. The Company's Therapy business and the services and hardware product portions of the Detection business are expected to remain unchanged in the coming year. The subscription licensing model is currently being evaluated and the short-term and long-term impacts on the Company's results of operations are being tested, although iCAD believes subscriptions will be relatively slow to accumulate over time and will be largely additive to the perpetual license business. Additive customers will have positive revenue impact and while the transition of perpetual license customers to subscription customers will have negative effects in the short term, iCAD expects this to impact a limited fraction of the overall revenue base of the Company in 2022. The Company is also currently evaluating the future potential of providing a SaaS subscription model with the Company hosting its software from the cloud.

Colon Cancer Screening Products

Colon cancer is the third most common cancer diagnosed globally, with more than 1.1 million new cases diagnosed worldwide in 2020. CT is a well-established and widely used imaging technology that is used to image cross-sectional "slices" of various parts of the human body. While the increased image quality and number of cross-sectional slices per scan offered by CT provides valuable diagnostic information, it adds to the challenge of managing and interpreting the large volume of data generated. CT Colonography ("CTC") is a less invasive technique for imaging the colon when screening for cancer than a traditional colonoscopy. However, the process of reading a CTC exam can be lengthy and tedious as the interpreting physician is often required to traverse the entire length of the colon multiple times. CAD technology can play an important role in improving the accuracy and efficiency of reading CTC images by automatically identifying and highlighting polyps that can progress into cancer.

VeraLook is the Company's FDA-cleared solution designed to support detection of colonic polyps in conjunction with CTC. Field testing of the product was initiated in 2008. Results of the Company's multi-reader clinical study demonstrated that the use of VeraLook improved reader sensitivity by 5.5% for patients with both small and large polyps, and slightly reduced specificity of readers by 2.5%. VeraLook was CE marked in 2009, received FDA 510(k) clearance in 2010 and is currently distributed with advanced visualization reading workstations and CTC applications manufactured by Canon Medical Systems and Philips Healthcare.

Potential Future Cancer Detection Products Development

The Company's current primary focus is on image analysis and workflow solutions leveraging AI in 2D mammography and DBT applications, however, iCAD's core technologies and product development capabilities can be applied to any imaging modality, including x-ray, CT, ultrasound, and Magnetic Resonance Imaging ("MRI"). Additionally, the Company could develop products that can be applied to screening and/or diagnosis of various additional cancer types such as prostate, lung, and brain cancers, as well as screening and/or diagnosis of disease related to visually differentiated tissue abnormalities. The Company continues to evaluate the adjacent or complementary opportunities in image analysis workflow solutions for future product development and commercialization possibilities.

Cancer Therapy Segment

Background and Overview

Radiation therapy is the medical use of ionizing radiation, generally as part of cancer treatment to control or kill rapidly dividing malignant cells. Radiation therapy may be curative in numerous types of cancer if the cancer cells are localized to one area of the body. It may also be used as part of curative therapy to prevent tumor

recurrence after surgical removal of a primary malignant tumor (for example, early-stage breast cancer). The clinical goal in radiation oncology is to deliver the highest radiation dose possible directly to the tumor to kill the cancer cells, while minimizing radiation exposure to healthy tissue surrounding the tumor to limit complications and side effects.

The three main types of radiation therapy are (i) external beam radiation therapy ("EBRT"), which involves a radiation source positioned outside the body, (ii) brachytherapy, in which sealed radiation sources are temporarily or permanently inserted in the body, within the treatment area, and (iii) systemic radioisotopes, which are given by infusion or oral ingestion.

Conventional EBRT typically involves up to 40 radiation treatment sessions for a tumor. Brachytherapy offers the benefit of reduced radiation exposure to healthy tissues further away from the radiation source. In addition, if the patient moves or if there is any tumor movement within the body during treatment, the radiation source retains its correct position in relation to the tumor. Thus, brachytherapy offers an advantage over EBRT in its ability to better direct high doses of radiation to the size and shape of the cancerous area while sparing healthy tissue and organs.

Brachytherapy is commonly used as an effective treatment for endometrial, cervical, prostate, breast, and skin cancer, and can also be used to treat tumors in many other body sites. Electronic Brachytherapy ("eBx") is a type of radiation therapy that utilizes a miniaturized, electronically stimulated, high dose rate X-ray source to apply radiation directly to the cancerous site. Unlike live isotope sources used in some brachytherapy, eBx only emits radiation when desired and the radiation dosage can be accurately controlled. eBx may also be used in Accelerated Partial Breast Irradiation ("APBI"), which concentrates the radiation therapy on a smaller focal point than conventional EBRT, allowing higher concentrations of radiation over fewer treatment sessions.

Cancer Therapy Products

The Xoft Axxent Electronic Brachytherapy System ("Xoft System") is iCAD's proprietary electronic brachytherapy platform designed to deliver isotope-free (non-radioactive) radiation treatment in virtually any clinical setting without the limitations of radionuclides. The Xoft System utilizes a miniaturized high dose rate, low energy X-ray source to apply the radiation dose directly to the size and shape of the cancerous area while sparing healthy tissue and organs. While delivering clinical dose rates similar to traditional radioactive systems, the electronic nature of the Xoft System technology provides a faster dose fall-off which lowers the radiation exposure outside of the targeted area and eliminates the need for dedicated shielded treatment environment such as that required with traditional isotope-based radiation therapy. As the Xoft System is relatively compact, it can easily be transported for use in virtually any clinical setting under radiation oncology supervision (including the operating room, where intraoperative radiation therapy ("IORT") is delivered).

The Xoft System is FDA-cleared, CE marked and licensed in an increasing number of countries for the treatment of cancer anywhere in the body. Active customers include university research and community hospitals, cancer care clinics, veterinary facilities, and dermatology offices with established strategic partnerships with radiation oncology service providers for supervised treatment delivery. The Company's commercial focus for the Xoft System has been the treatment of early-stage breast cancer, gynecological cancers, and non-melanoma skin cancer ("NMSC"). Emerging applications include a wide and growing array of cancers, including brain and rectal tumors. Given that the Xoft System has regulatory clearance for the treatment of cancer anywhere in the body, treatments for emerging applications may not require additional regulatory clearance.

The Company continues to make enhancements to the Xoft System controller (the "Controller") unit, including upgrades to the high voltage connection, and the Streamlined Module for Advanced Radiation Therapy ("SMART") platform which uses the Axxent Hub, iCAD's proprietary cloud-based oncology collaboration software solution. The SMART platform is an adaptive, patient-centric solution designed to improve the eBX

program's workflow efficiency, flexibility, safety, and security. This comprehensive Wi-Fi enabled platform provides all members of a care team with a collaborative environment in which to manage patient workflow and eliminate challenges related to exchanging current, accurate patient data among providers.

In addition to the Controller unit, the Company offers a 50kV isotope-free energy source, indication-specific applicators, a comprehensive service warranty program, and various accessories such as the Axxent eBx Rigid Shield for internal IORT shielding. The 50kV energy source is typically sold under an annual contract and is customized to individual customer volume and usage requirements. The Company offers FDA-cleared applicators for the utilization of the Xoft System, including breast applicators for IORT and APBI in the treatment of breast cancer, vaginal applicators for the treatment of endometrial cancer, cervical applicators for the treatment of cervical cancer, and skin applicators for the treatment of NMSC. The flexible single-use breast and brain applicators are offered in a variety of sizes and lengths based on clinical need. The endometrial, cervical, rectal, and skin applicators are reusable and are manufactured in various sizes based on the anatomical requirements of the patient or the size of the lesion.

Cancer Therapy Indications

Background and Overview

The Xoft System can be used to treat a wide and growing array of cancers, including breast cancer, NMSC, gynecological, recurrent glioblastoma ("GBM") and various other forms of brain cancer, and additional IORT indications.

Approximately 300,000 women are diagnosed with breast cancer every year in the United States. Currently, many early-stage breast cancer patients who are treated with radiation therapy follow a four-to-six-week daily protocol of traditional EBRT, while a small portion are treated with brachytherapy. Breast cancer therapy is one of the primary indications for the Xoft system. Xoft used in IORT aims to simplify radiation treatment for early-stage breast cancer patients by delivering a single ten to fifteen-minute precise dose of radiation directly to the lumpectomy cavity in a single, safe and effective procedure. Xoft used in APBI may reduce the daily radiation treatment duration from weeks to days.

There are approximately 3.5 million cases of NMSC diagnosed annually in the United States. The Xoft System is a viable alternative treatment option for patients with lesions in cosmetically challenging locations (e.g., ear, nose, scalp, neck), locations that experience difficulties in healing (e.g., lower legs, upper chest, fragile skin), patients on anticoagulants, and patients who are anxious about surgery. The Xoft System has been used to treat more than 10,000 NMSC lesions. Clinical data published from 2015 to 2017 demonstrates promising local control and supports eBx as a convenient, effective, nonsurgical treatment option offering minimal toxicity and improved cosmesis for eligible NMSC patients.

There are approximately 50,000 new cases of endometrial cancer each year in the United States and more than 800,000 new cases worldwide. In 2017, the first-ever European analysis of eBx using the Xoft System for endometrial and cervical cancer treatment was presented that demonstrated improved outcomes in acute toxicity in 29 endometrial or cervical cancer patients treated with the Xoft System from September 2015 to September 2016. Additional research showed that compared to an iridium isotope, the Xoft System delivered a lower dose of radiation to surrounding healthy organs at risk, such as the bladder and rectum.

Approximately 297,000 cases of brain and nervous system tumors are diagnosed worldwide per year. GBM is the most common and aggressive type of malignant primary brain tumor, with an estimated median survival of 10 to 12 months. The company is continuing to develop clinical support for brain IORT, primarily in the GLIOX trial, an international multi-center trial led by principal investigator and world-renowned oncologist, Santosh Kesari, MD, PhD, Chair and Professor, Department of Translational Neurosciences at the Saint John's Cancer Institute, Santa Monica, CA. The first patient in the GLIOX trial was treated in December 2021. The GLIOX trial is

designed to compare Xoft IORT plus Avastin® (bevacizumab) to the investigational arm of RTOG-1205 (EBRT plus bevacizumab). Researchers hope this study will validate the intriguing initial results from a prospective two center comparative study at the European Medical Center (the "EMC") in Moscow, Russia. The EMC study evaluated 15 patients with recurrent GBM who were treated with maximal safe resection and Xoft Brain IORT, and 15 patients with recurrent GBM treated with maximal safe resection and other modalities (control group), between June 2016 and June 2019. In October 2021, data supporting Xoft Brain IORT for the treatment of recurrent GBM were published with a subsequent erratum published in December 2021, in the peer-reviewed journal, Surgical Neurology International. The update reported that as of March 2021, patients treated in the EMC study with Xoft Brain IORT lived for up to 54 months after treatment without recurrence, whereas patients in the control group had a recurrence within 10 months and lived for up to 22.5 months after treatment. Researchers also found there were fewer complications, such as radionecrosis, in the IORT group. Radionecrosis refers to the breakdown of normal body tissue near the original tumor site after radiation therapy. One patient from the IORT group was still alive as of January 1, 2022, whereas none of the patients in the control group survived. Preliminary results from this study were presented in August 2021 at the American Association of Neurological Surgeons (AANS) 2021 annual scientific meeting.

Additionally, electronic brachytherapy is appropriate for use in other IORT clinical settings where surgical resection is unable to completely eliminate all cancer cells. The Company believes that IORT for prostate, pelvic, gastrointestinal, abdominal, spinal, and soft tissue sarcoma applications are potential markets given the minimal shielding requirements associated with this treatment modality. In September 2019, the Company unveiled new and updated advancements for the Xoft System at the American Society for Radiation Oncology ("ASTRO") annual meeting. This included an advanced prototype for early-stage rectal cancers, and extended-length balloon applicators, available in 25 cm and 50 cm lengths, which offer added versatility and the potential for additional applications for the Xoft System in different areas of the body. Based on these additional clinical applications and the potential to scale the Xoft System in the future to address other indications for use, the Company believes the Xoft System offers unique flexibility and opportunities for growth.

Additional Studies

In 2016, Melinda Epstein, PhD, of Hoag Memorial Hospital Presbyterian in Newport Beach, California and co-authors published two clinical papers on their experience with the Xoft System for the treatment of early-stage breast cancer with IORT. In June 2016, the *Annals of Surgical Oncology* published data on 702 patients treated from June 2010 to January 2016, demonstrating a 1.7% recurrence rate. Further, less than 5% of patients had significant complications, indicating that IORT allows some women who cannot (or decline to) undergo whole breast radiation to consider breast-conserving therapy rather than mastectomy. In August 2016, *The Breast Journal* published 20-month mean follow-up data on 146 patients with pure ductal carcinoma in situ treated with IORT. The data showed a 2.1% recurrence rate with relatively few complications and again concluded that x-ray based IORT has the potential to be a promising treatment modality that may simplify the delivery of post-excision radiation therapy.

In 2017, researchers from Hoag Memorial Hospital Presbyterian published another clinical paper in the *Annals of Surgical Oncology* on their experience with the Xoft System in treating 204 early-stage breast cancers in a prospective, X-ray IORT trial from June 2010 to September 2013. With a median follow-up of 50 months, results indicated there were seven ipsilateral breast tumor events, no regional or distant recurrences, and no breast cancer-related deaths. Kaplan-Meier analysis projects that 2.9% of patients will recur locally at 4 years. The site's low complication and recurrence rates support the cautious use and continued study of IORT in selected women with low-risk breast cancer. The Hoag Memorial Hospital Presbyterian IORT series is currently the largest single-facility IORT series with the Xoft System in the United States.

Also, in 2017, the Company announced results of a landmark study that demonstrated the economic benefits of IORT compared to EBRT in the treatment of early-stage breast cancer. The analysis demonstrated that IORT could result in direct cost savings for the U.S. healthcare system of more than $630 million over the lifetime of

patients diagnosed annually with early-stage breast cancer, as well as could significantly benefit patient health by minimizing radiation exposure and offering a better quality of life. The results of the study were published in November 2017 in the peer-reviewed *Cost Effectiveness and Resource Allocation* and the study determined IORT to be the preferred method of treatment for early-stage breast cancer.

As the Company continues to focus on broadening global awareness and patient access to IORT, 2017 also brought meaningful progress in the area of international research. Physicians from Taiwan published a clinical paper in November 2017 in the peer-reviewed *PLOS One* journal. The multi-center study examined patient selection and the oncologic safety of IORT with the Xoft System for the management of early-stage breast cancer. From 2013 to 2015, 26 hospitals in Taiwan performed a total of 261 IORT procedures. With a mean follow-up of 15.6 months, locoregional recurrence was observed in 0.8% of patients. The study concluded that preliminary results of IORT in Taiwan showed it is well accepted by patients and clinicians.

Finally, in 2017, the Company announced that results of a matched-pair cohort study of 369 early-stage NMSC patients treated with the Xoft System or Mohs micrographic surgery showed that rates of recurrence of cancer were virtually identical at a mean follow-up of 3.4 years. Mohs micrographic surgery is accepted as the most effective technique for removing basal cell carcinoma and squamous cell carcinoma. The study results were published online in the peer-reviewed *Journal of Contemporary Brachytherapy*.

In 2018, several additional key pieces of clinical evidence supporting IORT with the Xoft System were published. With a mean follow-up of 55 months, outcomes published in *The American Journal of Surgery* showed that breast cancer recurrence rates of patients who were treated with IORT using the Xoft System and complied with adjuvant medical therapy were comparable to those seen in the cornerstone TARGIT-A study, which evaluated IORT but did not use the Xoft System. The study reviewed results of 184 patients with breast cancer from November 2011 to January 2016 completing Institutional Review Board ("IRB")-approved IORT protocol. The recurrence rate for the 184 total IORT patients was 5.4 percent at a mean follow-up of 55 months; however, the recurrence rate was 2 percent lower for the patients who complied with adjuvant medical therapy. The difference in recurrence rates between the group complying with versus declining adjuvant medical therapy was statistically significant. To date, this study presents the most long-term research of IORT using the Xoft System published in a peer-reviewed journal.

Further in 2018, a long-term study of 1,000 tumors performed at Hoag Memorial Hospital Presbyterian and in the *Annals of Surgical Oncology* showed that IORT is a clinically effective, faster and easier alternative to whole breast radiation therapy following breast-conserving surgery for selected low-risk patients at a median follow-up of 36 months. To date, this study presents analysis of the largest series of early-stage breast cancers treated with IORT using the Xoft System published in a peer-reviewed journal.

In 2019, study results from the first cervical cancer cases for eight patients treated with the Xoft System at the Hospital Universitario Miguel Servet in Zaragoza, Spain were published in the *Journal of Applied Clinical Medical Physics.* Researchers found the treatment offered promising results at 1 month follow up, with no recurrences and low toxicity. The study concluded that electronic brachytherapy is a good alternative to treating cervical cancer in centers without access to conventional high-dose-rate interstitial brachytherapy.

Clinical data supporting the Xoft System for the treatment of various gynecological cancers, including cervical and uterine, were also presented in 2019 at the European Society for Radiotherapy and Oncology meeting by researchers from the Hospital Universitario Miguel Servet and the Jewish General Hospital in Montreal, Québec, Canada. A study conducted by researchers from the Hospital Universitario Miguel Servet concluded that electronic brachytherapy is an alternative to high dose-rate brachytherapy with a good rate of overall survival and progression free disease. The retrospective study conducted by researchers at the Jewish General Hospital suggested that electronic brachytherapy could replace high-dose-rate brachytherapy in uterine cancer with similar target coverage, maximum dose to surrounding structures, and treatment times and that additional studies would be needed to evaluate efficacy.

Preliminary results of the Company's international, multi-center clinical trial in the Xoft System were unveiled during an oral presentation at the 60th ASTRO annual meeting at the Henry B. Gonzalez Convention Center in San Antonio, Texas on October 23, 2018. In the presentation, A.M. Nisar Syed, MD, Principal Study Investigator, Medical Director, Radiation Oncology & Endocurietherapy, MemorialCare Cancer Institute, Long Beach Memorial Medical Center, and Professor of Radiation Oncology, UCI Medical Center and Harbor-UCLA School of Medicine, detailed clinical techniques and outcomes of IORT using the Xoft System at the time of breast conserving surgery with findings based upon ASTRO suitability criteria. The trial enrolled 1,200 patients between May 2012 and July 2018 at 28 international and U.S.-based institutions. With a median follow up of 1.6 years, less than one percent of patients had cancer regrowth (ipsilateral recurrence) or developed new primary cancers in the other breast. Treatment was generally well tolerated with grade 3, 4 and 5 adverse events occurring in 37 patients. Mean treatment time was 10.5 minutes.

At the ASTRO Virtual Annual Meeting in October 2020, researchers presented new data supporting the Xoft System for the treatment of early-stage breast cancer and endometrial cancer. In a study involving 1,200 patients with early-stage breast cancer treated with the Xoft System from May 2012 to July 2018 across 27 institutions worldwide, researchers concluded that IORT with the Xoft System is safe, with low morbidity, low local recurrence and excellent cosmetic results. In a study of 236 patients with endometrial cancer from September 2015 to May 2020, with a median follow up of 34 months, researchers concluded the Xoft System is a feasible alternative to HDR brachytherapy for the treatment of endometrial cancer that offers long-term benefits for patients, staff and the overall healthcare system.

Researchers from Miguel Servet University Hospital in Spain presented several studies supporting the Xoft System at the European Society for Radiotherapy & Oncology (ESTRO) virtual meeting in November 2020. In a study analyzing 193 patients from 2015 to 2019, where one group was treated with the Xoft System combined with external radiation and one group was treated with the Xoft System, researchers established electronic brachytherapy for endometrial cancer as a feasible alternative to HDR brachytherapy, equal in effectiveness to Iridium 192, with long-term benefits for patients. Researchers concluded that the Xoft System provided the same dosimetric coverage in the area of treatment as traditional brachytherapy with a marked reduction in dosage to organs at risk.

In another study presented at ESTRO 2020, researchers created 3D printed anatomic models that allowed them to create simulations to measure possible radiation doses in nearby organs, such as the lung and heart, where it is not possible to place a detector to perform in vivo dosimetry. Results calculated the maximum doses to radiochromic film representing the left lung and heart of 20 patients treated from the left breast measured retrospectively. Researchers concluded it was possible to measure and verify doses in the lung and heart for IORT treatments, enabling more accurate recommendations for a particular type of treatment.

A third study presented at ESTRO 2020 examined the results of 480 patients treated with IORT from May 2015 to October 2019 with treatment verification and in vivo dose measurements to understand the in vivo dose in the skin. Researchers concluded the skin doses were low with less than 1% of the cases exhibiting early toxicity of acute grade 3 dermatitis and no cases of higher-grade dermatitis.

Researchers presented a study supporting Xoft Breast IORT at the American Brachytherapy Society (ABS) 2021 Annual Conference. In a study evaluating the efficacy and outcome of IORT for early-stage breast cancer, researchers found recurrence rates to be similar to those reported in the TARGIT-A trial. Preliminary results from the ExBRT trial were presented at the ASBrS Annual Meeting in 2021. The multi-institutional study found at median 4-year follow-up, 1,200 breast cancer patients enrolled in the ExBRT trial were successfully treated with a single fraction of IORT to the lumpectomy cavity following breast conserving surgery with a favorable local recurrence rate. At the ESTRO meeting in 2021, researchers presented a study evaluating body mass index (BMI) in breast cancer patients treated with Xoft Breast IORT.

Sales and Marketing

Cancer Detection

In November 2020, iCAD announced that more than 1,000 ProFound AI licenses had been sold since the product was launched, and the Company has now sold more than 1,300 ProFound AI licenses through December 31, 2021 and more than 2,000 total product licenses including ProFoundAI, upgrades, and other products. In North America, iCAD sells its AI mammography products through a direct regional sales force and through the Company's OEM partners, which include GE Healthcare, a subsidiary of GE focused on the manufacture and distribution of diagnostic imaging agents, 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, the Company sells its AI mammography products through a direct sales force and has also developed reseller relationships with regional distributors.

In 2020, iCAD signed a distribution agreement with Change Healthcare Inc. ("Change Healthcare"), a leading independent healthcare technology company focused on insights, innovation and accelerating the transformation of the U.S. healthcare system. The agreement will expand access to ProFound AI for more hospitals and imaging centers across North America.

In June 2021, iCAD signed a global distribution agreement with Sectra AB ("Sectra"), an international medical imaging IT solutions and cybersecurity company. Through this agreement, ProFound AI and ProFound AI Risk will be offered through the Sectra Amplifier Marketplace, which will expand iCAD's access to more facilities and imaging centers worldwide.

In November 2021, iCAD signed a global distribution agreement with Arterys Inc. ("Arterys"), the world's leading cloud native, vendor-neutral AI platform under which Arterys will offer iCAD's AI-powered breast health solutions via Arterys' FDA-cleared and CE-marked MICA platform to its installed base.

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.

Cancer Treatment

iCAD markets the Xoft System in the United States and select countries worldwide through its wholly-owned subsidiary, Xoft, Inc. a Delaware corporation ("Xoft"). In the United States, Xoft utilizes a direct sales force and selected distribution partners. Xoft has been granted regulatory approval and has established partnerships in the United States, many European Union countries, the United Kingdom, Australia, Taiwan, China, and numerous other countries. iCAD continues to evaluate regulatory and distribution opportunities throughout the world.

A comprehensive medical education program is a key part to the Company's eBx market development strategy. Xoft actively participates in key industry scientific conferences and independent venues in the United States and Europe where the Company provides professional education programs and product demonstrations relating to eBx. The goal of these programs and demonstrations is to broaden physician awareness of the Xoft System and eBx technology.

Competition

The Company operates in highly competitive and rapidly changing markets with competitive products available from nationally and internationally recognized companies. Many of these 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 compete with the products the Company manufactures and distributes or that would 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.

Cancer Detection

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 a number of platforms and payment structures will provide it with a competitive advantage in breast AI.

The Company's VeraLook product faces competition from the traditional imaging CT equipment manufacturers and emerging CAD companies. Siemens Medical (Tarrytown, NY), GE Healthcare (Chicago, IL), and Philips Medical Systems (Andover, MA) currently offer polyp detection products outside the United States. A significant barrier to adoption in the United States has been a lack of reimbursement for CTC for colon cancer screening. The Company expects that CT manufacturers will offer a colonic polyp detection solution as an advanced feature of their image management and display products typically sold with their CT equipment, but current reimbursement policies present a significant barrier to wide-spread adoption and the Company believes that its market leadership in mammography AI may provide it with a competitive advantage within the CTC community.

Cancer Treatment

The Company's eBx products face competition in breast IORT primarily from Carl Zeiss Meditec Inc. ("Zeiss") (Dublin, CA), which has an established base of breast IORT installations in Europe. Zeiss manufactures and sells eBx products for the delivery of IORT, for both breast and additional anatomical areas, including the spine, gastrointestinal tract, skin, and endometrial cancers. Sensus Healthcare Inc. (Boca Raton, FL) and IntraOp Medical Corporation (Sunnyvale, CA) are other competitors in the breast IORT market.

The expansion of the Company's gynecological product portfolio and new IORT applications beyond breast IORT have increased the competitive dynamic of the Company's business. Larger and more diversified radiation therapy companies offer a wide variety of clinical solutions for HDR brachytherapy, including Varian Medical Systems (Milpitas, CA) and Elekta (Stockholm, Sweden). These companies offer broad product portfolios, which include a full range of HDR brachytherapy after loaders and applicators, traditional radiation therapy solutions, treatment planning solutions, and workflow management capabilities.

The Company's NMSC products face competition from other mobile non-surgical treatment options (such as Sensus Healthcare's Surface Radiation Therapy system and Elekta's Esteya system), surgical treatment options and traditional radiation therapy.

In September 2020, Centers for Medicare & Medicaid Services ("CMS") issued a final rule establishing the Radiation Oncology Advanced Payment Model, a bundled payment model for radiotherapy treatment that incentivizes physician selection of high quality, lower cost treatment modalities like Xoft's electronic brachytherapy for treatment of breast and other cancers. In the final notice, CMS did not include IORT treatments (including CPT codes 77424 and 77425) within the new alternative payment model for radiation oncology. As a result, whether or not a particular physician practice or hospital is subject to the new radiation oncology payment model, IORT services covered by Medicare will continue to be subject to the existing payment systems for physician services and hospital outpatient services. The model was supposed to begin in

2021, but Congress passed legislation to delay the start of the new payment model until 2023. Stakeholders are encouraging CMS to make significant changes to the model before it takes effect. Medicare has not yet posted the final version of the rule outlining the details of the program.

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.

Xoft's portable Xoft System is manufactured and assembled by contract manufacturers. Xoft's miniaturized eBx X-ray source is manufactured by the Company at its San Jose, CA facility. Once the product has shipped, it is typically installed by Xoft personnel at the customer site.

Xoft's professional services staff provides comprehensive product support, physician support, radiation therapist support and billing support on a post-sales basis. Field service staff is involved in product installation, maintenance, training and service repair.

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, 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 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 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.

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; and

- 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.

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.

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 $172,137 for each such arrangement or scheme. The penalties for violating the Stark Law also include civil monetary penalties of up to $25,820 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.

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.

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.

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).

In 2016, the American Medical Association ("AMA") implemented a skin-specific Category III CPT code for electronic brachytherapy for the treatment of NMSC. Reimbursement for the treatment delivery may be provided through the Category III CPT code, 0394T, defined as "high dose rate electronic brachytherapy, skin surface application, per fraction, and includes basic dosimetry, when performed". There are additional Category I CPT codes reportable with the service as determined by physician orders, medical necessity, and documentation.

Coverage policies and payment values associated with CPT code 0394T are determined by the regional Medicare Administrative Contractors (MACs) and the private payers. Coverage and payment for CPT code 0394T is individually determined by the MACs and private payers. Many of the MACs and some private payers cover and pay for 0394T.

Category III CPT codes are temporary codes for emerging technologies, services, and procedures that do not yet meet the criteria for Category I CPT codes. Without further action by the AMA, Category III CPT codes sunset five years after the initial publication or renewal of the code. The AMA has accepted the retention of CPT code 0394T, renewing the code through 2025. At that time, CPT code 0394T may be converted to a Category I CPT code. Alternatively, the AMA may determine the code should be further renewed or archived.

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.

On September 18, 2020, CMS finalized a rule regarding its new Radiation Oncology model (the "RO Model"), designed, according to CMS, to improve the quality of care for cancer patients receiving radiotherapy and reduce Medicare expenditures through bundled payments. In the final notice, CMS did not include IORT treatments (including CPT codes 77424 and 77425) within the new alternative payment model for radiation oncology. As a result, whether or not a particular physician practice or hospital is subject to the new radiation oncology payment model, IORT services covered by Medicare will continue to be subject to the existing payment systems for physician services and hospital outpatient services. On December 2, 2020, an interim final rule was published by CMS, to take effect no earlier than January 1, 2022, but was subsequently delayed until January 1, 2023.

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.

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 2022 and 2029. These patents help the Company maintain a proprietary position in its markets. The Company does not believe that the patents expiring in 2022 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, a non-exclusive patent license from Cytyc/Hologic which relates to balloon applicators for breast brachytherapy, and a non-exclusive license from Zeiss which relates to brachytherapy.

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, 2021, 2020 and 2019, we incurred $9.2 million, $8.1 million, and $9.3 million of research and development expense, respectively.

Human Capital Resources

As of December 31, 2021, the Company had 137 employees, 136 of whom are full time employees, with 57 involved in sales and marketing, 25 in research and development, 36 in service, manufacturing, quality assurance, technical support and operations functions, and 19 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.

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 CAD products and the Xoft System. 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 report 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 highlights some of the factors that have affected, and/or in the future could affect, the Company's operations.

The following is a summary of certain important factors that may make an investment in iCAD speculative or risky. You should carefully consider the fuller risk factor disclosure set forth in this Annual Report, 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 2021 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.
- Management expects the novel coronavirus (COVID-19) pandemic to continue to have a significant effect on the Company's results of operations. A continuation or worsening of the pandemic will have a material adverse impact on iCAD's business, results of operations and financial condition and on the market price of iCAD's common stock.
- The markets for the Company's products and treatments and newly introduced enhancements to iCAD's existing products and treatments may not develop as expected, the Company may continue to face barriers to broad market acceptance.
- Sales and market acceptance of Company products is dependent upon the coverage and reimbursement decisions made by third-party payers, including carve-out radiology benefits managers. The failure of third-party payers to provide appropriate levels of coverage and reimbursement, and/or meeting prior authorization and other requirements for approval to use Company products and treatments facilitated by the Company's products could harm the Company's business and prospects.
- A limited number of customers account for a significant portion of the Company's total revenue. The loss of a principal customer could seriously hurt the Company's business.

- The markets for many of the Company's products are subject to changing technology.
- 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 Company has incurred significant losses from inception through 2021 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 $11.2 million in 2021 and has an accumulated deficit of $253.1 million at December 31, 2021. The Company may not be able to achieve profitability. Substantially all of our operating losses have resulted from costs incurred in connection with research and development efforts, including clinical studies, and from general and administrative costs associated with our operations. We expect our operating expenses to significantly increase as we continue to invest in research and development efforts. We also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur substantial and increasing operating losses for the foreseeable future.

The Company's quarterly and annual operating and financial results and its gross margins are likely to fluctuate significantly in future periods.

The Company's quarterly and annual operating and financial results are difficult to predict and may fluctuate significantly from period to period. The Company's revenue and results of operations may fluctuate as a result of a variety of factors that are outside of the Company's control including, but not limited to, general economic conditions, the timing of orders from the Company's OEM partners, its OEM partners' ability to manufacture and ship their digital mammography systems, its timely receipt by the FDA for the clearance or approval to market Company products, its ability to timely engage other OEM partners for the sale of Company products, the timing of product enhancements and new product introductions by Company or its competitors, the pricing of Company products, changes in customers' budgets, changes to the economic strength of the Company's customers, economic changes in the markets served by the Company's customers, competitive conditions and the possible deferral of revenue under the Company's revenue recognition policies.

Risks Related to the Company and its Business

The Company expects the novel coronavirus (COVID-19) pandemic, including the emergence of new variants, to have a significant effect on the Company's results of operations. In addition, the pandemic has resulted in significant financial market volatility, and its impact on the global economy appears to be significant. A continuation or worsening of the pandemic will have a material adverse impact on the Company's business, results of operations and financial condition and on the market price of the Company's common stock.

As a provider of devices and services to the health care industry, the Company's operations have been materially affected, and may continue to be impacted, by the COVID-19 pandemic. Beginning with Q1 2020 through Q4

2021, the COVID-19 pandemic has presented a number of challenges and risks for the Company's business, including, but not limited to, decreased product demand due to reduced numbers of in-person meetings with potential clients; potential clients' singular focus on surging COVID-19 infection rates following the emergence of the Omicron variant, causing attention to be diverted from purchasing decisions; pandemic-related public health impacts, including significant shifts in workforce availability and priorities, on customer, supplier, and iCAD's business process; supply chain interruptions; disruptions to the Company's clinical trials; challenges operating in a virtual work environment; impacts resulting from travel limitations and mobility restrictions; and other challenges presented by disruptions to the Company's normal operations in response to the pandemic, as well as uncertainties regarding the duration and severity of the pandemic on the global economy and the Company's operations, and the unpredictable and periodic emergence of new variants of the COVID-19 virus.

The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continued or worsening level of market disruption and volatility observed since the start of the pandemic will have an adverse effect on the Company's ability to access capital, on its business, results of operations and financial condition, and on the market price of the Company's common stock. Although the Company does not provide guidance to investors relating to the Company's results of operations, the Company's quarterly results for the quarter ending March 31, 2022, and possibly future quarters, could reflect a continued negative impact from the COVID-19 pandemic for similar or additional reasons.

The Company's exposure to trade accounts receivable losses may increase if its customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID-19 pandemic, or other customer-specific factors. The Company has historically not experienced significant trade account receivable losses, but it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade account receivables as hospitals' cash flows are impacted by their response to the COVID-19 pandemic.

The markets for the Company's products and treatments and newly introduced enhancements to the Company's existing products and treatments may not develop as expected, the Company continues to face barriers to broad market acceptance.

The successful commercialization of the Company's newly developed products and treatments and newly introduced enhancements to the Company's existing products and treatments are subject to numerous risks, both known and unknown, including:

- market acceptance of the Company's products;
- uncertainty of the development of a market for such product or treatment;
- trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than the Company's products, technologies, treatments or therapies;
- the perceptions of the Company's products or treatments as compared to other products and treatments;
- recommendation and support for the use of the Company's products or treatments by influential customers, such as hospitals, radiological practices, breast surgeons and radiation oncologists and treatment centers and U.S. and international medical professional societies;
- the availability and extent of data demonstrating the clinical efficacy of the Company's products or treatments;
- competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and
- other technological developments.

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. On September 29, 2020, CMS finalized a rule regarding its new RO Model, designed, according to CMS, to improve the quality of care for cancer patients receiving radiotherapy and reduce Medicare expenditures through bundled payments. In the final notice, CMS did not include IORT treatments (including CPT codes 77424, 77425, and 77469) within the new alternative payment model for radiation oncology. As a result, whether or not a particular physician practice or hospital is subject to the new radiation oncology payment model, IORT services covered by Medicare will continue to be subject to the existing payment systems for physician services and hospital outpatient services. On December 10, 2021, the Protecting Medicare and American Farmers from Sequestration Cuts Act delayed the RO Model implementation until no earlier than January 1, 2023. 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.

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

The Company's business is dependent upon future market growth of full field digital mammography systems, digital computer aided detection products, and tomosynthesis as well as advanced image analysis and workflow solutions for use with MRI and CT and the market growth of electronic brachytherapy. This growth may not occur or may occur too slowly to benefit us.

The Company's future business is substantially dependent on the continued growth in the market for electronic brachytherapy, full field digital mammography systems, digital computer aided detection products and tomosynthesis as well as advanced image analysis and workflow solutions for use with MRI and CT. The market for these products may not continue to develop or may develop at a slower rate than the Company anticipates due to a variety of factors, including, general economic conditions, delays in hospital spending for capital equipment, the significant costs associated with the procurement of full field digital mammography systems and CAD products and MRI and CT systems and the reliance on third party insurance reimbursement. If the market for the products and technologies upon which the Company's products are dependent does not grow or grows too slowly, this could have a material adverse effect on the Company's business.

A limited number of customers 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 2021, the Company's OEM partners accounted for 22% of its total revenue, with one major customer, GE Healthcare, accounting for 14% of the Company's revenue. In addition, in 2021, four customers, consisting of both OEM and direct customers, accounted for 31% of the Company's total revenue. 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.

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, 2021 and its other intangible assets have been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect the Company's reported results of operations in future periods.

The Company's effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

As a global company, the Company is subject to taxation 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.

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.

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 for it by a sole manufacturer, by a limited number of manufacturers or assembled by the Company from supplies it obtains from a limited number of suppliers. Critical components required to manufacture the Company's products, whether by outside manufacturers or directly by the Company, may be available from a sole or limited number of component suppliers. The Company generally does not have long-term arrangements with any of its manufacturers or suppliers. The loss of a sole or key manufacturer or supplier could materially impair the Company's ability to deliver products to its customers in a timely manner and would adversely affect the Company's sales and operating results. The Company's business would be harmed if any of its manufacturers or suppliers could not meet its quality and performance specifications and quantity and delivery requirements.

Additionally, the Company's suppliers and manufacturers are, and will continue to be, subject to extensive government regulation in connection with the manufacture of any medical devices. The Company's suppliers and

manufacturers must ensure that they are compliant with applicable quality systems and other regulatory requirements, as mandated by the FDA and other regulatory authorities. If the Company's materials suppliers or manufacturers face manufacturing or quality control problems this may lead to delays in product production or shipment or the Company's supplier or manufacturer no longer being able to continue operations. The Company's business would be harmed if any of its manufacturers or suppliers could not meet its quality and performance specifications and quantity and delivery requirements.

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

The Company is devoting resources to the development of a new software license model to complement its traditional perpetual licensing models. This model allows the Company to license Detection software through subscription licenses that are cancelable at any time. The Company has limited operating history with subscription licensing models and may not be able to accurately predict initial subscription enrollment or future renewal or cancellation rates. Subscription renewal rates may decline or fluctuate as a result of a number of factors, including but not limited to customer satisfaction or dissatisfaction with Company products, the price of Company products, the prices of similar competitive products, or customer budget sensitivity. If any of the Company's assumptions about revenue from the subscription licensing model are incorrect, the Company's actual results may vary materially from those anticipated, estimated, or projected.

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. 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.

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 2021, approximately 8.6% of the Company's revenue was derived from customers located in Europe, and approximately 39.0% of the Company's export revenue was derived from customers located in Europe. In late February 2022, Russian military forces launched significant military action against Ukraine. Sustained conflict and disruption in the region is likely. The aggregate impact to Eastern Europe and Europe as a whole, 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.

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;

- slower than expected rates of patient recruitment and enrollment, which may be further negatively impacted by the COVID-19 global pandemic;
- inability to retain patients in clinical trials, which may be further negatively impacted by the COVID-19 global pandemic;
- lack of effectiveness during clinical trials;
- unforeseen safety issues;
- inability or unwillingness of medical clinical investigators and institutional review boards to follow the Company's clinical trial protocols;
- failure of clinical investigators or sites to maintain necessary licenses or permits or comply with good clinical practices, or GCP, or other regulatory requirements; and
- lack of sufficient funding to finance the clinical trials.

In addition, the Company or regulatory authorities may suspend the Company's clinical trials at any time if it appears that the Company is exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in the Company's regulatory submissions or the conduct of these trials. Any suspension of clinical trials will delay possible regulatory approval, increase costs, and adversely impact the Company's ability to develop products and generate revenue.

The Company's 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.

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 22% of the Company's revenue for 2021. 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.

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 2022 and 2029. 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 product, 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 product, 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.

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.

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 and Xoft Systems are medical devices subject to extensive regulation by the FDA under the FDCA. The FDA's regulation of the Company's products includes its manufacturing operations, product labeling, adverse event reporting, and the FDA's general prohibition against promoting products for unapproved or "off-label" uses.

The Company's failure to fully comply with applicable regulations could result in the issuance of warning letters, non-approvals, suspensions of existing approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution. Moreover, unanticipated changes in existing regulatory requirements or adoption of new requirements could increase the Company's operating and compliance burdens and adversely affect its business, financial condition and results of operations.

Sales of the Company's products in certain countries outside of the United States are also subject to extensive regulatory approvals. Obtaining and maintaining foreign regulatory approvals is an expensive and time-consuming process. The Company cannot be certain that it will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which the Company plans to market its CAD products and Xoft Systems, and if the Company fails to receive such approvals, its ability to generate revenue may be significantly diminished.

The Company may not be able to obtain regulatory approval for any of the other products that we may consider developing.

The Company has received the required premarket approvals from FDA or the equivalent foreign authority in the relevant jurisdictions in which its currently offers its products. Before the Company is able to commercialize any new product or promote a new indicated use of an existing product, it must obtain the required regulatory approvals. The process for satisfying these regulatory requirements is lengthy and costly and will require the Company to comply with complex standards for research and development, clinical trials, testing, manufacturing, quality control, labeling, and promotion of products. Additionally, even if the Company receives regulatory approval for a new product or indicated use in one jurisdiction, its products may be subject to separate regulatory approval in each country or jurisdiction in which the Company plans to market its products. The Company cannot be certain that it will be able to obtain the necessary regulatory approvals timely or at all in any country or jurisdiction. Successfully obtaining regulatory approval in one jurisdiction does not guarantee approval in another; however, a delay or failure to obtain regulatory approval in one jurisdiction may negatively affect the regulatory process in another. If the Company is unable to obtain regulatory approval for other products or indicated uses, its ability to generate sufficient revenue to continue its business may be significantly impacted.

The Company's products may be recalled even after it has received FDA or other governmental approval or clearance.

If the safety or efficacy of any of the Company's products is called into question, the Company may initiate or the FDA and similar governmental authorities in other countries may press the Company to implement or even require a product recall, even if the Company's product received approval or clearance by the FDA or a similar

governmental body. Such a recall would divert the focus of the Company's management and its financial resources and could materially and adversely affect the Company's reputation with customers and its financial condition and results of operations.

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.

Data protection laws in the United States, Europe and around the world may restrict the Company's activities and increase the Company's costs.

Various statutes and rules in the United States, Europe and around the world regulate privacy and data protection which may affect the Company's collection, use, storage, and transfer of information both abroad and in the United States. New laws and regulations are being enacted, so that this area remains in a state of flux. Monitoring and complying with these laws requires substantial financial resources. Failure to comply with these laws may result in, among other things, civil and criminal liability, negative publicity, restrictions on further use of data, and/or liability under contractual warranties. In addition, changes in these laws (including newly released interpretations of these laws by courts and regulatory bodies) may limit the Company's data access, use and disclosure, and may require increased expenditures by us.

The European Union's General Data Protection Regulation ("GDPR") requires the Company to meet new and more stringent requirements regarding the handling of personal data about EU residents. Failure to meet the GDPR requirements could result in penalties of up to 4% of worldwide revenue.

Risk Related to the Company's Common Stock

A substantial number of shares of the Company's common stock are eligible for future sale, and the sale of shares of common stock into the market, or the perception that such sales may occur, may depress the Company's stock price.

Sales of substantial additional shares of the Company's common stock in the public market, or the perception that these sales may occur, may significantly lower the market price of the Company's common stock. The Company is unable to estimate the amount, timing or nature of future sales of shares of its common stock. The Company has previously issued a substantial number of shares of common stock, which are eligible for resale under Rule 144 of the Securities Act of 1933, as amended (the "Securities Act"), and may become freely tradable. The Company has also registered shares that are issuable upon the exercise of options and warrants. If holders of options, or warrants choose to exercise or convert their securities and sell shares of common stock issued upon the such exercise or conversion in the public market or if holders of currently restricted common stock choose to sell such shares of common stock in the public market under Rule 144 or otherwise, or attempt to publicly sell such shares all at once or in a short time period, the prevailing market price for the Company's common stock may decline.

The Company has a limited number of shares of common stock available for future issuance which could adversely affect the Company's ability to raise capital or consummate acquisitions.

The Company is currently authorized to issue 60,000,000 shares of common stock under its amended Certificate of Incorporation ("Certificate of Incorporation"). As of December 31, 2021, the Company had issued 25,326,086 shares of common stock and had 2,486,511 shares of common stock reserved for issuance upon exercise of options granted, 875 shares of common stock reserved for vesting of restricted stock and 882,608 shares of common stock reserved for issuance under our Employee Stock Purchase Plan.

On March 5, 2021, the Company closed an underwritten public offering of 1,393,738 shares of common stock at a public offering price of $18.00 per share.

The Company's stockholders approved a proposal to amend the Certificate of Incorporation (the "Amendment to the Certificate of Incorporation") to increase the Company's authorized shares of common stock from 30,000,000 shares to 60,000,000 shares, and a proposal to approve an amendment to the Company's 2016 Stock Incentive Plan, as amended, to increase the number of shares of common stock available thereunder from 2,600,000 shares to 4,700,000 shares and to increase the aggregate number of incentive stock options available thereunder from 1,000,000 to 2,000,000 (the "Plan Amendment"). Following stockholder approval of

all Proposals at the Meeting, the Company filed the Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware on July 21, 2021, and the Plan Amendment was made effective as of July 15, 2021.

Due to the limited number of authorized shares of common stock available for issuance, the Company may not be able to raise additional equity capital or complete a merger, other business combination or partnership unless the Company increases the number of shares it is authorized to issue.

If the Company does not receive the requisite stockholder approval, its operations could be materially adversely impacted. In addition, an increase in the authorized number of shares of common stock and the subsequent issuance of such shares could have the effect of delaying or preventing a change in control of the Company without further action by the Company's stockholders.

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 to issue up to 1,000,000 shares of preferred stock. The preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by the Company's Board of Directors, without further action by stockholders, and may include, among other things, voting rights (including the right to vote as a series on particular matters), preferences as to dividends and liquidation, conversion and redemption rights, and sinking fund provisions. Although there are currently no shares of preferred stock outstanding, future holders of preferred stock may have rights superior to the Company's common stock and such rights could also be used to restrict the Company's ability to merge with or sell its assets to a third party.

The Company is also subject to the provisions of Section 203 of the Delaware General Corporation Law, which could prevent the Company from engaging in a "business combination" with a 15% or greater stockholder for a period of three years from the date such person acquired that status unless appropriate board or stockholder approvals are obtained.

These provisions could deter unsolicited takeovers or delay or prevent changes in the Company's control or management, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market price. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

The 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.

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.

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, 2021 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.

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.

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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

The Company's executive offices are leased pursuant to a lease originally entered into in December 2006 as amended. The lease covers approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire. The lease expires in February 2023 with monthly base rent of $17,901. 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 leases a facility consisting of approximately 24,350 square feet of office, manufacturing and warehousing space located at 101 Nicholson Lane, San Jose, CA, as amended. The operating lease commenced in September 2012 and expires in March 2023, with monthly base rent payments of $53,816 until March 31, 2022 and monthly base rent payments of $55,520 from April 2022 until March 2023. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the facility.

In addition to the foregoing leases relating to its principal properties, the Company also has a lease for an additional facility in Nashua, New Hampshire used for product repairs, manufacturing and warehousing and 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.

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.

PART II

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

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

As of March 21, 2022, there were 89 holders of record of the Company's common stock.

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.

Information with respect to the Company's equity compensation plans in effect at December 31, 2021 will be included in the Company's 2022 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, 2021.

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 and 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 medical technology company providing innovative cancer detection and therapy solutions. The Company reports in two segments: Detection and Therapy.

In the Detection segment, the Company's solutions include (i) advanced image analysis and workflow solutions that enable healthcare professionals to better serve patients by identifying pathologies and pinpointing the most prevalent cancers earlier, and (ii) a comprehensive range of high-performance, Artificial Intelligence and Computer-Aided Detection (CAD) systems and workflow solutions for 2D and 3D mammography, Magnetic Resonance Imaging (MRI) and Computed Tomography (CT).

In the Therapy segment, the Company offers the Xoft System, an isotope-free cancer treatment platform technology. The Xoft System can be used for the treatment of early-stage breast cancer, endometrial cancer, cervical cancer and nonmelanoma skin cancer.

The Company's headquarters are located in Nashua, New Hampshire, with a manufacturing and warehousing facility in New Hampshire and an operations, research, development, manufacturing and warehousing facility in San Jose, California.

Discussion of Operating Results:

Year Ended December 31, 2021 compared to Year Ended December 31, 2020

Revenue. Revenue for the year ended December 31, 2021 was $33.6 million compared with revenue of $29.7 million for the year ended December 31, 2020, an increase of $3.9 million, or 13.3%. Detection revenue increased by 0.1% and Therapy revenue increased by $3.9 million, or 50.9%.

The table below presents the components of revenue for 2021 and 2020 (in thousands):

	For the year ended December 31,			
	2021	2020	$ Change	% Change
Detection revenue				
Product revenue	$15,661	$16,291	$ (630)	(3.9)%
Service and supplies revenue	6,358	5,706	652	11.4%
Subtotal	22,019	21,997	22	0.1%
Therapy revenue				
Product revenue	5,530	2,612	2,918	111.7%
Service and supplies revenue	6,089	5,089	1,000	19.7%
Subtotal	11,619	7,701	3,918	50.9%
	$33,638	$29,698	$3,940	13.3%

Detection revenues were flat as they were approximately $22.0 million for each of the years ended December 31, 2021 and 2020, respectively.

Detection product revenue decreased by $0.6 million and Detection service revenue increased by $0.7 million. The Company believes that Detection product revenue was adversely affected in 2021 by the COVID-19 pandemic, as the typical sales cycle and ordering patterns were disrupted due to supply chain issues, travel restrictions, and some healthcare facilities' reprioritization of resources to provide additional focus on COVID-19. The impact on 2021 began in the second quarter and continued through the remainder of 2021 but was most acute in December. The Company is not able to predict how the COVID-19 pandemic will affect future revenue and order volume. The $0.7 million increase in Detection service revenue was due primarily to an increase in service revenue from direct customers. The Company did not see significant impact of the COVID-19 pandemic on Detection service revenue in 2021 as compared to 2020 but is not able to predict how the COVID-19 pandemic could affect future Detection service revenue.

Therapy revenue increased 50.9%, or $3.9 million, to $11.6 million for the year ended December 31, 2021 from $7.7 million in the year ended December 31, 2020.

Therapy product revenue increased by $2.9 million and Therapy service and supplies revenue increased by $1.0 million. Therapy product revenue for the year ended December 31, 2021 benefitted from reimbursement and regulatory policy changes in the dermatology market. Sales were also higher in international markets for Intraoperative Radiation Therapy indications. Therapy product revenue is related to the sale of our Xoft Systems including the Controller unit and re-usable applicators. Therapy service revenue was positively impacted by the additional controller placement leading to more service and source contracts and consumables usage.

Gross Profit. Gross profit was $24.2 million for the year ended December 31, 2021 compared to $21.4 million for the year ended December 31, 2020, a increase of $2.9 million, or 13.5%. Detection gross profit increased by $0.7 million from $17.9 million in the year ended December 31, 2020 to $18.5 million in the year ended December 31, 2021. Detection gross profit as a percentage of Detection revenue increased to 84% in the year ended December 31, 2021

from 81% in the year ended December 31, 2020. The increase was due primarily to an increase in high margin licenses added to existing servers rather than the lower margin license and server bundle. Therapy gross profit increased by $2.2 million from $3.5 million in the year ended December 31, 2020 to $5.7 million in the year ended December 31, 2021. Therapy gross profit as a percentage of Therapy revenue increased to 49% in the year ended December 31, 2021 from 45% in the year ended December 31, 2020. The increase was due primarily to revenue mix shifting to higher margin product revenues relative to service revenues.

Gross profit as a percentage of revenue was 72.1% for the year ended December 31, 2021 compared to 71.9% for the year ended December 31, 2020. Gross profit as a percentage of revenue is dependent on product and service mix within each segment and segment mix. The lower margin Therapy segment growing as a percentage of total revenue largely offset the margin gains within each individual segment.

The COVID-19 pandemic adversely affected revenues from both segments in the years ended December 31, 2021 and 2020, and as a result, gross profit in both segments. The primary impact of the COVID-19 pandemic started in the second quarter of 2020 and the Company undertook cost cutting measures to reduce operating expenses and manufacturing costs to offset some of the COVID-19 impact to gross profit. The Company lessened some of these cost control efforts, until COVID-19 negative impacts on revenues re-emerged in the second quarter of 2021, as the typical sales cycle and ordering patterns were disrupted due to supply chain issues, travel restrictions, and some healthcare facilities' reprioritization of resources to provide additional focus on COVID-19. The impact began in the second quarter and continued through the remainder of 2021, but was most acute in December. Starting in the second quarter of 2021, the company re-introduced cost management strategies to minimize the effect of 2021 COVID-19 impacts on gross profit. The Company is not able to predict how the COVID-19 pandemic, supply chain disruptions, macro-economic conditions and other factors will affect future gross profit.

Cost of revenue and gross profit for 2021 and 2020 were as follows (in thousands):

	For the year ended December 31,			
	2021	2020	Change	% Change
Products	$ 5,653	$ 5,000	$ 653	13.1%
Service and supplies	3,425	2,965	460	15.5%
Amortization and depreciation	317	379	(62)	(16.4%)
Total cost of revenue	9,395	8,344	1,051	12.6%
Gross profit	$24,243	$21,354	$2,889	13.5%
Gross profit %	72.1%	71.9%		

	For the year ended December 31,			
	2021	2020	Change	% Change
Detection gross profit	$18,510	$17,856	$ 654	3.7%
Therapy gross profit	5,733	3,498	2,235	63.9%
Gross profit	$24,243	$21,354	$2,889	13.5%

Operating Expenses:

Operating expenses for 2021 and 2020 were as follows (in thousands)**:**

	For the year ended December 31,			
	2021	2020	Change	% Change
Operating expenses:				
Engineering and product development	$ 9,194	$ 8,114	$1,080	13.3%
Marketing and sales	15,135	13,312	1,823	13.7%
General and administrative	10,406	9,117	1,289	14.1%
Amortization and depreciation	240	199	41	20.6%
Total operating expenses	$34,975	$30,742	$4,233	13.8%

Operating expenses were $35.0 million for the year ended December 31, 2021, compared to $30.7 million for the year ended December 31, 2020, an increase of $4.3 million or 13.8%. Operating expenses as a percentage of sales was 104.0% in the year ended December 31, 2021, compared to 103.5% for the year ended December 31, 2020. In early 2021, the Company reduced cost-cutting programs implemented in 2020 in response to COVID-19, returning furloughed employees and hiring a number of employees for positions vacant in early 2021. When the impacts of COVID-19 re-emerged in the second quarter of 2021, the Company continued to remain focused on a disciplined approach to spending.

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2021 increased by $1.1 million, or 13.3%, from $8.1 million in 2020 to $9.2 million in 2021. The increase was largely due to increased personnel as a result of the resumption of hiring for prioritized positions in early 2021 and an increase in consulting fees.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2021 increased by $1.8 million, or 13.7%, from $13.3 million in 2020 to $15.1 million in 2021. The increase in marketing and sales expense was due primarily to increased personnel and trade show costs after resumption of sales and marketing activity after the 2020 cost-cutting measures prompted by the COVID-19 pandemic and some additional management costs being reclassified and sales and marketing.

General and Administrative. General and administrative expenses for the year ended December 31, 2021 increased by $1.3 million, or 14.1%, from $9.1 million in 2020 to $10.4 million in 2021. The increase was due primarily to an increase in consulting fees related to corporate strategic projects and the interim consulting CFO and to insurance premium expenses as well as board of director related expenses. Employee compensation increased, but was offset by a decrease in external service expenses as multiple functions were brought in-house.

Amortization and Depreciation. Amortization and depreciation expenses for the year ended December 31, 2021 increased by $0.04 million, or 20.6%, from $0.20 million in 2020 to $0.24 million in 2021. The Company's depreciable and amortizable assets have remained relatively consistent between 2021 and 2020.

Other Income, Tax and Expense (in thousands):

	For the year ended December 31,			
	2021	2020	Change	Change %
Interest expense	$(141)	$ (476)	335	(70.4)%
Interest income	15	97	(82)	(84.5)%
Loss on extinguishment of debt	(386)	(341)	(45)	13.2%
Loss on fair value of debentures	—	(7,464)	7,464	(100.0)%
Total other expense	$(512)	$(8,184)	$7,672	(93.7)%
Income tax expense	$ 1	$ 38	(37)	(97.4)%

Interest Expense. The Company recorded $0.1 million of interest expense in the year ended December 31, 2021 as compared with $0.5 million of interest expense in the year ended December 31, 2020. The Western Alliance debt facility was fully paid and extinguished in April 2021.

Interest income. Interest income of $0 million and $0.1 million for the years ended December 31, 2021 and 2020, respectively, reflects income earned from our money market accounts.

Loss on Extinguishment of Debt. The Company recorded a loss on extinguishment of debt of $0.4 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively. The loss in 2021 was due to the April 27, 2021 extinguishment of the Loan and Security Agreement with Western Alliance Bank, originally issued on March 30, 2020. The loss in 2020 was due to the March 30, 2020, extinguishment of the amended Loan and Security Agreement with Silicon Valley Bank, entered into in August 2017.

Loss on fair value of debentures. The Company recorded a loss of $7.5 million in 2020, which reflected an increase in the fair value of the unsecured subordinated convertible debentures (the "Convertible Debentures") liability from approximately $13.7 million at December 31, 2019 to $21.2 million at February 21, 2020, the forced conversion date. Upon the consummation of the forced conversion, the Company issued 1,816,466 shares of common stock with a fair value of approximately $21.2 million, and the Convertible Debenture liability was reclassified to stockholders' equity.

Tax expense. The Company had tax expense of $1,000 for the year ended December 31, 2021 as compared to tax expense of $38,000 for the year ended December 31, 2020.

Discussion of Operating Results:

Year Ended December 31, 2020 compared to Year Ended December 31, 2019

Revenue. Revenue for the year ended December 31, 2020 was $29.7 million compared with revenue of $31.3 million for the year ended December 31, 2019, a decrease of $1.6 million, or 5.2%. Detection revenue decreased by $0.3 million and Therapy revenue decreased by $1.3 million.

The table below presents the components of revenue for 2020 and 2019 (in thousands):

	Twelve months ended December 31,			
	2020	2019	$ Change	% Change
Detection revenue				
Product revenue	$16,291	$16,788	$ (497)	(3.0)%
Service revenue	5,706	5,531	175	3.2%
Subtotal	21,997	22,319	(322)	(1.4)%
Therapy revenue				
Product revenue	2,612	2,979	(367)	(12.3)%
Service revenue	5,089	6,042	(953)	(15.8)%
Subtotal	7,701	9,021	(1,320)	(14.6)%
Total revenue	$29,698	$31,340	$(1,642)	(5.2)%

Detection revenues decreased by $0.3 million, or 1.4%, from $22.3 million for the year ended December 31, 2019 to $22.0 million for the year ended December 31, 2020.

Detection product revenue decreased by $0.5 million and Detection service revenue increased by $0.2 million. The Company believes that Detection product revenue was adversely affected in 2020 by the COVID-19 pandemic, as the typical sales cycle and ordering patterns were disrupted due to some healthcare facilities'

additional focus on COVID-19. The primary impact occurred during the second and third quarters of 2020. The total impact was partially offset by an increase in revenue in the fourth quarter of 2020 as compared to the fourth quarter of 2019. The Company is not able to predict how the COVID-19 pandemic will affect future revenue and order volume. The $0.2 million increase in Detection service revenue was due primarily to an increase in service revenue from direct customers. The Company did not see a significant impact of the COVID-19 pandemic on Detection service revenue in 2020 as compared to 2019 but is not able to predict how the COVID-19 pandemic could affect future Detection service revenue.

Therapy revenue decreased 14.6%, or $1.3 million, to $7.7 million for the year ended December 31, 2020 from $9.0 million in the year ended December 31, 2019.

Therapy product revenue decreased by $0.4 million and Therapy service revenue decreased by $1.0 million. Therapy product revenue for the year ended December 31, 2020 was adversely affected by the COVID-19 pandemic, due to stay-at-home and social distancing orders as well as the uncertainty in the market. Therapy product revenue is related to the sale of our Xoft Systems and can vary significantly from quarter to quarter due to changes in the number of units sold, and the average selling price. We expect Therapy sales to continue to vary as the sales of controller units can represent a significant component of Therapy product revenue. We believe Therapy service revenue was negatively impacted primarily due to the lack of ability to treat patients, mostly in the second and third quarters, due to the additional focus by healthcare professionals on the COVID-19 pandemic.

Gross Profit. Gross profit was $21.3 million for the year ended December 31, 2020 compared to $24.2 million for the year ended December 31, 2019, a decrease of $2.9 million, or 11.9%. Detection gross profit decreased by $0.8 million from $18.6 million in the year ended December 31, 2019 to $17.8 million in the year ended December 31, 2020. Detection gross profit as a percentage of Detection revenue decreased to 81.2% in the year ended December 31, 2020 from 84% in the year ended December 31, 2019. The decrease was due primarily to higher installation costs and equipment costs to support processing of higher resolution and increased volume of 3D images. Therapy gross profit decreased by $2.1 million from $5.6 million in the year ended December 31, 2019 to $3.5 million in the year ended December 31, 2020. This decrease is largely due to Therapy revenue being adversely affected by the COVID-19 pandemic, due to stay-at-home and social distancing orders as well as the uncertainty in the market. Therapy gross profit as a percentage of Therapy revenue decreased to 45% in the year ended December 31, 2020 from 62% in the year ended December 31, 2019.

Gross profit as a percentage of revenue was 71.9% for the year ended December 31, 2020 compared to 77.3% for the year ended December 31, 2019. Gross profit as a percentage of revenue will fluctuate due to the costs related to manufacturing, amortization and the impact of product mix in each segment.

The COVID-19 pandemic adversely affected revenues from Detection products and the Therapy segment in the year ended December 31, 2020, and as a result, gross profit in both segments. The primary impact of the COVID-19 pandemic was felt during the second and third quarters of 2020. However, the Company continued to follow steps taken during the second and third quarters of 2020 to reduce operating expenses, including cutting non-essential travel, implementing employee furloughs and terminations, reducing employee salaries by 10%, and cancelling most in-person trade shows. These measures offset some of the impact on gross profit caused by COVID-19. Salary reductions, employee furloughs, and certain other of these measures were ended in the fourth quarter of 2020.

Cost of revenue and gross profit for 2020 and 2019 were as follows (in thousands):

	Twelve months ended December 31,			
	2020	2019	Change	% Change
Products	$ 5,000	$ 3,278	$ 1,722	52.5%
Service and supplies	2,965	3,438	(473)	(13.8)%
Amortization and depreciation	379	397	(18)	100.0%
Total cost of revenue	$ 8,344	$ 7,113	$ 1,231	17.3%
Gross profit	$21,354	$24,227	$(2,873)	(11.9)%
profit %	71.9%	77.3%		

	For the year ended December 31,			
	2020	2019	Change	% Change
Detection gross profit	$17,856	$18,627	$ (771)	(4.1)%
Therapy gross profit	3,498	5,600	(2,102)	(37.5)%
Gross profit	$21,354	$24,227	$(2,873)	(11.9)%

Operating Expenses:

Operating expenses for 2020 and 2019 were as follows (in thousands):

	Year ended December 31,			
	2020	2019	Change	Change %
Operating expenses:				
Engineering and product development	$ 8,114	$ 9,271	$(1,157)	(12.5)%
Marketing and sales	13,312	13,634	(322)	(2.4)%
General and administrative	9,117	7,443	1,674	22.5%
Amortization and depreciation	199	276	(77)	(27.9)%
Total operating expenses	$30,742	$30,624	$ 118	0.4%

Operating expenses were $30.7 million for the year ended December 31, 2020, compared to $30.6 million for the year ended December 31, 2019, an increase of $0.1 million or 0.4%. The Company was able to keep operating expenses relatively flat after implementing ongoing cost-cutting measures prompted by the COVID-19 pandemic in the second quarter of 2020. These cost-cutting measures followed increased expenditures in the year ended December 31, 2019 as the Company invested in additional commercial resources prior to the onset of the COVID-19 pandemic.

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2020 decreased by $1.2 million, or 12.5%, from $9.3 million in 2019 to $8.1 million in 2020.The decrease was largely due to decreased personnel as a result of the cost-cutting measures prompted by the COVID-19 pandemic.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2020 decreased by $0.3 million, or 2.4%, from $13.6 million in 2019 to $13.3 million in 2020. The decrease in marketing and sales expense was due primarily to decreased personnel and trade show costs through the implementation of cost-cutting measures prompted by the COVID-19 pandemic. The decrease was offset by an increase in costs in the first three months of the year when the Company invested in additional commercial resources to help drive sales of new Detection products prior to the onset of the COVID-19 pandemic.

General and Administrative. General and administrative expenses for the year ended December 31, 2020 increased by $1.7 million, or 22.5%, from $7.4 million in 2019 to $9.1 million in 2020. The increase was due primarily to an

increase in stock compensation and legal expenses and was offset by cost-cutting measures prompted by the COVID-19 pandemic.

Amortization and Depreciation. Amortization and depreciation expenses for the year ended December 31, 2020 decreased by $0.1 million, or 27.9%, from $0.3 million in 2019 to $0.2 million in 2020. The Company's depreciable and amortizable assets have remained relatively consistent between 2020 and 2019.

Other Income, Tax and Expense (in thousands):

	Year ended December 31,			
	2020	2019	Change	Change %
Interest expense	$ (476)	$ (784)	$ 308	(39.3)%
Interest income	97	344	(247)	(71.8)%
Loss on extinguishment of debt	(341)	—	(341)	0.0%
Loss on fair value of debentures	(7,464)	(6,671)	(793)	11.9%
	$(8,184)	$(7,111)	$(1,073)	15.1%
Tax expense	$ 38	$ 43	$ (5)	(11.6)%

Interest Expense. The Company recorded $0.5 million of interest expense in the year ended December 31, 2020 as compared with $0.8 million of interest expense in the year ended December 31, 2019.

Interest income. Interest income of $0.1 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively, reflects income earned from our money market accounts.

Loss on fair value of debentures. The Company recorded a loss of $7.5 million in 2020, which reflected an increase in the fair value of the unsecured subordinated convertible debentures (the "Convertible Debentures") liability from approximately $13.7 million at December 31, 2019 to $21.2 million at February 21, 2020, the forced conversion date. Upon the consummation of the forced conversion, the Company issued 1,816,466 shares of common stock with a fair value of approximately $21.2 million, and the Convertible Debenture liability was reclassified to stockholders' equity.

Tax expense. The Company had tax expense of $38,000 for the year ended December 31, 2020 as compared to tax expense of $43,000 for the year ended December 31, 2019.

Segment Analysis

The Company operates in and reports results for two segments: Detection and Therapy. Segment operating income (loss) includes cost of sales, engineering and product development, marketing and sales, and depreciation and amortization for the respective segment. A summary of Segment revenues, segment gross profit and segment operating income (loss) for the fiscal years ended December 31, 2021, 2020, and 2019 are below (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Segment revenues:			
Detection	$ 22,019	$ 21,997	$ 22,319
Therapy	11,619	7,701	9,021
Total Revenue	$ 33,638	$ 29,698	$ 31,340
Segment gross profit:			
Detection	$ 18,510	$ 17,856	$ 18,627
Therapy	5,733	3,498	5,600
Total gross profit	$ 24,243	$ 21,354	$ 24,227

	Year Ended December 31,		
	2021	2020	2019
Segment operating income (loss):			
Detection	$ 1,563	$ 2,719	$ 2,564
Therapy	(1,835)	(3,028)	(1,476)
Segment operating income (loss)	$ (272)	$ (309)	$ 1,088
General administrative	$ (10,460)	$ (9,079)	$ (7,486)
Interest expense	(141)	(476)	(784)
Loss on extinguishment of debt	(386)	(341)	—
Other income	15	97	345
Fair value of convertible debentures	—	(7,464)	(6,671)
Loss before income tax	$ (11,244)	$(17,572)	$(13,508)

Detection gross profit increased to approximately $18.5 million, or 84% of revenue, for the year ended December 31, 2021 from $17.9 million, or 81% of revenue, for the year ended December 31, 2020. The increase in Detection gross profit was due primarily to the decrease in Detection cost of goods related to changes in product mix. Detection segment operating income for the year ended December 31, 2021 decreased by $1.1 million to $1.6 million from $2.7 million for the year ended December 31, 2020. The decrease in Detection segment operating income was due primarily to an increase in operating expenses relative to the increase in revenues. Detection operating expenses increased by $1.8 million to $16.9 million for the year ended December 31, 2021 from $15.1 million for the year ended December 31, 2020.

Detection gross profit decreased to approximately $17.9 million, or 81% of revenue, for the year ended December 31, 2020 from $18.6 million, or 84% of revenue, for the year ended December 31, 2019. The decrease in Detection gross profit was due primarily to the decrease in Detection revenue. Detection segment operating income for the year ended December 31, 2020 increased by $0.1 million to $2.7 million from $2.6 million for the year ended December 31, 2020. The increase in Detection segment operating income was due primarily to a decrease in operating expenses. Detection operating expenses decreased by $1.0 million to $15.1 million for the year ended December 31, 2021 from $16.1 million for the year ended December 31, 2020.

Therapy gross profit increased by approximately $2.2 million to $5.7 million, or 49% of revenue, for the year ended December 31, 2021 from approximately $3.5 million or 45% of revenue for the year ended December 31, 2020. The increase in Therapy gross profit was largely due to the $3.9 million increase in revenue. Therapy operating expenses decreased by $1.1 million to $7.6 million for the year ended December 31, 2021 from $6.5 million for the year ended December 31, 2020. Therapy segment operating loss decreased to $1.8 million for the year ended December 31, 2021 from $3.0 million for the year ended December 31, 2020. The decrease in Therapy segment operating loss was due primarily to the $2.2 million increase in gross profit partially offset by the increase in operating expenses.

Therapy gross profit decreased by approximately $2.1 million to $3.5 million, or 45% of revenue, for the year ended December 31, 2020 from approximately $5.6 million or 62% of revenue for the year ended December 31, 2019. The decrease in Therapy gross profit was partly due to the $1.3 million reduction in revenue and increased costs incurred prior to the implementation of cost-cutting measures in response to the COVID-19 pandemic. Therapy operating expenses decreased by $0.5 million to $6.6 million for the year ended December 31, 2020 from $7.1 million for the year ended December 31, 2029. Therapy segment operating loss increased to $3.0 million for the year ended December 31, 2020 from $1.5 million for the year ended December 31, 2019. The increase in Therapy segment operating loss was due primarily to the decreased revenue of $1.3 million.

Liquidity and Capital Resources

The Company believes that its cash and cash equivalents balance of $34.3 million as of December 31, 2021 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 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.

On April 27, 2020, the Company issued 1,562,500 shares of common stock to several institutional investors at a price of $8.00 per share in a registered direct offering. The gross proceeds of the offering were approximately $12.5 million, and the Company received net proceeds of approximately $12.3 million. The Company entered into an at-the-market offering program with JMP Securities (the "ATM") to provide for additional potential liquidity. The Company's ATM facility provided for the sale of common stock having a value of up to $25.0 million. On December 17, 2020 the company sold 470,704 shares of common stock under the ATM facility. The gross proceeds were approximately $6.6 million, and the Company received net proceeds of approximately $6.1 million. On March 2, 2021, the Company terminated the ATM.

On March 2, 2021, the Company entered into an underwriting agreement with Guggenheim Securities, LLC, as representative of the several underwriters thereto, in connection with an underwritten public offering of 1,393,738 shares of the Company's common stock at an offering price of $18.00 per share. The Offering closed on March 5, 2021 for gross proceeds of approximately $25.1 million and net proceeds of approximately $23.2 million to the Company.

The Company had net working capital of $35.3 million at December 31, 2021. The ratio of current assets to current liabilities at December 31, 2021 and 2020 was 3.36 and 2.53, respectively.

Net cash used for operating activities for the year ended December 31, 2021 was $9.4 million, compared to $7.0 million for 2020.

The net cash used for investing activities for the year ended December 31, 2021 was $0.6 million compared to $0.5 million for the year ended December 31, 2020. The cash used for investing activities in both 2021 and 2020 was due primarily to purchases of fixed assets.

Net cash provided by financing activities for the year ended December 31, 2021 was $17.1 million, which was primarily related to the aforementioned public offering resulting in net proceeds of $23.2 offset by the debt repayment (see below). Net cash provided by financing activities for the year ended December 31, 2020 was $19.3 million, which was primarily related to the registered direct offering resulting in net proceeds of $12.3 million and the sale of stock related to the ATM resulting in net proceeds of $6.1 million.

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 2021, the Company remitted $0.2 million which represented the first half of the amount due. As of December 31, 2021, the Company has recorded a $0.1 million deferral within "Accrued and other benefits" and this amount will be remitted during 2022.

Lease Obligations:

Operating Leases:

See item 2 of this annual report on Form 10-K.

Finance Leases:

In August 2017, the Company assumed an equipment lease obligation with payments, including interest payable, totaling $50,000. The lease was determined to be a capital lease and, accordingly, the equipment was capitalized and a liability of $42,000 was recorded. The equipment was depreciated over its expected life of 3 years. The lease term expired in August of 2020.

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, 2021, the remaining liability for minimum royalty obligations totaling $0.2 million is recorded within accrued expenses and accounts payable.

Notes Payable:

On March 30, 2020, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Western Alliance Bank (the "Bank") that provided an initial term loan ("Term Loan") facility of $7.0 million and a $5.0 million revolving line of credit.

Obligations to the Bank under the Loan Agreement were secured by a first priority security interest in the Company's assets, except for certain permitted liens that have priority to the Bank's security interest by operation of law.

On April 27, 2021, the Company repaid its obligations in the aggregate amount of $7,354,283 and terminated the Loan Agreement with the Bank, and the Company's collateral securing the facility was released. The Company accounted for this repayment and retirement as an extinguishment of the Loan Agreement. The Company recorded a loss on extinguishment of approximately $386,000 related to the repayment and retirement of the Loan Agreement. The loss on extinguishment was composed of approximately $140,000 for a prepayment fee, $122,000 for the unaccrued final payment, $65,000 termination and other fees, and $58,000 for the unamortized discount and other closing costs from origination of the loan.

Loan and Security Agreement – Silicon Valley Bank

On August 7, 2017, the Company entered into a Loan and Security Agreement with Silicon Valley Bank, which was subsequently amended several times (as amended, the "SVB Loan Agreement"). The SVB Loan Agreement provided an initial term loan facility of $6.0 million and a $4.0 million revolving line of credit.

On March 30, 2020, the Company elected to repay all outstanding obligations (including accrued interest) and retire the SVB Loan Agreement. The Company accounted for this repayment and retirement as an extinguishment of the SVB Loan Agreement. The Company also wrote off unamortized original closing costs as

of the extinguishment date. The Company recorded a loss on extinguishment of approximately $341,000 related to the repayment and retirement of the SVB Loan Agreement. The loss on extinguishment was composed of approximately $185,000 for the unaccrued final payment, the $114,000 termination fee, and $42,000 of unamortized and other closing costs.

Convertible Debentures

On December 20, 2018, the Company entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited investors (the "Investors"), including, but not limited to, all directors and executive officers of the Company at the time, pursuant to which the Investors purchased Convertible Debentures with an aggregate principal amount of approximately $7.0 million in a private placement.

On February 21, 2020 (the "Conversion Date"), the conditions permitting a forced conversion were met, and the Company elected to exercise its forced conversion right under the terms of the Convertible Debentures.

As a result of this election, all of the outstanding Convertible Debentures were converted, at a conversion price of $4.00 per share, into 1,742,500 shares of the Company's common stock. In accordance with the make-whole provisions in the Convertible Debentures, the Company also issued an additional 76,966 shares of its common stock. The make-whole amount represented the total interest which would have accrued through the maturity date of the Convertible Debentures, less the amounts previously paid, totaling $697,000. The conversion prices related to the make-whole amount were dependent on whether the Investors were related parties or unrelated third parties.

Accounting Considerations and Fair Value Measurements Related to the Convertible Debentures

The Company had previously elected to make a one-time, irrevocable election to utilize the fair value option to account for the Convertible Debentures as a single hybrid instrument at its fair value, with changes in fair value from period to period being recorded either in current earnings, or as an element of other comprehensive income (loss), for the portion of the change in fair value determined to relate to the Company's own credit risk. The Company believed that the election of the fair value option allowed for a more meaningful representation of the total fair value of its obligation under the Convertible Debentures and allowed for a better understanding of how changes in the external market environment and valuation assumptions impact such fair value.

As of the December 31, 2019 valuation and the prior measurement dates, the Company utilized a Monte Carlo simulation model to estimate the fair value of the Convertible Debentures. The simulation model was designed to capture the potential settlement features of the Convertible Debentures, in conjunction with simulated changes in the Company's stock price and the probability of certain events occurring. The simulation utilized 100,000 trials or simulations to determine the estimated fair value.

The simulation utilized the assumptions that if the Company was able to exercise its forced conversion right (if the requirements to do so were met), that it would do so in 100% of such scenarios. Additionally, if an event of default occurred during the simulated trial (based on the Company's probability of default), the Investors would opt to redeem the Convertible Debentures in 100% of such scenarios. If neither event occurred during a simulated trial, the simulation assumed that the Investor would hold the Convertible Debentures until the maturity date. The value of the cash flows associated with each potential settlement were discounted to present value in each trial based on either the risk-free rate (for an equity settlement) or the effective discount rate (for a redemption or cash settlement).

The Company also recorded a final adjustment to the Convertible Debentures based on their fair value on the Conversion Date, just prior to the forced conversion being completed. Given that the Company's prior simulation model included the assumption that the Company would elect to force conversion in 100% of scenarios when the requirements were met, the final valuation was based on the actual results of the forced conversion. As such, the

Company based the final fair value adjustment of approximately $7.5 million to the Convertible Debentures just prior to conversion on the number of shares of common stock that were issued to the Investors upon conversion and the fair value of the Company's common stock as of the Conversion Date in 2020.

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 U.S. Securities and Exchange Commission ("SEC") requires companies to provide additional disclosure and commentary on their most critical accounting policies and estimates. The SEC has defined critical accounting policies as the ones that are most important to the portrayal of a company's financial condition and operating results and requires management to make its most significant estimates and judgments in the preparation of its Consolidated Financial Statements. The SEC has defined critical accounting estimates as those estimates made in accordance with generally accepted accounting principles that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations of a company.

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 in determining the range of standalone selling prices.

Allowance for Doubtful Accounts

The allowance for doubtful accounts 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 believe we are not 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.

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 Form 10-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, 2021.

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, 2021, 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, 2021.

(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 year ended December 31, 2021, 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.

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 2022 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for the Company's 2022 Annual Meeting of Stockholders (the "2022 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 2022 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 2022 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 2022 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 2022 Proxy Statement and is incorporated herein by reference.

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	Underwriting Agreement, dated March 2, 2021, by and between iCAD, Inc. and Guggenheim Securities, LLC (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed with the SEC on March 5, 2021).
3(a)	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(b)	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(c)	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	Description of Registrant's Securities
10(a)	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(b)	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(c)	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(d)	Employment Agreement between the Company and Michael Klein dated January 13, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 17, 2020).*
10(e)	Amendment to Employment Agreement, dated March 26, 2020, between iCAD, Inc. and Michael Klein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on May 29, 2020).*
10(f)	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(g)	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(h)	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(i)	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).*

10(j)	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(k)	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(l)	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(m)	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(n)	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).
21.1	Subsidiaries
23.1	Consent of BDO USA, LLP, 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.
101	The following materials formatted in XBRL (eXtensible Business Reporting Language); (i) Consolidated Balance Sheets as of December 31, 2021 and December 31, 2020, (ii) Consolidated Statements of Operations for the years ended December 31, 2021, 2020 and 2019, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2021, 2020 and 2019, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019, 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.

** 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.

SIGNATURES

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

iCAD, INC.

Date: March 28, 2022

By: /s/ Stacey Stevens
Stacey Stevens
Chief Executive Officer, President and Director

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

Signature	Title	Date
/s/ Stacey Stevens Stacey Stevens	Chief Executive Officer, President, Director, (Principal Executive Officer)	March 28, 2022
/s/ Charles R. Carter Charles R. Carter	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2022
/s/ Michael Klein Michael Klein	Chairman, Director	March 28, 2022
/s/ Dana Brown Dana Brown	Director	March 28, 2022
/s/ Timothy Norris Irish Timothy Norris Irish	Director	March 28, 2022
/s/ Nathaniel Dalton Nathaniel Dalton	Director	March 28, 2022
/s/ Rakesh Patel Rakesh Patel, MD	Director	March 28, 2022
/s/ Andy Sassine Andy Sassine	Director	March 28, 2022
/s/ Susan Wood Susan Wood, Ph.D.	Director	March 28, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021**,** 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) relates 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 a 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 separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition - Identification of distinct performance obligations in certain customer agreements

As described in Note 2 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 and identifying distinct performance obligations that should be accounted for separately versus together may require significant judgment. 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 agreements as a critical audit matter. Significant judgment can be required to determine the performance obligations in a contract with a customer and whether they are distinct. Auditing these transactions involved especially challenging auditor judgment due to the nature and extent of audit 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 and assumptions related to the identification of each distinct performance obligation and its pattern of delivery.
- Testing a sample of these revenue agreements together with their underlying documents to evaluate management's identification of each distinct performance obligation and its respective pattern of revenue recognition.

/s/ BDO USA, LLP

We have served as the Company's auditor since 1989.

Boston, Massachusetts

March 28, 2022

iCAD, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

Assets	December 31, 2021	December 31, 2020
	(in thousands except shares and per share data)	
Current assets:		
Cash and cash equivalents	$ 34,282	$ 27,186
Trade accounts receivable, net of allowance for doubtful accounts of $268 in 2021 and $111 in 2020	8,891	10,027
Inventory, net	4,171	3,144
Prepaid expenses and other current assets	2,962	1,945
Total current assets	50,306	42,302
Property and equipment:		
Equipment	7,121	6,765
Leasehold improvements	172	62
Furniture and fixtures	319	319
Marketing assets	376	376
	7,988	7,522
Less accumulated depreciation and amortization	7,106	6,778
Property and equipment, net	882	744
Other assets:		
Operating lease assets	1,059	1,758
Other assets	899	1,527
Intangible assets, net of accumulated amortization of $8,724 in 2021 and $8,494 in 2020	683	889
Goodwill	8,362	8,362
Total other assets	11,003	12,536
Total assets	$ 62,191	$ 55,582
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,779	$ 2,869
Accrued and other expenses	5,642	7,039
Lease payable, current	889	726
Deferred revenue, current	5,652	6,117
Total current liabilities	14,962	16,751
Lease payable, long-term	266	1,075
Deferred revenue, long-term	441	267
Notes payable, long-term	—	6,960
Deferred tax	5	4
Total liabilities	15,674	25,057
Commitments and contingencies (Note 15)		
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 25,326,086 in 2021 and 23,694,406 in 2020. Outstanding 25,140,255 in 2021 and 23,508,575 in 2020.	253	236
Additional paid-in capital	300,859	273,639
Accumulated deficit	(253,180)	(241,935)
Treasury stock at cost, 185,831 shares in 2021 and 2020	(1,415)	(1,415)
Total stockholders' equity	46,517	30,525
Total liabilities and stockholders' equity	$ 62,191	$ 55,582

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

	For the Years Ended December 31,		
	2021	2020	2019
	(in thousands except per share data)		
Revenue:			
Products	$ 21,191	$ 18,903	$ 19,767
Service and supplies	12,447	10,795	11,573
Total revenue	33,638	29,698	31,340
Cost of Revenue:			
Products	5,653	5,000	3,278
Service and supplies	3,425	2,965	3,438
Amortization and depreciation	317	379	397
Total cost of revenue	9,395	8,344	7,113
Gross profit	24,243	21,354	24,227
Operating expenses:			
Engineering and product development	9,194	8,114	9,271
Marketing and sales	15,135	13,312	13,634
General and administrative	10,406	9,117	7,443
Amortization and depreciation	240	199	276
Total operating expenses	34,975	30,742	30,624
Loss from operations	(10,732)	(9,388)	(6,397)
Other expense			
Interest expense	(141)	(476)	(784)
Interest income	15	97	344
Loss on extinguishment of debt	(386)	(341)	—
Loss on fair value of convertible debentures	—	(7,464)	(6,671)
Other expense, net	(512)	(8,184)	(7,111)
Loss before income tax expense	(11,244)	(17,572)	(13,508)
Income tax expense	1	38	43
Net loss and comprehensive loss	$(11,245)	$(17,610)	$(13,551)
Net loss per share:			
Basic	$ (0.45)	$ (0.80)	$ (0.74)
Diluted	$ (0.45)	$ (0.80)	$ (0.74)
Weighted average number of shares used in computing net loss per share:			
Basic	24,778	22,140	18,378
Diluted	24,778	22,140	18,378

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Stockholders' Equity
	Number of Shares Issued	Par Value				
Balance at December 31, 2018	17,066,510	$171	$218,914	$(210,774)	$(1,415)	$ 6,896
Issuance of common stock relative to vesting of restricted stock, net of 29,887 shares forfeited for tax obligations	167,843	2	(198)	—	—	(196)
Issuance of common stock pursuant to stock option plans	429,980	4	1,396	—	—	1,400
Issuance of common stock, net	1,881,818	19	9,334	—	—	9,353
Stock-based compensation	—	—	1,169	—	—	1,169
Net Loss	—	—	—	(13,551)	—	(13,551)
Balance at December 31, 2019	19,546,151	$196	$230,615	$(224,325)	$(1,415)	$ 5,071
Issuance of common stock relative to vesting of restricted stock, net of 20,247 shares forfeited for tax obligations	97,830	—	(225)	—	—	(225)
Issuance of common stock pursuant to stock option plans	155,149	1	728	—	—	729
Issuance of common stock, net	2,033,204	20	18,264	—	—	18,284
Issuance of common stock pursuant employee stock purchase plan	42,606	1	267	—	—	268
Issuance of common stock upon conversion of debentures	1,819,466	18	21,146	—	—	21,164
Stock-based compensation	—	—	2,844	—	—	2,844
Net loss	—	—	—	(17,610)	—	(17,610)
Balance at December 31, 2020	23,694,406	$236	$273,639	$(241,935)	$(1,415)	$ 30,525
Issuance of common stock relative to vesting of restricted stock, net of 5,196 shares forfeited for tax obligations	44,706	1	(60)	—	—	(59)
Issuance of common stock pursuant to stock option plans	168,450	2	1,025	—	—	1,027
Issuance of common stock, net	1,393,738	14	23,215	—	—	23,229
Issuance of common stock pursuant to employee stock purchase plan	24,786	—	257	—	—	257
Stock-based compensation	—	—	2,783	—	—	2,783
Net loss	—	—	—	(11,245)	—	(11,245)
Balance at December 31, 2021	25,326,086	$253	$300,859	$(253,180)	$(1,415)	$ 46,517

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	For the Years Ended December 31,		
	2021	2020	2019
	(in thousands)		
Cash flow from operating activities:			
Net loss	$(11,245)	$(17,610)	$(13,551)
Adjustments to reconcile net loss to net cash used for operating activities:			
Amortization	230	309	377
Depreciation	327	268	297
Bad debt provision	167	94	62
Stock-based compensation expense	2,783	2,844	1,169
Amortization of debt discount and debt costs	17	78	149
Loss on extinguishment of debt	386	341	—
Deferred tax	1	1	1
Loss on disposal of assets	97	—	—
Change in fair value of convertible debentures	—	7,464	6,671
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	969	(302)	(3,478)
Inventory	(1,027)	(533)	(1,024)
Prepaid and other assets	391	(1,390)	294
Accounts payable	(90)	878	836
Accrued and other expenses	(2,123)	(207)	982
Deferred revenue	(291)	780	108
Total adjustments	1,837	10,625	6,444
Net cash used for operating activities	(9,408)	(6,985)	(7,107)
Cash flow used for investing activities:			
Additions to patents, technology and other	(24)	(13)	(10)
Additions to property and equipment	(563)	(461)	(296)
Net cash used for investing activities	(587)	(474)	(306)
Cash flow from financing activities:			
Issuance of common stock for cash, net	23,229	18,285	9,353
Issuance of common stock pursuant to Employee Stock Purchase Plan	257	266	—
Issuance of common stock pursuant to stock option plans	1,027	729	1,400
Taxes paid related to restricted stock issuance	(59)	(225)	(196)
Principal payments of capital lease obligations	—	—	(16)
Proceeds from notes payable		6,957	—
Principal repayment of notes payable	(7,363)	(4,638)	(2,000)
Debt issuance costs	—	(42)	—
Proceeds from line of credit	—	775	3,000
Repayment of line of credit	—	(2,775)	(1,000)
Net cash provided by financing activities	17,091	19,332	10,541
Increase in cash and equivalents	7,096	11,873	3,128
Cash and equivalents, beginning of year	27,186	15,313	12,185
Cash and equivalents, end of year	$ 34,282	$ 27,186	$ 15,313
Supplemental disclosure of cash flow information:			
Interest paid	$ 172	$ 272	$ 643
Taxes paid	$ —	$ 38	$ 43
Right-of-use assets obtained in exchange for new operating lease liabilities	79	69	3,105
Issuance of common stock upon conversion of debentures	$ —	21,164	—

See accompanying notes to consolidated financial statements.

Note 1 – Organization and Business

iCAD, Inc. and subsidiaries (the "Company" or "iCAD") is a global medical technology company providing innovative cancer detection and therapy solutions.

The Company operates in two segments: Cancer Detection ("Detection") and Cancer Therapy ("Therapy"). In the detection segment, offered 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. In the Therapy segment, the Company offers the Xoft System, which is a cancer treatment platform technology incorporating a miniaturized, isotope-free radiation source. The Company's commercial products are cleared with the United States Food and Drug Administration and various global regulatory agencies and use of iCAD's products are reimbursable in the U.S. under federal and most third-party insurance programs. 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 14 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, an operations, research, development, manufacturing and warehousing facility in San Jose, California, and an office in Lyon, France.

Note 2 – 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 subsidiaries: Xoft, Inc., Xoft Solutions, LLC, and iCAD France, LLC. All material inter-company transactions and balances have been eliminated in consolidation.

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 the COVID-19 pandemic, the United States and most countries of the world have imposed some level of unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. As a provider of devices and services to the health care industry, the Company's operations have been materially affected in all periods presented. Significant uncertainty remains as to the continuing impact of the COVID-19 pandemic on the Company's operations and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to

return to prior levels. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continued or worsening level of market disruption and volatility seen since the start of the pandemic will have an adverse effect on the Company's ability to access capital, on the Company's business, results of the Company's operations and financial condition, and on the market price of the Company's common stock. The Company's results for the years ended December 31, 2021 and 2020, as well as all quarterly results beginning with Q1 2020 through Q4 2021, reflect a negative impact from the COVID-19 pandemic, including but not limited to healthcare customers and potential customers providing additional focus on COVID-19; pandemic-related public health impacts, including significant shifts in workforce availability and priorities, on customer, supplier, and iCAD's business processes; and effects on healthcare customers and potential customers of pandemic related supply chain issues. The Company's quarterly results for the quarter ending March 31, 2022, and possibly future quarters, could reflect a continued negative impact from the COVID-19 pandemic for similar or additional reasons.

Although the Company did not see any material impact to trade accounts receivable losses in the year ended December 31, 2021, the Company's exposure may increase if its customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID-19 pandemic, or other customer-specific factors. The Company has historically not experienced significant trade account receivable losses, but it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of trade account receivables as clinical customers' cash flows are impacted by their response to the COVID-19 pandemic as well as public health considerations impacting their underlying businesses.

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. 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, 2021 and 2020.

Accounts Receivable and Allowance for Doubtful Accounts

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, 2021 are unbilled receivables of approximately $0.4 million which are scheduled to be invoiced in 2022.

The Company's policy is to maintain allowances for potential losses resulting from the inability of a portion of its customers to make required payments. The Company's senior management reviews accounts receivable on a periodic basis to determine if any receivables may potentially be uncollectible. The Company includes any accounts receivable balances that it determines may likely be uncollectible, along with a general reserve for estimated probable losses based on historical experience, in its allowance for doubtful accounts. An amount is written off against the allowance after all attempts to collect the receivable have failed. Based on the information available, the Company believes the allowance for doubtful accounts as of December 31, 2021 and 2020 is adequate.

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.

The two reporting units within iCAD are its segments, Detection and Therapy.

The Company records an impairment charge if such an assessment were to indicate that the fair value of a 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.

Fair values for the reporting units are 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.

The Company corroborates the total fair values of the reporting units using a market capitalization approach; however, this approach cannot be used to determine the fair value of each reporting unit value. The blend of the income approach and market approach is more closely aligned to our 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.

The Company performed the annual impairment assessment at October 1, 2021 and compared the fair value of each reporting unit to its carrying value as of this date. The fair value of the Detection reporting unit exceeded the carrying value. Accordingly, no impairment of goodwill was recorded. The carrying values of the reporting units were determined based on an allocation of our assets and liabilities through specific allocation of certain assets and liabilities, to the reporting units and an apportionment of the remaining net assets based on the relative size of the reporting units' revenues and operating expenses compared to the Company as a whole. The determination of reporting units also requires management judgment.

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).

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, 2021 or December 31, 2020.

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

Per 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 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, 2021 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.

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 goods 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 goods or services and excludes any sales incentives or taxes collected from customers which are subsequently remitted to government authorities. 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 goods or services to be transferred and identifies the payment terms related to those goods or services, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for goods 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 goods or services that will be transferred. A good or service is distinct if both a) the customer can benefit from the good 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 goods or services, the Company must apply judgment to determine whether the goods or services meet the criteria to be distinct. If these criteria are not met the promised goods or services are accounted for as a combined performance obligation. While the Company does not typically sell options to purchase goods 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. The Company has sold one contract with a material right that 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 goods 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 good 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.

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 good 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 and supplies. 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 license 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 licenses, cancer therapy systems, cancer therapy applicators, cancer therapy disposable applicators and other accessories that are typically shipped with a cancer therapy system. 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, and in certain cases leases equipment to hospitals, imaging centers, radiological practices and radiation oncologists and treatment centers. 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.

Supply and Source Usage Agreements. Revenue from supply and source usage agreements is recognized on a straight-line basis over the term of the supply or source 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.

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 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 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 transaction price and ensures compliance with the disclosure requirements of ASC 235.

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.

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

Engineering and product development costs relate to research and development efforts including Company sponsored clinical trials are expensed as incurred.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising expense for the years ended December 31, 2021, 2020 and 2019 was approximately $689,000, $274,000, and $1,101,000, 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. The Company has provided a full valuation allowance against its deferred tax assets at December 31, 2021 and 2020, as it is more likely than not that the deferred tax asset will not be realized. 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 3 – Recently Issued Accounting Standards

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 replaces the 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 is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-13 will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" ("ASU 2019-12"). ASU 2019-12 is intended to simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify US GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for the Company for the fiscal year and interim periods therein beginning January 1, 2021. The Company notes that the adoption of ASU 2019-12 resulted in the reclassification of an immaterial amount from income tax expense to non-income tax included in operating expenses related to the accounting for state and franchise taxes, with no impact to the Company's consolidated loss, equity or cash flows.

Note 4 – 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 thousand):

Fair Value Measurements (in thousands) as of December 31, 2021

	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$30,573	—	—	$30,573
Total Assets	$30,573	—	—	$30,573

Fair Value Measurements (in thousands) as of December 31, 2020

	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$24,635	$—	$—	$24,635
Total Assets	$24,635	$—	$—	$24,635

The following is a roll forward of the Company's Level 3 instruments for the years ended December 31, 2021 and 2020:

	Convertible Debentures
Balance, December 31, 2019	$ 13,642
Issuances	—
Fair value adjustments	7,522
Conversion	(21,164)
Balance, December 31, 2020	$ —

There were no Level 3 instruments measured at fair value at December 31, 2021 or December 31, 2020.

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, 2021 and 2020.

Note 5 – Revenue

Disaggregation of Revenue

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

	Year ended December 31, 2021		
	Reportable Segments		
	Detection	Therapy	Total
Major Goods/Service Lines			
Products	$15,661	$ 7,924	$23,585
Service contracts	6,358	1,517	7,875
Supply and source usage agreements	—	2,089	2,089
Professional services	—	89	89
	$22,019	$11,619	$33,638
Timing of Revenue Recognition			
Goods transferred at a point in time	$15,584	$ 8,012	$23,596
Services transferred over time	6,435	3,607	10,042
	$22,019	$11,619	$33,638
Sales Channels			
Direct sales force	$14,713	$ 4,421	$19,134
OEM partners	7,306	—	7,306
Channel partners	—	7,198	7,198
	$22,019	$11,619	$33,638

	Year ended December 31, 2020		
	Reportable Segments		
	Detection	Therapy	Total
Major Goods/Service Lines			
Products	$16,291	$4,535	$20,826
Service contracts	5,661	1,333	6,994
Supply and source usage agreements	—	1,804	1,804
Professional services	—	29	29
Other	45	—	45
	$21,997	$7,701	$29,698
Timing of Revenue Recognition			
Goods transferred at a point in time	$16,332	$4,624	$20,956
Services transferred over time	5,665	3,077	8,742
	$21,997	$7,701	$29,698
Sales Channels			
Direct sales force	$13,809	$3,773	$17,582
OEM partners	8,188	—	8,188
Channel partners	—	3,928	3,928
	$21,997	$7,701	$29,698

	Year ended December 31, 2019		
	Reportable Segments		
	Detection	Therapy	Total
Major Goods/Service Lines			
Products	$16,788	$4,957	$21,745
Service contracts	5,370	1,814	7,184
Supply and source usage agreements	—	2,036	2,036
Professional services	—	153	153
Other	161	61	222
	$22,319	$9,021	$31,340
Timing of Revenue Recognition			
Goods transferred at a point in time	$16,949	$5,391	$22,340
Services transferred over time	5,370	3,630	9,000
	$22,319	$9,021	$31,340
Sales Channels			
Direct sales	$11,968	$5,804	$17,772
OEM partners	10,351	—	10,351
Channel partners	—	3,217	3,217
	$22,319	$9,021	$31,340

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, 2021	Balance at December 31, 2020
Receivables, which are included in 'Trade accounts receivable'	$8,891	$10,027
Current contract assets, which are included in "Prepaid and other assets"	$1,895	$ 481
Non-current contract assets, which are included in "other assets"	$ 844	$ 1,434
Contract liabilities, which are included in "Deferred revenue"	$6,093	$ 6,384

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 unearned 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 earn 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, 2021	Year Ended December 31, 2020
Balance at beginning of period	$ 6,384	$ 5,604
Deferral of revenue	12,315	11,212
Recognition of deferred revenue	(12,606)	(10,432)
Balance at end of period	$ 6,093	$ 6,384

The Company expects to recognize estimated revenues related to performance obligation that are unsatisfied (or partially satisfied) in the amounts of approximately $7.1 million in 2022, $1.2 million in 2023, $1.0 million in 2024, and $1.0 million in 2025.

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. Certain commission programs implemented by

the Company require costs to be capitalized. The Company has classified the capitalized costs to obtain a contract as a component of prepaid expenses and other current assets as of December 31, 2021 and 2020, respectively.

Changes in the balance of capitalized costs to obtain a contract were as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Balance at beginning of period	$ 406	$ 379
Deferral of costs to obtain a contract	249	157
Recognition of costs to obtain a contract	(353)	(130)
Balance at end of period	$ 302	$ 406

Note 6 – Net Loss per Common Share (1o)

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):

	2021	2020	2019
Net loss available to common shareholders	$(11,245)	$(17,610)	$(13,551)
Basic shares used in the calculation of earnings per share	24,778	22,140	18,378
Effect of dilutive securities:			
Stock options	—	—	—
Restricted stock	—	—	—
Diluted shares used in the calculation of earnings per share	24,778	22,140	18,378
Net loss per share :			
Basic	$ (0.45)	$ (0.80)	$ (0.74)
Diluted	$ (0.45)	$ (0.80)	$ (0.74)

The following table summarizes the number of shares of common stock for convertible securities, warrants and restricted stock that were not included in the calculation of diluted net loss per share because such shares are antidilutive:

	Year Ended December 31,		
	2021	2020	2019
Common stock options	2,486,511	1,869,507	1,550,662
Restricted Stock	875	29,166	150,909
Convertible Debentures	—	—	1,742,500
	2,487,386	**1,898,673**	**3,444,071**

Restricted common stock can be issued to directors, executives or employees of the Company and are subject to time-based vesting. These potential shares were excluded from the computation of basic loss per share as these shares are not considered outstanding until vested.

Note 7 – Allowance for Doubtful Accounts

The rollforward of the Company's allowance for doubtful accounts for the years ended December 31 is as follows (in thousands):

	2021	2020	2019
Balance at beginning of period	$111	$ 136	$ 177
Additions charged to costs and expenses	167	94	62
Reductions	(10)	(119)	(103)
Balance at end of period	$268	$ 111	$ 136

Note 8 – Inventories

Inventory balances at December 31, 2021 and 2020 were as follows (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$2,962	$1,538
Work in process	173	76
Finished Goods	1,279	1,774
Inventory Gross	4,414	3,388
Inventory Reserve	(243)	(244)
Inventory Net	$4,171	$3,144

Note 9 – Goodwill and Intangible assets

At December 31, 2021 and 2020, all of the Company's goodwill of $8,362,000 is allocated to its Detection reporting. There were no additions, impairments or other changes to the Company's goodwill balance for either of the years ended December 31, 2021 or 2020.

Amortization expense related to intangible assets was approximately $230,000, $309,000 and $377,000 for the years ended December 31, 2021, 2020, and 2019, respectively.

	2021	2020	2019	Weighted average useful life
Gross Carrying Amount				
Patents and licenses	$ 619	$ 595	$ 581	5 years
Technology	8,257	8,257	8,257	10 years
Customer relationships	272	272	272	7 years
Tradename	259	259	259	10 years
Total amortizable intangible assets	9,407	9,383	9,369	
Accumulated Amortization				
Patents and licenses	$ 534	$ 529	$ 520	
Technology	7,769	7,571	7,299	
Customer relationships	162	135	108	
Tradename	259	259	259	
Total accumulated amortization	8,724	8,494	8,186	
Total amortizable intangible assets, net	$ 683	$ 889	$1,183	

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

For the years ended December 31:	Estimated amortization expense
2022	217
2023	186
2024	103
2025	103
2026	74
	$683

Note 10 – Accrued and Other expenses

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

	2021	2020
Accrued salary and related expenses	$2,016	$3,654
Accrued accounts payable	2,838	2,405
Accrued professional fees	497	598
Other accrued expenses	291	382
	$5,642	**$7,039**

Note 11 – Leases

The Company has leases for office space and office equipment. The leases expire at various dates through 2024. In connection with the 2019 lease amendment for the Nashua headquarters, the Company was eligible for $110,160 of lease incentives. During 2021 the leasehold improvements were completed and the Company received the related lease incentives in cash resulting in an increase to the lease payable.

In October 2021, the Company extended the term of its Nashua warehouse until 2024. This resulted in an increase of approximately $79,000 to the Company's right of use asset and related lease liability.

Lease Cost	Classification	Year Ended December 31, 2021	2020
Operating lease cost - Right of Use	Operating expenses	$ 862	$ 884
Operating lease cost - Variable Costs	Operating expenses	186	165
Total		$1,048	$1,049

	Year Ended December 31, 2021	2020
Cash paid for operating cash flows from operating leases	$919	$909

	As of December 31, 2021	2020
Weighted-average remaining lease term of operating leases (in years)	1.33	2.21
Weighted-average discount rate for operating leases	5.5%	5.6%

Maturities of the Company's lease liabilities as of December 31, 2021 were as follows (in thousands):

Year Ended December 31:	Total
2022	931
2023	253
2024	16
Total lease payments	1,200
Less: imputed interest	(45)
Total lease liabilities	1,155
Less: current portion of lease liabilities	(889)
Long-term lease liabilities	$ 266

Note 12 – Stockholders' Equity

(a) Financing Activity

On April 27, 2020, the Company issued 1,562,500 shares of common stock to several institutional investors at a price of $8.00 per share in a registered direct offering. The gross proceeds of the offering were approximately $12.5 million, and the Company received net proceeds of approximately $12.3 million. The Company also entered into an at-the-market offering program with JMP Securities (the "ATM") to provide for additional potential liquidity. The Company's ATM facility provided for the sale of common stock having a value of up to $25.0 million. On December 17, 2020 the company sold 470,704 shares of common stock under the ATM facility. The gross proceeds were approximately $6.6 million, and the Company received net proceeds of approximately $6.1 million which is net of brokerage fees and offering costs to open the ATM. On March 2, 2021, the Company terminated the ATM offering program with JMP Securities

On March 2, 2021, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Guggenheim Securities, LLC, as representative of the several underwriters (the "Underwriters"), in connection with an underwritten public offering of 1,393,738 shares of the Company's common stock, at a public offering price of $18.00 per share (the "Offering"). The Underwriting Agreement contained customary representations, warranties and covenants by the Company, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act, other obligations of the parties and termination provisions. In exchange for the Underwriters' services, the Company agreed to sell the shares to the Underwriters at a purchase price of $16.92 per share and to reimburse the representative of the Underwriters for up to $125,000 of its expenses in connection with the Offering. The Offering closed March 5, 2021. The net proceeds to the Company from the Offering were approximately $23.2 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

(b) Stock Options

The Company has two effective stock option or stock incentive plans, the 2012 Stock Incentive Plan (the "2012 Plan") and the 2016 Stock Incentive Plan (the "2016 Plan") (collectively the "Stock Plans"). Each of the Stock Plans provide 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 Stock Plans 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 Stock Plans may be granted to employees, directors and advisors to the Company and its subsidiaries.

At December 31, 2021, there were 37,871 shares available for issuance under the 2012 Plan.

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, 2021, there were 1,718,200 shares available for issuance under the 2016 Plan.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding, December 31, 2019	1,550,662	$ 4.33	
Granted	563,502	$10.09	
Exercised	(155,149)	$ 4.70	
Forfeited	(89,508)	$ 2.51	
Outstanding, December 31, 2020	1,869,507	$ 5.91	6.0 Years
Granted	865,938	$16.33	
Exercised	(168,450)	$ 6.10	
Forfeited	(80,484)	$13.74	
Outstanding, December 31, 2021	2,486,511	$ 9.27	5.42 Years
Exercisable at December 31, 2019	881,461	$ 4.43	
Exercisable at December 31, 2020	1,540,287	$ 5.55	
Exercisable at December 31, 2021	1,619,855	$ 6.47	

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

	Year Ended December 31,		
	2021	2020	2019
Cost of revenue	$ 15	$ 30	$ 3
Engineering and product development	356	376	226
Marketing and sales	785	657	226
General and administrative expense	1,627	1,781	713
	$2,783	**$2,844**	**$1,168**

As of December 31, 2021, there was approximately $4.3 million of total unrecognized compensation costs related to unvested options and restricted stock. That cost is expected to be recognized over a weighted average period of 1.7 years.

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,		
	2021	2020	2019
Average risk-free interest rate	0.42%	0.65%	1.88%
Expected dividend yield	None	None	None
Expected life	3.5 years	3.5 years	3.5 years
Expected volatility	65.57-67.42%	50.17-66.04%	50.01% to 54.23%
Weighted average fair value	$ 7.22	$4.37	$2.34

The Company's 2021, 2020 and 2019 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,		
	2021	2020	2019
Outstanding	$3,820	$13,626	$5,465
Exercisable	$3,730	$11,786	$3,067
Exercised	$1,453	$ 1,037	$ 509
Company's stock price at December 31	$ 7.20	$ 13.20	$ 7.77

(c) Restricted Stock

The Company's restricted stock awards typically vest in either one year or three equal annual installments with the first installment vesting one year from grant date. All of the Company's restricted stock grants in 2021 and 2019 had time-based vesting requirements. The grant date fair value for restricted stock awards is based on the quoted market value of Company stock on the grant date.

A summary of unvested restricted stock activity for the Stock Plans is follows:

	Year Ended December 31,		
	2021	2020	2019
Beginning outstanding balance	29,166	150,909	423,202
Granted	22,488	—	15,990
Vested	(50,779)	(118,077)	(197,730)
Forfeited	—	(3,666)	(90,553)
Ending outstanding balance	**875**	**29,166**	**150,909**

(d) 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 24,786 and 42,606 shares of common stock under the ESPP for the years ended December 31, 2021 and 2020, respectively. 882,608 shares of Company common stock are reserved for issuance under the ESPP as of December 31, 2021.

Note 13 – Income Taxes

Income Taxes

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

	2021	2020	2019
Current provision:			
Federal	$—	$—	$—
State	—	37	42
Foreign	—	—	—
	$—	$ 37	$ 42
Deferred provision:			
Federal	$ 1	$ 1	$ 1
State	—	—	—
Foreign	—	—	—
	$ 1	$ 1	$ 1
Total	$ 1	$ 38	$ 43

The Company adopted ASU 2019-12 as of January 1, 2021. In accordance with this standard non-income and state franchise taxes are now classified as a component of operating expenses in General and Administrative expense. Income based tax expense will continue to be recognized as tax expense in the Consolidated Financial Statements. Tax expense for the year ended December 31, 2020 represents non-income and state franchise tax, however, the expense was not reclassified to operating expenses in accordance with ASU 2019-12.

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:

	2021	2020	2019
Federal statutory rate	21.0%	21.0%	21.0%
State income taxes, net of federal benefit	5.2%	2.4%	1.7%
Net state impact of deferred rate change	0.8%	(0.7%)	(0.2%)
Stock compensation expense	1.3%	0.9%	(10.7%)
Other permanent differences	(0.1%)	(0.1%)	0.0%
Change in valuation allowance	(24.4%)	(13.4%)	(6.0%)
Tax credits	3.1%	1.4%	2.8%
Accrual to TR	(1.4%)	0.0%	1.3%
FV Mark to market on convertible notes	0.0%	(9.0%)	(10.4%)
Foreign Rate Differential	0.0%	0.0%	0.2%
True Ups - NOL Expiration/162(m) limits	(5.4%)	(2.8%)	0.0%
Effective income tax	0.1%	(0.3%)	(0.3%)

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 net deferred tax assets, as it is more likely than not that the deferred tax assets will not be utilized. Deferred tax assets (liabilities) are composed of the following at December 31, 2021 and 2020 (in thousands):

	2021	2020
Inventory (Section 263A)	$ 276	$ 248
Inventory reserves	61	60
Receivable reserves	67	28
Other accruals	854	1,081
Deferred revenue	107	75
Accumulated depreciation/amortization	8	37
Stock options	795	459
Developed technology	1,242	1,449
Tax credits	4,176	3,859
NOL carryforward	38,383	36,078
Lease Liability	290	415
Deferred tax assets	46,259	43,789
Valuation allowance	(45,994)	(43,356)
Right of Use Asset	(265)	(433)
Goodwill tax amortization	(5)	(4)
Deferred tax liability	$ (5)	$ (4)

The increase in the net deferred tax assets and corresponding valuation allowance during the year ended December 31, 2021 and December 31, 2020 is primarily attributable to net operating losses and research and development credits.

As of December 31, 2021, the Company has federal net operating loss carryforwards totaling approximately $159.0 million. Federal net operating loss carryforwards totaling $120.1 million will expire at various dates from 2022 and 2037. The remaining $39.0 million of the federal net operating losses generated since December 31, 2017 can be carried forward indefinitely. As of December 31, 2021, the Company has provided a valuation allowance for its 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. 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. There were no net operating losses utilized for the years ended December 31, 2021, 2020, or 2019.

The Company currently has approximately $5.2 million in net operating losses that are subject to limitations related to Xoft. 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 $4.2 million. The credits expire in various years through 2041. The Company has additional tax credits of $1.8 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.

As of December 31, 2021 and 2020, 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, 2021, 2020 and 2019. 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, 2021 will significantly change within the next 12 months.

Note 14 – Segment Reporting

(a) Segment Reporting

Operating segments are the components of our business for which separate financial information is available that is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Our chief operating decision maker is our chief executive officer. Our operating segments are generally organized by the type of product or service offered and by geography. Each reportable segment generates revenue from the sale of medical equipment and related services and/or sale of supplies. The Company has determined there are two segments: Detection and Therapy.

The Detection segment consists of the Company's advanced image analysis and workflow products, and the Therapy segment consists of the Company's radiation therapy products, and related services. The primary factors used by the Company's CODM to allocate resources are based on revenues, gross profit, operating income or loss, and earnings or loss before interest, taxes, depreciation, amortization, and other specific and non-recurring items of each segment. Included in segment operating income are stock compensation, amortization of technology and depreciation expense. There are no intersegment revenues.

The Company does not track its assets by operating segment and the CODM does not use asset information by segment to allocate resources or make operating decisions.

Segment revenues, gross profit, segment operating income or loss, and a reconciliation of segment operating income or loss to GAAP loss before income tax is as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Segment revenues:			
Detection	$ 22,019	$ 21,997	$ 22,319
Therapy	11,619	7,701	9,021
Total Revenue	$ 33,638	$ 29,698	$ 31,340
Segment gross profit:			
Detection	$ 18,510	$ 17,856	$ 18,627
Therapy	5,733	3,498	5,600
Total gross profit	$ 24,243	$ 21,354	$ 24,227
Segment operating income (loss):			
Detection	$ 1,563	$ 2,719	$ 2,564
Therapy	(1,835)	(3,028)	(1,476)
Segment operating income (loss)	$ (272)	$ (309)	$ 1,088
General administrative	$(10,460)	$ (9,079)	$ (7,486)
Interest expense	(141)	(476)	(784)
Loss on extinguishment of debt	(386)	(341)	—
Other income	15	97	345
Fair value of convertible debentures	—	(7,464)	(6,671)
Loss before income tax	$(11,244)	$(17,572)	$(13,508)

Segment depreciation and amortization included in segment operating income (loss) is as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Detection depreciation and amortization			
Depreciation	$123	$115	$103
Amortization	$158	164	240
Therapy depreciation and amortization			
Depreciation	$129	$124	$166
Amortization	$ 73	128	128

(b) Geographic Information

The Company's sales are made to customers, distributors and dealers of mammography, electronic brachytherapy equipment and other medical equipment, and to foreign distributors of mammography and electronic brachytherapy equipment. Export revenue to a single country did not exceed 10% of total revenue in any year. Total export revenues were approximately $7.5 million or 22% of total revenue in 2021, $6.1 million or 20% of total revenue in 2020, and $3.8 million or 12% of total revenue in 2019.

As of December 31, 2021 and 2020, the Company had outstanding receivables of $3.3 million and $3.4 million, respectively, from distributors and customers of its products who are located outside of the U.S.

	Percent of Export sales		
Region	2021	2020	2019
Europe	39%	45%	57%
Taiwan	12%	13%	15%
Canada	3%	5%	7%
China	35%	22%	8%
Other	11%	15%	13%
Total	100%	100%	100%
Total Export Revenue	$7,527	$6,081	$3,788

Significant export sales in Europe are as follows:

	Percent of Export sales		
Region	2021	2020	2019
France	47%	41%	34%
Spain	17%	17%	12%
Russia	8%	0%	0%
Switzerland	8%	0%	0%
Italy	5%	8%	2%
Germany	4%	12%	4%
United Kingdom	4%	6%	2%

(c) Major Customers

The Company had one major OEM customer, GE Healthcare, with revenues of approximately $4.8 million in 2021, $5.0 million in 2020 and $7.6 million in 2019 or 14%, 17% and 24% of total revenue, respectively. Cancer detection products are also sold through OEM partners, including GE Healthcare, Fujifilm Medical

Systems, Siemens Medical, and Vital Images. For the year ended December 31, 2021, these four OEM partners composed approximately 29% of Detection revenues and 19% of total revenue. Detection OEM partners in total composed approximately 40% of Detection revenue and 26% of total revenue for the year ended December 31, 2021, 37% of Detection revenue and 28% of total revenue for the year ended December 31, 2020 and 46% of Detection revenue and 33% of total revenue for the year ended December 31, 2019. The Company also had one major direct customer with revenues of approximately $.8 million, or 2% of total revenue for year ended December 31, 2021.

OEM partners represented $5.5 million or 60% of outstanding receivables as of December 31, 2021, with GE Healthcare accounting for $.7 million or 8% of this amount. The four largest Therapy customers composed 2.8 million or 31% of outstanding receivables as of December 31, 2021. The largest Detection direct customer represents $.3 million or 3% of outstanding receivables as of December 31, 2021. These customers in total represented $8.6 million or 94% of outstanding receivables as of December 31, 2021.

Note 15 – 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 $7.2 million.

(b) Employment Agreements

The Company has entered into employment agreements with certain key current and former executives. The employment agreements provide for minimum annual salaries and performance-based annual bonus compensation as defined in their respective agreements. In addition, the employment agreements provide that if employment is terminated without cause, the executive will receive an amount equal to their respective base salary then in effect for (i) fifteen months from the date of termination, for Mr. Klein, CEO, (ii) eighteen months from the date of termination, for Ms. Stevens, President, and (iii) twelve months from the date of termination, for Mr. Carter, CFO, and in each case, plus the pro rata portion of any annual bonus earned in any employment year through the date of termination.

(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 $0.2 million.

(d) Legal Matters

In December 2016, the Company entered into an Asset Purchase Agreement with Invivo Corporation (the "Asset Purchase Agreement"). In accordance with the Asset Purchase Agreement, the Company sold to Invivo all right, title and interest to certain intellectual property relating to the Company's VersaVue Software and DynaCAD product and related assets for $3.2 million. The Company closed the transaction on January 30, 2017 less a holdback reserve of $350,000 for net proceeds of approximately $2.9 million.

On September 5, 2018, third-party Yeda Research and Development Company Ltd. ("Yeda"), filed a complaint (the "Complaint") against the Company and Invivo in the United States District Court for the Southern District of New York, captioned Yeda Research and Development Company Ltd. v. iCAD, Inc. and Invivo Corporation, Case No. 1:18-cv-08083-GBD, related to the Company's sale of the VersaVue software and DynaCAD product under the Asset Purchase Agreement. Yeda alleged, among other things, that the Company infringed upon Yeda's source code, which was originally licensed to the Company, by using it in the products that the Company sold to Invivo and that it is entitled to damages that could include, among other things, profits relating to the sales of these products. On April 13, 2021, the Company and Yeda entered into a Settlement and Release Agreement (the "Settlement Agreement") whereby the Company furnished to Yeda a one-time cash payment of $85,000 and received a full, non-conditional release from Yeda of any and all claims related to the Complaint and the subject of the Complaint. Neither the Company nor Invivo acknowledged any wrongdoing at any point in connection with the Complaint or the subject matter thereof. The Escrowed Amount was reserved, in part, to cover any legal expenses related to the Asset Purchase Agreement and the transactions contemplated therein. The remaining balance of the Escrowed Amount following such expenses is due and payable to the Company in accordance with the terms of the Asset Purchase Agreement. The Company and Invivo agreed that Invivo would pay $50,000 of the Escrowed Amount and the Company expensed approximately $93,000 in the second quarter of 2021.

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 16 – Notes Payable

(a) Loan and Security Agreement – Western Alliance Bank

On March 30, 2020, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Western Alliance Bank (the "Bank") that provided an initial term loan ("Term Loan") facility of $7.0 million and a $5.0 million revolving line of credit.

On April 27, 2021, the Company repaid its obligations in the aggregate amount of $7,354,283 under and terminated the Loan Agreement with the Bank, and its collateral securing the facility was released. The Company accounted for this repayment and retirement as an extinguishment of the Loan Agreement. The Company recorded a loss on extinguishment of approximately $386,000 related to the repayment and retirement of the Loan Agreement. The loss on extinguishment was composed of approximately $140,000 for a prepayment fee, $122,000 for the unaccrued final payment, $65,000 termination and other fees, and $58,000 for the unamortized and other closing costs from origination of the loan.

(b) Loan and Security Agreement – Silicon Valley Bank

On August 7, 2017, the Company entered into a Loan and Security Agreement, (as amended, the "SVB Loan Agreement"), with Silicon Valley Bank that provided an initial term loan facility of $6.0 million and a $4.0 million revolving line of credit.

On March 30, 2020, the Company elected to repay all outstanding obligations (including accrued interest) and retire the SVB Loan Agreement. The Company accounted for this repayment and retirement as an

extinguishment of the SVB Loan Agreement. In addition to the outstanding principal and accrued interest, the Company was required to pay the $510,000 final payment, a termination fee of $114,000 and other costs totaling $10,000. The Company also wrote off unamortized original closing costs as of the extinguishment date. In March 2020 the Company recorded a loss on extinguishment of approximately $341,000 related to the repayment and retirement of the SVB Loan Agreement. The loss on extinguishment was composed of approximately $185,000 for the unaccrued final payment, $114,000 termination fee, and $42,000 of unamortized and other closing costs.

(c) Convertible Debentures

On December 20, 2018, the Company entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited investors (the "Investors"), including, but not limited to, all directors and executive officers of the Company at the time, pursuant to which the Investors purchased unsecured subordinated convertible debentures (the "Convertible Debentures") with an aggregate principal amount of approximately $7.0 million in a private placement.

On February 21, 2020 (the "Conversion Date"), the conditions permitting a forced conversion were met, and the Company elected to exercise its forced conversion right under the terms of the Convertible Debentures.

As a result of this election, all of the outstanding Convertible Debentures were converted, at a conversion price of $4.00 per share, into 1,742,500 shares of the Company's common stock. In accordance with the make-whole provisions in the Convertible Debentures, the Company also issued an additional 76,966 shares of its common stock. The make-whole amount represented the total interest which would have accrued through the maturity date of the Convertible Debentures, less the amounts previously paid, totaling $697,000. The conversion prices related to the make-whole amount were dependent on whether the Investors were related parties or unrelated third parties.

Accounting Considerations and Fair Value Measurements Related to the Convertible Debentures

The Company had previously elected to make a one-time, irrevocable election to utilize the fair value option to account for the Convertible Debentures as a single hybrid instrument at its fair value, with changes in fair value from period to period being recorded either in current earnings, or as an element of other comprehensive income (loss), for the portion of the change in fair value determined to relate to the Company's own credit risk. The Company believed that the election of the fair value option allowed for a more meaningful representation of the total fair value of its obligation under the Convertible Debentures and allowed for a better understanding of how changes in the external market environment and valuation assumptions impact such fair value. The Company utilized a Monte Carlo simulation model to estimate the fair value of the Convertible Debentures.

The Company recorded a final adjustment to the Convertible Debentures based on their fair value on the Conversion Date, just prior to the forced conversion being completed. Given that the Company's prior simulation model included the assumption that the Company would elect to force conversion in 100% of scenarios when the requirements were met, the final valuation was based on the actual results of the forced conversion. As such, the Company based the final fair value adjustment to the Convertible Debentures just prior to conversion on the number of shares of common stock that were issued to the Investors upon conversion and the fair value of the Company's common stock as of the Conversion Date.

The Company notes that the key inputs to the simulation model that were utilized to estimate the fair value of the Convertible Debentures at each valuation date included:

Input	December 31, 2019	February 21, 2020
Company's stock price	$ 7.77	$ 11.64
Conversion price	4.00	4.00
Remaining term (years)	1.97	0.00
Equity volatility	49.00%	N/A
Risk free rate	1.57%	N/A
[1] Probability of default event	0.45%	N/A
[1] Utilization of Forced Conversion (if available)	100.00%	100.00%
[1] Exercise of Default Redemption (if available)	100.00%	N/A
[1] Effective discount rate	18.52%	N/A

[1] Represents a Level 3 unobservable input, as defined in Note 4 - Fair Value Measurements, below.

The Company's stock price is based on the closing stock price on the valuation date. The conversion price is based on the contractual conversion price included in the SPA.

The remaining term was determined based on the remaining time period to maturity of the Convertible Debentures.

The Company's equity volatility estimate was based on the Company's historical equity volatility, the Company's implied and observed volatility of option pricing, and the historical equity and observed volatility of option pricing for a selection of comparable guideline public companies.

The risk-free rate was determined based on U.S. Treasury securities with similar terms.

The probability of the occurrence of a default event was based on Bloomberg's one year estimate of default risk for the Company (extrapolated over the remaining term).

The utilization of the Forced Conversion right and the default redemption right is based on management's best estimate of both features being exercised upon the occurrence of the related contingent events.

The effective discount rate utilized at the December 31, 2019 and February 21, 2020 valuation dates was solved for utilizing the simulation model based on the principal value of the Convertible Debentures, as the transaction was determined to represent an 'arm's length' transaction. The effective discount was corroborated against market yield data which implied the Company's credit rating, and this implied credit rating will be utilized to determine the changes in the effective discount rate at future valuation dates. The effective discount rate utilized at the December 31, 2019 valuation date was based on yields on CCC-rated debt instruments with terms equivalent to the remaining term of the Convertible Debentures. The credit rating estimate was based on the implied credit rating determined at issuance and no changes were identified by the Company that would impact this assessment.

The fair value and principal value of the Convertible Debentures as of December 31, 2019 and the Conversion Date was as follows (in thousands):

Convertible Debentures	December 31, 2019	February 21, 2020
Fair value, in accordance with fair value option	$13,642	$21,164
Principal value outstanding	$ 6,970	$ 6,970

The Company recorded a loss from the change in fair value of the Convertible Debentures of approximately $7.5 million for the year ending December 31, 2020. Upon the consummation of the forced conversion, the Company issued 1,816,466 shares of common stock with a fair value of approximately $21.2 million, which was reclassified to stockholders' equity.

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 $.5 million during each of the years ended December 31, 2021 and 2020, respectively.

Note 18 – Subsequent Events

The Company has evaluated 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.

Exhibit 4

DESCRIPTION OF SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2021, iCAD, Inc. (the "Company," "we," "us" or "our") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.01 per share ("Common Stock).

General

The following description of our capital stock and certain provisions of our certificate of incorporation, as amended (our "Certificate of Incorporation") and by-laws, as amended (our "Bylaws"), are summaries, and are qualified in their entirety by reference to our Certificate of Incorporation and Bylaws. Copies of these documents can be accessed through hyperlinks to those documents in the list of exhibits in our Annual Report on Form 10-K for the fiscal year ending December 31, 2021 (our "Annual Report"). Capitalized terms used and not defined herein have the meanings ascribed to such terms in the Annual Report.

Our authorized capital stock consists of 60,000,000 shares of Common Stock, and 1,000,000 shares of "blank check" preferred stock.

Common Stock

The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any then outstanding preferred stock.

Voting Rights

Each share of Common Stock is entitled to one vote on all matters to be voted on by stockholders. There are no cumulative voting rights in the election of directors, minority stockholders will not be able to elect directors on the basis of their votes alone.

Dividend Rights

The holders of Common Stock are entitled to receive dividends when, as and if declared by our Board of Directors out of funds legally available therefor.

No Preemptive or Similar Rights

Holders of shares of Common Stock have no conversion, preemptive or other subscription rights, and there are no redemption provisions applicable to the Common Stock. All outstanding shares of Common Stock are fully paid and nonassessable.

Right to Liquidation Distributions

In the event of liquidation, dissolution or winding up of our Company, the holders of Common Stock are entitled to share in all assets remaining, if any, which are available for distribution to them after payment of liabilities and after provision has been made for each class of stock, if any, having preference over the Common Stock.

Limitations on Liability and Indemnification of Officers and Directors

Section 102 of the DGCL allows a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware law or obtained an improper personal benefit.

Section 145 of the DGCL provides, among other things, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, agent or employee of the corporation or is or was serving at the corporation's request as a director, officer, agent, or employee of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgment, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding. The power to indemnify applies (a) if such person is successful on the merits or otherwise in defense of any action, suit or proceeding or (b) if such person acted in good faith and in a manner he reasonably believed to be in the best interest, or not opposed to the best interest, of the corporation, and with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of defense expenses (including attorneys' fees but excluding amounts paid in settlement) actually and reasonably incurred and not to any satisfaction of judgment or settlement of the claim itself, and with the further limitation that in such actions no indemnification shall be made in the event of any adjudication of negligence or misconduct in the performance of duties to the corporation, unless the court believes that in light of all the circumstances indemnification should apply.

We have entered into indemnification agreements with each of our directors and officers. Generally, these agreements attempt to provide the maximum protection permitted by Delaware law with respect of indemnification. The indemnification agreements provided that we will pay certain amounts incurred in connection with any action, suit, investigation or proceeding arising out of or relating to the performance of services by the director or officer, or by acting as a director, officer or employee.

Liability Insurance.

We have obtained directors' and officers' liability insurance which covers certain liabilities, including liabilities to us and our stockholders.

Certificate of Incorporation

The Certificate of Incorporation eliminates, to the fullest extent permitted by the DGCL, a director's personal liability to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director.

Bylaws

The Bylaws provide that the Company will indemnify its officers and directors to the full extent permitted by the laws of the State of Delaware and the employment agreements with the Company's executive officers and indemnification agreements between the Company and its directors and certain of its officers provide that the Company will indemnify them to the full extent provided by the DGCL.

Anti-Takeover Provisions

Our Certificate of Incorporation authorizes the Board of Directors 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 our Board of Directors, without further action by stockholders, and may include, among other things, voting rights (including the right to vote as a series on particular matters), preferences as to dividends and liquidation, conversion and redemption rights, and sinking fund provisions. Although there are currently no shares of preferred stock outstanding, future holders of preferred stock may have rights superior to our Common Stock and such rights could also be used to restrict our ability to merge with, or sell our assets to a third party.

Section 203 of the DGCL

We are also subject to the provisions of Section 203 of the DGCL, which could prevent us 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 our 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 existence of the foregoing provisions of our certificate of incorporation and bylaws and the DGCL may have an anti-takeover effect and could delay, defer or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of our Common Stock held by stockholders.

Transfer Agent

The transfer agent and registrar for the Common Stock is Continental Stock Transfer & Trust Company.

Listing

Our Common Stock is listed on The Nasdaq Stock Market under the symbol “ICAD.”

EXHIBIT 21

Subsidiaries of iCAD, Inc.

Name	Jurisdiction of Incorporation/Organization
Xoft, Inc.	Delaware
Xoft Solutions, LLC	Delaware
iCad France, LLC	Delaware
iCad Italy, LLC	Delaware

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

iCAD, Inc.
Nashua, New Hampshire

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-228514, 333-229452 and 333-235887) and Form S-8 (No. 333-201874, 333-187660, 333-99973, 333-119509, 333-139023, 333-144671, 333-161959, 333-211656, 333-229453 and 333-235580) and Form S-3MEF (No. 333-253808) of iCAD, Inc. and subsidiaries of our report dated March 28, 2022, relating to the consolidated financial statements which appear in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Boston, Massachusetts

March 28, 2022

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Stacey Stevens, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of iCAD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and;

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2022

/s/ Stacey Stevens

Stacey Stevens
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Charles Carter, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of iCAD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and;

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2022

/s/ Charles Carter

Charles Carter
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

iCAD, Inc.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of iCAD, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 (the "Report"), I, Stacey Stevens, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stacey Stevens

Stacey Stevens
Chief Executive Officer
(Principal Executive Officer)

Date: March 28, 2022

EXHIBIT 32.2

iCAD, Inc.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of iCAD, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 (the "Report"), I, Charles Carter, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Charles Carter
Charles Carter
Chief Financial Officer
(Principal Financial Officer)

Date: March 28, 2022