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, 2020

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, 2020 was $208,752,980. Shares of voting stock held by each officer and director and by each person who, as of June 30, 2020, 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 8, 2021, the registrant had 24,918,458 shares of its common stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2021 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.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995:

Certain information included in this Annual Report on Form 10-K that are not historical facts contain forward looking statements that 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, its 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 ("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", "Company", "we", "our" "registrant", and "us" means 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.

iCAD continues to evolve from a business focused on image analysis for the early detection of cancers to a broader player 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 2020. 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 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 artificial-intelligence algorithms designed to rapidly and accurately analyze image data and mark suspicious areas in the image that may warrant a second look or possibly contain a significant abnormality. iCAD's technology has potential applications to aid in the diagnosis of many 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 its clinical value in cancer detection. However, DBT presents significant workflow challenges to radiologists who face the additional workload and time required to accurately read the extensive amount of increased 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 has the potential to address each of these challenges.

The Company offers a variety of AI, CAD, and breast density and risk assessment solutions for use with mammography, breast tomosynthesis, and Computed Tomography ("CT") imaging, at both the detection and diagnosis stages of the cancer care cycle. These products have the potential to help healthcare providers better detect cancer and improve workflow efficiency. The Company completed development of a DBT cancer detection and workflow solution built on AI using deep learning in 2015 and launched the product in the European market in April 2016, in Canada in June 2016, and in the United States after U.S. Food and Drug Administration ("FDA") premarket approval in April 2017. 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. The Company's 2D FFDM breast density solution received FDA 510(k) clearance in December 2013 and the Company added 2D synthetic image support in December 2018.

In July 2020, the Company introduced ProFound AI Risk, the world's first image-based 2-year risk assessment model. This novel risk model, which assesses short-term breast cancer risk based primarily on information found in a 2D mammogram, received a CE mark in Europe. In September of 2020, ProFound AI Risk was introduced in the U.S. market as a decision support tool for radiologists. On March 12, 2021, ProFound AI 3.0 was cleared by the FDA, through a 510(k) review, for commercial use in the United States for reading DBT exams from compatible DBT systems. This new version offers additional clinical and workflow improvements when compared to the previous version of the product.

According to the FDA, as of January 2021, the United States alone had approximately 8,677 Mammography Quality Standards Act ("MQSA") certified facilities providing mammography screening, which contained approximately 22,553 MQSA accredited FFDM and DBT units. While the majority of these centers are still using 2D FFDM systems either alone or in combination with DBT, the Company believes approximately 73% of the units are DBT capable units based on January 2021 MQSA data.

Based on the number of DBT units relative to the total units left to be converted to DBT, and accordingly the large number of installation opportunities, the Company believes that its cancer detection and breast density 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 radiologists using AI, rather than having two radiologists read each case. Furthermore, some western European countries have 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 for 2D and 3D mammography, automated breast density assessment for 2D and 3D mammography, and breast cancer risk assessment for 2D mammography with plans to introduce support for breast cancer risk assessment for 3D mammography in 2021. 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 the AI algorithm solutions and manages the communications between (i) imaging acquisition systems, and (ii) image storage and review systems such as Picture Archive and Communication Systems ("PACS") and breast imaging viewing and interpretation systems. As workflow and efficiency are critical in digital imaging environments, 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 platform have also been optimized for and tested with each supported digital imaging acquisition manufacturer based upon characteristics of their unique detectors.

The Company has released a new generation of the PowerLook platform (version 10.0), which consists of a hybrid-server environment, where algorithm processing still occurs on-premise (within the hospital) but the tracking of the usage is possible in the cloud. This makes it possible for iCAD to implement operational-budget pricing models and a gradual switch to the recurring revenue stream. This is a stepping stone to potentially hosting the Company's algorithms purely in the cloud, and could enable scalability and a future SaaS business model for the Company.

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 enables 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, Europe, and Asia.

Automated Density Assessment

The Company's Automated Density Assessment solution aids radiologists by standardizing their approach to breast density assessment and categorization. The solution provides an automated, consistent and standardized density assessment based on the American College of Radiation's BI-RADS 5th Edition density categorization system, which is particularly important in states that mandate reporting a breast density score to patients as part of their annual mammogram. The latest version of the Company's automated density solution, which added support for the synthetic 2D images from GE and Hologic, received FDA 510(k) clearance in August 2018.

ProFound AI

DBT was introduced in the United States in 2010. Tomosynthesis has been demonstrated to have multiple advantages over 2D mammography, including improved tissue visualization and detection, resulting 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. This helps reduce the number of unnecessary biopsies and false positive recall rates. Initial studies have indicated that physicians using tomosynthesis have the ability to detect 41% more invasive cancers than those using conventional mammography, and also have reduced false-positives by up to 15%. While DBT has been shown to have clinical benefits for screening mammography, it can also significantly increase radiologist's interpretation time.

AI can also play an important role in improving the efficiency of reading breast tomosynthesis cases by identifying suspicious breast masses and calcifications.

In early 2018, the Company received the CE mark for its multi-vendor, artificial intelligence DBT cancer detection and workflow solution, Powerlook Tomo Detection 2.0, which was later rebranded as ProFound AI for DBT. The product also received clearance for clinical use in Canada in mid-2018 and was FDA 510(k) cleared in December 2018. On March 12, 2021, ProFound AI 3.0 was cleared by the FDA, through a 510(k) review, for commercial use in the United States for reading DBT exams from compatible DBT systems. This new version offers additional clinical and workflow improvements when compared to the previous version of the product.

ProFound AI for DBT is a 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 non-FDA large multi-reader, multi-case crossover design clinical reader study, which concluded that ProFound AI increased radiologist clinical performance by improving radiologist sensitivity by an average of 8%, improving radiologist specificity by an average of 6.9% and reducing 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.

iCAD will continue to focus on advancing the performance of its ProFound AI for DBT solution through algorithm improvements and training on larger datasets.

The Company has Original Equipment Manufacturer ("OEM") relationships with GE, Siemens, and Fuji Medical Systems' women's health businesses and expects to use ProFound AI to expand its OEM partnerships with other mammography system and PACS providers. In 2020, one of the largest outpatient medical imaging providers and largest physician radiology practices in the United States adopted ProFound AI throughout its nationwide network. In 2020 iCAD entered into a five-year partnership with Solis Mammography, the largest independent provider of mammography and breast health services in the United States, whereby iCAD will provide Solis Mammography's nationwide network with its latest AI breast health solutions, including ProFound AI for DBT and ProFound AI Risk.

The Company also developed ProFound AI for 2D Mammography, which is targeted at the European market, where 2D mammography remains the primary procedure for breast cancer screening. ProFound AI for 2D Mammography was launched in Europe in June 2019 at the Société Française d'Imagerie de la Femme medical conference and received CE approval in July 2019.

ProFound AI™ Risk

ProFound AI Risk is the first and only commercially available clinical decision support tool that provides an accurate and personalized two-year breast cancer risk estimation, based solely on a screening mammogram. The Company worked with leading researchers at the Karolinska Institutet in Stockholm, Sweden, one of the

world's foremost medical research universities, to create ProFound AI Risk. ProFound AI Risk is driven primarily by data from existing mammography images. Unlike existing risk models that focus on longer term risk based on family history and clinical lifestyle factors, ProFound AI Risk focuses on a short-term interval. ProFound AI Risk received a CE Mark in Europe in July 2020, and Profound AI 3.0 was cleared by the FDA, through a 510(k) review, on March 12, 2021. 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.

Magnetic Resonance Imaging ("MRI") Applications—Breast and Prostate Cancer Detection

In addition to mammography and CT imaging modalities, the interpretation of MRI exams also benefits from advanced image analysis and clinical decision support tools. Radiologists turn to MRI to examine the soft tissues, blood vessels, and organs in the head, neck, chest, abdomen, and pelvis to help them diagnose and monitor tumors, heart problems, liver diseases and other organs, such as breast and prostate for possible links to cancer. MRI uses magnets and radio waves instead of x-rays to produce very detailed, cross-sectional images of the body, and can be used to look specifically at those areas. We previously developed MRI assets which were subsequently sold, and are exploring future possible opportunities in MRI applications.

MRI is an effective tool to detect breast cancer as well as prostate cancer. While MRI is a more expensive option than traditional mammography, it enables physicians to view tumors which may have been missed during routine screenings. The American Cancer Society published guidelines in the March/April 2007 *CA: A Cancer Journal of Clinicians*, recommending that women at high risk for breast cancer augment their annual mammogram with an annual breast MRI. The guidelines recommended MRI scans for women with a lifetime risk of breast cancer of 20%-25% or greater, including women with a strong family history of breast or ovarian cancer and women who were treated for Hodgkin's disease. The American College of Radiology and Society of Breast Imaging endorsed these recommendations in the *Journal of the American College of Radiology*.

Accurate staging of prostate cancer has been a significant challenge for practitioners. Of the over 225,000 men who are diagnosed with prostate cancer every year in the United States, most have slow-growing tumors that likely will not lead to death or require invasive treatment, though the diagnosis does cause patient anxiety and requires close monitoring. With advanced diagnostic imaging tools, physicians may more accurately stage the severity of prostate cancer and minimize a patient's exposure to unnecessary and painful biopsies.

In the future, the Company believes that MRI imaging may have an expanded role in the management of prostate cancer patients, particularly for management strategies involving active surveillance. As more men consider "watchful waiting" or delaying active treatment of their cancer, advances in imaging will help inform these decisions, based more on better imaging than on assumptions relating to estimates of growth of prostate cancer.

Prostate Cancer Screening

Prostate Al

In the United States alone, there are over 225,000 cases of prostate cancer diagnosed annually. The annual global volume is estimated to be at least 650,000 in developed countries.

Over the past several years, the use of the Prostate – Specific Antigen ("PSA") screening has declined, resulting in sub-optimal screening for prostate cancer. More recently, multi-parametric MRI has been relied upon increasingly for both initial diagnosis and for tracking of men previously diagnosed and in "active surveillance."

The Company intends to explore opportunities in the prostate screening market, including to seek to acquire large data sets of prostate images and develop new and unique algorithms to assist with the reading, interpretation and detection of proliferative prostate disease.

The Company will be required to complete development and then seek and obtain clearance from the FDA prior to being able to offer and sell the product to end users.

Colon Cancer Screening

Background and Overview

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. When combined, these "slices" provide detailed volumetric representations of the imaged areas. With recent image quality improvements and greatly increased imaging speeds, CT imaging use has expanded in both the number of procedures performed as well as the applications for which it is utilized. While the increased image quality and number of cross-sectional slices per scan provides valuable diagnostic information, it adds to the challenge of managing and interpreting the large volume of data generated. The Company believes that the challenges in CT imaging present it with opportunities to provide automated image analysis and clinical decision support solutions.

CT Colonography ("CTC") is a less invasive technique than traditional colonoscopy for imaging the colon when screening for cancer. 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. CAD technology has been developed to aid radiologists in their review of CTC images as a means of improving polyp detection. The Company believes that CAD could become an important adjunct to CTC**.**

Colon Cancer Screening Products

VeraLook

VeraLook is the Company's FDA-cleared solution designed to support detection of colonic polyps in conjunction with CTC. The product is distributed with advanced visualization reading workstations manufactured by Vital Images (an affiliate of Toshiba Medical System Group) and Philips Healthcare. It is a natural extension of the Company's core competencies in image analysis and image processing.

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%. The clinical relevance of VeraLook was improved overall reader performance while maintaining high reader specificity.

VeraLook received FDA 510(k) clearance in 2010 and was CE marked in 2009.

The VeraLook CTC computer aided detection product is distributed globally by Vital Images, an affiliate of Canon Group, and by Philips Healthcare in the U.S. market. VeraLook is integrated with the CTC applications of both companies.

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 malignant cells. Radiation therapy may be curative in a number of 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 surgery to remove 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 in order 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, which uses sealed radioactive sources placed precisely inside the body in the treatment area, and (iii) systemic radioisotopes, which are given by infusion or oral ingestion. Brachytherapy uses temporary or permanent placement of radioactive sources.

Conventional EBRT typically involves multiple treatments of a tumor in up to 40 radiation sessions. 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 radiotherapy that utilizes a miniaturized high dose rate X-ray source to apply radiation directly to the cancerous site.

Cancer Therapy

Introduction

The Xoft Axxent Electronic Brachytherapy ("eBx") System ("Xoft System") is a proprietary electronic brachytherapy platform designed to deliver isotope-free (non-radioactive) radiation treatment in virtually any clinical setting without the limitations of radionuclides. It is FDA-cleared, CE marked and licensed in a growing number of countries for the treatment of cancer anywhere in the body, including early-stage breast cancer, non-melanoma skin cancers ("NMSC"), and gynecological cancers. The Xoft System utilizes a miniaturized high dose rate, low energy X-ray source to apply radiation directly to the cancerous site. The goal is to direct the radiation dose to the size and shape of the cancerous area while sparing healthy tissue and organs.

The Company's commercial focus for the Xoft System in recent years has been the treatment of early-stage breast cancer, gynecological cancers and NMSC. Emerging applications include a wide and growing array of cancers including brain, prostate 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 Xoft System delivers clinical dose rates similar to traditional radioactive systems. However, because of the electronic nature of the Xoft System technology, the dose fall-off is faster. This lowers the radiation exposure outside of the targeted area and eliminates the need for a dedicated shielded treatment environment such as that required with traditional isotope-based radiation therapy. Because the Xoft System is relatively small in size, 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). Current customers of the Xoft System include university research and community hospitals, cancer care clinics, veterinary facilities, and dermatology offices that have established strategic partnerships with radiation oncology service providers for supervised treatment delivery.

Cancer Therapy Products

Background and Overview

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 external beam radiation, while a small portion are treated with brachytherapy. IORT aims to simplify radiation treatment for early-stage breast cancer patients by delivering one precise dose of radiation directly to the lumpectomy cavity in a single, safe and effective procedure. The Xoft System may also be used for accelerated partial breast irradiation ("APBI").

The Company continues to make enhancements to the Xoft System controller, including upgrades to the software interface and the high voltage connection, and the Streamlined Module for Advanced Radiation Therapy ("SMART") platform which uses the Axxent Hub cloud-based oncology collaboration software solution. The SMART platform is an adaptive, patient-centric solution designed to improve workflow efficiency, flexibility, safety and security of a skin eBx program. This comprehensive platform provides all members of the care team with a collaborative environment in which to manage patient workflow, and is Wi-Fi enabled, eliminating challenges related to exchanging current, accurate patient data among providers.

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 applicators are offered in a variety of sizes and lengths based on clinical need. The endometrial, cervical 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. The Xoft System includes a 50kV isotope-free energy source, 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 primary applications of the Xoft System involve localized breast cancer treatment using a ten to fifteen-minute breast IORT protocol. However, the Xoft System can also be used to treat a wide and growing array of additional cancers, including NMSC, gynecological, various forms of brain cancer, including recurrent glioblastoma ("GBM"), and other non-breast IORT clinical indications. The Company believes an additional strategic growth opportunity exists in the application of the Xoft System for the treatment of other cancers beyond NMSC and breast cancer in the IORT setting, including integration with minimally invasive surgical techniques and systems.

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 a median survival estimated to be 10 to 12 months. In 2020, the first metastatic brain tumor was treated in the United States with IORT using the Xoft System. This procedure marked the start of a clinical trial at the James Graham Brown Center at the University of Louisville on IORT for patients with large brain metastases treated with neurological resection with the Xoft System. As of December 2020, researchers at the James Graham Brown Cancer Center had treated four patients in this trial.

A retrospective analysis published in World Neurosurgery in 2019 by Alexey Krivoshapkin, MD, PhD, et al. examined the repeat resection and the various methods of IORT for the treatment of malignant brain gliomas, including high-energy linear accelerators and modern, integrated brachytherapy solutions using both solid and balloon applicators.

The Xoft System is also currently being studied for the treatment of other types of brain tumors in various institutions worldwide, including the European Medical Center, in Russia. In a matched study by Alexey Gaytan, MD, PhD, neurosurgeon at the European Medical Center in Moscow, Russia, 30 patients were treated for recurrent GBM. The IORT group was treated with a single fraction of radiation immediately following surgical resection, without chemotherapy or temozolomide following surgery. The comparison group was treated with routine postoperative adjuvant chemotherapy with or without concomitant or sequential EBRT.

Updated clinical findings from this study were presented at the American Society of Clinical Oncology Virtual Scientific Program in May 2020. As of December 2019, overall survival was 27 months in the IORT group, compared to 21 months in the EBRT group. The local progression free survival range for the IORT group was between 3.5 and 39 months, compared to two to 10 months for the EBRT group. As of December 2019, eight patients from the IORT group were still alive, whereas none of the patients in the EBRT group survived.

New data from this study were also presented at the EANS Virtual Congress in October 2020. As of May 2020, five patients from the IORT group were still alive, whereas none of the patients in the EBRT group survived. The survival of patients in the IORT group ranged from 16 to 59 months after the initial GBM diagnosis.

In 2020, iCAD announced the appointment of Santosh Kesari, MD, PhD, a world-renowned neuro-oncologist, as Principal Investigator of an international multi-center clinical trial evaluating the Xoft System as the sole radiation therapy to treat recurrent GBM following surgical excision of malignancy.

In addition, the Xoft System was used for the first time in Europe to treat brain cancer in 2020. The treatment occurred at the Miguel Servet University Hospital in Spain, where a patient was treated for a brain metastasis from Ewing’s Sarcoma.

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 (ear, nose, scalp, neck), locations that experience difficulties in healing (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 electronic brachytherapy using the Xoft System for endometrial and cervical cancer treatment was presented at the European Society for Radiotherapy and Oncology annual meeting. Researchers from Miguel Servet University Hospital in Zaragoza, Spain presented promising study results demonstrating 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. In April 2019, two additional Spanish centers announced adoption of the Xoft System, bringing the number of installations across Spain with the Xoft System to seven, spread across four major regions.

In August 2018, the Xoft System received regulatory consent from India’s Atomic Energy Regulatory Board, making the Company’s full suite of electronic brachytherapy products available to clinicians and patients across

India. In 2017, the Company's balloon applicators were cleared by China's National Medical Products Administration ("NMPA") for the treatment of early-stage breast cancer. With NMPA authorization, the complete suite of Xoft System products is now available to clinicians and patients in China. In addition to the Chinese market, the Company continues to build positive momentum and has regulatory authorization in key geographies such as Spain, Australia, and Switzerland.

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 new applicators for minimally-invasive robotic surgery, including prostate, 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.

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.

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 almost 1,200 licenses through December 31, 2020. 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, Hologic, Fujifilm Medical Systems, and Siemens Medical Systems. In Europe, the Company has also developed reseller relationships with regional distributors, which it plans to expand. In 2019, the Company announced that its Breast Health Solutions suite will be available on the Nuance AI Marketplace, the first portal for improving radiologist productivity with one-stop

access to a wide range of AI diagnostic models from within the industry's most widely used radiology reporting platform. This portal will provide the Company's consolidated, at-scale access to users of Nuance PowerScribe, the radiology reporting system trusted by approximately 80 percent of U.S. radiologists and its PowerShare Network, which connects more than 8,000 healthcare organizations.

In 2020, iCAD signed a distribution agreement with 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.

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. ("Xoft"). In the United States, Xoft utilizes a direct sales force and selected partners. Xoft has established partnerships in Australia, Bangladesh, Bulgaria, China, Egypt, Germany, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Russia, Saudi Arabia, Spain, Sweden, Switzerland, Taiwan, Turkey, and the United Kingdom. Additionally, further commercial efforts are being targeted in Central and South America.

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 we provide 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 our products obsolete or noncompetitive. Moreover, competitors may achieve patent protection, regulatory approval, or product commercialization before we do, which would limit our ability to compete with them. We believe that efficacy, safety profile, cost, and reimbursement are the primary competitive factors that will affect the success of our products.

Cancer Detection

The Company currently faces direct competition in its cancer detection and breast density assessment businesses from Hologic (Marlborough, MA), Volpara (Rochester, NY), ScreenPoint Medical (Nijmegen, Netherlands), Densitas (Halifax, Nova Scotia, Canada), and Therapixel (Paris, France). The Company believes that its market leadership in mammography cancer detection, density assessment, risk assessment and strong relationships with its strategic partners will provide it with a competitive advantage in the cancer detection and breast density assessment businesses.

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 regulatory requirements for the sector present a significant barrier to entry 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 ("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 (Boca Raton, FL) and IntraOp Medical (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 afterloaders 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 2022.

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 CAD 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 pre-sales and post-sales basis. Product support includes pre-sale 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 therapists and billing support on a pre-sales and post-sales basis. Field service staff is involved in product installation, maintenance, training and service repair. Customer service staff provides pre-sale product demonstrations, customer support, troubleshooting, service dispatch and call center management.

Government Regulation

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

Manufacturing and Sales

In the United States, numerous laws and regulations govern the processes by which our products are brought to market. These include the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing 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 our products require submission of a premarket notification demonstrating that our 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 we receive an order from FDA declaring our device to be substantially equivalent, our product is "cleared" for commercial marketing in the United States. Other products of ours require submission of a PMA, which requires non-clinical and clinical data supporting the safety and effectiveness of the device. Once we receive FDA approval of our 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), we may market the device.

After our products enter the market, we 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. Our 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 our 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 our operations are found to violate any of the foreign, federal, state or local laws and regulations which govern our activities, we 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 our operations. Compliance obligations under these various laws are often detailed and onerous, further contributing to the risk that we 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 we make every effort to comply with applicable laws, we cannot rule out the possibility that the government or other third parties could interpret these laws differently and challenge our 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 our operations.

We are 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. We 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 our 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. We cannot predict what impact, if any, such changes might have on our 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. We train and educate employees and marketing representatives on the AKS and their obligations thereunder, and we endeavor 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 our 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, we cannot offer assurances that, with respect to any arrangements that do not squarely meet an exception or safe harbor, we 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 we are found to have violated the Anti-Kickback Statute or a similar state statute, we 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 us to enter into a Corporate Integrity Agreement.

Physician Self-Referral Laws

We are 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.

We have financial relationships with physicians in the form of equipment leases and services arrangements. Our 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. We attempt to structure our 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, we 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 our business, financial condition and results of operations. In addition, expansion of our operations to new jurisdictions, new interpretations of laws in our existing jurisdictions, or new physician self-referral laws could require structural and organizational modifications of our relationships with physicians to comply with those jurisdictions' laws. Such structural and organizational modifications could result in lower profitability and failure to achieve our growth objectives.

If we fail 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, we 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 our 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 we violate the AKS or Stark Law, improperly bill for our services, retain overpayments longer than 60 days after identification, or fail to act with reasonable diligence to investigate credible information regarding potential overpayments, we 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 our interactions with healthcare providers. As a result, we are 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 our business. We have 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 our 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 we expect to receive payment for our products directly from our customers, we do not anticipate relying directly on payment for any of our products from third-party payers, such as Medicare, Medicaid, commercial health insurers and managed care companies. However, our 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, our 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 our 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 our competitors or perform a medical procedure without our 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, which covers 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. Though some Medicare Administrative Contractors do not reimburse for CPT code 0394T, there are several others that either have published rates for the 0394T code or reimburse on a case-by-case basis.

Category III CPT codes are designed as temporary codes for experimental services. Without further action by the AMA, Category III CPT codes sunset five years after the initial publication or extension of the code. The AMA has accepted the retention of CPT code 0394T, extending the code until 2025. At that time, CPT code 0394T may receive a Category I CPT code. Alternatively, the AMA may determine the code should be further extended 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 and in subsequent years. While we believe 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 our business, including the demand for and availability of our products, the reimbursement available for our 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.

We are 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 our business. We 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, we cannot quantify or predict the effect of such repeal, replacement, or modification might have on our business and results of operations. However, any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our 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 our medical products in both the United States and other countries is dependent upon the purchasing and procurement practices of our customers, patient demand for our 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 2021 and 2029. These patents help the Company maintain a proprietary position in its markets. The Company does not believe that the patents expiring in 2021 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

Our products have been developed by our own research and development staff or were developed by the companies we 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. We believe our products are competitive and that none of the current versions of our products are approaching obsolescence. We have invested, and expect to continue to invest in new research and development and enhancements of our current products to maintain our competitive position. For the years ended December 31, 2020, 2019 and 2018, we incurred $8.2 million, $9.4 million, and $9.6 million of research and development expense, respectively.

Human Capital Resources

As of December 31, 2020, the Company had 114 employees, of whom 113 are full time employees, with 42 involved in sales and marketing, 28 in research and development, 30 in service, manufacturing, technical support and operations functions, and 14 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.

Our human capital resources 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, and 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, certain and 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 current reports on Form 8-K, 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.

We operate in a changing environment that involves numerous known and unknown risks and uncertainties that could materially adversely affect our operations. The following highlights some of the factors that have affected, and/or in the future could affect, our operations.

The following is a summary of certain important factors that may make an investment in our company 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 our financial statements and related notes.

- We have incurred significant losses from inception through 2020 and there can be no assurance that we will be able to achieve and sustain future profitability.
- Our quarterly and annual operating and financial results and our gross margins are likely to fluctuate significantly in future periods.
- We expect the novel coronavirus (COVID-19) pandemic to have a significant effect on our results of operations. In addition, it 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 our business, results of operations and financial condition and on the market price of our common stock.
- The markets for our products and treatments and newly introduced enhancements to our existing products and treatments may not develop as expected, we continue to face barriers to broad market acceptance.
- An unfavorable resolution of the Yeda litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.
- Sales and market acceptance of our 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 our products and treatments facilitated by our products could harm our business and prospects.
- A limited number of customers account for a significant portion of our total revenue. The loss of a principal customer could seriously hurt our business.
- The markets for many of our products are subject to changing technology.
- We distribute our products in highly competitive markets and our sales may suffer as a result.
- We rely on intellectual property and proprietary rights to maintain our competitive position and may not be able to protect these rights.
- Our future prospects depend on our ability to retain current key employees and attract additional qualified personnel.
- The market price of our common stock has been, and may continue to be volatile, which could reduce the market price of our common stock.
- Future issuances of shares of our common stock may cause significant dilution of equity interests of existing holders of common stock and decrease the market price of shares of our common stock.

Risks Related to our Financial Position, Operating Results and Need for Additional Capital

We have incurred significant losses from inception through 2020 and there can be no assurance that we will be able to achieve and sustain future profitability.

We have incurred significant losses since our inception. We incurred a net loss of $17.6 million in 2020 and have an accumulated deficit of $241.9 million at December 31, 2020. We may not be able to achieve profitability.

Our quarterly and annual operating and financial results and our gross margins are likely to fluctuate significantly in future periods.

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

Risks Related to Our Business and Our Company

We expect the novel coronavirus (COVID-19) pandemic to have a significant effect on our results of operations. In addition, it 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 our business, results of operations and financial condition and on the market price of our common stock.

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, many countries in Europe, as well as Canada and China, have imposed 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, our operations have been materially affected. Significant uncertainty remains as to the continuing impact of the COVID-19 pandemic on our operations and on the global economy as a whole. 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 continuation or worsening of the levels of market disruption and volatility seen in the recent past will have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock. Our results for the year ending December 31, 2020 reflect a negative impact from the COVID-19 pandemic, as the typical sales cycle and ordering patterns were still disrupted due to some healthcare facilities' additional focus on COVID-19. Although we do not provide guidance to investors relating to our results of operations, our results for future quarters could reflect a continuing negative impact from the COVID-19 pandemic for similar reasons. Depending upon the duration and severity of the pandemic, the continuing effect on our results over the long term is uncertain.

The impact of the COVID-19 pandemic on our future revenue is also relevant to the minimum revenue covenant under our Loan and Security Agreement ("Loan Agreement") with Western Alliance Bank (the "Bank"). If at any point the Company is not in compliance with this covenant and is unable to obtain an amendment or waiver from the Bank, such noncompliance may result in an event of default under the Loan Agreement, which could permit acceleration of the outstanding indebtedness and require the Company to repay such indebtedness before the scheduled due date. The Company was required, historically, to seek modifications from its prior lender to avoid non-compliance with certain earlier covenants. With the COVID-19 pandemic affecting the world economy, the company cannot assure that it will be able to continue to satisfy the applicable minimum revenue covenant.

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 our products and treatments and newly introduced enhancements to our existing products and treatments may not develop as expected, we continue to face barriers to broad market acceptance.

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

- market acceptance of our 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 our products, technologies, treatments or therapies;
- the perceptions of our products or treatments as compared to other products and treatments;
- recommendation and support for the use of our 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 our 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 we are unable to successfully commercialize and create a significant market for our newly developed products and treatments and newly introduced enhancements to our existing products and treatments, our business and prospects could be harmed.

Unfavorable results of legal proceedings could materially adversely affect our financial results

From time to time, we are 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 our 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 our operations. For these and other reasons, we may choose to settle legal proceedings and claims, regardless of their actual merit.

A legal proceeding finally resolved against us, 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 our 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 our ability to market one or more of our material products or services, our 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 our reputation, which could adversely impact our business.

An unfavorable resolution of the Yeda litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In December 2016, the Company entered into an Asset Purchase Agreement with Invivo Corporation ("Invivo"). On September 5, 2018, a third-party, Yeda Research and Development Company Ltd., filed a complaint (the "Yeda Litigation") against the Company and Invivo in the United States District Court for the Southern District of New York, asserting various claims against the Company and Invivo. The Company and Invivo filed motions to dismiss the complaint. On September 5, 2019, the Court granted Invivo's Motion to Dismiss in its entirety and granted the Company's Motion to Dismiss as it relates to Yeda's breach of contract and misappropriation of trade secrets claims. On October 22, 2019, Yeda filed an Amended Complaint against only the Company asserting claims for (i) copyright infringement; and (ii) a replead breach of contract claim. The Company filed its Answer to Yeda's Amended Complaint on November 5, 2019. Yeda alleges, 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. If the Company is found to have infringed Yeda's copyright or breached its agreements with Yeda, the Company could be obligated to pay to Yeda substantial monetary damages. We cannot predict the outcome of the Yeda Litigation or the amount of time and expense that will be required to resolve the lawsuit. If such litigation were to be determined adversely to our interests, or if we were forced to settle such matter for a significant amount, such resolution or settlement could have a material adverse effect on our business, results of operations and financial condition. Please refer to the detailed discussion regarding litigation set forth in Part I, Item 3 of this Annual Report on Form 10-K.

We may be exposed to significant product liability for which we may not have sufficient insurance coverage or be able to procure sufficient insurance coverage.

Our 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 our reputation and business.

Sales and market acceptance of our 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 our products and treatments facilitated by our products could harm our business and prospects.

Sales and market acceptance of our medical products and the treatments facilitated by our 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 our products

and treatments has and will continue to depend upon our customers' ability to obtain an appropriate level of coverage for, and reimbursement from third-party payers for, these products and treatments. In the United States, 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 our 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 our 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 18, 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 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, CMS announced the interim final rule related to CMS's new RO Model, which will take effect no earlier than January 1, 2022. We cannot provide assurance that government or private third-party payers will continue to reimburse our products or services, nor can we provide assurance that the payment rates will be adequate. If providers and physicians are unable to obtain adequate reimbursement for our products or services, this could have a material adverse effect on our 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 our business and business operations. We cannot guarantee that providers and physicians will be able to obtain adequate reimbursement for our products or services under the RO model as proposed, or at all.

Our 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.

Our 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 we anticipate 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 our products are dependent does not grow or grows too slowly, this could have a material adverse effect on our business.

A limited number of customers account for a significant portion of our total revenue. The loss of a principal customer could seriously hurt our business.

A limited number of major customers have in the past and may continue in the future to account for a significant portion of our revenue. Our principal sales distribution channel for our digital products is through our OEM partners. In 2020, our OEM partners accounted for 28% of our total revenue, with one major customer, GE Healthcare, accounting for 17% of our revenue. In addition, in 2020, five customers, consisting of both OEM and direct customers, accounted for 37% of our total revenue. The loss of our relationships with principal customers or a decline in sales to principal customers could materially adversely affect our business and operating results.

If goodwill and/or other intangible assets that we have recorded in connection with our acquisitions become impaired, we could have to take significant charges against earnings.

In connection with the accounting for our acquisitions, we have recorded a significant amount of goodwill and other intangible assets. We have recorded multiple impairments in the past: $26.8 million in September 2011, $14.0 million in June 2015, $4.7 million in September 2017 and $2.0 million in December 2017. Under current accounting, we must assess, at least annually and potentially more frequently, whether the value of our goodwill of $8.4 million at December 31, 2020 and our 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 our reported results of operations in future periods.

Our 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, we are subject to taxation in numerous countries, states and other jurisdictions. In preparing our financial statements, we record the amount of tax payable in each of the countries, states and other jurisdictions in which we operate. Our future effective tax rate, however, may be lower or higher than prior years due to numerous factors, including a change in our geographic earnings mix, changes in the measurement of our deferred taxes, and recently enacted and future tax law changes in jurisdictions in which we operate. We are also subject to ongoing tax audits in various jurisdictions, and tax authorities may disagree with certain positions we have taken and assess additional taxes. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could adversely affect our business, results of operations and cash flows.

Our ability to use our 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, we can carryforward our NOLs to offset our future taxable income, if any, until such NOLs are used 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. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards or other tax attributes is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Acquisitions may not result in the benefits and revenue growth we expect.

We integrate companies that we acquire including the operations, services, products and personnel of each company within our management policies, procedures and strategies. We cannot be sure that we will achieve the benefits of revenue growth that we expect from these acquisitions or that we will not incur unforeseen additional costs or expenses in connection with these acquisitions. To effectively manage our expected future growth, we must continue to successfully manage our integration of these companies and continue to improve our operational systems, internal procedures, working capital management, and financial and operational controls. If we fail in any of these areas, our business could be adversely affected.

The markets for many of our products are subject to changing technology.

Our business depends on our ability to adapt to evolving technologies and industry standards and introduce new technology solutions and services accordingly. If we cannot adapt to changing technologies, our technology solutions and services may become obsolete, and our business may suffer. Because the healthcare information technology market is constantly evolving, our existing technology may become obsolete and fail to meet the requirements of current and potential customers. Our success will depend, in part, on our ability to continue to enhance our existing technology solutions and services, develop new technology that addresses the increasingly sophisticated and varied needs of our customers, and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of our proprietary technology entails significant technical and business risks. We may not be successful in developing, using, marketing, selling, or maintaining new technologies effectively or adapting our proprietary technology to evolving customer requirements or emerging industry standards, and, as a result, our business and reputation could suffer. We 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 our results of operations. Our failure to introduce new products or to introduce these products on schedule could have an adverse effect on our business, financial condition and results of operations.

We depend upon a limited number of suppliers and manufacturers for our products, and certain components in our products may be available from a sole or limited number of suppliers.

Our products are generally either manufactured and assembled for us by a sole manufacturer, by a limited number of manufacturers or assembled by us from supplies we obtain from a limited number of suppliers. Critical components required to manufacture our products, whether by outside manufacturers or directly by us, may be available from a sole or limited number of component suppliers. We generally do not have long-term arrangements with any of our manufacturers or suppliers. The loss of a sole or key manufacturer or supplier could materially impair our ability to deliver products to our customers in a timely manner and would adversely affect our sales and operating results. Our business would be harmed if any of our manufacturers or suppliers could not meet our quality and performance specifications and quantity and delivery requirements.

Additionally, our suppliers and manufacturers are, and will continue to be, subject to extensive government regulation in connection with the manufacture of any medical devices. Our suppliers and manufacturers must ensure that they are compliant with applicable quality system and other regulatory requirements, as mandated by the FDA and other regulatory authorities. If our materials suppliers or manufacturers face manufacturing or quality control problems this may lead to delays in product production or shipment or our supplier or manufacturer no longer being able to continue operations. Our business would be harmed if any of our manufacturers or suppliers could not meet our quality and performance specifications and quantity and delivery requirements.

We distribute our products in highly competitive markets and our sales may suffer as a result.

We operate 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 us and are well established. In addition, some companies have developed or may develop technologies or products that could compete with the products we manufacture and distribute or that would render our products obsolete or noncompetitive. Our competitors may achieve patent protection, regulatory approval, or product commercialization that would limit our ability to compete with them. These and other competitive pressures could have a material adverse effect on our business.

Disruptions in service or damage to our third-party providers' data centers could adversely affect our business.

We rely on third parties who provide access to data centers. Our 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. We conduct business continuity planning and work with our 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 we utilize. In addition, the occurrence of any of these events could result in interruptions, delays or cessations in service to our customers. Any of these events could impair or prohibit our ability to provide our services, reduce the attractiveness of our services to current or potential customers and adversely impact our financial condition and results of operations.

In addition, despite the implementation of security measures, our infrastructure, data centers, or systems that we interface 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, we 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.

If our products fail to perform properly due to errors or similar problems, our business could suffer.

Despite testing, complex software; may contain defects or errors. Addressing software errors may delay development of our solutions, and if discovered after deployment, may require the expenditure of substantial time and resources to correct. Errors in our software could result in:

- harm to our reputation;
- lost sales;
- delays in commercial releases;
- product liability claims;
- delays in or loss of market acceptance of our solutions;
- license terminations or renegotiations;
- unexpected expenses and diversion of resources to remedy errors; and
- privacy and security vulnerabilities.

Furthermore, our customers might use our 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 our software does not cause these problems, the existence of these errors might cause us to incur significant costs, divert the attention of our technical personnel from our solution development efforts; impact our reputation and cause significant customer relations problems.

We rely on intellectual property and proprietary rights to maintain our competitive position and may not be able to protect these rights.

We rely heavily on proprietary technology that we protect 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 we are 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 us. There can also be no assurance that our trade secrets or non-disclosure agreements will provide meaningful protection of our proprietary information. Further, we cannot assure you that others will not independently develop similar technologies or duplicate any technology developed by us or that our technology will not infringe upon patents or other rights owned by others. Unauthorized third parties may infringe our intellectual property rights or copy or reverse engineer portions of our 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 our technology. Moreover, there is a risk that foreign intellectual property laws will not protect our 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 2021 and 2029. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology.

In addition, in the future, we 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 us. Any resulting litigation or proceeding could result in significant expense to us and divert the efforts of our management personnel, whether or not such litigation or proceeding is determined in our favor. In addition, if any of our intellectual property and proprietary rights are deemed to violate the proprietary rights of others, we may be prevented from using those intellectual property or proprietary rights, which could prevent us from being able to sell our products. Litigation could also result in a judgment or monetary damages being levied against us.

Healthcare industry consolidation could impose pressure on our prices, reduce potential customer base and reduce demands for our 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 our customers could result in fewer overall customers. If this consolidation trend continues, it could reduce the size of our potential customer base, reduce demand for our systems, give the resulting enterprises greater bargaining or purchasing power, and may lead to erosion of the prices for our systems or decreased margins for our systems, all of which would adversely affect our ability to generate revenue.

Clinical trials are very expensive, lengthy, and difficult to design and implement and have uncertain outcomes, and, as a result, we may suffer delays or suspensions in current or future trials which would have a material adverse effect on our ability to obtain regulatory approvals timely or at all, and if we fail to receive such approvals, our 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, we may encounter problems at any stage of the trials that cause us 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 our clinical trial protocols or suspension or termination of our 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 our 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, we or regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials. Any suspension of clinical trials will delay possible regulatory approval, increase costs, and adversely impact our ability to develop products and generate revenue.

Our future prospects depend on our ability to retain current key employees and attract additional qualified personnel.

Our success depends in large part on the continued service of our executive officers and other key employees. We may not be able to retain the services of our executive officers and other key employees. The loss of executive officers or other key personnel could have a material adverse effect on us.

In addition, in order to support our continued growth, we will be required to effectively recruit, develop and retain additional qualified personnel. If we are unable to attract and retain additional necessary personnel, it could delay or hinder our plans for growth. Competition for such personnel is intense, and there can be no assurance that we 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 our business, financial condition and results of operations.

Our international operations expose us to various risks, any number of which could harm our business.

Our revenue from sales outside of the United States represented approximately 20% of our revenue for 2020. We are subject to the risks inherent in conducting business across national boundaries, any one of which could adversely impact our 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 our current or future operations and, as a result, harm our overall business.

Our existing and future debt obligations could impair our liquidity and financial condition, and our lenders could foreclose on our assets in the event we are unable to meet our debt obligations.

In connection with our Loan Agreement, the Bank agreed to provide up an initial term loan facility of $7.0 million and a $5.0 million revolving line of credit. The Loan Agreement requires the Company to either (i) meet a minimum revenue covenant, or (ii) maintain a ratio of unrestricted cash at the Bank to aggregate indebtedness owed to the Bank of at least 1.25 to 1.00. The Company was compliant with these covenants as of December 31, 2020 but cannot provide any assurance as to its future compliance due to, in part, the uncertainty of the effect of the COVID-19 pandemic on the world economy and the U.S. health system. If at any point the Company is not in compliance with certain covenants under the Loan Agreement and is unable to obtain an amendment or waiver, such noncompliance may result in an event of default under the Loan Agreement, which could permit acceleration of the outstanding indebtedness and require the Company to repay such indebtedness before the scheduled due date. The Company was required, periodically in the past, to seek modifications from its prior lender to avoid non-compliance with its earlier covenants.

The Loan Agreement

- requires us to dedicate a portion of our cash flow to payments on our debt obligations, which reduces the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;
- imposes restrictions on our ability to incur indebtedness, other than permitted indebtedness, and could impede us from obtaining additional financing in the future for working capital, capital expenditures, mergers, acquisitions and general corporate purposes;
- imposes restrictions on us with respect to the use of our available cash, including in connection with future acquisitions;
- requires us to agree by a certain date with the Bank regarding minimum revenue levels for the 2021 calendar year. Failure to agree will result in acceleration of the indebtedness under the Loan Agreement; and
- requires us to provide certain financial information on a monthly and annual basis. Failure to do so will result in acceleration of the indebtedness under the Loan Agreement.

In addition, the Loan Agreement

- could impair our liquidity;
- could make it more difficult for us to satisfy our other obligations;

- make us more vulnerable in the event of a downturn in our business prospects and could limit our flexibility to plan for, or react to, changes in our licensing markets;
- could result in a prepayment or make-whole premium if we elected to prepay the indebtedness under the Loan Agreement prior to its maturity date; and
- could place us at a competitive disadvantage when compared to our competitors who have less debt.

We have pledged substantially all of our assets to secure our obligations under the Loan Agreement. If we were to fail in the future to make any required payment under the Loan Agreement or fail to comply with the financial and operating covenants contained in the therein, in some cases subject to applicable cure periods, we would be in default regarding the Loan Agreement. Such default would enable the lenders under the Loan Agreement to foreclose on the assets securing such debt and could significantly diminish the market value and marketability of our common stock and could result in the acceleration of the payment obligations under our indebtedness.

Risks Related to Regulation of our Industry

The healthcare industry is highly regulated, and government authorities may determine that we have failed to comply with applicable laws, rules or regulations. Additionally, we may incur substantial costs defending our interpretations of U.S. federal and state government regulations, and if we lose, the government could force us to restructure our operations and subject us to fines, monetary penalties and possibly exclude us 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 us. 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 ours, from engaging in practices that may influence professional decision-making, such as splitting fees with physicians. In addition, we believe that our 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 we cannot predict. Such proposals, if implemented, could impact our operations, the use of our services, and our ability to market new services, and could create unexpected liabilities for us.

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 our operations, including our arrangements with physicians and professional corporations. Further, healthcare laws differ from jurisdiction to jurisdiction and it is difficult to ensure our business complies with evolving laws in all jurisdictions.

Consequently, our operations, including our arrangements with healthcare providers, are subject to audits, inquiries and investigations from government agencies from time to time. We believe we are in substantial compliance with these laws, rules and regulations based upon what we believe 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 we cannot predict. Accordingly, we may in the future become the subject of regulatory or other investigations or proceedings, and our interpretations of applicable laws, rules and regulations may be challenged. Any challenge to our operations or arrangements with third parties that we have structured based upon our 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 we successfully defend our interpretation. In addition, if the government successfully challenges our interpretation of the applicability of these laws, rules and regulations as they relate to our operations and arrangements, it may have a material adverse effect on our business, financial condition, results of operations, cash flows, and the trading price of our common stock.

In the event regulatory action were to limit or prohibit us from carrying on our business as we presently conduct it or from expanding our operations into certain jurisdictions, we may need to make structural, operational and organizational modifications to our Company or our contractual arrangements with physicians and professional corporations. Our operating costs could increase significantly as a result. We could also lose contracts, or our revenues could decrease under existing contracts. Any restructuring would also negatively impact our operations because our management's time and attention would be diverted from running our business in the ordinary course.

Compliance with the many laws and regulations governing the healthcare industry could restrict our sales and marketing practices, and other relationships with healthcare professionals.

Once our products are sold, we 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 our sales and marketing practices, and any challenge to our practices could disrupt our operations and lead to substantial defense costs and a diversion of management's time and attention, even if we successfully defend our practices. If we are unable to successfully defend our practices, in addition to incurring significant expense in defending ourselves, we could be subject to a significant settlement, monetary penalties, and costs related to implementation of changes to our practices, which could have a material adverse effect on our business.

Healthcare reform legislation in the United States may adversely affect our business and/or results of operations.

In March 2010, significant reforms to the U.S. healthcare system were adopted in the form of the ACA. The ACA includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. While the ACA is intended to expand health insurance coverage to uninsured persons in the United States, other elements of this legislation, such as Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, make it difficult to determine the overall impact on sales of, and reimbursement for, our products. We are unable to predict what additional 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 our business. Any cost containment measures or other health care system reforms that are adopted could have a material and adverse effect on our ability to commercialize our existing and future products successfully. We 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, we cannot quantify or predict the effect of such repeal, replacement, or modification might have on our business and results of operations. However, any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

Our products and manufacturing facilities are subject to extensive regulation with potentially significant costs for compliance.

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

Our 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 our operating and compliance burdens and adversely affect our business, financial condition and results of operations.

Sales of our 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. 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 Xoft Systems, and if we fail to receive such approvals, our ability to generate revenue may be significantly diminished.

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

We have received the required premarket approvals from FDA or the equivalent foreign authority in the relevant jurisdictions in which we currently offer our products. Before we are able to commercialize any new product or promote a new indicated use of an existing product, we must obtain the required regulatory approvals. The process for satisfying these regulatory requirements is lengthy and costly and will require us to comply with complex standards for research and development, clinical trials, testing, manufacturing, quality control, labeling, and promotion of products. Additionally, even if we receive regulatory approval for a new product or indicated use in one jurisdiction, our products may be subject to separate regulatory approval in each country or jurisdiction in which we plan to market our products. We cannot be certain that we 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 we are unable to obtain regulatory approval for other products or indicated uses, our ability to generate sufficient revenue to continue our business may be significantly impacted.

Our products may be recalled even after we have received FDA or other governmental approval or clearance.

If the safety or efficacy of any of our products is called into question, we may initiate or the FDA and similar governmental authorities in other countries may press us to implement or even require a product recall, even if our product received approval or clearance by the FDA or a similar governmental body. Such a recall would divert the focus of our management and our financial resources and could materially and adversely affect our reputation with customers and our financial condition and results of operations.

We are subject to complex and evolving U.S. and foreign laws and regulations regarding privacy, data protection, and other matters. We may be subject to criminal or civil sanctions if we fail 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 our customers, we and our third-party vendors may collect, use, maintain and transmit patient health information in ways that are subject to many of these laws and regulations. We are 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.

Our customers are covered entities, and we are a business associate of our customers under HIPAA as a result of our contractual obligations to perform certain functions on behalf of and provide certain services to those customers. In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information received from of our customers. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures and business controls, our 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 our networks and the information stored thereon could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information by us or our subcontractors could (i) result in legal claims or proceedings, liability under laws that protect the privacy of personal information and regulatory penalties, (ii) disrupt our operations and the services we provide to our customers and (iii) damage our reputation, any of which could adversely affect our 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 us and our customers and potentially exposing us to additional expense, adverse publicity and liability. We may not remain in compliance with the diverse privacy requirements in each of the jurisdictions in which we do 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 us to incur significant additional costs to re-design our products in a timely manner to reflect these legal requirements, which could have an adverse impact on our 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 we must handle healthcare related data, and the cost of complying with standards could be significant. If we do not properly comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions.

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

Various statutes and rules in the United States, Europe and around the world regulate privacy and data protection which may affect our 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 require 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 our data access, use and disclosure, and may require increased expenditures by us.

The European Union's General Data Protection Regulation ("GDPR") requires us 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 our Common Stock

A substantial number of shares of our 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 our stock price.

Sales of substantial additional shares of our common stock in the public market, or the perception that these sales may occur, may significantly lower the market price of our common stock. We are unable to estimate the amount, timing or nature of future sales of shares of our common stock. We have 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. We have 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 our common stock may decline.

We have a limited number of shares of common stock available for future issuance which could adversely affect our ability to raise capital or consummate acquisitions.

We are currently authorized to issue 30,000,000 shares of common stock under our amended Certificate of Incorporation ("Certificate of Incorporation"). As of December 31, 2020, we had issued 23,508,575 shares of common stock and had approximately 1,869,507 shares of common stock reserved for issuance upon exercise of options granted, 29,166 shares of common stock reserved for vesting of restricted stock and 907,394 shares of common stock reserved for issuance under our Employee Stock Purchase Plan. On March 5, 2021, we closed an underwritten public offering of 1,393,738 shares of common stock at a public offering price of $18.00 per share, such that as the date of this Annual Report on Form 10-K we have issued 24,918,458 shares of common stock.

Due to the limited number of authorized shares of common stock available for issuance, we may not be able to raise additional equity capital or complete a merger, other business combination or partnership unless we increase the number of shares we are authorized to issue. We intend to seek stockholder approval to increase the number of our authorized shares of common stock at our 2021 annual meeting of stockholders, but we can provide no assurance that we will succeed in amending our Certificate of Incorporation to increase the number of shares of common stock we are authorized to issue.

If we do not receive the requisite stockholder approval, our 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 our stockholders.

Provisions in our Certificate of Incorporation and in Delaware law could make it more difficult for a third party to acquire us, discourage a takeover and adversely affect existing stockholders.

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.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law**,** 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 market price of our common stock has been, and may continue to be volatile, which could reduce the market price of our common stock.

The publicly traded shares of our common stock have experienced, and may experience in the future, significant price and volume fluctuations**.** This market volatility could reduce the market price of our common stock without regard to our operating performance. In addition, the trading price of our common stock could change significantly in response to actual or anticipated variations in our quarterly operating results, announcements by us or our competitors, factors affecting the medical imaging industry generally, changes in national or regional economic conditions, changes in securities analysts' estimates for us or our competitors' or industry's future performance or general market conditions**,** making it more difficult for shares of our common stock to be sold at a favorable price or at all. The market price of our 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 our industry.

General Risk Factors

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer and could subject us to substantial liabilities.

If our security measures are breached or fail and unauthorized access is obtained to a customer's data, our service may be perceived as insecure, the attractiveness of our services to current or potential customers may be reduced, and we may incur significant liabilities.

Our services involve the storage and transmission of customers' proprietary information and patient information, including health, financial, payment and other personal or confidential information. We rely 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 we will not be subject to cybersecurity incidents that bypass our security measures, impact the integrity, availability or privacy of personally identifiable information or other data subject to privacy laws or disrupt our information systems, devices or business, including our ability to deliver services to our customers. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our 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 our financial position and results of operations and harm our business reputation.

Changes in interpretation or application of Generally Accepted Accounting Principles may adversely affect our operating results.

We prepare our 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 our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

As our operations evolve over time, we may introduce new products or new technologies that require us to apply different accounting principles, including ones regarding revenue recognition, than we have applied in past periods. The application of different types of accounting principles and related potential changes may make it more difficult to compare our financial results from quarter to quarter, and the trading price of our common stock could suffer or become more volatile as a result.

We cannot be certain of the future effectiveness of our internal controls over financial reporting or the impact of the same on our operations or the market price for our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), we are required to include in our Annual Report on Form 10-K our assessment of the effectiveness of our internal controls over financial reporting. We have dedicated a significant amount of time and resources to ensure compliance with this legislation for the year ended December 31, 2020 and will continue to do so for future fiscal periods. Although we believe that we currently have adequate internal control procedures in place, we cannot be certain that our

internal controls over financial reporting will continue to be effective. If we cannot adequately maintain the effectiveness of our internal controls over financial reporting, we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Changes in credit markets or to our credit rating could impact our ability to obtain financing for business operations or result in increased borrowing costs and interest expense.

Our credit ratings reflect each credit rating agency's opinion of our financial strength, operating performance and ability to meet our debt obligations at the time such opinion is issued. We utilize the short- and long-term debt markets to obtain capital from time to time. Adverse changes in our 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 our operating flexibility. Macroeconomic conditions, such as continued or increased volatility or disruption in the credit markets, may adversely affect our ability to refinance existing debt or obtain additional financing for working capital, capital expenditures or fund new acquisitions.

Future issuances of shares of our common stock may cause significant dilution of equity interests of existing holders of common stock and decrease the market price of shares of our common stock.

We have previously issued options that are exercisable or convertible into a significant number of shares of our common stock. Should existing holders of options exercise their options for shares of our common stock, it may cause significant dilution of equity interests of existing holders of our common stock and reduce the market price of shares of our 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. The lease covers approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire. As amended, the lease expires in February 2023 and the annual base rent is $214,812. 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. The operating lease commenced September 2012. As amended, the lease expires in March 2023, with annual payments of $628,260 until March 2021, $645,792 from April 2021 to March 2022 and $666,240 from April 2022 to 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.

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.

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. In the Complaint, Yeda asserted claims for: (i) copyright infringement and misappropriation of trade secrets against both the Company and Invivo, (ii) breach of contract against the Company only, and (iii) tortious interference with existing business relationships and unjust enrichment against Invivo only. The Company and Invivo filed Motions to Dismiss the Complaint on December 21, 2018. On January 18, 2019, Yeda filed Oppositions to the Motions to Dismiss. The Company and Invivo submitted responses to the Opposition to the Motion to Dismiss on February 8, 2019. The Court held oral argument on the Motions to Dismiss on March 27, 2019. On September 5, 2019, the Court granted Invivo's Motion to Dismiss in its entirety and granted the Company's Motion to Dismiss as it relates to Yeda's breach of contract and misappropriation of trade secrets claims. On October 22, 2019, Yeda filed an Amended Complaint against only the Company asserting claims for (i) copyright infringement, and (ii) a replead breach of contract claim. The Company filed its Answer to Yeda's Amended Complaint on November 5, 2019. Yeda alleges, 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. If the Company is found to have infringed Yeda's copyright or breached its agreements with Yeda, the Company could be obligated to pay to Yeda substantial monetary damages.

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.

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 8, 2021, there were 96 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. The Company's Loan and Security Agreement with Western Alliance Bank restricts the Company's present ability to pay dividends.

Information with respect to the Company's equity compensation plans in effect at December 31, 2020 will be included in the Company's 2021 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 quarter ended December 31, 2020.

Item 6. Selected Financial Data.

Not applicable.

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

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.

On January 30, 2017, the Company completed the sale of certain intellectual property relating to the VersaVue Software and the DynaCAD product and related assets to Invivo for $3,200,000 in cash with a holdback amount of $350,000. The Company is currently involved in litigation with a third-party relating to this transaction, as further described in "Item 3—Legal Proceedings."

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

Critical Accounting Estimates

The Company's discussion and analysis of its financial condition, results of operations, and cash flows are based on its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States.

The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates these estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory valuation and obsolescence, intangible assets, goodwill, income taxes, contingencies and litigation. Additionally, the Company uses assumptions and estimates in calculations to determine stock-based compensation, the fair value of convertible debentures and the evaluation of litigation. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As of January 1, 2019, the Company adopted ASC Topic 842. Refer to Note 1 to the consolidated financial statements for disclosure of the changes related to this adoption.

The Company's critical accounting policies include:

- Revenue recognition;
- Valuation of long-lived and intangible assets;
- Goodwill;
- Stock based compensation; and
- Income taxes;

Revenue Recognition

On January 1, 2018, the Company adopted FASB ASC Topic 606, "Revenue from Contracts with Customers" and all the related amendments ("Topic 606") using the modified retrospective method for all contracts not completed as of the date of adoption. The Company recognized the cumulative effect of initially applying the new standard as an adjustment to the opening balance of retained earnings at the adoption date. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

The Company recognizes revenue primarily from the sale of products and from the sale of services and supplies. Under Topic 606, revenue is recognized when a customer obtains control of promised goods or services. 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. To achieve this core principle, the Company applies the following five steps:

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.

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 to the customer that are both capable of being distinct, whereby 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 are distinct in the context of the contract, whereby the transfer of the goods or services 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 promised goods or services are capable of being distinct and distinct in the context of the contract. If these criteria are not met the promised goods or services are accounted for as a combined performance obligation. If options to purchase additional goods or services are included in customer contracts, the Company evaluates the option in order to determine if the Company's arrangement include promises that may represent a material right and needs to be accounted for as a performance obligation in the contract with the customer.

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 based on a relative standalone selling 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 single performance obligation.

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 to which we expect to be entitled in exchange for those goods or services. For product revenue, control has transferred upon shipment provided 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. Determining whether products and services are considered 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. The Company generally determines standalone selling prices based on the prices charged to customers when each of the products and services are sold separately. If the standalone selling price of a product or service is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company's hardware is generally highly dependent on, and interrelated with, the underlying license. In these cases, the hardware and 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.

Upon the adoption of ASC 842, effective January 1, 2019, the lease components of certain fixed fee service contracts are no longer being separately accounted for under the lease guidance, and the entire contract is being accounted for under ASC 606. Upon the adoption of ASC 606, effective January 1, 2018, and until the adoption of ASC 842 referred to above, these lease components were accounted for as a lease in accordance with ASC 840, "Leases" ("ASC 840"), and the remaining consideration was allocated to the other performance obligations identified in accordance with ASC 606.

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 also recognizes an asset for the incremental costs of obtaining a contract with a customer if we expect the benefit of those costs to be longer than one year, in accordance with ASC Topic 340-40, "Other Assets and Deferred Costs: Contracts with Customers." The Company has determined that certain commissions programs meet the requirements to be capitalized.

See Note 1 to the consolidated financial statements for details of the Company's accounting policies related to revenue recognition.

Goodwill

In accordance with FASB ASC Topic 350-20, "Intangibles—Goodwill and Other," the Company tests goodwill for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of the Company is less than the carrying value of the Company.

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

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

The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer. The Company determined that it has two reporting units and two reportable segments based on the information that is provided to the CODM. The two segments and reporting units are Detection and Therapy. Each reportable segment generates revenue from the sale of medical equipment and related services and/or sale of supplies. Upon initial adoption, goodwill was allocated to the reporting units based on the relative fair value of the reporting units.

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. The Company utilizes either discounted cash flow models or other valuation models, such as comparative transactions and market multiples, to determine the fair value of its reporting units. The Company makes assumptions about future cash flows, future operating plans, discount rates, comparable companies, market multiples, purchase price premiums and other factors in those models. Different assumptions and judgment determinations could yield different conclusions that would result in an impairment charge to income in the period that such change or determination was made.

Other significant assumptions include terminal value margin rates, future capital expenditures, and changes in future working capital requirements. While there are inherent uncertainties related to the assumptions used and to the application of these assumptions to this analysis, the income approach provides a reasonable estimate of the fair value of the reporting units.

The Company determines the fair value of reporting units based on the present value of estimated future cash flows, discounted at an appropriate risk adjusted rate. This approach was selected as it measures the income producing assets, primarily technology and customer relationships. This method estimates the fair value based upon the ability to generate future cash flows, which is particularly applicable when future profit margins and growth are expected to vary significantly from historical operating results.

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, 2020 and compared the fair value of each of reporting unit to its carrying value as of this date. Fair value of the Detection reporting unit exceeded the carrying value by approximately 2,044%. Goodwill for the Therapy reporting unit was fully impaired prior to the year ended December 31, 2017. 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 for the years ended December 31, 2020 or December 31, 2019.

A considerable amount of judgment and assumptions are required in performing the impairment tests, principally in determining the fair value of the Asset Group and the reporting unit. While the Company believes the judgments and assumptions are reasonable, different assumptions could change the estimated fair values and, therefore additional impairment charges could be required. Significant negative industry or economic trends, disruptions to the Company's business, loss of significant customers, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets may adversely impact the assumptions used in the fair value estimates and ultimately result in future impairment charges.

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.

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. 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.

Income Taxes

The Company follows the liability method under ASC 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, 2020 and 2019 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.

ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and 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. ASC 740-10 also provides guidance on de-recognition, classification, interest and penalties, disclosure and transition.

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.

Discussion of Operating Results:

Year Ended December 31, 2019 compared to Year Ended December 31, 2018

Revenue. Revenue for the year ended December 31, 2019 was $31.3 million compared with revenue of $25.6 million for the year ended December 31, 2018, an increase of $5.7 million, or 22.3%. Detection revenue increased by $5.4 million and Therapy revenue increased by $0.3 million.

The table below presents the components of revenue for 2019 and 2018 (in thousands):

	Twelve months ended December 31,			
	2019	2018	Change	% Change
Detection revenue				
Product revenue	$16,788	$10,783	$6,005	55.7%
Service revenue	5,531	6,081	(550)	(9.0)%
Subtotal	22,319	16,864	5,455	32.3%
Therapy revenue				
Product revenue	2,979	2,328	651	28.0%
Service revenue	6,042	6,429	(387)	(6.0)%
Subtotal	9,021	8,757	264	3.0%
Total revenue	$31,340	$25,621	$5,719	22.3%

Detection revenues increased 32.3%, or $5.4 million, from $16.9 million for the year ended December 31, 2018 to $22.3 million for the year ended December 31, 2019. Detection product revenue increased by $6.0 million and Detection service revenue decreased by $0.6 million. The $6.0 million increase in Detection product revenue was due primarily to a $2.1 million increase in OEM system sales and a $3.9 million increase in direct product sales. Detection service revenue decreased by $0.6 million, which was due primarily to a decrease of approximately $0.8 million primarily due to the conversion and upgrade cycle from Secondlook digital to Tomosynthesis 3D CAD offset by an increase of $0.2 million of service related to our 3D products.

Therapy revenue increased 3.0%, or $0.3 million, to $9.0 million for the year ended December 31, 2019 from $8.7 million in the year ended December 31, 2018. The increase in Therapy revenue was due to an increase in Therapy product revenue of $0.7 million offset by a decrease in Therapy service revenue of $0.4 million.

The increase in Therapy product revenue for the year ended December 31, 2019 was due primarily to an increase of $0.6 million related to sales outside of the United States (“OUS”) controller sales in 2019. The decrease in Therapy service revenue was due to reductions in source agreements and disposable applicators in the United States. Overall, the Therapy business increased by $1.1 million, or 67% OUS, offset by decreases in the U.S. business of $0.8 million, or 12%. We expect Therapy sales to continue to vary as the sales of controller units can represent a significant component of Therapy product revenue.

Gross Profit. Gross profit was $24.2 million for the year ended December 31, 2019 compared to $19.4 million for the year ended December 31, 2018, an increase of $4.8 million, or 24.8%. Detection gross profit increased by $3.9 million from $14.7 million in the year ended December 31, 2018 to $18.6 million in the year ended December 31, 2019. Detection gross profit increased due primarily to the increase in Detection revenue. Detection gross profit as a percentage of Detection revenue decreased to 84% in the year ended December 31, 2019 from 87% in the prior year as a result of higher equipment costs to support processing higher resolution 3D images. Therapy gross profit increased by $0.9 million from $4.7 million in the year ended December 31, 2018 to $5.6 million in the year ended December 31, 2019. Therapy gross profit as a percentage of Therapy revenue improved to 62% in the year ended December 31, 2019 from 54% in the prior year. The improvement in Therapy gross profit as a percentage of revenue was due to the reduced cost of services and cost structure improvements related to the exit of the skin subscription business in January 2018.

Gross profit percent was 77.3% for the year ended December 31, 2019 compared to 75.8% for the year ended December 31, 2018. Gross profit will fluctuate due to the costs related to manufacturing, amortization and the impact of product mix in each segment. Cost of revenue and gross profit for 2019 and 2018 were as follows (in thousands):

	Twelve months ended December 31,			
	2019	2018	Change	% Change
Products	$ 3,278	$ 2,161	$1,117	51.7%
Service and supplies	3,438	3,627	(189)	(5.2)%
Amortization and depreciation	397	403	(6)	100.0%
Total cost of revenue	$ 7,113	$ 6,191	$ 922	14.9%
Gross profit	$24,227	$19,430	$4,797	24.7%
profit %	77.3%	75.8%		

Operating Expenses:

Operating expenses for 2019 and 2018 were as follows (in thousands):

	For the year ended December 31,			
	2019	2018	Change	% Change
Operating expenses:				
Engineering and product development	$ 9,271	$ 9,445	$ (174)	(1.8)%
Marketing and sales	13,634	8,693	4,941	56.8%
General and administrative	7,443	9,117	(1,674)	(18.4)%
Amortization and depreciation	276	305	(29)	(9.5)%
Total operating expenses	$30,624	$27,560	$ 3,064	11.1%

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2019 decreased by $0.2 million, or 1.9%, from $9.5 million in 2018 to $9.3 million in 2019. Detection engineering and product development costs increased by $0.2 million. The increase in Detection research and development expense was due to an increase in personnel and data collection costs offset by decreases in clinical expenses and consulting costs. Therapy engineering and product development costs decreased by approximately $0.4 million. The decrease in the Therapy segment was due primarily to a decrease in personnel expenses and clinical expenses. Engineering and product development costs support the Company's strategy to build improved and larger datasets to train the Detection algorithm and support for clinical data in the Therapy segment.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2019 increased by $4.9 million, or 56.8%, from $8.7 million in 2018 to $13.6 million in 2019. Detection marketing and sales expenses increased by $4.6 million. The increase in Detection marketing and sales expense was due to increases in personnel costs, commissions and tradeshow expenses. Therapy marketing and sales expenses increased approximately $0.3 million. The increase in Therapy marketing and sales expense was due primarily to an increase in personnel expenses, and travel. The Company made significant investments in the commercial infrastructure to support its strategy to grow top line revenue.

General and Administrative. General and administrative expenses for the year ended December 31, 2019 decreased by $1.7 million, or 18.4%, from $9.1 million in 2018 to $7.4 million in 2019. The decrease in general and administrative expenses was due primarily to $1.0 million of severance costs incurred in the year ended December 31, 2018, legal settlement costs of $0.4 million and decreases in stock compensation and bad debt.

Amortization and Depreciation. Amortization and depreciation expenses were consistent between 2019 and 2018 at $0.3 million. The Company's depreciable and amortizable assets have remained relatively consistent between 2019 and 2018.

Other Income and Expense (in thousands)

	For the year ended December 31,			
	2019	2018	Change	Change %
Interest expense	$ (784)	$(504)	(280)	55.6%
Interest income	344	110	234	212.7%
Financing costs	—	(451)	451	(100.0)%
Loss on fair value of debentures	(6,671)	—	(6,671)	—
	$(7,111)	$(845)	$(6,266)	741.5%
Income tax (benefit) expense	$ 43	$ 42	1	2.4%

Interest Expense. The Company recorded $0.8 million of interest expense in 2019 as compared with $0.5 million of interest expense during the year ended December 31, 2018. In December 2018, the Company issued the unsecured subordinated convertible debentures (the "Convertible Debentures") and as a result, interest expense increased.

Interest income. Interest income of $0.3 million and $0.1 million for the years ended December 31, 2019 and 2018, respectively, reflects income earned from our money market accounts.

Financing costs. The Company recorded $0.5 million of expenses in 2018 in connection with the issuance of the Convertible Debentures in December 2018.

Loss on fair value of debentures. The Company recorded a loss of $6.7 million in 2019, which reflects an increase in the fair value of the Convertible Debentures liability from approximately $7.0 million at December 31, 2018 to $13.6 million at December 31, 2019. The Company expects the fair value of the Convertible Debentures to change from quarter to quarter as changes in the underlying stock price of the Company drive changes in the fair value of these instruments.

Tax expense. The Company had tax expense of $43,000 for the year ended December 31, 2019 as compared to tax expense of $42,000 for the year ended December 31, 2018. Tax expense for both the years ended December 31, 2019 and 2018 was due primarily to state non-income and franchise-based taxes.

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, 2020, 2019, and 2018 are below (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Segment revenues:			
Detection	$ 21,997	$ 22,319	$16,864
Therapy	7,701	9,021	8,757
Total Revenue	$ 29,698	$ 31,340	$25,621
Segment gross profit:			
Detection	$ 17,856	$ 18,627	$14,709
Therapy	3,498	5,600	4,721
Segment gross profit	$ 21,354	$ 24,227	$19,430
Segment operating income (loss):			
Detection	$ 2,719	$ 2,564	$ 3,412
Therapy	(3,028)	(1,476)	(2,373)
Segment operating income (loss)	$ (309)	$ 1,088	$ 1,039
General administrative	$ (9,079)	$ (7,486)	$ (9,169)
Interest expense	(476)	(784)	(504)
Financing costs	—	—	(451)
Loss on extinguishment of debt	(341)		
Other income	97	345	110
Fair value of convertible debentures	(7,464)	(6,671)	
Loss before income tax	$(17,572)	$(13,508)	$ (8,975)

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, 2019. 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, 2020 from $16.1 million for the year ended December 31, 2019.

Detection gross profit increased to approximately $18.6 million, or 83% of revenue, for the year ended December 31, 2019 from $14.7 million, or 87% of revenue, for the year ended December 31, 2018. The increase in Detection gross profit was due primarily to the increase in Detection revenue. Detection segment operating income for the year ended December 31, 2019 decreased by $0.8 million to $2.6 million from $3.4 million for the year ended December 31, 2018. The decrease in Detection segment operating income for the year ended December 31, 2019 as compared to the year ended December 31, 2018 was due primarily to increased operating expenses for the year ended December 31, 2019 compared to the year ended December 31, 2018. Detection operating expenses increased by $4.8 million to $16.1 million for the year ended December 31, 2019 compared to $11.3 million for the year ended December 31, 2018, reflecting increased research and development and increased marketing and sales expenses, primarily due to clinical development costs, personnel related expenses and consulting costs.

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, 2019. 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.

Therapy gross profit increased by approximately $0.9 million to $5.6 million, or 62% of revenue, for the year ended December 31, 2019 from approximately $4.7 million or 54% of revenue for the year ended December 31, 2018. The increase in Therapy gross profit was due to decreased manufacturing costs of $0.5 million and increased revenue of $0.3 million. Therapy operating expenses for both the years ended December 31, 2019 and 2018 were approximately $7.1 million, respectively. Therapy segment operating loss decreased to a loss of $1.5 million for the year ended December 31, 2019 from a loss of $2.4 million for the year ended December 31, 2018. The decrease in loss was due primarily to the decreased manufacturing costs of $0.5 million and increased revenue of $0.3 million.

Liquidity and Capital Resources

The Company believes that its cash and cash equivalents balance of $27.2 million as of December 31, 2020, and projected cash balances are sufficient to sustain operations through at least the next 12 months. The Company's ability to generate cash adequate to meet its future capital requirements will depend primarily on operating cash flow. If sales or cash collections are reduced from current expectations, or if expenses and cash requirements are increased, the Company may require additional financing, although there are no guarantees that the Company will be able to obtain the financing if necessary. The Company will continue to closely monitor its liquidity and the capital and credit markets.

The Company's cash on hand includes proceeds from the Loan and Security Agreement entered into with the Bank on March 31, 2020. The Company and the Bank amended the Loan and Security Agreement on June 22, 2020 (as amended, the "Loan Agreement"). The Loan Agreement includes certain financial covenants tied to minimum revenue and the ratio of the Company's unrestricted cash at the Bank to its indebtedness under the Loan Agreement. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to maintain compliance with the covenants under the Loan Agreement. If at any point the Company is not in compliance with certain covenants and is unable to obtain an amendment or waiver from the Bank, such noncompliance may result in an event of default under the Loan Agreement, which could permit acceleration of the outstanding indebtedness and require the Company to repay such indebtedness before the scheduled due date.

Even if an event of default were to occur under the Loan Agreement, the Company believes that its current liquidity and capital resources are sufficient to sustain operations through at least the next 12 months, primarily due to cash on hand of $27.2 million and anticipated revenue and cash collections. However, the resurgence of the COVID-19 pandemic could affect our liquidity.

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 has 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 provides 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. As of December 31, 2020, $18.4 million in capacity remains under the ATM facility. On March 2, 2021, the Company terminated the ATM.

The Company had net working capital of $25.6 million at December 31, 2020. The ratio of current assets to current liabilities at December 31, 2020 and 2019 was 2.53 and 1.55, respectively.

Net cash used for operating activities for the year ended December 31, 2020 was $7.0 million, compared to $7.1 million for 2019.

The net cash used for investing activities for the year ended December 31, 2020 was $0.5 million compared to $0.3 million for the year ended December 31, 2019. The cash used for investing activities in both 2020 and 2019 was due primarily to purchases of fixed assets.

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. Net cash provided by financing activities for the year ended December 31, 2019 was $10.5 million which was primarily related to $9.4 million in net proceeds from an issuance of common stock and $1.4 million received from the exercise of employee stock options.

The CARES Act allowed employers to defer the depot and payment of employers share of Social Security payroll taxes that would otherwise have been owed from the date of enactment of the legislation through December 31, 2020. 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. As of December 31, 2020, the Company has recorded the $0.4 million payment deferral within "Accrued and other benefits."

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 and resulted in net proceeds of approximately $23.2 million to the Company.

Lease Obligations:

Operating Leases:

As of December 31, 2020, the Company had three lease obligations related to its facilities.

The Company's executive offices are leased pursuant to a five-year lease that commenced on December 15, 2006, consisting of approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire. As amended, the lease expires in February 2023 and the annual base rent is $214,812. 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. The operating lease commenced September 2012. As amended, the lease expires in March 2023, with annual payments of $628,260 until March 2021, $645,792 from April 2021 to March 2022 and $666,240 from April 2022 to 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.

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 is being depreciated over the 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, 2020, the remaining liability for minimum royalty obligations totaling $0.1 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.

The Loan Agreement was amended effective June 16, 2020. The Loan Agreement requires the Company to either (i) meet a minimum revenue covenant, or (ii) maintain a ratio of unrestricted cash at the Bank to aggregate indebtedness owed to the Bank of at least 1.25 to 1.00. The Company was compliant with these covenants as of December 31, 2020.

If at any point the Company is not in compliance with certain covenants under the Loan Agreement and is unable to obtain an amendment or waiver, such noncompliance may result in an event of default under the Loan Agreement, which could permit acceleration of the outstanding indebtedness and require the Company to repay such indebtedness before the scheduled due date. The Company was required, periodically in the past, to seek modifications from its prior lender to avoid non-compliance with its earlier covenants.

Interest in arrears on the Term Loan began to be repaid on April 1, 2020 and will continue to be paid on the first of each successive month thereafter until the principal repayment starts. Commencing on the principal repayment date March 1, 2022 and continuing on the first day of each month thereafter, the Company will make equal monthly payments of principal, together with applicable interest in arrears, to the Bank. The interest rate is set at 1% above the Prime Rate, which is defined in the Loan Agreement as the greater of 4.25% or the Prime Rate published in the Money Rates section of the Western Edition of the Wall Street Journal. The Prime Rate as of December 31, 2020 was 3.25%.

The Company has the option to prepay all, but not less than all, of the Term Loan advanced by the Bank under the Loan Agreement. The Company prepayment is subject to payment of (1) all outstanding principal of the Term Loan plus accrued and unpaid interest thereon through the prepayment date, (2) the final payment ($122,500 or 1.75% of the original loan amount), (3) a prepayment fee (3% of the principal balance if prepaid prior to first March 30, 2021, 2% of principal if prepaid after March 30, 2021 but before June 30, 2022, or 1% of principal if prepaid after March 30, 2022) plus (4) all other obligations that are due and payable, including the Bank's expenses and interest at the default rate with respect to any past due amounts.

Obligations to the Bank under the Loan Agreement are 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.

In connection with the Loan Agreement, the Company incurred approximately $141,000 of closing costs. The closing costs have been deduced from the carrying value of the debt and will be amortized through March 30, 2022, the maturity date of the Term Loan.

The maturity date of the revolving loan is March 30, 2022 and there was no outstanding amount as of December 31, 2020.

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. 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. 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.

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 1 (t) 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. 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 and Schedule 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, 2020.

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, 2020, 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, 2020.

(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 quarter ended December 31, 2020, 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.

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 2021 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for the Company's 2021 Annual Meeting of Stockholders (the "2021 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 2021 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 2021 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 2021 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 2021 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).
2	Asset Purchase Agreement, dated December 16, 2016, between the Company and Invivo Corporation. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 22, 2016). **
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.
4	Description of Registrant's Securities
10(a)	2016 Stock Incentive Plan as Amended December 2018 (incorporated by reference to Annex A to the definitive proxy statement on Form DEF14A filed with the SEC on November 20, 2018).*
10(b)	Amendment to 2016 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on February 19, 2021).
10(c)	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(d)	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(e)	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(f)	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(g)	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(h)	Employment Agreement, dated May 26, 2020, between the Company and Scott Areglado (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on May 29, 2020). *
10(i)	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(j)	Asset Purchase Agreement, dated December 16, 2016, between the Company and Invivo Corporation (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 22, 2016).
10(k)	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(l)	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(m)	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(n)	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(o)	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(p)	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).

21.1	Subsidiaries
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief 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, 2020 and December 31, 2019, (ii) Consolidated Statements of Operations for the years ended December 31, 2020, 2019 and 2018, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2020, 2019 and 2018, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018, 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 15, 2021

By: /s/ Michael Klein
Michael Klein
Chief Executive Officer, Executive Chairman

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/ Michael Klein Michael Klein	Executive Chairman, Director, Chief Executive Officer (Principal Executive Officer)	March 15, 2021
/s/ R. Scott Areglado R. Scott Areglado	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2021
/s/ Nathaniel Dalton Nathaniel Dalton	Director	March 15, 2021
/s/ Rakesh Patel Rakesh Patel, MD	Director	March 15, 2021
/s/ Andy Sassine Andy Sassine	Director	March 15, 2021
/s/ Susan Wood Susan Wood, Ph.D	Director	March 15, 2021

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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, on January 1, 2019, the Company changed its method of accounting for leases due to the adoption of ASU 2016-02, *Leases* (ASC 842).

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 arrangements with non-standard terms

As described in Note 1(k) to the consolidated financial statements, management assesses relevant contractual terms in its customer arrangements to determine the performance obligations and recognizes revenue upon transfer of control of the promised goods or services in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. The Company enters into certain contracts with customers with non-standard terms and conditions that may include promises to transfer multiple products and services where management exercises significant judgment in assessing contractual terms in these arrangements to identify and evaluate whether performance obligations should be accounted for separately versus together.

We identified the determination of distinct performance obligations within contracts with non-standard terms as a critical audit matter. Significant judgment can be required to determine the performance obligations in a contract with non-standard terms and whether they are distinct. Auditing these aspects involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters and the evaluation of audit evidence obtained related to whether such performance obligations were appropriately identified and evaluated by management.

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 these agreements together with their underlying documents and company assessments to evaluate the appropriate 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 15, 2021

iCAD, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

Assets	December 31, 2020	December 31, 2019
	(in thousands except shares and per share data)	
Current assets:		
Cash and cash equivalents	$ 27,186	$ 15,313
Trade accounts receivable, net of allowance for doubtful accounts of $111 in 2020 and $136 in 2019	10,027	9,819
Inventory, net	3,144	2,611
Prepaid expenses and other current assets	1,945	1,453
Total current assets	42,302	29,196
Property and equipment:		
Equipment	6,765	6,304
Leasehold improvements	62	62
Furniture and fixtures	319	319
Marketing assets	376	376
	7,522	7,061
Less accumulated depreciation and amortization	6,778	6,510
Property and equipment, net	744	551
Other assets:		
Operating lease assets	1,758	2,406
Other assets	1,527	50
Intangible assets, net of accumulated amortization of $8,494 in 2020 and $8,186 in 2019	889	1,183
Goodwill	8,362	8,362
Total other assets	12,536	12,001
Total assets	$ 55,582	$ 41,748
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,869	$ 1,990
Accrued and other expenses	7,039	6,590
Notes payable, current	—	4,250
Lease payable, current	726	758
Deferred revenue, current	6,117	5,248
Total current liabilities	16,751	18,836
Lease payable, long-term	1,075	1,837
Deferred revenue, long-term	267	356
Notes payable, long-term	6,960	2,003
Convertible debentures payable to non-related parties, at fair value	—	12,409
Convertible debentures payable to related parties, at fair value	—	1,233
Deferred tax	4	3
Total liabilities	25,057	36,677
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $ .01 par value: authorized 1,000,000 shares; none issued.	—	—
Common stock, $ .01 par value: authorized 30,000,000 shares; issued 23,693,735 in 2020 and 19,546,151 in 2019. Outstanding 23,508,575 in 2020 and 19,360,320 in 2019.	236	196
Additional paid-in capital	273,639	230,615
Accumulated deficit	(241,935)	(224,325)
Treasury stock at cost, 185,831 shares in 2019 and 2018	(1,415)	(1,415)
Total stockholders' equity	30,525	5,071
Total liabilities and stockholders' equity	$ 55,582	$ 41,748

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

	For the Years Ended December 31,		
	2020	2019	2018
	(in thousands except per share data)		
Revenue:			
Products	$ 18,903	$ 19,767	$13,111
Service and supplies	10,795	11,573	12,510
Total revenue	29,698	31,340	25,621
Cost of Revenue:			
Products	5,000	3,278	2,161
Service and supplies	2,965	3,438	3,627
Amortization and depreciation	379	397	403
Total cost of revenue	8,344	7,113	6,191
Gross profit	21,354	24,227	19,430
Operating expenses:			
Engineering and product development	8,114	9,271	9,445
Marketing and sales	13,312	13,634	8,693
General and administrative	9,117	7,443	9,117
Amortization and depreciation	199	276	305
Total operating expenses	30,742	30,624	27,560
Loss from operations	(9,388)	(6,397)	(8,130)
Other expense			
Interest expense	(476)	(784)	(504)
Interest income	97	344	110
Financing costs	—	—	(451)
Loss on extinguishment of debt	(341)	—	—
Loss on fair value of convertible debentures	(7,464)	(6,671)	—
Other expense, net	(8,184)	(7,111)	(845)
Loss before income tax expense	(17,572)	(13,508)	(8,975)
Income tax expense	38	43	42
Net loss and comprehensive loss	$(17,610)	$(13,551)	$ (9,017)
Net loss per share:			
Basic	$ (0.80)	$ (0.74)	$ (0.54)
Diluted	$ (0.80)	$ (0.74)	$ (0.54)
Weighted average number of shares used in computing net loss per share:			
Basic	22,140	18,378	16,685
Diluted	22,140	18,378	16,685

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, 2017	16,711,512	$ 167	$ 217,389	$ (201,865)	$ (1,415)	$ 14,276
Cumulative impact from the adoption of ASC 606 (see Note 1)	—	—	—	108	—	108
Issuance of common stock relative to vesting of restricted stock, net of 56,946 shares forfeited for tax obligations	265,442	3	(183)	—	—	(180)
Issuance of common stock pursuant to stock option plans	89,556	1	203	—	—	204
Stock-based compensation	—	—	1,505	—	—	1,505
Net loss	—	—	—	(9,017)	—	(9,017)
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

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	For the Years Ended December 31,		
	2020	2019	2018
		(in thousands)	
Cash flow from operating activities:			
Net loss	$ (17,610)	$ (13,551)	$ (9,017)
Adjustments to reconcile net loss to net cash used for operating activities:			
Amortization	309	377	383
Depreciation	268	297	325
Bad debt provision	94	62	225
Stock-based compensation expense	2,844	1,169	1,505
Amortization of debt discount and debt costs	78	149	170
Loss on extinguishment of debt	341	—	—
Deferred tax	1	1	(12)
Loss on disposal of assets	—	—	12
Change in fair value of convertible debentures	7,464	6,671	—
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	(302)	(3,478)	2,003
Inventory	(533)	(1,024)	536
Prepaid and other assets	(1,390)	294	172
Accounts payable	878	836	(209)
Accrued and other expenses	(207)	982	494
Deferred revenue	780	108	(454)
Total adjustments	10,625	6,444	5,150
Net cash used for operating activities	(6,985)	(7,107)	(3,867)
Cash flow used for investing activities:			
Additions to patents, technology and other	(13)	(10)	(15)
Additions to property and equipment	(461)	(296)	(301)
Net cash provided by (used for) investing activities	(474)	(306)	(316)
Cash flow from financing activities:			
Issuance of common stock for cash, net	18,285	9,353	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	266	—	—
Issuance of common stock pursuant to stock option plans	729	1,400	204
Taxes paid related to restricted stock issuance	(225)	(196)	(180)
Proceeds from convertible debentures	—	—	6,970
Principal payments of capital lease obligations	—	(16)	(13)
Proceeds from notes payable	6,957	—	—
Principal repayment of notes payable	(4,638)	(2,000)	—
Debt issuance costs	(42)	—	—
Proceeds from line of credit	775	3,000	—
Repayment line of credit	(2,775)	(1,000)	—
Net cash provided by financing activities	19,332	10,541	6,981
Increase in cash and equivalents	11,873	3,128	2,798
Cash and equivalents, beginning of year	15,313	12,185	9,387
Cash and equivalents, end of year	$ 27,186	$ 15,313	$ 12,185
Supplemental disclosure of cash flow information:			
Interest paid	$ 272	$ 643	$ 294
Taxes paid	$ 38	$ 43	$ 51
Right-of-use assets obtained in exchange for new operating lease liabilities	69	3,105	—
Issuance of common stock upon conversion of debentures	$ 21,164	—	—

See accompanying notes to consolidated financial statements.

(1) Summary of Significant Accounting Policies

(a) Nature of Operations and Use of Estimates

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

The Company has grown primarily through acquisitions to become a broad player in the cancer detection and therapy market. Its 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 ("CAD") systems and workflow solutions for digital breast tomosynthesis ("DBT"), full-field digital mammography ("FFDM"), MRI and CT, and the Xoft System which is an isotope-free cancer treatment platform technology. CAD is reimbursable in the U.S. under federal and most third-party insurance programs.

The Company intends to continue the extension of its image analysis and clinical decision support solutions for DBT, FFDM, MRI and CT imaging. iCAD believes that advances in digital imaging techniques should bolster its efforts to develop additional commercially viable CAD/advanced image analysis and workflow products. The Company's management believes that early detection in combination with earlier targeted intervention will provide patients and care providers with the best tools available to achieve better clinical outcomes resulting in a market demand that will drive top line growth.

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

The Company operates in two segments: Cancer Detection ("Detection") and Cancer Therapy ("Therapy"). The Detection segment consists of advanced image analysis and workflow products, and the Therapy segment consists of radiation therapy products. The Company sells its products throughout the world through its direct sales organization as well as through various OEM partners, distributors and resellers. See Note 8 for segment, major customer and geographical information.

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 and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. 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.

(b) 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, many countries in Europe, as well as Canada and China, have imposed 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 part due to stay-at-home and social distancing orders as well as uncertainty in the market. Significant uncertainty remains as to the continuing impact of the COVID-19 pandemic on the Company's operations and on the global economy as a whole.

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 continuation or worsening of the levels of market disruption and volatility seen in the recent past 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 its common stock.

The Company's results for the year ending December 31, 2020 reflect a negative impact from the COVID-19 pandemic, as the typical sales cycle and ordering patterns were still disrupted due to some healthcare facilities' additional focus on COVID-19. Depending upon the duration and severity of the pandemic, the continuing effect on the Company's results over the long term is uncertain.

Although the Company did not see any material impact to trade accounts receivable losses in the year ended December 31, 2020, 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 hospitals' cash flows are impacted by their response to the COVID-19 pandemic.

(c) Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Xoft, Inc. and Xoft Solutions, LLC. All material inter-company transactions and balances have been eliminated in consolidation.

(d) 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, which are unrestricted as to withdrawal. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Insurance coverage is $250,000 per depositor at each financial institution, and the Company's non-interest bearing cash balances exceed federally insured limits. Interest-bearing amounts on deposit in excess of federally insured limits at December 31, 2020 approximated $26.7 million.

(e) Financial instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, contract assets, accounts payable, notes payable and convertible debentures. Due to their short term nature and market rates of interest, the carrying amounts of the financial instruments, except the convertible debentures, approximated fair value as of December 31, 2020 and 2019.

The Company has elected to record the convertible debentures at fair value at each reporting date in accordance with the fair value option election. See Note 3(c) for further details.

(f) Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are customer obligations due under normal trade terms. Credit limits are established through a process of reviewing the financial history and stability of each customer. The Company performs continuing credit evaluations of its customers' financial condition and generally does not require collateral.

The Company's policy is to maintain allowances for estimated losses from the inability 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 overall allowance for doubtful accounts. An amount would be written off against the allowance after all attempts to collect the receivable had failed. Based on the information available, the Company believes the allowance for doubtful accounts as of December 31, 2020 and 2019 is adequate.

The following table summarizes the allowance for doubtful accounts for the three years ended December 31, 2020 (in thousands):

	2020	2019	2018
Balance at beginning of period	$ 136	$ 177	$ 107
Additions charged to costs and expenses	94	62	225
Reductions	(119)	(103)	(155)
Balance at end of period	$ 111	$ 136	$ 177

(g) Inventory

Inventory is valued at the lower of cost or net realizable value, with cost determined by the first-in, first-out method. The Company regularly reviews inventory quantities on hand and records a reserve for excess and/or obsolete inventory primarily based upon the estimated usage of its inventory as well as other factors. At December 31, 2020 and 2019, inventories consisted of the following (in thousands), which includes an inventory reserve of approximately $0.2 million and $0.5 million as December 31, 2020 and 2019, respectively.

Inventory balances, net of reserves, were as follows:

Inventory balances, net of reserves, were as follows:

	December 31, 2020	December 31, 2019
Raw materials	$ 1,356	$ 1,265
Work in process	76	39
Finished Goods	1,712	1,307
Inventory Net	$ 3,144	$ 2,611

(h) 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 or the remaining lease term, if shorter, for leasehold improvements (see below).

	Estimated life
Equipment	3-5 years
Leasehold improvements	3-5 years
Furniture and fixtures	3-5 years
Marketing assets	3-5 years

(i) 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 and circumstances indicate it is more likely than not that the fair value of the reporting unit is less than the carrying value of the reporting unit.

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

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

The Company records an impairment charge when such assessment indicates that the fair value of a reporting unit was less than the carrying value. In evaluating potential impairments outside of the annual measurement date, judgment is required in determining whether an event has occurred that may impair the value of goodwill or intangible assets. The Company utilizes either discounted cash flow models or other valuation models, such as comparative transactions and market multiples, to determine the fair value of reporting units. The Company makes assumptions about future cash flows, future operating plans, discount rates, comparable companies, market multiples, purchase price premiums and other factors in those models. Different assumptions and judgment determinations could yield different conclusions that would result in an impairment charge to income in the period that such change or determination was made.

The Company determines the fair value of reporting units based on the present value of estimated future cash flows, discounted at an appropriate risk adjusted rate. This approach was selected as it measures the income producing assets, primarily technology and customer relationships. This method estimates the fair value based upon the ability to generate future cash flows, which is particularly applicable when future profit margins and growth are expected to vary significantly from historical operating results.

The Company uses internal forecasts to estimate future cash flows and includes an estimate of long-term future growth rates based on the most recent views of the long-term forecast for the reporting unit. Accordingly, actual results can differ from those assumed in the forecasts. Discount rates are derived from a capital asset pricing model and analyzing published rates for industries relevant to the reporting unit 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 the internally developed forecasts.

Other significant assumptions include terminal value margin rates, future capital expenditures, and changes in future working capital requirements. While there are inherent uncertainties related to the assumptions used and to the application of these assumptions to this analysis, the income approach provides a reasonable estimate of the fair value of the Therapy reporting unit.

The Company performed the annual impairment assessments at October 1, 2020 and 2019, respectively, and compared the fair value of each reporting unit to its carrying value as of each date. The fair value exceeded the carrying value for the Detection reporting unit as of each date of these impairment assessments. Goodwill for the Therapy reporting unit was fully impaired as of December 31, 2017. As such, the Company did not record any impairment charges for the years ended December 31, 2020 or 2019. The carrying values of the reporting units were determined based on an allocation of the Company's 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.

The Company determines the fair values for each reporting unit using 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 the Company's most recent views of the long-term forecast for each segment. Accordingly, actual results can differ from those assumed in the Company's forecasts. Discount rates are derived from a capital asset pricing model and by analyzing published rates for industries relevant to the Company's 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 its 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 the Company, as well as 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 the 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 the business profile of the Company, 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. In addition, 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 will assess each valuation methodology based upon the relevance and availability of the data at the time the valuation is performed and weights the methodologies appropriately.

A rollforward of goodwill activity by reportable segment is as follows (in thousands):

	Consolidated reporting unit	Detection	Therapy	Total
Accumulated Goodwill	$ 47,937	$ —	$ —	$ 47,937
Accumulated impairment	(26,828)	—	—	(26,828)
Fair value allocation	(21,109)	7,663	13,446	—
Acquisition of DermEbx and Radion	—	—	6,154	6,154
Acquisition measurement period adjustments	—	—	116	116
Acquisition of VuComp	—	1,093	—	1,093
Sale of MRI assets	—	(394)		(394)
Impairment	—	—	(19,716)	(19,716)
Prior to December 31, 2019	—	8,362	—	8,362
Balance at December 31, 2020	$ —	$ 8,362	$ —	$ 8,362

(j) 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 asset's (or asset group's) fair value.

Undiscounted cash flows exceeded the carrying value of the asset group and that long-lived assets were not impaired.

The Company did not record any impairment charges related to long lived assets for the years ended December 31, 2020 or 2019.

A considerable amount of judgment and assumptions are required in performing the impairment tests, principally in determining the fair value of the asset group. While the Company believes the judgments and assumptions are reasonable, different assumptions could change the estimated fair values, and, therefore additional impairment charges could be required. Significant negative industry or economic trends, disruptions to the Company's business, loss of significant customers, inability to effectively integrate acquired businesses, unexpected significant changes or planned changes in use of the assets may adversely impact the assumptions used in the fair value estimates and ultimately result in future impairment charges.

Intangible assets subject to amortization consist primarily of patents, technology, customer relationships and trade names purchased in the Company's previous acquisitions. These assets, which include assets from the acquisition of the assets of VuComp, DermEbx and Radion and the acquisition of Xoft, Inc., are amortized on a straight-line basis consistent with the pattern of economic benefit over their estimated useful lives of 5 to 10 years. A summary of intangible assets for 2020 and 2019 is as follows (in thousands):

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

Amortization expense related to intangible assets was approximately $309,000, $377,000 and $383,000 for the years ended December 31, 2020, 2019, and 2018, respectively. Estimated remaining amortization of the Company's intangible assets is as follows (in thousands):

For the years ended December 31:	Estimated amortization expense
2021	291
2022	207
2023	186
2024	103
2025	102
	$ 889

(k) Revenue Recognition

On January 1, 2018, the Company adopted FASB ASC Topic 606, "Revenue from Contracts with Customers" and all the related amendments ("Topic 606"), using the modified retrospective method for all contracts not completed as of the date of adoption. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price in accordance with practical expedient ASC 606-10-65-1-(f)-4, which did not have a material effect on the Company's assessment of the cumulative effect adjustment upon adoption. The Company recognized the cumulative effect of initially applying the new standard as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

The Company recorded a net increase to opening retained earnings of $0.1 million as of January 1, 2018 due to the cumulative impact of adopting Topic 606, with the impact primarily related to the deferral of commissions on the Company's long-term service arrangements and warranty periods greater than one year, which previously were expensed as incurred but, under the amendments to ASC 340-40, are now generally capitalized and amortized over the period of contract performance or a longer period if renewals are expected and the renewal commission is not commensurate with the initial commission.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. 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. To achieve this core principle, the Company applies the following five steps:

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 master service agreements which although include the terms under which the parties will enter into contracts do not require any minimum purchases and therefore, do not represent contracts 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, in the case of a new customer, 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 to the customer that are

both capable of being distinct, whereby 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 are distinct in the context of the contract, whereby the transfer of the goods or services 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 promised goods or services are capable of being distinct and distinct in the context of the contract. If these criteria are not met the promised goods or services are accounted for as a combined performance obligation. The Company's contracts typically do not include options that would result in a material right. If options to purchase additional goods or services are included in customer contracts, the Company evaluates the option in order to determine if the Company's arrangement include promises that may represent a material right and needs to be accounted for as a performance obligation in the contract with the customer. The Company did not note any significant provisions within its typical contracts that would create a material right.

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 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 single 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. Under Topic 606, revenue is recognized when control of the promised goods or services is transferred to a customer, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For product revenue, control has transferred upon shipment provided 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. The Company's hardware is generally highly dependent on, and interrelated with, the underlying software and the software is considered essential to the functionality of the product. In these cases, the hardware and 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.

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, 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

	Year ended December 31, 2018		
	Reportable Segments		
	Detection	Therapy	Total
Major Goods/Service Lines			
Products	$ 10,783	$ 4,393	$ 15,176
Service contracts	5,311	1,450	6,761
Supply and source usage agreements	—	2,261	2,261
Professional services	—	264	264
Other	229	389	618
	$ 16,323	$ 8,757	$ 25,080
Timing of Revenue Recognition			
Goods transferred at a point in time	$ 10,835	$ 4,676	$ 15,511
Services transferred over time	5,488	4,081	9,569
	$ 16,323	$ 8,757	$ 25,080
Sales Channels			
Direct sales force	$ 8,335	$ 7,554	$ 15,889
OEM partners	7,988	—	7,988
Channel partners	—	1,203	1,203
	$ 16,323	$ 8,757	$ 25,080
Total Revenue			
Revenue from contracts with customers	$ 16,323	$ 8,757	$ 25,080
Revenue from lease components	541	—	541
	$ 16,864	$ 8,757	$ 25,621

Products. Product revenue consists of sales of cancer detection products, 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.

Upon the adoption of ASC 842, effective January 1, 2019, the lease components of certain fixed fee service contracts are no longer being separately accounted for under the lease guidance, and the entire contract is being accounted for under ASC 606. Upon the adoption of ASC 606, effective January 1, 2018, and until the adoption of ASC 842 referred to above, these lease components were accounted for as a lease in accordance with ASC 840, "*Leases*" ("ASC 840"), and the remaining consideration was allocated to the other performance obligations identified in accordance with ASC 606. The consideration that was allocated to the lease component was recognized as lease revenue on a straight-line basis over the specified term of the agreement. Revenue for the non-lease components, such as service contracts, was recognized on a straight-line basis over the term of the agreements.

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. Determining whether products and services are considered 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.

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).

Contract balances

	Balance at December 31, 2020	Balance at December 31, 2019
Receivables, which are included in “Trade accounts receivable”	$ 10,027	$ 9,819
Current contract assets, which are included in “Prepaid and other assets”	481	14
Non-current contract assets, which are included in “other assets”	1,434	—
Contract liabilities, which are included in “Deferred revenue”	6,384	5,604

Timing of revenue recognition may differ from timing of invoicing to customers. 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 is in excess of amounts billed or billable. The Company classifies the net contract asset as either a 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 one customer 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. The balance of deferred revenue at December 31, 2020 and December 31, 2019 is as follows (in thousands):

Contract liabilities	December 31, 2020	December 31, 2019
Short term	$ 6,117	$ 5,248
Long term	267	356
Total	$ 6,384	$ 5,604

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
Balance at beginning of period	$ 5,604	$ 5,209
Deferral of revenue	11,212	11,005
Recognition of deferred revenue	(10,432)	(10,610)
Balance at end of period	$ 6,384	$ 5,604

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 2021, $1.2 million in 2022 and $1.0 million in each year from 2023-2025.

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. The Company has determined that certain commissions programs meet the requirements to be capitalized. As of December 31, 2020, the balance of capitalized costs to obtain a contract was $406,000 compared to $379,000 as of December 31, 2019. 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, 2020 and 2019, respectively.

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

	Years Ended December 31,	
	2020	2019
Balance at beginning of period	$ 379	$ 282
Deferral of costs to obtain a contract	157	294
Recognition of costs to obtain a contract	(130)	(197)
Balance at end of period	$ 406	$ 379

Practical Expedients and Exemptions

The Company has elected to make the following accounting policy elections through the adoption of the following practical expedients:

Right to Invoice

Where applicable, the Company will recognize 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 entity has a right to invoice.

Sales and Other Similar Taxes

The Company will exclude sales taxes and similar taxes from the measurement of transaction price and will ensure that it complies with the disclosure requirements of ASC 235-10-50-1 through 50-6.

Significant Financing Component

The Company will 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.

Cost to Obtain a Contract

The Company will recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less and there are no renewal periods on which the Company does not pay commissions that are not commensurate with those originally paid.

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

The Company has elected to assess promised goods or services as performance obligations that are deemed to be immaterial in the context of a contract. As such, the Company will not aggregate and assess immaterial items at the entity level. That is, 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.

(k) 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 medical device tax.

(l) 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 provisions and claims for the years ended December 31, 2020, 2019 and 2018, were as follows (in thousands):

	2020	2019	2018
Beginning accrual balance	$ 17	$ 12	$ 10
Warranty provision	58	41	19
Usage	(58)	(36)	(17)
Ending accrual balance	$ 17	$ 17	$ 12

(m) Engineering and Product Development Costs

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

(n) Advertising Costs

The Company expenses advertising costs as incurred. Advertising expense for the years ended December 31, 2020, 2019 and 2018 was approximately $211,000, $1,084,000 and $811,000 respectively.

(o) Net Loss per Common Share

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

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

	2020	2019	2018
Net loss available to common shareholders	$ (17,610)	$ (13,551)	$ (9,017)
Basic shares used in the calculation of earnings per share	22,140	18,378	16,685
Effect of dilutive securities:			
Stock options	—	—	—
Restricted stock	—	—	—
Diluted shares used in the calculation of earnings per share	22,140	18,378	16,685
Net loss per share :			
Basic	$ (0.80)	$(0.74)	$(0.54)
Diluted	$ (0.80)	$(0.74)	$(0.54)

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,		
	2020	2019	2018
Common stock options	1,869,507	1,550,662	1,983,477
Restricted Stock	29,166	150,909	423,202
Convertible Debentures	—	1,742,500	1,742,500
	1,898,673	**3,444,071**	**4,149,179**

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.

(p) 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, 2020 and 2019, 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.

ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and 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. ASC 740-10 also provides guidance on de-recognition, classification, interest and penalties, disclosure and transition.

(q) Stock-Based Compensation

The Company maintains stock-based incentive plans, under which it provides stock incentives to employees, directors and contractors. The Company may grant 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 also has an Employee Stock Purchase Plan, adopted in 2019, which became effective as of January 1, 2020. The Company follows FASB ASC Topic 718, "*Compensation – Stock Compensation*", for all stock-based compensation. Under this application, the Company is required to record compensation expense over the vesting period for all awards granted.

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, the risk free rate, expected dividend yield, and the number of options that will be forfeited prior to the completion of their vesting requirements.

The fair value of restricted stock is determined based on the stock price of the underlying option on the date of the grant. From time to time, the Company may grant performance based restricted stock awards, based on the achievement of certain performance targets. Compensation cost for performance based restricted stock awards requires significant judgment regarding probability of achieving the performance objectives and compensation cost is adjusted for the probability of achieving these objectives. As a result, compensation cost could vary significantly during the performance measurement period.

Compensation cost for stock purchase rights under the employee stock purchase plan is measured and recognized on the date the Company becomes obligated to issue shares of the Company's common stock and is based on the difference between the fair value of the Company's common stock and the purchase price on such date.

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.

(r) Fair Value Measurements

The Company follows the provisions of FASB ASC Topic 820, "*Fair Value Measurement and Disclosures*" ("ASC 820"). ASC 820 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 under ASC 820 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 under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value 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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's assets and liabilities that are measured at fair value on a recurring basis include the Company's money market accounts and convertible debentures.

The money market funds are 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 convertible debentures are recorded as a separate component of the Company's consolidated balance sheets are considered a Level 3 measurement due to the utilization of significant unobservable inputs in their valuation. See Note 3(c) below for a discussion of these fair value measurements.

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

Fair Value Measurements as of December 31, 2020

	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$ 27,186	—	—	$ 27,186
Total Assets	$ 27,186	—	—	$ 27,186
Liabilities				
Convertible debentures	—	—	—	—
Total Liabilities	—	—	—	—

Fair Value Measurements as of December 31, 2019

	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$ 15,313	—	—	$ 15,313
Total Assets	$ 15,313	—	—	$ 15,313
Liabilities				
Convertible debentures	—	—	$ 13,642	$ 13,642
Total Liabilities	—	—	$ 13,642	$ 13,642

The following is a roll forward of the Company's Level 3 instruments for the years ended December 31, 2020 and 2019, see Note 3 (c) *convertible debentures* below for more details:

	Convertible Debentures
Balance, December 20, 2019	$ 13,642
Issuances	—
Fair value adjustments	7,522
Conversion	(21,164)
Balance, 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, 2020 and 2019.

(t) Recently Issued and Recently Adopted Accounting Standards

Recently Adopted Accounting Standards

On January 1, 2020, the Company adopted ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement" ("ASU 2018-13"). ASU 2018-13 removes, modifies and adds certain disclosure requirements of ASC Topic 820. ASU 2018-13 is effective for Company for the fiscal year and interim periods therein beginning January 1, 2020. The Company notes that the adoption of ASU 2018-13 did not have a material impact on its consolidated financial statements.

On January 1, 2019, the Company adopted ASU 2016-02, "Leases (Topic 842)" and all the related amendments, which are codified under ASC 842. The Company has applied its transition provisions at the beginning of the period of adoption (i.e., on the effective date), and so did not restate comparative periods. Under this transition provision, the Company has applied the legacy guidance under ASC 840, "*Leases*" ("ASC 840"), including its disclosure requirements, in the comparative periods presented. As part of the adoption, the Company elected the package of practical expedients, which among other things, permits the carry forward of historical lease classifications. The Company did not elect to use the practical expedient permitting the use of hindsight in determining the lease term and in assessing impairment of right-of-use assets. The adoption of the standard did not have a material impact on our operating results or cash flows. See Note 5 for the disclosures required upon adoption of ASC 842.

Recently Issued Accounting Standards Not Yet Adopted

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 will adopt ASU 2019-12 on January 1, 2021 and will account for income taxes in accordance with ASU 2019-12 at that time. This update will not make a material difference to the Company's financial statements.

In March 2020, the FASB issued ASU 2020-04, "Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting" ("ASU 2020-04"). ASU 2020-04 was issued because the London Interbank Offered Rate ("LIBOR") is a benchmark interest rate referenced in a variety of agreements that are used by all types of entities, and at the end of 2021, banks will no longer be required to report information that is used to determine LIBOR. As a result, LIBOR is expected to be discontinued as a benchmark interest rate. Other interest rates used globally could also be discontinued for similar reasons. ASU 2020-04 provides companies with optional guidance to ease the potential accounting burden associated with transitioning away from reference rates that are expected to be discontinued. Companies can apply the ASU immediately. However, the guidance will only be available for a limited time (generally through December 31, 2022). The Company is currently evaluating the impact that the adoption of ASU 2020-04 will have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"). ASU 2020-06 was issued to simplify the accounting for convertible instruments by removing major separation models required under current U.S. GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument and more convertible preferred stock as a single equity instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. ASU 2020-06 also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for the Company for the fiscal year and interim periods therein beginning January 1, 2022. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2020-06 will have on its consolidated financial statements.

(u) Subsequent Events

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 contains 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.

On March 2, 2021, the Company terminated its at-the-market offering program with JMP Securities (See Note 6 hereto).

(2) Sale of MRI Assets

In December 2016, the Company entered into an Asset Purchase Agreement with Invivo Corporation ("Invivo"). In accordance with the 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 a net of approximately $2.9 million. The holdback reserve of $350,000 has been recorded as an asset in other assets and will be paid to the Company upon resolution of the litigation matter described in Note 9(f), less amounts, if any, due and payable or reserved under the indemnification provisions in the Asset Purchase agreement.

(3) Financing Arrangements

(a) Loan and Security Agreement – Western Alliance Bank

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

The Loan Agreement was amended effective June 16, 2020. The Loan Agreement requires the Company to either (i) meet a minimum revenue covenant, or (ii) maintain a ratio of unrestricted cash at the Bank to aggregate indebtedness owed to the Bank of at least 1.25 to 1.00. The Company was compliant with these covenants as of December 31, 2020.

If at any point the Company is not in compliance with certain covenants under the Loan Agreement and is unable to obtain an amendment or waiver, such noncompliance may result in an event of default under the Loan Agreement, which could permit acceleration of the outstanding indebtedness and require the Company to repay such indebtedness before the scheduled due date. The Company was required, periodically in the past, to seek modifications from its prior lender to avoid non-compliance with its earlier covenants.

Interest in arrears on the Term Loan began to be repaid on April 1, 2020 and will continue to be paid on the first of each successive month thereafter until the principal repayment starts. Commencing on the principal repayment date of March 1, 2022, and continuing on the first day of each month thereafter, the Company will make equal monthly payments of principal, together with applicable interest in arrears, to the Bank. The interest rate is set at 1% above the Prime Rate, which is defined in the Loan Agreement as the greater of 4.25% or the Prime Rate published in the Money Rates section of the Western Edition of the Wall Street Journal. The Prime Rate as of December 31, 2020 was 3.25%.

The Company has the option to prepay all, but not less than all, of the Term Loan advanced by the Bank under the Loan Agreement. The Company prepayment is subject to payment of (1) all outstanding principal of the Term Loan plus accrued and unpaid interest thereon through the prepayment date, (2) the final payment ($122,500 or 1.75% of the original loan amount), (3) a prepayment fee (3% of the principal balance if prepaid prior to first March 30, 2021, 2% of principal if prepaid after March 30, 2021 but before June 30, 2022, or 1% of principal if prepaid after March 30, 2022) plus (4) all other obligations that are due and payable, including the Bank's expenses and interest at the default rate with respect to any past due amounts.

Obligations to the Bank under the Loan Agreement are 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.

In connection with the Loan Agreement, the Company incurred approximately $141,000 of closing costs. The closing costs have been deducted from the carrying value of the debt and will be amortized through March 30, 2022, the maturity date of the Term Loan.

The maturity date of the revolving loan is March 30, 2022 and there was no outstanding amount as of December 31, 2020.

	December 31, 2020 (Western Alliance Bank) *
Principal Amount of Term Loan	$ 7,000
Unamortized closing costs	(63)
Accrued Final Payment	23
Amount Drawn on Line of Credit	—
Carrying amount of Term Loan	6,960
Less current portion of Term Loan	—
Notes payable long-term portion	$ 6,960

* No December 31, 2019 balance. Debt opened in 2020

(b) Loan and Security Agreement – Silicon Valley Bank

On August 7, 2017, the Company entered into a Loan and Security Agreement, which was modified several times through November 1, 2019 (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. 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.

	December 31, 2019 (Silicon Valley Bank) *
Principal Amount of Term Loan	$ 4,000
Unamortized closing costs	(40)
Accrued Final Payment	293
Amount Drawn on Line of Credit	2,000
Carrying amount of Term Loan	6,253
Less current portion of Term Loan	(4,250)
Notes payable long-term portion	$ 2,003

* No December 31, 2020 balance. Debt closed in 2020

(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.

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 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] Probabilty 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 8 - 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 period ending December 31, 2019 through the conversion date of February 21, 2020, compared to $6.7 million in the period ending December 31, 2019, which is described in the additional fair value disclosures related to the Convertible Debentures in Note 8.

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.

(d) Principal and Interest Expense Payments Related to Financing Arrangements

Future principal and interest payments related to the Loan Agreement are as follows (in thousands):

Fiscal Year	Amount Due
2021	1,238
2022	2,875
2023	2,735
2024	1,003
Total	$ 7,851

The following amounts are included in interest expense in the Company's consolidated statements of operations for the years ended December 31, 2020, 2019 and 2018 (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Cash interest expense, notes payable	$327	$274	$299
Cash interest expense, convertible debentures	49	349	9
Amortization of debt costs	45	28	29
Accrual of notes payable final payment	55	131	163
Interest expense capital lease	—	2	4
Total interest expense	$476	$784	$504

Cash interest expense, notes payable, represents the cash interest paid monthly related to the Loan Agreement. Cash interest expense, convertible debentures represents cash interest paid or accrued in connection with the Convertible Debentures issued in December 2018. The amortization of debt costs represents the closing costs incurred with the Term Loan and the SVB Loan Agreement, which have been capitalized and expensed using the effective interest method.

(4) Accrued and Other Expenses

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

	2020	2019
Accrued salary and related expenses	$ 3,654	$ 3,200
Accrued accounts payable	2,405	2,718
Accrued professional fees	598	510
Other accrued expenses	382	162
	$ 7,039	$ 6,590

(5) Leases

Under ASC 842, the Company determines if an arrangement contains a lease at inception. A lease is a contract, or part of a contract, that conveys the right to control the use of identified property, plant or equipment (i.e., an identified asset) for a period of time in exchange for consideration. Leases are classified as either operating or financing.

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. The Company used its incremental borrowing rate to determine the present value of the lease payments. The Company determined the incremental borrowing rates for its leases by applying its 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 option to extend the lease if the Company is reasonably certain to exercise that option. The Company considered a number of factors when evaluating whether the options in its lease contracts were reasonably certain of exercise, such as length of time before option exercise, expected value of the leased asset at the end of the initial lease term, importance of the lease to overall operations, costs to negotiate a new lease, and any contractual or economic penalties.

Right-of-use assets and obligations for short-term leases (leases with an initial term of 12 months or less) are not recognized in the consolidated balance sheet. Lease expense for short-term leases is recognized on a straight-line basis over the lease term. The Company does not sublease any of its leased assets to third parties. 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. As the Company has determined that the non-lease component of these agreements is the predominant component, the Company is accounting for the complete agreement under ASC 606 upon adoption of ASC 842 (see discussion in Note 1(j)).

ASC 842 includes a number of reassessment and re-measurement requirements for lessees based on certain triggering events or conditions, including whether a contract is or contains a lease, assessment of lease term and purchase options, measurement of lease payments, assessment of lease classification and assessment of the discount rate. The Company reviewed the reassessment and re-measurement requirements and identified three lease modifications which are reflected in the table below showing the maturity of the Company's lease liabilities as of December 31, 2020. This includes an extension of operating leases for the two facilities leased by the Company in New Hampshire and the facility lease in California. In addition, there were no impairment indicators identified during the year ended December 31, 2020 that required an impairment test for the Company's right-of-use assets or other long-lived assets in accordance with ASC 360-10.

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 not separate the accounting for lease components and non-lease components for real estate and equipment leases.

The Company has leases for office space and office equipment. The leases have remaining lease terms ranging from less than one year to three years and three months as of December 31, 2020.

The components of lease expense for the period are as follows (in thousands):

Lease Cost	Classification	Year Ended December 31, 2020	2019
Operating lease cost - Right of Use	Operating expenses	$ 884	$ 804
Operating lease cost - Variable Costs	Operating expenses	165	$ 173
Finance lease costs			
Amortization of leased assets	Amortization and depreciation	12	15
Interest on lease liabilities	Interest expense	1	2
Total		$ 1,062	$ 994

Other information related to leases was as follows (in thousands):

	2020	2019
Cash paid for operating cash flows from operating leases	$ 909	$ 840
Cash paid for operating cash flows from finance leases	1	2
Cash paid for financing cash flows from finance leases	13	17

	2020	2019
Weighted-average remaining lease term of operating leases (in years)	2.21	3.12
Weighted-average remaining lease term of finance leases (in years)	—	1.00
Weighted-average discount rate for operating leases	5.6%	5.6%
Weighted-average discount rate for finance leases	—	5.4%

Maturities of the Company's lease liabilities as of December 31, 2020 was as follows (in thousands):

Year Ended December 31, 2020:	Operating Leases
2021	$ 920
2022	899
2023	211
2024	5
Total lease payments	2,035
Less: imputed interest	(234)
Total lease liabilities	1,801
Less: current portion of lease liabilities	(726)
Long-term lease liabilities	$ 1,075

(6) 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 provides 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. As of December 31, 2020, $18.4 million in capacity remains under the facility.

(b) Stock Options

The Company has two effective stock option or stock incentive plans which are described as follows:

The 2012 Stock Incentive Plan (the "2012 Plan").

The 2012 Plan was adopted by the Company's stockholders in May 2012 and amended in May 2014. The 2012 Plan, as amended, provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. Awards may be granted singly, in combination, or in tandem. Subject to anti-dilution adjustments as provided in the amended 2012 Plan, (i) the amended 2012 Plan provides for a total of 1,600,000 shares of the Company's common stock to be available for distribution pursuant to the amended 2012 Plan, and (ii) the maximum number of shares of the Company's common stock with respect to which stock options, restricted stock, deferred stock, or other stock-based awards may be granted to any participant under the amended 2012 Plan during any calendar year or part of a year may not exceed 250,000 shares.

The 2012 Plan provides that it will be administered by the Company's Board of Directors or a committee of two or more directors appointed by the Board of Directors. The administrator will generally have the authority to administer the 2012 Plan, determine participants who will be granted awards under the 2012 Plan, the size and types of awards, the terms and conditions of awards and the form and content of the award agreements representing awards. Awards under the 2012 Plan may be granted to employees, directors, consultants and advisors of the Company and its subsidiaries. However, only employees of the Company and its subsidiaries will be eligible to receive options that are designated as incentive stock options.

With respect to options granted under the 2012 Plan, the exercise price must be at least 100% (110% in the case of an incentive stock option granted to a 10% stockholder) of the fair market value of the common stock subject to the award, determined as of the date of grant. Restricted stock awards are shares of common stock that are awarded subject to the satisfaction of the terms and conditions established by the administrator. In general, awards that do not require exercise may be made in exchange for such lawful consideration, including services, as determined by the administrator. At December 31, 2020, there were 129,126 shares available for issuance under the 2012 Plan.

The 2016 Stock Incentive Plan (the "2016 Plan").

The 2016 Plan was adopted by the Company's stockholders in May 2016 and amended in November 2018. The 2016 Plan provides for the grant of any or all of the following types of awards: (a) non-qualified stock options and incentive stock options, (b) stock appreciation rights, (c) restricted stock awards and restricted stock units, (d) unrestricted stock awards, (e) cash-based awards, (f) performance share awards and (g) dividend equivalent rights.

Subject to anti-dilution adjustments as provided in the 2016 Plan, (i) the amended 2016 Plan provides for a total of 2,600,000 shares of the Company's common stock to be available for distribution pursuant to the 2016 Plan, and (ii) the maximum number of shares of the Company's common stock with respect to which stock options or stock appreciation rights may be granted to any one individual under the 2016 Plan during any one calendar year period may not exceed 1,000,000 shares. No more than 1,000,000 shares of common stock may be issued in the form of incentive stock options and no more than 120,000 shares of stock may be issued pursuant to awards to non-employee directors.

The 2016 Plan provides that it will be administered by the Company's Compensation Committee. The Compensation Committee has the authority to administer the 2016 Plan, determine participants, from among the individuals eligible for awards, who will be granted awards under the 2016 Plan, make any combination of awards to participants and determine the specific terms and conditions of awards subject to the 2016 Plan. Awards under the 2016 Plan may be granted to full or part-time officers, employees, non-employee directors and other key persons (including consultants) of the Company and its subsidiaries.

With respect to stock options granted under the 2016 Plan, the exercise price will be determined by the Compensation Committee but may not be less than 100% of the fair market value of the common stock subject to the award, determined as of the date of grant. Regarding incentive stock options, including that the aggregate grant date fair market value of the shares of stock with respect to which incentive stock options granted under the 2016 Plan and any other plan of the Company or its parent and subsidiary corporations become exercisable for the first time by an optionee during any calendar year shall not exceed $100,000. To the extent that any incentive stock option exceeds this limit, it shall constitute a non-qualified stock option. Restricted stock awards are shares of common stock that are awarded subject to the satisfaction of the terms and conditions established by the Compensation Committee. In general, awards that do not require exercise may be made in exchange for such lawful consideration, including services, as determined by the Compensation Committee. At December 31, 2020, there were 333,091 shares available for issuance under the 2016 Plan.

A summary of stock option activity for all stock option plans is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding, December 31, 2018	1,983,477	$ 4.25	
Granted	392,270	$ 5.81	
Exercised	(379,980)	$ 3.39	
Forfeited	(445,105)	$ 6.06	
Outstanding, December 31, 2019	1,550,662	$ 4.33	5.0 Years
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
Exercisable at December 31, 2018	1,296,439	$ 4.90	
Exercisable at December 31, 2019	881,461	$ 4.43	
Exercisable at December 31, 2020	1,540,287	$ 5.55	

There were 462,218 shares available for future grants from all plans at December 31, 2020.

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

	Year Ended December 31,		
	2020	2019	2018
Cost of revenue	$ 30	$ 3	$ 4
Engineering and product development	376	226	399
Marketing and sales	657	226	190
General and administrative expense	1,781	713	912
	$2,844	**$1,168**	**$1,505**

As of December 31, 2020, there was $0.7 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 1.0 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,		
	2020	2019	2018
Average risk-free interest rate	0.65%	1.88%	2.65%
Expected dividend yield	None	None	None
Expected life	3.5 years	3.5 years	3.5 years
Expected volatility	50.17-66.04%	50.01% to 54.23%	50.4% to 61.6%
Weighted average exercise price	$10.14	$5.92	$2.96
Weighted average fair value	$4.37	$2.34	$1.23

The Company's 2020, 2019 and 2018 average expected volatility and average expected life is based on the average of the Company's historical information. The risk-free rate is based on the rate of U.S. Treasury zero-coupon issues with a remaining term equal to 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

	Years Ended December 31,		
	2020	2019	2018
Outstanding	$13,626	$5,465	$1,021
Exercisable	11,786	3,067	499
Exercised	1,037	509	224
Company's stock price at December 31	$ 13.20	$ 7.77	$ 3.70

(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.

The Company did not grant any restricted stock units in 2020. The Company granted 15,990 shares with time-based vesting during the year ended December 31, 2019. The Company granted 334,083 shares with time-based vesting and 45,356 shares with immediate vesting during the year ended December 31, 2018.

A summary of restricted stock activity for all equity incentive plans is as follows:

	Years Ended December 31,		
	2020	2019	2018
Beginning outstanding balance	150,909	423,202	415,147
Granted	—	15,990	379,439
Vested	(118,077)	(197,730)	(322,388)
Forfeited	(3,666)	(90,553)	(48,996)
Ending outstanding balance	29,166	150,909	423,202

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

	Years Ended December 31,		
	2020	2019	2018
Outstanding	$ 385	$1,173	$1,566
Vested	1,559	1,536	1,193
Company's stock price at December 31	$13.20	$ 7.77	$ 3.70

(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 not eligible to purchase shares under 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 42,606 shares under the ESPP as of December 31, 2020.

(7) Income Taxes

The components of income tax expense for the years ended December 31, 2020, 2019 and 2018 are as follows (in thousands):

	2020	2019	2018
Current provision (benefit):			
Federal	$—	$—	$—
State	37	42	54
	$ 37	$ 42	$ 54
Deferred provision:			
Federal	$ 1	$ 1	$ (10)
State	—	—	(2)
	$ 1	$ 1	$ (12)
Total	$ 38	$ 43	$ 42

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, 2020, 2019 and 2018 is as follows:

	2020	2019	2018
Federal statutory rate	21.0%	21.0%	21.0%
State income taxes, net of federal benefit	2.4%	1.7%	3.6%
Net state impact of deferred rate change	(0.7%)	(2.0%)	0.6%
Stock compensation expense	0.9%	(10.7%)	(1.1%)
Tax amortization on goodwill	0.0%	0.0%	0.1%
Goodwill impairment	0.0%	0.0%	0.0%
Other permanent differences	(0.1%)	0.0%	(0.5%)
Change in valuation allowance	(13.4%)	(6.0%)	(27.6%)
Tax credits	1.4%	2.8%	3.1%
Federal Rate Change	0.0%	0.0%	0.0%
Accrual to tax return	0.0%	1.3%	0.3%
Increase Xoft NOLs under 382 Study	0.0%	0.0%	0.0%
Change in FV of convertible debt	(9.0%)	(10.4%)	0.0%
Foreign Rate Differential	0.0%	0.2%	0.0%
True Ups - NOL Expiration/162(m) limits	(2.8%)	0.0%	0.0%
Effective income tax	(0.3%)	(0.3%)	(0.5%)

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, 2020 and 2019 (in thousands):

	2020	2019
Inventory (Section 263A)	$ 248	$ 242
Inventory reserves	60	118
Receivable reserves	28	35
Other accruals	1,081	1,151
Deferred revenue	75	123
Accumulated depreciation/amortization	37	66
Stock options	459	267
Developed technology	1,449	1,702
Tax credits	3,859	3,663
NOL carryforward	36,078	33,640
Lease liability	415	625
Net deferred tax assets	43,789	41,632
Valuation allowance	(43,356)	(41,025)
Right of Use Asset	(433)	(607)
Goodwill tax amortization	(4)	(3)
Deferred tax liability	$ (4)	$ (3)

The increase in the net deferred tax assets and corresponding valuation allowance during the year ended December 31, 2020 and December 31, 2019 is primarily attributable to additional accruals, net operating losses, and research and development credits.

As of December 31, 2020, the Company has federal net operating loss carryforwards totaling approximately $149.1 million. Federal net operating loss carryforwards totaling $122.1 million will expire at various dates from 2021 and 2037. The remaining $27.0 million of the federal net operating losses generated since December 31, 2017 can be carried forward indefinitely. As of December 31, 2020, 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, 2020, 2019, or 2018.

The Company currently has approximately $6.6 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 $3.9 million. The credits expire in various years through 2039. 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, 2020 and 2019, 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, 2020, 2019 and 2018. The Company files United States federal and various state income tax returns. The Company will also file a tax return in France. Generally, the Company's three preceding tax years remain subject to examination by federal and state tax 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, 2020 will significantly change within the next 12 months.

(8) Segment Reporting, Geographical Information and Major Customers

(a) Segment Reporting

In accordance with FASB Topic ASC 280, Segments, operating segments are defined as components of an enterprise that engage in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance.

The Company's CODM is the Chief Executive Officer. 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 its 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,		
	2020	2019	2018
Segment revenues:			
Detection	$ 21,997	$ 22,319	$16,864
Therapy	7,701	9,021	8,757
Total Revenue	$ 29,698	$ 31,340	$25,621
Segment gross profit:			
Detection	$ 17,856	$ 18,627	$14,709
Therapy	3,498	5,600	4,721
Segment gross profit	$ 21,354	$ 24,227	$19,430
Segment operating income (loss):			
Detection	$ 2,719	$ 2,564	$ 3,412
Therapy	(3,028)	(1,476)	(2,373)
Segment operating income (loss)	$ (309)	$ 1,088	$ 1,039
General administrative	$ (9,079)	$ (7,486)	$ (9,169)
Interest expense	(476)	(784)	(504)
Financing costs	—	—	(451)
Loss on extinguishment of debt	(341)		
Other income	97	345	110
Fair value of convertible debentures	(7,464)	(6,671)	
Loss before income tax	$(17,572)	$(13,508)	$ (8,975)

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

	Year Ended December 31,		
	2020	2019	2018
Detection depreciation and amortization			
Depreciation	$115	$103	$106
Amortization	164	240	248
Therapy depreciation and amortization			
Depreciation	$124	$166	$177
Amortization	128	128	129

(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 sales to a single country did not exceed 10% of total revenue in any year. Total export sales were approximately $6.1 million or 20% of total revenue in 2020, $3.8 million or 12% of total revenue in 2019 and $3.2 million or 12% of total revenue in 2018.

As of December 31, 2020 and 2019, the Company had outstanding receivables of $3.4 million and $2.1 million, respectively, from distributors and customers of its products who are located outside of the U.S.

	Percent of Export sales		
Region	2020	2019	2018
Europe	45%	57%	51%
Taiwan	13%	15%	22%
Canada	5%	7%	7%
China	22%	8%	0%
Other	15%	13%	20%
Total	100%	100%	100%
Total Export sales	$6,081	$3,788	$3,255

Significant export sales in Europe are as follows:

	Percent of Export sales		
Region	2020	2019	2018
France	41%	34%	36%
Spain	17%	12%	8%
Germany	12%	4%	3%
Italy	8%	2%	1%
United Kingdon	6%	2%	0%

(c) Major Customers

The Company had one major OEM customer, GE Healthcare, with revenues of approximately $5.0 million in 2020, $7.6 million in 2019 and $6.1 million in 2018 or 17%, 24% 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, 2020, these four OEM partners composed approximately 35% of Detection revenues and 26% of total revenue. Detection OEM partners in total composed approximately 37% of Detection revenues and 28% of total revenue for the year ended December 31, 2020, 46% of Detection revenues and 33% of total revenue for the year ended December 31, 2019 and 50% of Detection revenues and 33% of total revenue for the year ended December 31, 2018. The Company also had one major direct customer with revenues of approximately $2.8 million, or 9% of total revenue for year ended December 31, 2020.

OEM partners represented $4.4 million or 44% of outstanding receivables as of December 31, 2020, with GE Healthcare accounting for $1.5 million or 34% of this amount. The four largest Therapy customers composed $1.7 million or 17% of outstanding receivables as of December 31, 2020. The largest Detection direct customer represents $1.1 million or 11% of outstanding receivables as of December 31, 2020. These twenty-one customers in total represented $7.1 million or 72% of outstanding receivables as of December 31, 2020.

(9) Commitments and Contingencies

(a) Other Commitments

The Company has non-cancelable purchase orders with key suppliers executed in the normal course of business that total approximately $3.4 million. In connection with the Company's employee savings plans, the matching contribution for 2020 was approximately $0.5 million in cash. The matching contribution for 2021 is estimated to be approximately $0.5 million in cash.

(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, (ii) eighteen months from the date of termination, for Ms. Stevens, and (iii) twenty-four months from the date of termination, for Mr. Ferry, and in each case, plus the pro rata portion of any annual bonus earned in any employment year through the date of termination.

On November 8, 2018, Mr. Ferry retired as Chief Executive Officer of the Company and from his position as Chairman of the Board of Directors. Mr. Ferry and the Company entered into a Separation Agreement on that date, pursuant to which Mr. Ferry will generally receive the payments that would have been payable had he been terminated by the Company without cause. The Company accrued $1,009,000 representing 24 months of severance and 18 months of health benefits as of November 2018 upon Mr. Ferry's agreeing to the Separation Agreement, which the Company began paying monthly in May 2019 and has completed all payments as of December 31, 2020.

(c) Royalty Obligations

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

(d) Litigation

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 of which the ultimate resolution would have a material adverse effect on its financial condition or results of operations. However, should the Company fail to prevail in any legal matter or should several legal matters be resolved against us 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. 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.

In December 2016, the Company entered into an Asset Purchase Agreement with Invivo Corporation. In accordance with the 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 a net 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. In the Complaint, Yeda asserted claims for: (i) copyright infringement and misappropriation of trade secrets against both the Company and Invivo; (ii) breach of contract against the Company only; and (iii) tortious interference with existing business relationships and unjust enrichment against Invivo only. The Company and Invivo filed Motions to Dismiss the Complaint on December 21, 2018. On January 18, 2019, Yeda filed Oppositions to the Motions to Dismiss. The Company and Invivo submitted responses to the Opposition to the Motion to Dismiss on February 8, 2019. The Court held oral argument on the Motions to Dismiss on March 27, 2019. On September 5, 2019, the Court granted Invivo's Motion to Dismiss in its entirety and granted the Company's Motion to Dismiss as it relates to Yeda's breach of contract and misappropriation of trade secrets claims. On October 22, 2019, Yeda filed an Amended Complaint against only the Company asserting claims for (i) copyright infringement; and (ii) a replead breach of contract claim. The Company filed its Answer to Yeda's Amended Complaint on November 5, 2019. Yeda alleges, 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. If the Company is found to have infringed Yeda's copyright or breached its agreements with Yeda, the Company could be obligated to pay to Yeda substantial monetary damages.

EXHIBIT 21

Subsidiaries of iCAD, Inc.

Name	Jurisdiction of Incorporation/Organization
Xoft, Inc.	Delaware
Xoft Solutions, LLC	Delaware
PMDE ICAD	France

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 15, 2021, relating to the consolidated financial statements which appear in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Boston, Massachusetts

March 15, 2021

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Michael Klein, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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 15, 2021

/s/ Michael Klein

Michael Klein
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, R. Scott Areglado, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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 15, 2021

/s/ R. Scott Areglado

R. Scott Areglado
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, 2020 (the "Report"), I, Michael Klein, 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/ Michael Klein
Michael Klein
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 15, 2021

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, 2020 (the "Report"), I, R. Scott Areglado, 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/ R. Scott Areglado
R. Scott Areglado
Chief Financial Officer
(Principal Financial Officer)

Date: March 15, 2021